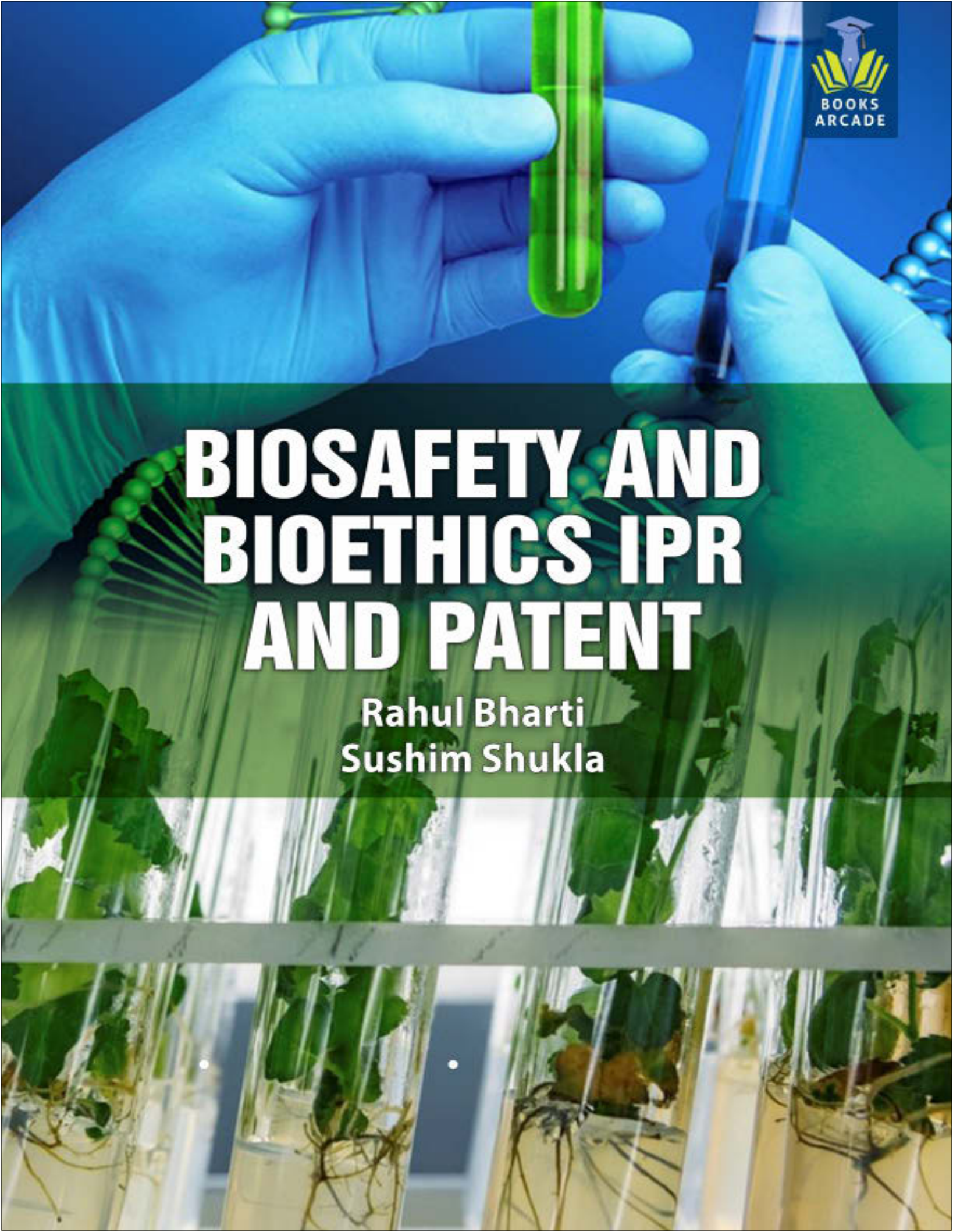
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CONTENTS

CHAPTER 1

AN OVERVIEW ON BIOSAFETY AND BIOETHICS

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ABSTRACT:

Definition of ethics and bioethics Biological pest control, no-till farming, cotton grown without pesticides, a reduced need for fertiliser, slowly ripening fruits, and other conventional examples of the ethical ramifications of the good and negative effects of biotechnology regulated rapidly growing fish and plants. Cloning, gene therapy, human genetic engineering, life extension, astroethics or life in space, and modification of fundamental biology via changed XNA, DNA, or proteins are only a few examples of how biotechnology may broaden the scope of bioethics. Future evolution may be impacted by these advances, which may call for new ethical principles that meet life's fundamental needs. One such concept is biotic ethics, which values life at its most fundamental biological levels and works to preserve them.

KEYWORDS:

Biosafety, Bioethics, Cloning, Medical ethics, philosophy.

INTRODUCTION

The study of bioethics examines the often contentious moral dilemmas that arise from novel circumstances and opportunities brought on by biological and medical advancements. In terms of medical practise and policy, it is also moral judgement. The ethical issues that emerge in the interactions between life sciences, medicine, politics, biotechnology, law, and philosophy are of interest to bioethicists. The more everyday ethical issues that come up in primary care and other areas of medicine are also studied (referred to as "the ethics of the ordinary").The development of technology will probably tame a number of the earth's existing biological forms. Due of the challenges in containing the illnesses they produce, microorganisms constitute a major problem[1]. Dealing with lethal disease-causing bacteria for their characterisation, diagnostics, or therapeutic reasons, as well as for the creation of vaccines, is presenting a rising risk to laboratory workers' biosafety. Hence, a biosafe working environment may shield employees against illnesses brought on by working in a lab.The development of technology will probably tame a number of the earth's existing biological forms. Due of the challenges in containing the illnesses they produce, microorganisms constitute a major problem. Dealing with lethal disease-causing bacteria for their characterisation, diagnostics, or therapeutic reasons, as well as for the creation of vaccines, is presenting a rising risk to laboratory workers' biosafety. Hence, a biosafe working environment may shield employees against illnesses brought on by working in a lab[2].

With the world's population set to rise, biotechnology has the potential to provide solutions. Yet, there is often a lack of public acceptance and support for biotechnology goods in business, agriculture, and medicine. GM crops and human cloning have a lot of safety and moral concerns. Growing transgenic animals and plants has increased ethical issues, and scientists have encountered a lot of opposition while working on human reproductive cloning research or genetically modified agricultural plants[3]. In order to reconcile the logic of ever-

growing scientific knowledge in biotechnology, which often conflicts with the long-standing social and moral value system of our society, biosafety and bioethics are continually being extended.

Yet, despite the fact that biotechnology techniques have produced high-yielding agricultural plants, more nutritious food grains, longer-lasting produce, and pest and insect resistance, the general public's adoption of these biotechnological goods is very poor. For instance, Europe and India do not accept GM foods very much. As the years go by, public support continues to wane, likely as a result of media attention and public discussions on GM crops owing to concerns about their long-term impacts, unknown hazards, and environmental safety problems[4]. A detrimental effect on GM crops has resulted from the debates from nongovernmental organisations (NGOs), scientists, and the media. The use of GM crops has generated controversy, with concerns regarding the Flavr Savr tomato and other crops raised. Due to labelling concerns, GM food has once again been in the news. The emergence of insect resistance posed a problem for Bt crops. Due of the insertion of undesirable sterility features in the seeds, so-called terminator technology and a gene usage restriction technology (GURT) encountered significant opposition and were never commercially successful.

Many ethical and safety issues have also been raised by the production of cloned animals and its effects on other creatures of the wild and the environment. Animal welfare, suffering, and well-being were hotly contested topics of discussion throughout the globe on whether or not they should be employed in research[5]. Several plants and animals in India are revered and worshipped for their role in enhancing human existence and are connected to religious beliefs.

The use of embryonic stem cells has raised questions and debates. Protestants agree that stem cell research should be governed by strong laws. Yet, since it kills the embryo, many are against embryonic stem cell research. The probable source of these cells is at the core of all discussions and problems related to stem cells. The use of embryonic stem cells is either outlawed or strictly regulated by the government. Therapy may make use of somatic stem cells and dedifferentiated somatic cells[6].

Due to safety concerns and concerns about the spread of unknown pollutants, there was little public support for xenotransplantation. To treat cutaneous wounds and burn victims, however, various xenogeneic tissue-engineered materials are now readily accessible. Biological warfare, or the use of live organisms or their products to murder people, is now prohibited.

Bio risk and Biosafety

The technological aspects of medical sciences including diagnostics and therapies have greatly advanced with biotechnology. Together with all of these, microbes are undergoing quick and harmful changes, particularly for the purpose of building antibiotic resistance. Microbiological pathogens are the cause of several illnesses, and because of gene mutation, they have evolved multi-drug resistance. Controlling these pathogenic infectious bacteria that are multidrug resistant is becoming harder and harder. Several scientists and healthcare professionals are working with these pathogenic organisms in an effort to find ways to combat their MDR. This presents significant biohazards and creates important "biosafety" concerns, such as the use of proper tools and equipment in a biosafe environment[7].

The biosafety elements have grown in importance under many circumstances and need many safety measures in health-care systems including hospitals, diagnostic labs, animal care systems, biological laboratories, etc. The procedures that may be done to lessen or eliminate

the risk associated with samples by continually identifying possible dangers, assessing their risk, and taking preventative actions to minimise exposure that might lead to infection. Each employee should have the proper training and understand the containment (conditons under which infectious agents may be handled safely) and excellent laboratory techniques that can reduce exposure to infections[1].

Bio risk

Risk is the probability that a negative event will occur, and biorisk is the probability that a major illness will arise as a result of exposure to pathogenic microorganisms or biohazards. Upon exposure, the pathogen may cause minor to serious infections, allergies, or other clinical issues. Risk assessment, efficient biosafety procedures, and biocontainment may all be used to control biorisk. Several additional diseases and fatalities related to labs were recorded after this 1978 study. Arboviruses, Brucella spp., Coxiella burnetii, Cryptosporidium spp., Hantavirus, Mycobacterium tuberculosis, HBV, Salmonella spp., Shigella spp., and were also the infecting agents in these instances.

With the world's population set to rise, biotechnology has the potential to provide solutions. Yet, there is often a lack of public acceptance and support for biotechnology goods in business, agriculture, and medicine. GM crops and human cloning have a lot of safety and moral concerns. Growing transgenic animals and plants has increased ethical issues, and scientists have encountered a lot of opposition while working on human reproductive cloning research or genetically modified agricultural plants. In order to reconcile the logic of ever-growing scientific knowledge in biotechnology, which often conflicts with the long-standing moral and social value system of our society, biosafety and bioethics are continually being extended[8].

Etymology

In a 1926 article about the "bioethical imperative" regarding the scientific use of animals and plants, Fritz Jahr, who "anticipated many of the arguments and discussions now current in biological research involving animals," is credited with coining the term "bioethics" (Greek bios, life; ethos, behaviour). In order to ensure the survival of both human beings and other animal species, American biochemist Van Rensselaer Potter expanded the term's meaning to include solidarity with the biosphere in 1970. This led to the creation of the field of "global ethics," which integrates biology, ecology, medicine, and human values.

Goal and range

The field of bioethics has addressed a wide range of human inquiry, from arguments over the limits of life (such as abortion, euthanasia), surrogacy, the distribution of limited health care resources (such as organ donation, health care rationing), to the right to refuse medical treatment for ethical or religious reasons. Bioethicists often argue with one another on the specific boundaries of their area, discussing whether the field should be concerned with the ethical assessment of all biological and medical problems, or just a subset of these questions. Some bioethicists would limit ethical analysis to solely considering the morality of medical interventions or technical advancements, as well as the appropriateness of human medical care. Some people would expand the definition of ethics to include the morality of any behaviours that can benefit or hurt species that are capable of experiencing fear. Scope.

Principles

Human experimentation was one of the first topics contemporary bioethicists attempted to address. In order to determine the fundamental ethical principles that should guide the

conduct of biomedical and behavioural research involving human beings, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was first founded in 1974. Yet, the essential tenets of autonomy, beneficence, and justice stated in the Belmont Report (1979) have shaped bioethicists' perspectives on a broad variety of topics. Others have expanded on this list of fundamental principles by include the sanctity of life, human dignity, and non-maleficence. The emphasis it places on debate and presentation is another key tenet of bioethics. To promote precisely these objectives, there are several discussion-based bioethics organisations at institutions all around the United States. The Bioethics Society of Cornell and the Ohio State Bioethics Society are two examples. There are also professional versions of these organisations.

Medical morals

The study of moral standards and judgements as they relate to medicine is known as medical ethics. Medical ethics is an academic field that includes research on its history, philosophy, religion, and sociology in addition to its practical use in therapeutic settings. In contrast to bioethics, which seems to have focused on more wide themes that touch both the philosophy of science and questions of biotechnology, medical ethics is often viewed narrowly as an applied professional ethics. The two areas often overlap, therefore making the difference is more a question of taste than of agreement among professionals. Other fields of healthcare ethics, including nursing ethics, share many of the same values as medical ethics. A bioethicist works with the medical and scientific communities to examine moral questions related to how we view life and death and to find ethical solutions. Perspectives and approach Bioethicists have training in a broad range of fields and come from a wide diversity of backgrounds.

The subject, which was originally dominated by philosophers with formal training, has grown more multidisciplinary, and some detractors have even said that the techniques of analytic philosophy have had a detrimental impact on the profession's advancement. Several religious groups have historically researched bioethical concerns and created norms and recommendations for how to approach them from the perspective of their own religions. Each of the three major world religions Judaism, Christianity, and Islam has produced a sizable amount of writing on these topics. There is often no clear distinction between philosophy and religion in non-Western civilizations. For instance, bioethical concerns are the subject of vigorous debate in many Asian cultures. In general, Buddhist bioethics is distinguished by a naturalistic perspective that yields a rationalistic, pragmatic approach. Damien Keown is a Buddhist bioethicist. Leading bioethicist Vandana Shiva represents the Hindu heritage in India. The discussion of bioethics in Africa, and to a lesser extent Latin America, typically centres on its application to underdevelopment and geopolitical power dynamics. According to Masahiro Morioka, feminists and disability activists in Japan started the bioethics movement in the early 1970s, whereas academic bioethics emerged in the middle of the 1980s. The academic community and the media both published original philosophical discourses on brain death and disability during this time. Critics of bioethics have also existed. Farmer refers to the bioethics of managing challenging clinical circumstances, which are often seen in hospitals in developed nations, as "quandary ethics." He also describes bioethicists as "constantly repeating the dangers of too much caring."

Animal Welfare

Animal ethics is a subfield of ethics that looks at the moral consideration of animals, the interactions between humans and animals, and how nonhuman creatures should be treated. Animal rights, animal welfare, animal law, speciesism, animal cognition, wildlife

conservation, pain inflicted on wild animals, the moral standing of nonhuman animals, the idea of nonhuman personality, the past of animal usage, and notions of justice are among the topics covered[9]. According to the many ideas now being advocated in moral and political philosophy, a number of distinct theoretical techniques have been presented to investigate this area. Due to the many interpretations of what is meant by ethics, there is no theory that is universally accepted by society; yet, certain views, such as animal rights and utilitarianism, are more acceptable than others.

Animal liberties

From 1635 and 1780, the first animal rights legislation were put into place. The first animal protection law was enacted in Ireland in 1635 under the name "An Act against Plowing by the Tayle, and tearing the Wooll off Living Sheep." The Body of Liberties, which Massachusetts colony established in 1641, forbade "Tirranny or Cruelty" against animals. Japan reinstated its prohibition on consuming meat and killing animals in 1687. An Introduction to the Principles of Morals and Law, written by philosopher Jeremy Bentham in 1789, said that an animal's potential for suffering, rather than its intellect, made it justifiable to award it rights. In the same year, Gompertz released Moral Inquiries on the Condition of Man and of Brutes, one of the first works that promoted what would come to be recognised as veganism more than a century later. The philosopher and ethicist Peter Singer popularised this phrase in his 1975 book Animal Liberation. The animal rights movement, which promoted the idea that animals ought to be acknowledged as sentient creatures and shielded from unnecessary cruelty, had its start in the late 1970s. Many organisations supporting various facets of animal rights and carrying out their support in various ways have been established since the 18th century. On the one hand, the American organisation "People for Ethical Treatment of Animals," founded in the US, supports the same objectives as "The Animal Liberation Front," an English organisation that broke the law by planning the Penn break-in.

DISCUSSION

Ethical standards for using animals in research

Regarding the use of animals in research, there are many different ethical viewpoints. There are widespread beliefs that treating animals ethically should be taken into account because of their moral standing. Some of these beliefs include the following: Animals have inherent values that should be respected our treatment of all animals, even laboratory animals, reflects our values and shapes our moral character since animals have feelings of suffering. The following principles for using animals in research were developed by the Norwegian National Council for Research Ethics in Science and Technology (NENT):

Respect the dignity of animals

Regardless of the value of the animals or their interests as living, sentient beings, researchers must respect the animals' worth. By selecting their techniques and themes, as well as when extending their study, researchers must show respect. Also, each laboratory animal must get care that is tailored to its requirements by researchers. Taking responsibility for weighing alternatives Researchers are in charge of researching alternatives to animal testing when such options are accessible. When there are no viable alternatives, researchers must decide if the study may be delayed until a viable alternative is created. Researchers must take responsibility for the lack of available alternatives and the need to find the answer while yet being able to defend the use of animals in their investigations. The obligation of taking into account and weighing benefit and pain is known as the proportionality principle. Researchers must weigh the potential for pain and suffering inflicted on lab animals against the

importance of the link between the study on animals, humans, and the environment. It is the obligation of researchers to determine if their work will benefit humans, animals, or the environment. The study's potential advantages must be taken into account, supported, and described in both the short- and long-term. This responsibility also comprises the need to take into account both the experiment's scientific value and its potential for providing pertinent scientific benefits.

Only when there are significant and likely advantages for animals, humans, or the environment can there be animal suffering. As there are several ways to weigh the advantages and disadvantages of an experiment, researchers must apply the techniques of analysis while organising any animal studies. Research organisations must teach their staff on appropriate models. The duty to think about minimising the number of animals it is the obligation of researchers to decide if it is appropriate to minimise the number of animals used in an experiment and only use the number required for the experiment's scientific validity and relevance to the findings.

Before starting an experiment, researchers must do reading studies, weigh different designs, and carry out the necessary computations. Responsible for reducing the possibility of animal pain and enhancing animal welfare: It is the duty of researchers to evaluate the anticipated impact on laboratory animals. Animal welfare must be great and the possibility of suffering must be minimised. Pain, hunger, malnutrition, thirst, and unusual cold or heat are examples of suffering. Fear, stress, disease, injury, and other conditions that prevent the animal from acting properly and spontaneously.

The animal that suffers the most should be the basis for a researcher's evaluation of what constitutes a significant degree of pain. If there is any uncertainty about the pain that the animals will endure, then the animals must be taken into account. There are dangers before and after the actual suffering, such as those associated with breeding, transportation, trapping, euthanasia, labelling, anaesthesia, and stabling, which researchers must take into account. The necessity for adaption time before and after an experiment must thus be considered by all researchers. Researcher responsibility for preserving biological variety: Researchers are also accountable for preventing the disruption or endangerment of biological diversity via the use of laboratory animals. As a result, scientists must take into account the effects on the stock and the ecosystem as a whole. It is necessary to exploit endangered animals as little as possible. Researchers must adhere to the precautionary principle where there is credible and unconfirmed information that using animals in study or using certain techniques may have morally objectionable effects on the stock or the environment as a whole.

Being responsible while entering an environment

Researchers have a duty to minimise any disturbance to the population, their environment, and any influence on the normal behaviours of the animals, even those who aren't used as direct test subjects in study. The majority of technological research initiatives, such as those involving environmental technology and monitoring, may have an effect on the animals and their living conditions. In certain circumstances, researchers must work to uphold the proportionality principle and lessen any potential harmful effects.

Responsibility for transparency and material sharing

It is the duty of researchers to facilitate the sharing of the data and materials from all animal studies and to ensure the transparency of the study results. To avoid doing the same animal tests again, transparency and sharing are crucial. Transparency is essential for data dissemination and is a duty of researchers. Data release to the public depends on it. Bad outcomes of animal experimentation must to be made widely known. By sharing

unfavourable findings with other researchers, you may help them learn more about which trials are not worthwhile, highlight poor study designs, and cut down on the usage of animals in research.

Need for animal knowledge

Researchers and other individuals working with live animals must possess complete, up-to-date paperwork on each animal. This entails having an understanding of the biology of the relevant animal species and being willing to be able to properly care for the animals.

The need for proper treatment

Both researchers and research managers must abide by many laws, regulations, international conventions, and agreements addressing the use of laboratory animals. Everyone who wishes to conduct animal studies should get acquainted with the existing regulations.

Technology for Reproductive Bioethics

In cases of male or female infertility, assisted reproductive technology (ART) methods are used. Ovulation, artificial insemination, in vitro fertilisation, and implantation are all steps in the ART process. Moreover, it could entail sex selection, gamete donation, gestational surrogacy, and preimplantation genetic testing.

Ethical Concerns in the Development of Transgenic Animals

Much debate has been created by the use of transgenic animals in several contexts. Several individuals and organisations believe that the creation of genetically modified organisms interferes with normal biological processes or states. They believe that since these biological states have developed naturally over a long period of time, they shouldn't be changed. A few other organisations are worried about the inability of contemporary science to completely understand the potential drawbacks and unexpected outcomes of genetic tinkering.

While transgenic animals are crucial for biological research, there have been some questions raised concerning their usage. Compared to typical research animals, transgenic animals experience greater abnormalities. It may be quite complicated to introduce DNA into an animal, and it might be difficult to foresee any potential negative consequences. The procedures required to remove and reimplant embryos surgically, the collection of tissue from the tail tip for genotyping, or nonspecific effects brought on by injury to genes around the changed region are all potential sources of harm. Moreover, this technique may lead to larger or less fertile pregnancies. In the majority of instances, the mutations have a significant negative impact on certain metabolic functions or cell receptors without really causing illness, but rather discomfort, pain, or dysfunction in the animals.

Transgenic animals that do not express foreign DNA or lack a specific gene alteration are killed. Transgenesis is not completely effective since it is a difficult science. The precision of transgenesis is, however, being improved by the development of new techniques. Remember once again that such genetic modification may only be performed if the authorities are certain that there is no other way to carry out crucial study. Transgenics have too many environmental, human, and animal health concerns to be used safely. Risks to persons who deal with animals and the effects of unintentional or deliberate releases on the environment are covered under the Environmental Protection Act (1990) and the Genetic Modification of Organisms rules.

Genetic alteration may diminish animals' inherent value and compromise their integrity. Transgenic animals have not voluntarily decided to acquire further genetic alterations or foreign DNA. Yet, this possible "cost" to the animals is regularly evaluated in the context of

the ethical evaluation of suggested operations and contrasted with any potential advantages. Medical researchers only use this technique when there are no other options for doing research, but only when they have access to the right animal breeding facilities. The use of transgenic animals in biomedical research is basically not much different from the use of ordinary animals, as the Royal Society stated in its 2001 Study "The Use of Genetically Modified Animals."

Yet, the technology has opened up new horizons for biomedical applications and given rise to new chances to investigate the molecular processes' structure, biological route, control, and pathological function.

It claims that since so many humans value them, animals are valuable. The virtue of morality is humanity. As a result, humans have duties towards other creatures. It claims that since animals can experience pain, they have moral significance. It decides to choose the course of action that will make everyone happy. As a result, it is unbiased, meaning that both pleasure and suffering are taken into account, and its objective is to enhance global happiness substance of animal activists whatever the theme, there is no justification for hurting animals for human interests, according to them.Ruthless opinion Regardless of how they are utilised, animals are not an issue in this.

The 3Rs, which stand for replace, reduce, and refine, are the principles that regulate animal rights, however. It entails employing animals in an ethical and compassionate manner. Alternatives to using animals in research were also investigated. The 3Rs stand for replacing conscious live animals with nonsentient materials or animals, reducing the number of animals used in a treatment or experiment, and improving the methods employed to lessen the likelihood or severity of animal suffering and distress.

Bioethics and Genetically Modified Crops

GM crops, often known as genetically modified crops, have expanded the scope of agriculture. The agricultural output has grown, the nutritional content of the food has improved, the need for pesticides and insecticides has significantly decreased, and medicinal compounds (vaccines) are now manufactured in plants thanks to technological breakthroughs.Yet, because of unproven and unfounded worries about their impact on the ecology and health hazards for humans, GM foods have come under increased public scrutiny. Moreover, since GM foods are not labelled, consumers are mistrustful and afraid for their food safety.

Since GM foods are not labelled, it is unclear what would happen if the GM may cause allergies owing to the insertion of an unrelated gene. For instance, a Brazil nut gene was inserted into a soybean variety, and many people developed allergies to this nut gene result. Since GM goods are not labelled, customers may ingest soybeans without being aware that they contain nut gene products. This might result in the customers experiencing severe allergic responses. Nevertheless, the resulting modified crop was never made available to the general population.According to a deal between Syngenta and the US government regarding the unintentional sale of GM (Bt10) maize seed to farmers, the human food chain may include GM items.

Societal and economic issues

Only large farmers and landowners can purchase these seeds, which has a severe impact on small-scale producers. Because they are unable to harvest, preserve, and sow these seeds, the farmers must purchase seeds every year. Just one country would have vastly different

agricultural methods, and the divide between industrialised and underdeveloped countries would increase considerably. Public trust and acceptance of GE food would be very difficult since it is not labelled.

Genetically Modified Crops' Benefits

Since the GM crops are pest-resistant, disease-related losses are reduced and yield is increased. They make use of the previously unusable terrain by being designed to endure high salt and frost levels. Also, they aid in reducing herbicides and insecticides, helping to keep them out of soil, water, and organic matter. The environment and customers would eventually be impacted by all of these issues. Biotechnology can meet the growing need for food while using the land to the fullest. Insecticides and pesticides may be reduced via biotechnology by avoiding their entrance into the food chain.

It may improve the nutritional content of the meal; for instance, golden rice can help prevent blindness caused by a vitamin A dietary shortage. Using basic storage practises, fruits and vegetables' extended shelf lives may reduce loss and enhance availability. It is also possible to alter the genes for allergens to successfully eradicate them from food crops.They thereby benefit both people and animals. Tran’s fats may be eliminated as well, resulting in healthier cuisine.Nowadays, plants are being researched and exploited to make biopharmaceuticals including vaccines, ScFv, antibodies, and other drugs. The protein passes through posttranslational changes, which reduces the probability of unfavourable responses in terms of the transfer of animal pathogens.

In India and Europe, these genetically engineered cultivars encountered fierce opposition. Their widespread acceptability has come up against obstacles from disputes, anxieties, and acceptance. The dispute sparked by NGOs, the media, and scientists has had a terrible effect on GM crops. The European Union's environmental council added to the debate by stopping the regulatory approval of GM crops. By assessing their safety as well as other perks and hazards, GM officers' ethical and safety difficulties may be resolved. Together with the desire to do good, the hazards posed by people, animals, and plants should be carefully examined. Together with advancing with advantageous parts of technology, it is crucial for the sustainability of life to take into account the well-being of everyone (including people, animals, plants, and the environment)[10]. The ultimate goal of technology should be to enhance and maintain all life forms while having as little of a harmful impact as possible on the environment and other living things.

Bioethical concerns are significant because they have a direct impact on society

The technique makes it possible for couples with fertility issues to have children, making it an excellent medical intervention for childless couples. Nonetheless, it makes it possible to conceive children who are not genetically related to either one or both of their parents (using donor sperm or ovum). Despite the fact that preimplantation genetic diagnosis is advised for medical reasons, it is not without risk. Assisted reproductive technologies would be used by male and female gay couples, single males, single women, or postmenopausal women. The kid has a legal right to live with his or her biological parents. If this technology is not handled carefully, it might lead to fractured and dispersed families and disrupt the social, gestational, and genetic connections between parents and children.

Despite the fact that many individuals support IVF and surrogacy, a poll reveals that opposition to reproductive cloning and the collection of postmortem sperm exists. Many concerns about the formation and destruction of embryos surround the technique. Justice, non-maleficence, and beneficence of all parties concerned in any situation are sought in

bioethical matters. In order to create legislation for national controls and prohibitions on inappropriate activities, adequate ethical principles and moral assessments of new technology are necessary.

Stem cells and bioethics

The therapeutic use of stem cells has expanded the scope of medicine. These cells are being considered as a viable option for the treatment of many illnesses since they have the ability to develop into practically every kind of cell. To meet the growing need for organs, scientists will likely be able to create whole organs in the future using stem cells and tissue engineering. Each tissue in the human body contains adult stem cells, which aid in renewing cells that are lost due to normal cellular wear and tear. Human embryos include embryonic stem cells at the blastocyst stage (5–6 days of age). Some parents may be able to give their extra embryos for study since at this stage, they are often undesirable in assisted reproductive technologies. There are often quite tight legal restrictions on their use. When there is no other choice, several of the countries advice using them. The umbilical cord, which is sometimes yet regularly discarded upon delivery, is where cord blood stem cells are produced from.

The use and killing of human embryos to acquire embryonic stem cells is one of the ethical concerns stated for stem cell research. As the embryo is where life first starts, destroying it is wrong; hence, its use and the extraction of embryonic stem cells are also wrong. The use of adult stem cells or umbilical cord blood stem cells, as opposed to the use of embryonic stem cells, has been seen to be more morally superior. Exploring their therapeutic potential to the fullest would be very difficult due to their rejection and unchecked expansion.

Bioethics and Human Cloning

Discussing human cloning, which may be done for "therapeutic" or "research" purposes as well as "reproductive" purposes, is a highly contentious topic. Both words are often used even if they are not scientifically correct. The somatic cell's nucleus is transported into the enucleated egg by a process known as somatic cell nuclear transfer (SCNT). The resultant embryo may either be utilised for study or put into a mother or surrogate mother for development (the cloned sheep Dolly was the product of SCNT). Reproductive cloning is the process of implanting an embryo for pregnancy, while therapeutic cloning involves harvesting embryonic stem cells. Embryonic stem cells may be used to create various types of cells when they are stimulated to do so. Individuals and the scientific community that support human cloning claim that it is effective in treating infertility and has many medicinal uses. Many individuals oppose the development and use of embryos for research, and others are worried about the hazards involved, such as ovarian hyperstimulation syndrome in egg donors. As embryos are the first stage of human existence and are thus ethically similar to persons, many more people oppose the killing of embryos. As a result, they see therapeutic cloning on par with reproductive cloning. Several scientists and philosophers believe that human reproductive cloning is inappropriate and immoral. The majority of nations have outlawed all forms of human cloning.Human reproductive cloning is one of the practises that violates human dignity, according to the 1997 Universal Declaration on the Human Genome and Human Rights.

The WHO also adopted a resolution that said that human reproductive cloning violated human dignity and asked member governments to prohibit it. The Charter of Fundamental Rights of the European Union (2000) and the Additional Protocol to the Convention on Human Rights and Biomedicine of the Council of Europe both prohibit the reproductive cloning of human beings. When we ourselves are the targets of biotechnology, we must exercise care due to the potential and power of the technology.

Biotechnology's Effect on Society: Future Possibilities

The human race has been significantly impacted by biotechnology. Technology has the power to alter the nature of humanity. Transhumans may eventually become humans. The goal of the global movement known as transhumanism is to improve human intelligence, physical potential, and psychological skills by using technology to boost brain function. Their objectives include extending human life, enhancing the brain's capabilities, delaying ageing, and improving physical health (so-called superhumans). We may go far away from our own species to "superhuman" function by attempting technology augmentation of normal human function. Hence, technological advancements have the potential to transform humanity from Homo sapiens into Homo sapiens technologicus, a "superhuman" species that utilises, fuses, and integrates technology to improve itself.

The rapid economic expansion of several nations throughout the globe serves as evidence that we are living in the finest possible period. The foundation of research is being strengthened by a number of projects that were undertaken in the areas of molecular biology, genetics, and recombinant DNA technology. The development of technology has simplified our lives. In order to serve the interests of society, it is important to give ethical dilemmas the proper attention. Our ultimate goal should be to provide comprehensive information on every facet of contemporary biology and to achieve greatness in the creation of a society that is ethically, economically, and socially viable.

CONCLUSION

In regard to pharmaceuticals, novel illness diagnoses, regenerative treatments, food and feed solutions, nutrient-dense food, and numerous other accomplishments, biotechnology has achieved enormous strides.The constant exposure of laboratory and healthcare personnel to infectious and highly contagious pathogenic organisms makes biosafety a crucial factor. They use these compounds for either research or diagnostic reasons.There have been several reports of illnesses among lab employees, some of which have been severe and have killed them. These infections in the lab were brought on by organisms from the biorisk-3 and biorisk-4 categories.

Hence, it becomes crucial to do proper risk assessments, monitor them, establish suitable preventative measures including biosafety standards and containment facilities, and provide training to laboratory staff members on prevention. There are bioethical concerns with all of the main biotechnology advancements. The problems were brought up in order to guarantee that experiments are carried out in a manner that assures the safety of everyone involved, including people, animals, and the environment, regardless of whether the experiment was correct or wrong. The development of resistance in insect-resistant crops and its effects on the environment, animals, and people are bioethical concerns concerning genetically modified crops. Many moral concerns about the suffering of genetically engineered animals have been brought forward. Genetically modified crops, assisted reproductive technologies, and embryonic stem cell therapies all encountered a lot of ethical debate and opposition. Because human reproductive cloning caused such a stir, most nations have outlawed all types of human cloning.

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CHAPTER 2

EMBRYONIC STEM CELL

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ABSTRACT:

The biggest therapeutic promise of human embryonic stem cells (hESC) is the production of specialised cells to repair damaged tissue in patients with various degenerative diseases. Current research focuses on the signalling networks that enable ESC to restrict their lineage and adopt various cellular phenotypes. In order to avoid any negative consequences upon transplantation, proper growing conditions must be developed to establish genetically stable homogenous populations of cells. This will facilitate the development of hESC-based therapies for therapeutic use. Effective cell implantation has a number of important challenges, including problems with the transplanted cells' survival and functionality.

KEYWORDS:

Cells, Cloning, Embryonic, Pluripotent, Signaling Pathways.

INTRODUCTION

The inner cell mass of a blastocyst, a preimplantation embryo in its early stages, is where pluripotent stem cells called embryonic stem cells (ES cells or ESCs) are generated. In the human embryo they are 50–150 cells strong during the 4-5 days after fertilisation blastocyst stage. Embryos in the pre-implantation stage of development should have the same moral concerns as embryos at the post-implantation stage of development, or so the argument goes. Isolating the embryoblast, or inner cell mass (ICM), results in the death of the blastocyst. Nowadays, a lot of research is being done on the medicinal potential of embryonic stem cells, with many labs aiming towards clinical use[1].

Pluripotent cells called embryonic stem cells (ESC) give birth to all somatic cell types in the developing embryo. ESC may be a useful tool for comprehending the intricate processes involved in the formation of organ architecture and the generation of specialised cells. Moreover, the endless capacity for self-renewal and adaptability of ESC enable for the in vitro production of an infinite variety of different cell types, opening up new possibilities for regenerative medicine. The ability of human ESC (hESC) to produce specialised cells to repair damaged tissue in patients with different degenerative illnesses represents its greatest therapeutic potential. The signalling pathways that allow ESC to limit their lineage and adopt different cellular phenotypes are currently being studied[2]. Moreover, in order to advance hESC-based treatments towards clinical applications, suitable growth conditions must be devised. These conditions must produce genetically stable homogeneous populations of cells in order to prevent any side effects after transplantation. Additional significant obstacles that must be overcome for effective cell implantation include issues with the transplanted cells' survival and functional performance. This study begins with a description of hESC's origins before concentrating on current developments in the production, characterization, and upkeep of these cells. We also provide an overview of the differentiation techniques used to transform hESC into various cell types. Lastly, we'll go through research on the safety and functional recovery of hESC transplantations.

ESC Derivation

Many mitotic cell divisions during early embryogenesis produce a structure known as a blastocyst after fertilisation of an egg and creation of a diploid zygote. An inner layer of cells called the embryoblast and an outer layer of cells called the trophoblast make up the blastocyst.

The extra-embryonic tissue, also known as the trophectoderm or outside cell mass, ultimately gives birth to the placenta, chorion, and umbilical cord. The embryo develops from the embryoblast, also known as the inner cell mass (ICM). The expansion and differentiation of trophoblast cells as well as the proliferation of the inner cell mass in long-term cultures in their early investigations of mouse blastocyst formation[3]. During the course of more than a year, four cell lines were acquired and maintained. These lines, however, comprised cell types outside undifferentiated ESC, were unable to in vivo differentiate into all three germ layers, and subsequently exhibited chromosomal abnormalities. After the successful development of the first stable mouse embryonic stem cell lines in 1981, proper culture conditions and the best stage of isolating pluripotent embryonic stem cells were determined using existing cultures of embryonal cancer stem cells.

The first successful generation of hESC lines by Thompson and coworkers (1998) and Reubinoff and coworkers (2001) was made possible by early research on mouse ESC and later advancements in culturing techniques that were developed to culture nonhuman primate ESC lines. These human embryonic stem cells (hESC) were from human embryos created via in vitro fertilisation for medical use. When grown on mouse embryonic fibroblast (MEF) feeders, the human ESC lines described by Thompson and colleagues maintained their pluripotency, were karyotypically normal, and met all the requirements for ESC, including the ability to produce large germ cell tumours that contained multiple types of tissue (teratomas) when grafted onto severe combined immunodeficient (SCID) mice. Without the use of immunosuppressant medications, the SCID mice may be utilised to analyse the behaviour of transplanted hESC in vivo since it is deficient in both B and T cells[4].

From donated embryos, hundreds of hESC lines have so far been produced. The majority of the time, immunosurgery or mechanical dissection has been used to separate the ICM from the trophectoderm at the blastocyst stage. The immunosurgical approach, which necessitates the use of animal-derived materials such anti-human serum antibodies and guinea pig complement, was used to create the first hESC lines. The use of hESC for transplantation therapy would be prohibited by exposure to animal-derived goods owing to the potential transmission of infections that might activate the patient's innate immune system and raise the risk of graft rejection[5]. Hence, it would be ideal for future clinical applications to mechanically or enzymatically separate the ICM from the trophectoderm in a way that prevents interaction between the ICM and animal products throughout the derivation process. Moreover, laser beams have been utilised to generate hESC lines by making a tiny hole in the zona pellucida, which covers the blastocyst, and then isolating the ICM with the use of a laser.

As the blastocyst stage requires the killing of the embryo in order to generate hESC lines, this has created ethical and political questions. Many efforts have been made to isolate cells from earlier stages of embryonic development without harming the embryo in order to overcome this problem. Variable success rates were seen in the first efforts to remove one cell at the 8-cell or morula stage, necessitating co-culture of isolated blastomeres with established hESC lines. Since the aggregates produced from the blastomere largely gave birth to vesicles that resembled trophectoderm, blastomere differentiation to ICM was very inefficient. A modified

strategy utilising culture medium enriched with laminin was used to get around this issue and boost the effectiveness of hESC derivation. This approach was nearly as effective in producing hESC lines from entire blastocysts as more traditional techniques. This crucial action of laminin was thought to be caused by a mimic of the ICM niche seen in nature, which inhibited the polarisation of the blastomeres into the ICM and trophectoderm. Also, this novel method's optimised culture conditions enabled for the effective production of hESC produced from blastomeres in feeder-free circumstances, negating the necessity for co-cultures with hESC lines obtained from animals or already established hESC lines.

In vitro hESC development and maintenance

Success in hESC cultivation is fundamentally characterised by indefinite self-renewal. MEF feeder layers were employed to promote the growth of hESC in its undifferentiated, early condition when the first hESC lines were produced. Since then, numerous strategies utilising human-derived cell types, such as fibroblast feeder cells derived from fallopian tube epithelium, foetal foreskin, muscle, bone marrow, or amniotic epithelium, have Instead, with the presence of extracellular matrices like matrigel and fibronectin, hESC may be sustained in feeder-free settings[6]. Nevertheless, to maintain hESC in an undifferentiated form in such feeder-free circumstances, medium conditioned by feeder fibroblast cells and supplementation with basic fibroblast growth factor (bFGF) were first utilised.

hESC often develop into fibroblast or stromal-like cells in feeder-free culture methods, which may act as supporting cells to assist the undifferentiated proliferation of hESC. Research looking into the characteristics of these feeder cells have shown that hESC-derived feeder cells may be employed to promote their own proliferation. While these cells meet the hESCs' growth needs, they cannot be used indefinitely since they will senescence after a few of passes. The creation of fresh feeder cells may be laborious and lead to culture systems that are very variable.So, further work is needed to create a controlled environment for hESC development and totally do away with the necessity for feeder cells[7]. Several elements necessary for maintaining the pluripotency of hESC have been found via studies on secreted factors that are produced from MEF feeder layers and have the ability to sustain the self-renewal of hESC. High levels of bFGF and noggin's inhibition of bone morphogenetic protein (BMP) signalling have also been proposed as mechanisms for maintaining hESC's undifferentiated proliferation in serum-free media. Activin A and transforming growth factor-beta 1 (TGF-1) are two additional human recombinant protein and signalling molecule cocktail external therapies of hESC that have been used for hESC production. It has been suggested that keeping hESC in feeder-free culture systems might reduce their stability and make them more likely to acquire genetic defects (Draper et al., 2004), however it is unclear if this holds true for all feeder-free culture methods.

Commercially accessible feeder-free culture methods that exclusively use human-sourced recombinant proteins have been created for the cultivation of hESC, although these conditions may not be ideal for a variety of hESC lines. Hence, even though specific feeder-free and serum-free settings for hESC preservation have been devised, further research is required to identify the variables influencing the stability of hESC lines generally and the maintenance of the pluripotent phenotype in particular[8].

Techniques for hESC growth

hESC need numerous passages and transfers to newly made cultures since they have a high potential for self-renewal. Generally, hESC are mechanically or enzymatically separated from their supporting feeder cell layer in co-culture with other murine or human cell types. Collagenase IV, dispase, and trypsin are examples of frequently used animal-derived

enzymes. Recombinant animal protein-free enzymes and human collagenase have also been employed for hESC cultivation in light of prospective therapeutic uses. Enzymatic passaging offers a more defined and repeatable culture system than mechanical isolation since it requires less work and is simple to use on a wide scale. Nevertheless, the employment of enzymatic techniques in hESC production has been substantially associated with the incidence of genetic defects. Several groups have developed enzymatic techniques involving bulk passaging and single cell dissociation to address issues with enzymatic passaging that don't compromise pluripotency or genetic stability over lengthy culture periods (more than 100 passages). Moreover, an automated technique for reliable mechanical large-scale growth of undifferentiated hESC has been devised.

Three-dimensional hESC culturing

The physical habitat and niche where hESC naturally exist should be replicated in ideal hESC growing conditions. In order to avoid differentiation, hESC are often cultivated in colonies that must stay within a certain size range throughout passaging operations. It is evident that hESC are kept in an undifferentiated state through cell-to-cell contacts as well as paracrine or autocrine signals within colonies[9].

As compared to three-dimensional (3D) culture methods, which more closely mirror the in vivo hESC environment, there is a significant variation in cell signalling, gene expression, and structure in two-dimensional (2D) cultures. According to a research by Nur-E-Kamal et al. (2006), 3D culture significantly increased cell proliferation and self-renewal as compared to growth on 2D tissue culture surfaces, demonstrating the importance of physical and mechanical signals in simulating the natural milieu of mouse ESC. The authors modelled the fibrillar network of the basement membrane using synthetic polyamide matrix scaffolds. The activation of the small GTPase Rac, the phosphoinositide 3-kinase (PI3K) pathway, and the increased expression of Nanog led to an increase in the ability of the cells to proliferate (Nur-E-Kamal et al., 2006).

A different kind of polymeric fibrous scaffold is made of cellulose acetate, which produces a meshwork that allows different extracellular matrix (ECM) molecules and growth factors to be immobilised on its surface. The study of uncommitted human embryonic germ cell derivatives, which have certain characteristics in common with hESC, has made use of this form of 3D matrix. According to reports, the better cell contact seen in 3D preparations improves cell survival, proliferation, and multipotency maintenance.

Biocompatible poly-glycerolco-sebacate-acrylate (PGSA) elastomers that are photo-polymerized to create porous scaffolds have also been used to encapsulate human embryonic stem cells (hESC). Even though hESC continue to multiply in these circumstances, after seven days of culture, it was discovered that the cells had differentiated into EB structures rather than staying in an undifferentiated state. Hyaluronic acid (HA) hydrogel has been developed as the most physiologically relevant matrix to date for the culture of undifferentiated hESC. The HA hydrogel can maintain hESC in an undifferentiated state while preserving their full capacity for differentiation because it replicates key ECM elements that are prevalent in embryos and stem cell niches.

Synthetic hydrogels' structure and chemistry may be altered by outside influences, much as PGSA scaffolds can, to control the temporal and geographic availability of bioactive compounds. To promote differentiation, components including growth factors and ECM proteins may be added. It is certainly extremely desired to develop techniques that may regulate cell-cell interactions in scaled culture by encapsulating hESC in size-specified scaffolds, but the release of cells from these 3D constructs requires enzymatic digestion.

Hyaluronidase, for instance, is added to the growth media in order to liberate hESC from HA hydrogel, however it is unknown how this enzymatic treatment may influence hESC in long-term cultures[10].

Diabetes and heart disease therapy are two potential applications

For therapeutic treatments, models of genetic diseases, and cellular/DNA repair, the cells are being researched. Nevertheless, unfavourable outcomes in clinical and scientific procedures, such as tumours and unintended immunological reactions.

Adverse outcomes

The main issue with the potential use of ESC therapy in patients is their propensity to develop malignancies, particularly teratoma. The FDA halted the first ESC clinical study due to safety concerns, however no malignancies were found. Differentiating ESC into certain cell types (such as neurons, muscle, or liver cells) that have reduced or abolished tumor-causing potential is the primary method for improving the safety of ESC for prospective therapeutic application. After differentiation, the cells go through flow cytometric sorting for further purification. Since ESC are not genetically altered with genes like c-Myc, which have been associated to cancer, ESC are believed to be intrinsically safer than IPS cells produced using genetically-integrating viral vectors. However, ESC express very high levels of the iPS inducing genes, and these genes, including Myc, are crucial for ESC self-renewal and pluripotency therefore, it is unlikely that potential safety improvement measures involving the elimination of c-Myc expression will maintain the cells' "stemness". N-myc and L-myc, however, have been shown to produce iPS cells with comparable efficacy when used in place of c-myc. By using non-integrating RNA viral vectors, such as the sendai virus or mRNA transfection, more modern 13 techniques to induce pluripotency totally get around these issues.

Ethics discussion

There are many divisive viewpoints on the subject since embryonic stem cell research is contentious in nature. The moral standing of the embryo is called into question since obtaining embryonic stem cells requires killing the embryo from which those cells were derived. Others argue that the 5-day-old clump of cells is too early to develop into a human or that, if given from an IVF clinic (where laboratories normally get embryos from), the embryo would otherwise end up in medical trash. Some who oppose ESC research contend that because an embryo is a human life, killing it constitutes murder and that it should be protected in the same way as a fully formed human person.Religions have different perspectives on the early human embryo's moral standing before the embryo is implanted in the uterus.

Conservative Protestant, Orthodox, and Roman Catholic Churches: As a human embryo is thought to have the status of a human person from the time the egg is fertilised, it has the right to live, and any action taken against the embryo's wishes constitutes a violation of that right. No good purpose (such as employing stem cells to produce additional differentiated cells to be used in what seem to be promising therapeutic techniques), which is seen to be an incorrect action, can justify the killing of the embryo. The sanctity of human life at all stages of development is affirmed by Orthodox Christians, Roman Catholics, and Conservative Protestants. They also hold that the zygote, which is committed to a developmental course that will ultimately result in a human person, is where the process towards authentic human personhood begins.

Less fundamentalist Protestant churches believe that the embryo has the capacity to become a human being because of how gradually it transforms from simple cells to a foetus. As a result, certain embryo research may be allowed. The potential social benefits of embryo research are evaluated against the embryo's life. Although the life of the human embryo is sacred from the moment of conception, there are some circumstances in which embryo research may be permitted before the embryo reaches the 14th day after fertilisation, or the "primitive streak" stage, keeping in mind the severity of some potential medical conditions.

Judaism

The Jewish faith tradition places a strong emphasis on the value of life preservation and views saving lives as the ultimate purpose of human embryonic stem cell research. In Judaism, healing is not only acceptable, it is also necessary to actively participate in the world's restoration and perfection. The planet must be built and developed by man in any way that benefits people. Hence, nothing that leads to global progress can be seen as being against God's laws. The ability to develop new technology is also credited to God, according to another popular belief. Everything that is not forbidden for whatever reason is allowed without the need to provide justification. Judaism does not recognise the full human status of a human foetus less than 40 days old or a pre-implantation embryo. The embryo in the uterus is regarded as a part of the mother after those first 40 days and up to delivery.

DISCUSSION

Most Muslim philosophers throughout history have endorsed abortion up to the forty-first or fourth month of pregnancy as morally acceptable. During the 40th day after fertilisation, it is said that the soul "breathes in" to the human foetus, and this is when life is revered. The foetus is only given the status of a legal person later in its development, when observable shape and voluntary motions occur, according to all schools of Islamic philosophy. Theorists distinguish between a biological person and a moral person, with the moral person's stage occurring after the first trimester of pregnancy. Muslims disagree on whether the soul "breathes in" after 40 or 120 days, however.

Also, it is thought that every ailment has a treatment option available, thus finding the treatment is a good idea. Since stem cell research has therapeutic advantages, it is appropriate and supports the high value of medical advancement. The excess embryos cannot be transferred to other spouses in the Muslim religion since the father's lineage must be honoured. According to this argument, using superfluous embryos that won't be utilised for in vitro fertilisation for scientific reasons rather than killing them is the better option.

Buddhism and Hinduism: Buddhism forbids the harming of any sentient creatures, which may put constraints on research using embryos and animals. Additionally, murdering is only one example of a behaviour that is seen as unethical since it regards people as non-humans. Nevertheless, not all applications of medical biotechnology are morally problematic for Buddhists: more sophisticated medical biotechnology where research is done at the molecular level is probably permissible.

In the case of studying human stem cells, the goal is crucial. Such study is regarded as ethical if its goal is to assist and benefit humanity. On the other hand, doing research just for the purpose of profiting from it is seen as immoral. Buddhism, however, has strong objections to any scientific method or practise that entails the extinction of life, whether it be plant or animal. This is because Buddhism attaches high emphasis to the concept of non-harming. Yet, the idea of non-harming might be taken to mean that only living things with the capacity for feeling are allowed to be harmed. Buddhism might thus approve of research on non-

sentient embryos before day 14 of development. Similar to Buddhism, Hinduism forbids harming sentient creatures. Hindu tradition opposes both the use of animals in research and the killing of sentient embryos. The lesser of two evils is opting to do research on extra embryos that will no longer be utilised for in vitro fertilisation rather killing them. The Human Genome Project (HGP) was a global endeavour that included scientists to identify and map the base pairs that make up human DNA as well as to determine their composition. Each and every gene in the human genome, both physically and biologically. It continues to be the biggest collaborative biological effort in the world Planning began after the US government adopted the proposal in 1984, the project was officially begun in 1990, and it was finished on April 14, 2003.

Several additional organisations from all around the globe as well as the National Institutes of Health (NIH) of the US government provided funding. The Celera Company, or Celera Genomics, which was legally established in 1998, carried out a similar effort outside the government. Twenty universities and research facilities in the United States, the United Kingdom, Japan, France, Germany, Spain, and China undertook the majority of the government-sponsored sequencing work.

The Human Genome Project's first objective was to map the nucleotides in a reference human haploid genome (more than three billion). Every person has a unique "genome," therefore to map the "human genome," a small sample of people had to have their chromosomal sequences completed before they could be put together. The final human genome is thus a mosaic and does not reflect any one person.

In order to promote fundamental and applied research on the ethical, legal, and social implications of the Human Genome Project (HGP), the National Human Genome Research Institute (NHGRI) Ethical, Legal, and Social Implications (ELSI) Research Program was formed in 1990.For individuals, families, and communities as a whole, the social ramifications of genetic and genomic research.The ELSI Research Program sponsors seminars, research consortiums, policy conferences, and studies on these subjects. It also finances and supervises related projects.

Research Goals for ELSI

Charting a route for genomic medicine from base pairs to bedside is the title of the NHGRI's strategy plan for the future of human genome research, which was published on February 10 in Nature magazine. In the section on Genomics and Society of this plan, four issues are outlined that must be resolved as genomic research and medicine advance. The NHGRI has created the following general research goals based on these categories.

Genome-wide analysis. The problems that crop up during the planning and execution of genomic research, in particular as it increasingly entails the generation, analysis, and widespread dissemination of personal genetic data that is commonly combined with in-depth medical data.Genomics-based healthcare How quickly genetic technologies are developing and how much more genomic information is becoming available will alter how healthcare is delivered and how it will impact the health of people individually, in families, and in communities.

Wider societal problems. The normative foundations of attitudes, behaviours, and laws relating to genetic data and technology, as well as how genomics affects how we think and comprehend things like health, sickness, and personal responsibility.Problems with law, regulation, and public policy. The implications of current genetic research, shealth and public policies and regulations and the creation of new policies and sregulatory methods.

When the Human Genome Project got underway, a number of ethical, legal, and societal issues were brought up on how better understanding of the human genome can be used to prejudice against individuals. The idea that both employers and health insurance companies will reject applicants or deny coverage to people due to a health problem suggested by a person's DNA was one of the top worries of most people. The Health Insurance Portability and Accountability Act (HIPAA), enacted in 1996 in the United States, forbids the unapproved and unconsented disclosure of personally identifiable health information to any organisation not actively involved in providing healthcare services to a patient. Other countries did not adopt such safeguards.

The Human Genome Project aimed out to discover every one of the roughly 20,000–25,000 genes that make up the human genome, as well as to solve the social, ethical, and legal problems that were brought on by the project's inception. The Ethical, Legal, and Social Implications (ELSI) programme was established in 1990 in response to this. The ELSI resulting from the initiative received an allocation of 5% of the yearly budget. In the year 1990, this budget was around $1.57 million, but by the year 2014, it had grown to almost $18 million. While some writers have underlined the need to address the possible societal ramifications of mapping the human genome, the endeavour may yield enormous advantages to science and health. "Molecularizing disease and its potential treatment will significantly alter what people anticipate from medical care and how the next generation of clinicians see sickness.

CONCLUSION

A challenge in the experimental control of directed differentiation of hESC is the requirement for lineage restriction and induction of differentiation of hESC to produce particular cell types. This requires a complex interplay between graded concentrations of several patterning cues under temporal constraints. To fully comprehend the signalling pathways that control the specification of hESC to various cellular identities, it is also necessary to analyse the critical roles that the extracellular environment plays in differentiation.

Current research has been very successful in identifying the crucial moments in hESC development and cell fate determination. Moreover, it is anticipated to help define the steps that lead from unspecialized cells to cell types of interest by identifying genetic profiles and unique molecular markers indicative of certain cellular phenotypes. Nonetheless, it is probable that advanced techniques for evaluating genetic and phenotypic stability would be needed if these encouraging fundamental science results are to be successfully translated into cell replacement treatment in human beings. The in vivo survival and functional effectiveness of these cells will need to be increased, and the potential for unchecked expansion of hESC-derived cell offspring will need to be carefully evaluated. In order to ensure the safety of hESC-based treatments, it is crucial to develop more effective approaches for the identification and eradication of remnant undifferentiated hESC that may one day result in malignancies.

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CHAPTER 3

HUMAN GENE THERAPY

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ABSTRACT:

Since the gene was identified as the fundamental component of heredity, the capacity to alter the human genome at precise sites has been a goal in medicine. Gene therapy is therefore defined as the capacity to change a person's genetic makeup via the repair of altered (mutated) genes or site-specific alterations that are intended to cure a medical condition. The development of genetics and bioengineering, which allowed for the manipulation of vectors for the transfer of extrachromosomal material to target cells, made this treatment conceivable. The optimization of delivery vehicles (vectors), which are mostly plasmids, nanostructured materials, or viruses, is one of the key areas of concentration of this method. Due of their prowess in invading cells and introducing their genetic material, viruses are more frequently studied. Exacerbated immunological reactions and genome alteration, particularly in germ line cells, are of major concern. Somatic cell in vivo investigations using authorised methods in clinical trials produced good findings.

KEYWORDS:

Biosafety, Bioethics, Cloning, Gene Therapy, MedicalEthics, Philosophy.

INTRODUCTION

Many individuals claim they are frightened about the alterations in our genetic instructions. But, they (genetic instructions) are just the result of evolution, tailored to allow us to adapt to circumstances that may no longer exist. Humans have known from the beginning of time that the unusual traits of the parents may be passed on to their offspring. Greek scholars are credited with creating the earliest hypotheses, some of which persisted for many years. Through a series of experiments with green peas, the Austrian monk Gregor Mendel defined the inheritance pattern by analysing the traces that were inherited as discrete units, which we now know as genes. This discovery launched the field of genetic science in the early 1850s. Nothing was known about the physical makeup of genes until 1950, when James Watson, an American biochemist, and Francis Crick, a British biophysicist, created the ground-breaking double strand DNA model. The separation of genes at specific locations along the DNA molecule and their repeatable reinsertion were made possible in 1970 by the discovery of a number of enzymes. These genetic developments paved the way for the development of genetic engineering that resulted in the creation of novel medications and antibodies, and as of 1980, gene therapy had been adopted by researchers. In this overview, we discuss gene therapy, the many genetic engineering techniques utilised for it, as well as its drawbacks, potential uses, and future directions[1]–[4].

Gene Treatment

With the discovery of DNA as the fundamental building block of heredity, the goal of medicine has been to be able to locally alter the human genome. The ability to enhance genes via the repair of misplaced (mutated) genes or site-specific alterations with therapeutic

treatment as the aim is known as gene therapy. Several tactics that are often used for this objective are explained in the following sections.

Gene therapy is now a field that mostly exists in research labs, and its applicability is still being tested. The majority of trials take place in the US, Europe, and Australia. It has the potential to cure acquired genetic illnesses like cancer and certain viral infections, including AIDS, as well as diseases brought on by recessive gene defects like Cystic Fibrosis, Hemophilia, Muscular Dystrophy, and Sickle Cell Anemia. Using genes to cure illness is known as gene therapy. In the next 10 years, it will have a big impact on medicine since it represents a quantum leap in how we treat human illness. In 1990, William French Anderson, Michael Biase, and Ken Culver successfully administered the first case of gene therapy to a person[5]. They created a strategy for treating severe combined immune insufficiency, or "Boy in the Bubble illness," also known as adenosine deaminase (ADA) deficiency. Inheriting two copies of the damaged ADA gene causes ADA deficiency (in other words it is a recessive disease). A normal gene causes cells all throughout the body to produce ADA continuously and regularly. Children cannot transform the waste product deoxyadenosine into inosine without at least one gene operating correctly. Deoxyadenosine builds up quickly as a result, and when it is phosphoralyzed, it transforms into a hazardous triphosphate that kills T cells. Early mortality and practically total immune system breakdown are the outcomes.

Gene Therapy Theory

Initially, potential cures for genetic illnesses that included swapping a faulty gene for its healthy counterpart were referred to as "gene therapy." The word is currently used to refer to any medical procedures that include inserting genetic material into bodily cells in order to cure a range of ailments. There are two potentially viable methods used in gene therapy: 1) Somatic gene therapy is when a gene or genes are transferred into body cells other than germ (egg or sperm) cells, with the patient as the only recipient. It is impossible to pass on the new genetic material to kids. Somatic gene therapy has already shown therapeutic efficacy in certain cases. Two children, ages 4 and 11, received the first adenosine deaminase deficiency therapy in 1990 and 1991. With ongoing care, both are prospering. In 1992, a 29-year-old lady had the first effective therapy for familial hypercholesterolemia, a hereditary disorder that disrupts the liver's control of cholesterols in the blood[6]. Her progress remained steady throughout the course of the 18-month trial, and a liver biopsy revealed that the implanted gene was active and that there were no obvious abnormalities. As of 1994, five patients have received treatment.

Many domains are the subject of current somatic gene therapy research. A therapy for the hereditary disease cystic fibrosis is undergoing clinical testing. 19 2) Genetic manipulation of germ cells would be a component of a germline gene therapy. Such treatment would alter the genetic make-up of an individual's egg or sperm, which would be passed on to next generations. This would provide the opportunity to permanently eradicate an inherited illness from a family line. Other approaches, like the current practise of diagnosing known risks prior to embryo implantation during IVF, might be used to accomplish this. Germ line treatment is a distant possibility and is now prohibited in the majority of Europe due to considerable public opposition. Issues related to somatic and germ line gene therapy vary. The possibility of efficient treatment and a cure for diseases that were formerly deadly is presented by somatic gene therapy[7]. Even in these instances, therapy is complicated, challenging, and the outcome is unknown. Until date, it has only been used experimentally for a limited spectrum of hereditary illnesses. Details of Gene Therapy Technology The ability to successfully transport a therapeutic gene to a target cell is the most important prerequisite for gene therapy to be successful. Once transported, the gene must get to the cell

wall's nucleus, where it will serve as a model for making protein molecules. The principal therapeutic action is then produced by the protein. For instance, cell destruction may be used in the treatment of tumours, whereas cell preservation might be used in the case of neurodegenerative illness. Genes may enter cells in a variety of ways[8]. The most effective of them makes use of modified, disabled viruses. Since viruses have evolved over a long length of time to transmit their own genes to cells, these systems are effective. Whenever we get a viral illness, such as a cold or AIDS, the virus in question inserts its genes into our cells to reprogram them to make more virus. When we employ viruses for gene therapy, we disable them so that they can't spread illness and design them so that they take up and deliver our desired genes rather than their own genes. Viral vectors are the versions of viruses that are utilised to transmit genes. There are two kinds of viral vectors that are most often utilised. Adenovirus-based vectors are often utilised for therapeutic approaches that only need the therapeutic gene to be active briefly. Adenoviruses are extraordinarily effective at delivering genes, but since the genes are not properly integrated into the target cell's chromosomes, they gradually disappear. Certain therapeutic approaches, including cell death in the therapy of various malignancies, restinosis, or inflammatory illness, do not suffer from this drawback. It is a drawback, however, when long-term maintained gene activity is needed, as in the case of HIV infection, the therapy of certain cancers, and neurological diseases. The second most common form of vector is based on the retrovirus known as the murine leukaemia virus (MLV). Genes supplied by MLV derivatives are incorporated into the target cell's chromosomes and are kept there for as long as the cell is alive. Gene activity can be easily controlled and lasts for a very long time. These MLV-based systems have undergone several clinical studies and have shown to be well tolerated with no negative side effects[2], [3], [9], [10].

Adenovirus vectors and MLV vectors vary significantly in that the former can transfer genes to cells that are not replicating via cell division while the latter cannot. This has meant that, up until recently, options for gene therapy that call for sustained gene activity in cells that are not dividing have proven practical. Neurons, certain immune system cells, and some epithelial cells are examples of significant target cells that do not divide. Lentiviruses are a subclass of the larger retrovirus family, however they differ from MLV-like viruses in that they may infect non-dividing cells. HIV is the most well-studied lentivirus, and when it was discovered, around ten years ago, that HIV could infect terminally differentiated macrophages, which do not divide, a movement to create gene delivery vectors from HIV emerged. Early technological challenges included a number, and first-generation vectors could not be employed in the clinic because they may produce contagious HIV[11]. In the last two years, novel HIV-based vectors that are severely handicapped and only carry the few HIV components necessary for effective gene delivery to non-dividing cells have emerged.

These so-called minimum vectors are now contenders for use as therapeutic gene delivery systems in gene therapy. Chimeraplasty is the name of the procedure, which was created for mammalian gene therapy. Its ability to target any single gene and create small alterations with great accuracy gives it an edge over conventional genetic engineering techniques. Chimeraplasty just turns on or off a function for which the plant already possesses a gene, as opposed to inserting a new gene to mislead the plant into performing something it would not ordinarily do. Up until now, a whole gene had to travel into the nucleus on a virus that had been defused and could insert itself into the genome. The virus might, however, choose any site on the 21 genome, sometimes picking one that is not the best for the replication of additional genes. The risk of introducing big gene segments that may have negative side effects, such harming beneficial insects, is also removed by this technique[12]. Chimeraplasty begins with oligonucleotides, or "oligos," which are discrete pieces of synthetic genetic

material with around 25 bases apiece. Except for a few of nucleotide mismatches, they are exact replicas of a single plant gene. The pieces are attached to microscopic gold particles, which are then fired with a particle cannon into the cell's nucleus. The DNA repair machinery attempts to "correct" the mismatch when the oligos join their cell-based counterparts by employing the new base sequence as a template. Those with deformed blood cells, like sickle cell anaemia sufferers, don't benefit much from increasing blood cell synthesis. Gene therapy's ultimate objective is to entirely eradicate hereditary illnesses rather than treat them. There is reason to believe that aim could be achievable based on preliminary research that was published in the September 6 edition of science[1]. Cells bearing a defective gene that produces sickle cell anaemia were the subject of experiments by a team at Thomas Jefferson University in Philadelphia headed by Allyson Colestrauss and Kyonggeum Yoon. They coupled RNA for the same gene with DNA from its normal form to create their genetic medicine. The RNA/DNA particles found the specific region of the genome that matched their codes when they were put into the sick cells, forming triple stranded DNA that covered the mutation. A mutation was then reportedly restored by the original coding by the cell's natural DNA repair mechanism, permanently healing 10 to 20 percent of cells.

The effectiveness of this approach in human cells and bodies still has to be shown by researchers. A gene called p53 that controls programmed cell death has mutated, and this occurs in around 50% of lung cancer cases. Cancer may spread without this protein, which works to stop the formation of damaged or aberrant cells. In investigations on a few individuals as well as in research on animals, replacing such damaged p53 genes with new ones has shown promise against a range of malignancies. Researchers now claim further advancements in this kind of localised gene therapy. They used a virus to transport p53 to tumour locations in 28 patients with lung cancer, and in more than half of cases, this temporarily stabilised or reversed the course of the disease. The lung cancer in the patients, who were on average 65 years old, was either incurable or was no longer responding to radiation therapy or 22 chemotherapy. An adenovirus designed to include p53 genes was injected into the tumours by the researchers. The virus was altered to stop it from reproducing and potentially spreading the upper respiratory sickness that it would otherwise cause.

Patients got one to six monthly injections of the modified virus during the course of the six-month therapy period. To test for treatment toxicity, the researchers administered a variety of dosages, ranging from 1 million to 100 billion viral units. Before physicians could conduct a 1-month follow-up assessment, 3 of the 28 patients passed away from cancer. Tumors decreased in size in two of the 25 more patients, remained stable in 16, and grew in one more. The viral dosage was important; three out of five patients who got injections of 10 million or less viral units saw their malignancy develop unabatedly. Just 4 of the 20 individuals who received the higher dosage, in contrast, developed cancer development. Human gene therapy defence Think about the advantages a country might experience if parents were allowed to genetically modify their offspring. It is assumed that genetic enhancement technology improves children's capacity for learning and cognitive function, and subsequently for knowledge production and knowledge acquisition. So, allowing or promoting genetic improvement would raise the total amount of human capital present in a country's workforce. The impact of further government spending in education, training, and scientific or engineering research would be amplified by the rising frequency of high ability genes. The impact of these expenditures on the stock of human capital is cumulative since genetic improvements are heritable, unless enhanced children or their descendants depart. Third, allowing genetic enhancement would be an inexpensive approach for a state to raise overall human capital since some parents would choose to pay for it out of their own money due to parental rivalry. In economic competitions among nations, small initial differences in the

distribution of capable people can eventually multiply to large international differences in the rate of economic growth if expanding stocks of a nation's human capital bring increasing returns in productivity and economic growth. So, states have an incentive to break the international taboo on genetic modification in order to advance in the development of human capital. It is believed that soon parents will be able to purchase a hazel-eyed, red-headed extrovert with excellent pitch by looking through gene catalogues. Every new finding helps to frame the discussion, which we have only just started. Even doubters concede that these problems will eventually materialise. While self-improvement has always been a religion in America, social standards are always evolving. Notwithstanding the enormous promise of gene therapy, opponents of biological reductionism will likely raise a number of arguments.

A person's sickness experience includes a variety of social and psychological factors (such as emotional impact of the disease, the stigmatism attached to it, the cost and employment implications, etc). Therapeutic strategies focused only on the genetic level ignore these significant features of illness. In many nations today, governments appoint committees to study the issue that include not only scientists and physicians but also religious authorities, attorneys, and ethicists. It is important to distinguish between altering the genetic makeup of germinal cells vs somatic cells. Somatic gene therapy is used to treat a single patient, for example, by inserting a healthy gene into the patient's bone marrow cells in vitro before putting the cells into the patient's body. Nevertheless, gene therapy differs from conventional medicine in that it does not involve the repetitive administration of an external force or substance and instead causes an intrinsic and presumably permanent alteration in the organism. An analogue is the transplanting of organs, which likewise entails integrating cells with foreign DNA into a person. It is prohibited to use germline gene therapy, in which alterations would be applied to the germ cells and passed on to the progeny.

DISCUSSION

The gene therapy procedure is very complicated, and many approaches still need fresh innovations, despite the fact that a number of regimens have proved effective. Identification and accessibility of the precise bodily cells that need therapy are necessary. The illnesses and the stringent genetic ties underlying them must be well understood, and a method for efficiently distributing the gene copies to the cells must be accessible. The target cell type for gene therapy, which is now split into two major categories—gene therapy of the germline and gene therapy of somatic cells—is another crucial problem. Functional genes are introduced and incorporated into the genome of stem cells used in germline gene therapy, such as sperm and egg. The alterations are genetic and are passed on to next generations. Theoretically, this strategy ought to be quite successful in the fight against inherited and genetic illnesses. Therapeutic genes are transmitted to a patient's somatic cells during somatic cell gene therapy. Future generations are not affected by any modifications or effects, which are limited to just that patient.

Gene Therapy Procedure

A normal gene is put into the genome during gene therapy to replace a defective gene that is responsible for a particular illness. The difficulty in releasing the gene into the stem cell is one of the most important difficulties in the procedure. In order to release the gene, a molecular carrier known as a "vector" must be very specific, show efficiency in releasing one or more genes of the sizes required for clinical applications, not be recognised by the immune system, and be purified in large quantities and high concentrations so that it can be produced and made accessible on a large scale. After the vector has been implanted, it cannot cause allergic responses or inflammatory processes; instead, it must enhance healthy functions,

make up for inadequacies, or prevent harmful behaviours. Additionally, it must be secure not only for the patient but also for the environment and the experts using it. The vector should also be able to express the gene generally throughout the duration of the patient's life.

While the effectiveness of viral vectors has been established, new research has shown that using these carriers has a number of drawbacks. A significant exacerbating aspect is the presence of viral genetic material in the plasmid, which may cause an immediate immune response in addition to a potential oncogenic transformation. There are now two major methods for altering a cell's genetic makeup: virus-mediated and physical processes using materials created using sophisticated nanotechnology techniques. Included in this context are polymers such DNA microinjections, cationic polymers, cationic liposomes, and particle bombardment that build networks that trap a gene and release its cargo when they reach the cells.

Human Hematopoietic Stem Cells and Gene Therapy

Due to their tremendous potential for lifespan and aptitude for self-renovation, hematopoietic stem cells have emerged as perfect candidates for gene transfer. The generation of gene transfer vectors for the formation of induced pluripotent stem cells (iPS), in order to create the differentiation of the iPS and offer an extra phenotype from this differentiated derived cell, would be one example of this combination of gene therapy with stem cells. The hepatic transplantation of mature hepatocytes or those produced from iPS may be an option for patients who need a liver transplant and have chronic liver disease and hepatitis virus infection (such as hepatitis B virus and hepatitis C virus). Since the transplanted cells are prone to re-infection by the hepatitis virus, the transfer of a vector that encodes a short hairpin RNA directed against the virus would give the transferred cells resistance or "immunity" to re-infection. Gene transfer alone may not be sufficient to transform stem cells into hepatocytes. Over time, resistant cells might repopulate the liver and bring it back to its pre-infection state.

Treatment Using T Lymphocytes from the Chimeric Antigen Recipient

Receiver of a chimeric antigen T (CAR-T) cell treatment is a kind of immunotherapy that involves the alteration or reprogramming of the patient's own immune cells (T lymphocytes) to detect and combat the tumour T cells. The fusing of a single chain fragment variable (scFv) to a transmembrane domain as well as an intracellular signalling unit: chain CD3 zeta, was the first significant step in the creation of the first CAR generation. This approach increased the recognition of the tumor-specific epitope and the activation of T lymphocytes without relying on components from the histocompatibility complex by combining the active component of a well-characterized monoclonal antibody with a signalling domain.

By including co-stimulating chemicals required for signal transduction, the first generation of CAR was improved. In this CAR generation, CD28 is the stimulatory recipient that is most often employed. This receiver serves as the second activating event along the pathway, causing the production of cytokines to rise and T cells to proliferate significantly.To improve CAR function, the most recent generation of CAR included the inclusion of a co-stimulatory domain. With this technique, co-stimulatory molecules (CD134 or CD137) acting as tumour necrosis factor receivers are necessary. scFv, the CD3- initial chain, as well as the stimulatory chains of CD28 and CD134 or CD137, are the most modern versions of CAR.

Zhong et al. showed an improvement in T cell activation of the protein kinase B (Akt) pathway, which controls the cell cycle, with the third CAR generation. Compared to the second generation of CAR, this most recent generation has better T cell persistence,

according to previous research.The identification of non-tumor cells that express the target epitope by CAR is the most important aspect of the side effects of CAR-T treatment. While they are not just found in tumour cells, tumour antigens are substances that are significantly expressed in these cells. For instance, the CD19 antigen may be detected on either healthy or cancerous B cells, and the CAR design for the CD19 target is unable to tell the difference. The cytokine release syndrome is another frequent side effect of CAR-T treatment as well as several other kinds of immunotherapy for cancer (CRS). After receiving a CAR-T injection, the immune system may become activated, which can cause an abrupt rise in inflammatory cytokine levels.

Recent advances in CAR-T trials and vector design provide stability and reinforcement in safety for amplification of the clinical use. As was shown from the first to the third generation, the CAR trials have already seen a steady improvement. The success of the incremental upgrades for next trials will be increased by the knowledge and experience gained in the evaluation of CAR-T toxicity.

CRISPR-Cas9

In the 1980s, a portion of the Escherichia coli genome was found to have an unusual pattern in which a repeatedly occurring sequence with no known purpose intercalated a highly variable sequence. The CRISPR system (Clustered Regularly Interspaced Short Palindromic Repeats) and Cas (Associated Proteins) were invented in 2005 under the presumption that the variable sequences were of extra-chromosomal origin and served as an immune memory against phages and plasmids. Since 2012, this system has been one of the most important biotechnological tools for gene editing. This process, which has its roots in the immune-adaptive system of procaryontes, detects the invasive genetic material, cleaves it into little pieces, and incorporates the fragments into its own DNA. Upon a subsequent infection with the same agent, the CRISPR locus is transcribed, RNAm is processed, and tiny RNA fragments (crRNAs) are produced. These complexes with the Cas proteins allow them to detect foreign nucleic acids and ultimately destroy them.

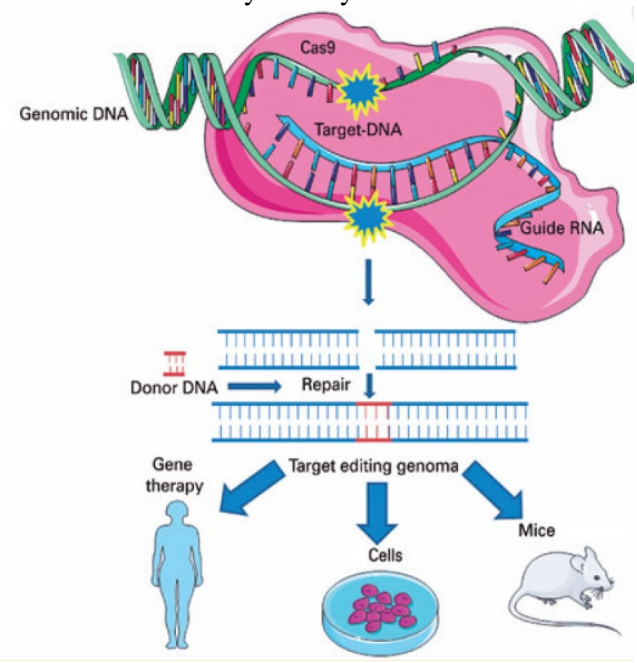

Figure 1: Illustrate the CRISPR Cas-9 technology.

Based on this natural process, the CRIPSR technology was created, allowing editing of the target-specific DNA sequences of the genome of any creature using just three molecules: the target DNA, an RNA guide, and the nuclease (Cas9) responsible for cleaving the double-stranded DNA.The CRISPR system emerges as a versatile tool that promotes genetic editing by means of inactivation (knockout gene KO), integration of exogenous sequences (knock-in), as well as allele substitution, among others. This is due to its simplicity as well as its precision when compared to other techniques. The target DNA and the guide RNA hybridise. In the presence of (homologous) donor DNA, Cas-9 should mediate the cleavage of the DNA double strand and repair since it identifies this complex. Allele replacement or the incorporation of a foreign sequence into the genome are the outcomes of this process.The quick development of this new technology made it possible to conduct translational studies employing CRISPR-based genome editing in human somatic cells. The initial therapeutic-focused applications were notable for outlining even the delivery system optimization processes and providing detail for the system's safety and efficacy, as shown Figure 1.

Recently, scientists from the Universities of California and Utah were successful in reversing the haemoglobin gene mutation that causes sickle cell anaemia. After being separated and edited using CRISPR-Cas9 for 16 weeks, CD34+ cells from sickle cell carrier patients revealed a decrease in the expression levels of the mutant gene and an increase in the gene expression of the wild type. The method mentioned is mostly used in monogenic genetic illnesses, which, while being uncommon, may reach over 10,000 previously known diseases. Phase 1 clinical studies and the emergence of businesses focused on the therapeutic use of this technology are anticipated for 2017.

Ethical Concerns

The idea of genetically altering germlines has long been the subject of contentious debate in the scientific community. As new procedures are developed, bioethics is always there to evaluate the procedure's hazards and moral ramifications. Genetic treatment in somatic cells is widely accepted in the scientific community, particularly in situations of severe diseases like cystic fibrosis and Duchenne muscular dystrophy.Nevertheless, Chinese scientists disclosed the first use of the CRISPR-Cas9 method to genetically modify embryonic cells in 2015, moving beyond moral concerns. Thereafter, another Chinese group reported carrying out the identical procedure with the goal of introducing the CCR5 gene mutation to give HIV resistance. Four out of the 26 embryos were effectively changed, according to the DNA study. The outcome amply demonstrates the need for method improvement and raises the possibility that similar experiments may have previously been undertaken in animal models.

These most recent papers reopened the conversation on genetic modification. On the one hand, the Japanese Ethics Committee ruled that the experiment was carried out properly since the local Ethics Commission had approved the research and the egg donors had given their agreement. The first experiment for modifying healthy human embryos was allowed in the United Kingdom. Nonetheless, American research organisations maintained a conservative stance, repeating that they opposed this kind of trial and that they were waiting for advancements in both the methods and the definitions of ethical difficulties.

CONCLUSION

Since James Watson's prediction in 1991 that human genetics would likely be optimised, gene therapy has advanced over the years, whether through the improvement of vector types, the introduction of fresh methods like the use of induced pluripotent stem cells in conjunction with modern genetic editing techniques (CRISPR-Cas9), or even through trials in germ cells, bringing with them the contradictory ethical and moral issues that accompany the technique.

Gene therapy is a viable therapeutic option for people with cancer, congenital illnesses, or monogenic disorders, particularly when pharmaceutical or surgical procedures do not provide the desired effects. Local successes have previously shown this. The development of novel experimental vectors, improvements in efficacy, the specificity of delivery methods, and a deeper understanding of the production of the inflammatory response may strike a compromise between the expansion of clinical application approaches and the enhancement of safety. Yet major improvements in the use of these techniques are also made possible by the information and experience gained through the rigorous evaluation of toxicity of these technologies. Hence, historically, the development of new technologies such as gene therapy, antibiotics, and chemotherapeutic medicines required more thorough preclinical research. Future applications of these methods across a variety of medical specialties and a higher proportion of clinical trials are promised.

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CHAPTER 4

GENETICALLY MODIFIED ORGANISM

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ABSTRACT:

Using conventional breeding methods, people have been modifying the genomes of plants and animals for a long time. Sweet corn to hairless cats are just a few of the many species that have been produced as a consequence of artificial selection for certain, desired qualities. Yet, this artificial selection, which selects organisms with certain qualities to produce new generations, has only been applied to naturally existing variants. Yet in recent years, developments in the science of genetic engineering have made it possible to precisely regulate the genetic alterations made to a creature. Using genetic engineering, we may now introduce novel genes from one species into a species that is entirely unrelated to it, improving agricultural productivity or making it easier to produce important pharmaceuticals. Some of the most well-known examples of creatures that have been subjected to genetic engineering include crop plants, livestock, and soil microbes.

KEYWORDS:

Biosafety, environmental, Gene Therapy, Genetically Modified Organism (GMO).

INTRODUCTION

Genetically Engineered Organisms: Current Applications

In a picture, five silver fish are arranged vertically and horizontally in a row. The backdrop is dark. Five more little fish are positioned similarly below. A third of the length of the larger fish at the top are the tiny fish at the bottom. One of the most often used instances of genetically modified organisms is agricultural plants (GMOs)[1]. Increased crop yields, lower costs for food or drug production, less need for pesticides, improved nutrient composition and food quality, pest and disease resistance, greater food security, and medical benefits for the world's expanding population are a few advantages of genetic engineering in agriculture. Moreover, progress has been made in creating crops that mature more quickly and can withstand environmental stresses including drought, cold, salt, aluminum, and boron. This enables plants to grow in environments where they could not normally thrive[2]. Production of non-protein (bioplastic) or non-industrial (ornamental plant) products are examples of further uses. Many animals have also undergone genetic engineering in an effort to boost productivity and reduce illness susceptibility. For instance, salmon have been genetically altered to mature and become bigger more quickly, while cattle have been improved to withstand mad cow disease.

Any creature whose genetic makeup has been changed through genetic engineering methods is referred to as a genetically modified organism (GMO)[3]. A genetically modified organism is one that has undergone changes that "do not occur spontaneously via mating and/or natural recombination," according to the most widely used definition of genetic engineering. Genetically modified (GM) organisms include a broad range of species, including microbes, plants, and animals. Within the same species, across species (producing transgenic organisms), and even between kingdoms, genes have been transported[4]. Endogenous genes

may be strengthened, changed, or cancelled off in addition to new genes being added. A genetically modified organism must go through many steps to be created. A promoter and terminator region, as well as often a selectable marker, must be added to the gene that genetic engineers seek to implant into the host organism. The isolated gene may be inserted into the host genome using a variety of methods. The creation of GMOs has become considerably easier because to recent developments in genome editing technologies, particularly CRISPR. In 1973, Herbert Boyer and Stanley Cohen created the first genetically engineered organism—a kanamycin-resistant strain of bacteria[5]. Rudolf Jaenisch developed the first genetically altered mouse in 1974, and the first genetically altered plant was made in 1983. The first GM product to be commercially marketed was the Flavr Savr tomato, which was introduced in 1994. The first genetically altered animal to be authorised for use in food was the AquAdvantage salmon in 2015, while the first genetically altered animal to be sold was the GloFish in 2003. In research, food production, industrial protein purification (including medicine manufacture), agriculture, and art, bacteria have been exploited since they are the simplest species to design. They may be used for medical, environmental, or other applications[6]. Fungi were developed 26 with much the same objectives.

Viruses are crucial tools for introducing genetic material into other species. Particularly pertinent to human gene therapy is this usage. There are plans to make vaccinations by removing the virulent genes from viruses. Plants have been modified to deliver vaccinations, produce new colours in plants, conduct scientific study, and produce improved harvests. The most divisive GMOs in the public eye are genetically engineered crops. Most are created with herbicide tolerance or pest resistance in mind[7]. Three genes that boost the nutritional value of golden rice have been added via genetic engineering. GM crops might also be used as bioreactors to create biopharmaceuticals, biofuels, or pharmaceuticals. Animals are often far more difficult to alter, and for the most majority, research is still in its early stages. Since mammals provide the ideal model creatures for studying human biology, developing therapies for significant human illnesses depends on creating genetically modified versions of these animals. Compared to proteins produced in plants or microbes, human proteins expressed in mammals are more likely to resemble their natural counterparts. Improvements to livestock are made with the goal of enhancing economically significant qualities including growth rate, meat quality, milk composition, illness resistance, and survival.

Fish that have been genetically engineered are utilised as pets, food, and for scientific study. Mosquitoes are a vector for many dangerous illnesses, hence genetic engineering has been suggested as a control measure. Human gene therapy has been utilised to cure genetic diseases such severe combined immunodeficiency and Leber's congenital amaurosis, despite its still-relative youth. The creation of GMOs has drawn a lot of criticism, especially when it comes to commercialization. Several of them concern GM crops, including whether the food they produce is safe and what effect their cultivation will have on the environment. The integrity and rigour of regulatory agencies, the tainting of non-genetically modified foods, the regulation of the food supply, the patenting of life, and the use of intellectual property rights are further issues. GM food safety is a major concern for detractors even though there is scientific agreement that presently available food made from GM crops does not represent a larger danger to human health than traditional food[8]. The main environmental problems include gene flow, influence on creatures other than the target, and escape. To address these issues, nations have established regulatory measures. The legislation governing the introduction of GMOs varies across nations, with the US and Europe having some of the most pronounced variances. The status of gene-edited organisms and whether GM food should be labelled are two major concerns for regulators.

An Outline of Biotechnology's Legal and Socioeconomic Effects—Biosafety Regulations Biosafety as it is presently being addressed in the worldwide "Convention on Biological Diversity" (CBD), which aims to establish legally obligatory biosafety guidelines. Like with any technology, the use of biotechnology to food and agriculture may have potential hazards and advantages, but it can also raise concerns about the human implications of the technology. They include effects on stakeholders, social institutions, the economy, and communities, both good and bad. Biosafety affects a variety of fields, such as: I Agricultural and food system concerns Market and consumer problems Institutional concerns, commercial issues, and social issues round out the list. Food system and agriculture concerns. These include the way biotechnology affects how the agricultural industry is organised, structured, and behaves; the coexistence of conventional organic and biotechnology-oriented agriculture; the ability of the food system to separate genetically modified products from those produced for specific markets; the effects of biotechnology on the trade of agricultural commodities; and the financial effects of establishing oversight, uniform regulations, and public policies. Consumer and market-related concerns The needs, wants, and concerns of consumers in domestic and international markets; the impact of culture, advertising, product labelling, scientific information, and recent new events on consumer decision-making regarding the use of biotechnology products; various techniques for most effectively increasing understanding on which agricultural biotechnology products are used are among these limitations. 28 Institutional problems and commercial problems[9]. Among these are the effects of biotechnology on specific forms or groups of forms relating to purchasing or selling biotechnology goods and services; modifications to corporate procedures; alliances; and local and international marketplaces, especially those in Third World nations.

Social problems

These include consumer perceptions of risks and benefits, general environmental protection, agro-terrorism, research vandalism, and their effects on Third World countries. They also include the needs of various public to obtain meaningful information for participation in decision-making on development and the use of agricultural biotechnology. Concerns about genetically engineered foods GMOs are controversial, particularly in light of their introduction outside of laboratory settings[10]. Consumers, producers, biotechnology firms, governmental authorities, non-governmental groups, and scientists are all parties to the argument. Several of these worries are related to GM crops, including whether the food they produce is safe and what effect their cultivation would have on the environment. These concerns have sparked legal action, demonstrations, and debates over international commerce, as well as the tight regulation of commercial items in certain nations. The impacts of GMOs on human health and the environment are of most concern. They include the possibility of an allergic response, the possibility of transgenes spreading to human cells, and the possibility of genes not deemed safe for human consumption outbreeding into the food chain.

DISCUSSION

The use of GMOs in the pharmaceutical sector is another emerging area. Human growth hormone was the first medicinal protein produced in plants in 1986. Tobacco was employed by both research teams, and it has since taken the lead as the most extensively researched and used plant species for the production of foreign genes. Many plant-produced antibodies have reached clinical testing as of 2003. In medical research, the use of genetically altered animals has become indispensable. It is common practise to breed transgenic animals with human genes or gene mutations, enabling the study of the development and genetic underpinnings of numerous disorders.

Possible Uses for GMOs

Further GMO research has the potential to assist several sectors. For instance, a variety of microorganisms are being investigated as potential biodegraders and generators of clean fuel in the future. Moreover, recombinant vaccines may one day be created using genetically altered plants. In fact, the idea of an oral vaccine expressed in plants (fruits and vegetables) for direct consumption by people is being investigated as a potential remedy to the spread of disease in underdeveloped countries, one that would significantly reduce the costs associated with conducting extensive vaccination campaigns. The development of plant-derived vaccine candidates against the hepatitis B virus (HBV), enterotoxigenic Escherichia coli (ETEC), and norwalk virus is now being done in potatoes and lettuce. Researchers are also examining the creation of other proteins in plants that are useful for industry, such as the protein found in spider silk and polymers used in tissue regeneration or surgery. Even human transplant organs and tissues have been grown in genetically altered animals, a process known as xenotransplantation. Humans may benefit from a wide range of GMO usage, but many people are also concerned about possible hazards.

Risks and Disputations Concerns Relating to the Usage of GMOs

The effects of changing an organism's natural state via the expression of foreign genes remain unclear, even when the genes being transferred exist naturally in other species. After all, such modifications may affect the organism's metabolism, pace of development, and/or reaction to environmental elements. These effects have an impact on both the GMO as a whole and the environment in which it is permitted to flourish in nature. The likelihood of being exposed to novel allergens in genetically modified foods as well as the transmission of antibiotic-resistant genes to gut flora are potential health concerns to humans.

In addition to putting people at danger, horizontal gene transfer of pesticide, herbicide, or antibiotic resistance to other species would upset the ecological balance, enabling formerly harmless plants to proliferate unchecked and so facilitating the spread of disease among both plants and animals. While there is a chance of horizontal gene transfer from GMOs to other species, this danger is really regarded as being relatively low. In most circumstances, horizontal gene transfer cannot be replicated in an ideal laboratory setting without actively changing the target genome to boost susceptibility. Horizontal gene transfer happens naturally at a very low rate.

In contrast, research on transgenic fish introduced into wild populations of the same species has brought to light the frightening effects of vertical gene transfer between GMOs and their wild-type counterparts (Muir & Howard, 1999). The survivability of the fish's progeny was decreased as a result of their improved mate-attracting abilities. As a result, when a novel transgene is introduced into a population of wild fish, it spreads and may ultimately endanger the survival of both the genetically modified creatures and their wild-type counterparts.

Effects on Unintended Species

The controversy surrounding Bt corn is one instance of the public discussion about the usage of genetically engineered plants. A Bacillus thuringiensis protein is expressed in Bt corn. The protein was effectively utilised as an eco-friendly pesticide for many years before to the creation of the recombinant corn. It has long been recognised to be harmful to a variety of pestiferous insects, including the monarch caterpillar. The advantage of corn plants producing this protein is that farmers will need to use less pesticide on their crops as a result. Regrettably, seeds harbouring recombinant protein genes may unintentionally disseminate recombinant genes or expose non-target species to fresh environmental toxins.

The now-famous Bt corn dispute began in a lab when it was discovered that feeding monarch larvae milkweed, which is their natural food source, coated in transgenic corn pollen was more lethal than feeding them milkweed covered in pollen from conventional corn.

Scientists from other labs questioned the results, saying that the extraordinarily high quantity of pollen employed in the laboratory study was impractical, and came to the conclusion that monarch butterflies do not migrate through the area where maize is growing while it is shedding pollen. Six teams of experts from the government, academia, and business looked at the matter over the course of the next two years and came to the conclusion that there was "very little" danger from Bt maize to monarchs, which allowed the US EPA to authorise the crop for a further seven years.

Unwanted Economic Repercussions

Another issue with GMOs is that private firms may claim ownership of the organisms they develop and refuse to make them accessible to the general population at a fair price. If these allegations are true, it is argued that using genetically modified crops will harm the economy and environment because large-scale farm production centres (who can afford the expensive seeds) will use monoculture practises, which will predominate over the diversity provided by small farmers who cannot afford the technology. Yet, a recent meta-analysis of 15 research shows that, generally, only one-third of the advantages of first-generation genetically modified crops are gained upstream and two-thirds are distributed downstream. Both industrialised and developing nations display these benefit shares. As a result, the data from first-generation genetically modified crops does not support the claim that private corporations will not share ownership of GMOs.

GMOs and the Public: Theological and Philosophical Issues

In a 2007 poll of 1,000 American citizens, the International Food Information Council (IFIC) found that 23% of respondents were unaware that biotech foods had already hit the market, while 33% thought that biotech food items would help them or their family. Just 5% of those surveyed also said that they would change their shopping patterns as a consequence of worries about utilising biotech items.The Food and Agriculture Organization of the United Nations reports that public acceptance patterns vary depending on the nation and the state of the world at the time of the study in Europe and Asia. Depending on people's degree of knowledge and how they define each of these concepts, attitudes about cloning, biotechnology, and genetically modified goods vary. Support varies depending on the sort of biotechnology, but it always drops when animals are involved.

Additionally, despite extensive safety testing and equitable technology distribution, some individuals might still be unwilling to consume GMOs due to ethical or personal convictions. The argument about our ability to "play God" and the introduction of foreign material into meals from which some refrain for religious reasons are only two examples of the ethical problems with GMOs. Some individuals feel that messing with nature is inherently evil, while others uphold the moral wrongness of introducing plant DNA into animal or vice versa. Some who firmly believe that the creation of genetically modified crops is against nature or religion have advocated for clear labelling regulations so people may make educated decisions when selecting which products to buy. As crucial as having protections to avoid combining genetically modified goods with non-genetically modified foods is respecting customer choice and perceived risk. There has to be a consensus on what defines a GMO and how goods should be labelled in order to establish the standards for such protections.

With to advances in whole genome sequencing technology, gene cloning and transfer methods, and our knowledge of gene expression networks, these challenges are becoming more and more crucial to take into account as the number of GMOs rises. Legislative procedures that govern this research must thus evolve. Governments conduct risk assessments on GMOs before approving their use for commercial purposes in order to ascertain any potential repercussions. Yet, it may be impossible to predict how commercial GMO usage would affect society.

International GMO Research and Development Laws in History

The first discussion about the dangers of ingesting GMOs in humans started in 1971 when DNA from a virus that causes tumours was introduced into the E. coli, a common intestinal bacteria. Those working with GMOs in labs and adjacent people were first concerned about safety risks. Later on, however, controversy developed due to worries that recombinant organisms may be used into weapons. The National Institutes of Health (NIH) formed the Recombinant DNA Advisory Committee in 1974 to start addressing some of these challenges as a result of the expanding discussion, which was first limited to scientists but soon reached the general public.

When GMOs were first intentionally released into the environment in the 1980s, the United States had very few laws in place. Industry's adherence to the recommendations made by the NIH was optional. The utilisation of transgenic plants was developing into a worthwhile enterprise for the creation of novel drugs throughout the 1980s, and many businesses, organisations, and even nations started to see biotechnology as a potential source of income. The global commercialization of biotech products sparked fresh debates on a variety of topics, including whether or not living things can be patentable, the dangers of exposure to recombinant proteins, concerns about privacy, the ethics and reliability of scientists, and the role of government in regulating science. The Congressional Office of Technology Assessment projects originated in the United States and ultimately spread around the globe as a top-down method of counselling politicians by predicting the social effects of GMOs.

Subsequently, in 1986, the Organization for Economic Cooperation and Development (OECD) issued a statement titled "Recombinant DNA Safety Issues" that was the first international document to discuss concerns related to the use of GMOs. This report suggested carrying out risk analyses on a case-by-case basis. Since then, the case-by-case method to assessing the risks associated with genetically modified goods has gained widespread acceptance; nevertheless, the U.S. has often adopted a product-based approach to evaluation, while the European approach is more process-based. While adequate regulation was absent in many nations in the past, governments worldwide are now enacting stronger testing and labelling rules for genetically modified crops in response to popular demand.

More Research and Safer Practices Walk hand-in-hand

GMO proponents think that with enough study, these organisms might be safely marketed. To reduce possible dangers, there are a variety of experimental approaches that may be used to regulate and express altered genes. Some of these procedures are currently required by new regulations, such as preventing unnecessary DNA transfer (vector sequences) and substituting harmless plant-derived markers for selectable marker genes often employed in laboratories (antibiotic resistance). By having built-in identifying markers, such as coloration, that permit monitoring and separation of genetically modified crops from non-GMOs, problems such as the possibility of vaccine-expressing plants being mixed up with conventional consumables may be addressed. Additional built-in control strategies include the use of male-sterile plants,

geographical isolation, inducible promoters (e.g., caused by stress, chemicals, etc.), different growth seasons, and inducible promoters.

There is scientific agreement that food made from GM crops that is now on the market does not represent a larger danger to human health than traditional food, but that each GM product should be examined individually before it is released. Nonetheless, the general population is significantly less inclined than experts to believe that Transgenic foods are safe. The legal and regulatory status of genetically modified foods varies by nation, with some prohibiting or limiting them while others allowing them with varying levels of restriction. Herbicide-resistant weed populations are perhaps more likely as a result of gene flow between GM crops and suitable weeds and an increase in the usage of broad-spectrum herbicides. When a report was released in 2001 revealing transgenes had been discovered in landrace maize in Mexico, the crop's hub of variety, the debate about the scope and effects of gene flow heated up. It has been shown that gene flow from GM crops to other species is often less than what would happen normally. Several GMOs have been created with characteristics to assist regulate their spread in attempt to solve some of these issues. All of the fish bred for food are females, triploid, 99% are reproductively sterile, and they are kept in regions where escaped salmon could not survive in order to avoid the genetically engineered salmon from unintentionally reproducing with wild salmon. Moreover, genetic usage restriction technology has been created, while it hasn't yet been commercialised, that makes the second generation of GM plants sterile. Bacteria have also been altered to rely on nutrients that aren't present in nature. A decline in biodiversity, a rise in secondary pests (pests that are not addressed), and the emergence of resistant insect pests are some other environmental and agronomic challenges.

The total variety of insects has risen and the effect of secondary pests has decreased in parts of China and the US where Bt crops are grown. When best practise techniques are used, resistance was observed to develop slowly. Once a 1999 research showed that Bt crops could be hazardous to monarch butterflies, the effect of Bt crops on beneficial nontarget creatures became a topic of public discussion. The toxicity levels found in the field were not high enough to damage the larvae, according to subsequent investigations. The technology has been blamed for accusations that scientists are "playing God" and other theological problems. There are ethical questions about the appropriate use of this technology and how far it should be taken now that it is feasible to genetically alter people. Where to draw the boundary between therapy and enhancement and whether or not the changes should be passable across generations are hotly contested topics. Other issues include the contamination of the non-GMO food supply, the strictness of the regulatory framework, the concentration of power over the food industry in the hands of firms that produce and sell GMOs, the exaggeration of the advantages of genetic modification, or issues with the use of herbicides containing glyphosate. The patenting of life and the use of intellectual property rights are other problems that have been brought up. Consumer approval of GMOs varies greatly, with Europeans less likely than North Americans to be favourable towards GE food. Due to previous food catastrophes like bovine spongiform encephalopathy and other scandals involving government regulation of goods in Europe, public trust in food safety was low when GMOs first appeared on the scene. This has been highly effective in preventing or restricting the adoption of GM crops, coupled with efforts launched by several non-governmental organisations (NGO). NGOs including the Organic Consumers Association, the Union of Concerned Scientists, Greenpeace, and other organisations have claimed that risks have not been properly identified and managed and that there are unanswered questions regarding the potential long-term impact on human health from food derived from GMOs. They suggest either obligatory labelling or a ban on certain items.

CONCLUSION

By the middle of the twenty-first century, GMOs are the most likely candidates to find a solution to the conflict between population expansion and the scarcity of arable land, but there are several issues with their commercialization. From a scientific perspective, transgene escape from GMO fields to unmanaged ecosystems or conventional crop fields is the top concern that has to be resolved before substantial GMO planting. An escaping transgene may give a plant with high fitness and a competitive advantage via pollen distribution or seed dispersal, having detrimental effects on the natural environment and biological diversity. To prevent transgene escape, molecular biology is a very helpful technique. For various reasons, several molecular techniques are created. Pollen-mediated gene flow may be stopped by maternal inheritance patterns and male sterility. TPS in GMOs has the ability to stop transgenic escape via seeds. Moreover, the gene self-deleting system might be utilised to eliminate transgenes from complete GM plants or even particular tissues, preventing the effects of transgene escape from manifesting in pollen or seeds dispersed from a GM containing this system. To make these molecular tools better, shortcomings of these techniques such gene transfer between the chloroplast and nucleus of the maternal inheritance strategy and biosafety of external stimulation and system components of TPS need to be addressed.

Public worries, in contrast to those of scientists, are mostly directed towards the biosafety of SMGs in GMOs. SMGs, which are used to recognise successful transformation events, are an essential part of the transformation process, but they do not provide GMOs with any beneficial properties. In order to satisfy the severe regulatory requirements and reassure the public, the SMG should be eliminated after a GMO has been confirmed. The most effective strategy for excluding SMGs from GMOs among the molecular techniques is cotransformation. The rule of independent segregation ensures that no SMG cassette-related DNA will remain in the GMO genome. This tactic's effectiveness has to be increased, and it is inappropriate for crops that reproduce vegetatively. Because of their great efficiency, site-specific recombination systems are the most widely used systems. The GMO genome will still include short recognition DNA sequences like loxP and FRT, nevertheless. Even though these little DNA sequences won't be hazardous to the environment or people's health, additional work will be needed to make this system "cleaner."

There are issues with the introduction of GMOs, particularly transgene escape, but genetic modification is really the only instrument we have to deal with the likely food crisis in the near future. When GMOs are employed to improve the accessibility, quality, and affordability of food, healthcare, and the environment, humanity benefits. They have the potential to reduce hunger and illness globally, and if employed intelligently, they could enhance the economy without causing more damage than good. Yet, without careful consideration and close attention to the hazards connected with each new GMO on an individual basis, the full potential of GMOs cannot be fulfilled.

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CHAPTER 5

GENETICALLY MODIFIED (GM) CROPS AND BIOSAFETY

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ABSTRACT:

A unique combination of technologies known as genetic modification is used to change the genetic code of living things including bacteria, plants, and animals. Medicines, vaccines, food, food additives, feed, and textiles are all examples of GM goods. The Transgenic food holds out a lot of potential for improving global diets as well as feeding the world's expanding population. The "safe application of biotechnology" is referred to as "biosafety." It encompasses the methods used to guarantee the security of people, other creatures, and the environment. With relation to GM foods, there are several biosafety concerns, such as toxicity, allergenicity, antibiotic resistance, ingesting foreign DNA, using promoters of viral origin, altering nutritional value, gene flow, target species resistance, influence on biodiversity, ethical concerns, etc. The Convention on Biological Diversity's first regulatory framework for biosafety is the Cartagena Protocol on Biosafety (CBD). Included in India's regulatory biosafety framework are RDAC, RCGM, GEAC, and SBCC. The use of the very promising GM technology has been met with suspicion due to worries about the environment and human health safety. From this point forward, a case-by-case analysis of the features of the novel food against those of its conventional equivalent should be used to determine the safety of GM foods. In order for the public to embrace GM foods, it is also necessary for nutrition experts, plant scientists, and ecologists to work together to evaluate the biosafety of the GM foods for the environment and human health.

KEYWORDS:

Genetically Modified (GM), GM foods, Recombinant DNA technology, Vaccines.

INTRODUCTION

Biotechnology and genetic engineering are often used interchangeably. The term "genetic modification" refers to a certain collection of methods used to alter the genetic structure of living things including bacteria, plants, and animals. Using live things or their parts is referred to as biotechnology, which has a broader definition. Recombinant DNA technology, which combines genes from many creatures, creates what are referred to as genetically modified, genetically engineered, or transgenic organisms. Medicine, vaccines, food, feeds, and fibres are all examples of GM goods. One of the most difficult parts of the process is finding the genes that give critical features, including those that provide insect resistance or needed nutrients. Yet, comprehensive maps are being created for hundreds of different creatures by genome sequencing and discovery projects, together with the data analysis tools needed to comprehend and apply them.

Hence, crop development has become more exact thanks to recombinant DNA technology. Traditionally, desirable features are selected via crosses between crops and their wild relatives (a laborious and relatively imprecise method). Plant features may be controlled via genetic modification in a number of ways, and depending on the changed qualities, the results of one manipulation may be quite different from another. While this technology promises to address significant third-world problems, genetically modified organisms are advantageous

not just to farmers but to communities worldwide. Hunger, which is caused by the world's population growth. Other advantages of GMOs include GMOs allow for the production of food on less area and with less inputs such as pesticides, herbicides, chemical fertilisers, and water than previous methods. Bt crops, which need less pesticides, and drought-tolerant Transgenic crops are beneficial to the environment and farmers alike. Also resistant to devastating viral infections, GM crops are preserving both the companies that cultivate them and our food supply.

For instance, Hawaiian Rainbow papaya was genetically modified to become virus resistant, saving the crop and the business. Herbicide-tolerant crops are advantageous for farmers because they decrease the need for chemical herbicides and enable the use of minimal or no-till farming techniques. Reducing tilling also lessens soil erosion and nutrient runoff, both of which avoid river contamination. Less tilling increases crop output and nutritional value by maintaining soil moisture. Transgenics aid in reducing food wastes as well. GM apples will resist browning, reducing food waste in markets and kitchens, while GM potatoes will resist bruising during handling and shipment. GMOs offer improved nutritional characteristics, such as Golden Rice, which generates and accumulates Vitamin A and will aid in the annual eradication of Vitamin A deficiency in millions of children worldwide. Similar to this, GMO soybean oils had lower trans-fat levels and higher Omega 3 levels. Beneficial effects of GMOs on the environment one of the biggest issues that farmers deal with is salinity of the soil. Due to the salinity of the soil, many once productive agricultural lands have turned unproductive. Recombinant DNA technology makes it feasible for farmers to grow crops that can withstand salt. One example is a transgenic tobacco plant that can withstand salt stress and other ionic stressors thanks to a salt-tolerant gene from Avicennia marina. Since transgenic potato plants are utilised for diarrhoea vaccination, GMOs have the potential to produce edible plant vaccines that can be used to immunise people against a broad range of illnesses.

One of the most cutting-edge developments in the biological sciences, biotechnology is now touching practically every facet of daily life. Modern biotechnology has made significant strides thanks to recent scientific advancements in genetics, biochemistry, molecular biology, and cell biology, which have made genetic engineering possible. In the last 25 years, agricultural biotechnology has advanced at an extremely fast rate. The potential to create variability for a number of economically significant qualities in crop plants via biotechnology has also been demonstrated, in addition to the ability to genetically alter a broad range of crop species. Biological stress tolerance Crop production is severely impacted by biotic stressors in agricultural settings. According to reports, biotic stressors in India brought on by weeds, nematodes, and bacterial, viral, and fungal diseases, as well as insect pests, result in an average yield loss of 45%. The use of resistant cultivars produced using traditional methods and chemical pesticides have been the major methods used to manage the significant biotic stressors, such as insect pests and fungal infections. Also, the indiscriminate use of chemical pesticides had a negative impact on the environment and human health. The germplasm either lacks genes that provide resistance to a range of insect pests and illnesses or makes it very difficult to transmit such genes via sexual hybridization. The production of genotypes that can withstand biotic stressors more effectively has been sped up thanks to the growth of molecular biology and genetic engineering[1]–[4].

This requirement is especially clear in the rapidly developing and increasing field of molecular genetics. Few government organisations can afford to hire specialised specialists whose level of comprehension is adequate to internally verify the applicant's claims before the judgement is issued. Their only option is often to choose from a tiny pool of accessible

specialists, who are frequently offered either by groups that support the introduction of GMOs or those who are openly opposed to them. The decision-maker may not want to simply choose a "middle stance" between these opposing extremes. To make a choice that satisfies the decision-ultimate maker's obligation to his or her country and constituency, it will become increasingly important to understand the scientific, economic, and social issues and to be able to independently evaluate the evidence and scientific justifications for the opposing positions. The biosafety problem therefore provides a paradigm and explanation for the ongoing need to fund independent research (i.e., research that is not connected to commercial or industrial development). The fact that the vast bulk of the research and data pertaining to the creation of GMOs are kept extremely carefully by corporate companies, as has been mentioned previously, is perhaps the one aspect that has had the most impact on the topic as a whole. As is widely emphasised, a company's need to safeguard its R&D activities and procedures against commercial "espionage" is undoubtedly the driving force behind this approach towards data security. However, the existence of test results and materials that are not accessible to independent researchers gives the impression that these files contain data indicating higher levels of risk than are typically alleged. If true, this information would make it impossible for the applicant to get approval for the introduction of a GMO. Certainly, both applicants who are operating in good faith and civil society organisations that are wary of the introduction of GMOs would eventually benefit from a wider awareness and verification of the present scientific state of GMO activity in a given region.

Indian Genetically Modified (GM) Crops

Many transgenic crops have been reported in the western world, and the development of transgenic crops has received significant interest on a worldwide scale. Some significant crops' nutritional quality and agricultural production underwent radical change with the introduction of genetically modified crops. Insect pest resistance, herbicide tolerance, and viral resistance are among the genetically engineered features. The "Bt-cotton" confers resistance to boll worm, a threat to cotton crops, and is the first and currently only GM crop permitted for production in India. In India, there are now 1.2 million hectares of transgenic crops. Because to its high yielding and boll worm resistance, the area is expected to grow significantly in the next years. In India, the transgenic cotton crop is expanding[5]. Several transgenic crops, including rice, mustard, cabbage, pigeon pea, potato, tomato, brinjal, and mustard, are in the experimental and assessment stages.

According to the gene, the crop, the characteristic, and the target geographic areas, the main environmental risks resulting from the potential release of transgenics should be assessed case by case. Identification of the transgenics' environmental impact assessment's priorities and criteria is necessary. Before GM crops are released, biosafety concerns need to be carefully examined. In order to create GMOs with unique features via genetic engineering, genetic modification, or recombinant DNA technology, modern molecular biology technologies are increasingly being applied. They include isolating nucleic acid molecules from one creature and introducing them into another, irreversibly changing the genetic makeup of the recipient and enabling the molecules to be passed on to progeny. From the early 1970s, GMOs have been successfully created and used in confined environments, and since the middle of the 1980s, they have been used for commercial purposes in the field and in an open setting. The number of GMO applications has been expanding quickly. Yet, it is generally agreed that due to concerns about the possible damage that GMOs pose to the environment and human health, their use should be constrained by proper safety precautions. Together, these steps ought to guarantee biosafety. Several national and international

recommendations, guidelines, and laws have been created as a consequence of consultations on the safety of using GMOs.

Control Mechanism

India has a clear regulatory framework for the creation and assessment of GMOs and their byproducts. The two main regulatory organisations are the Department of Biotechnology (DBT) and the Ministry of Environment & Forests (MoEF). Since the government is responsible for both the creation and preservation of the environment, the MoEF announced rules under the Environmental Protection Act of 1986 (EPA) in 1989. These regulations include the processes for the production, importation, usage, study, and release of GMOs as well as the goods created with these organisms. The rule's goal is to make sure that using these items or living forms is safe for the environment and advantageous for people[6]. It has also been established who the relevant authorities are and how they would handle any matters relating to GMOs and their byproducts. The Department of Biotechnology (DBT) released safety regulations in 1990 that apply to biotechnology research, field tests, and commercial applications. Moreover, in 1998 and 1999, DBT released distinct guidelines for research on transgenic plants and therapeutic products.

Other rules including the Medicines and Cosmetics Act (8th Amendment), 1988, the Drug Policy, 2002, and the National Seed Policy, 2002, also apply to activities using GMOs. There are now six competent authorities in the nation responsible for carrying out rules and directives: i. Advisory Committee on Recombinant DNA (RDAC) ii. The Genetic Engineering Approval Committee (GEAC), iii. the Review Committee of Genetic Manipulation (RCGM) (apex bodies) State Biosafety Coordination Committees (SBCC), District Level Committees, Institutional Biosafety Committees (IBSC) connected to any entity doing rDNA research, and (DLC) Among the aforementioned committees, the IBSC is made up of institutions engaged in GMO research with DBT's consent[7]. The IBSC serves as the hub for communication within the institution for the execution of the rules. Every research project involving genetically modified organisms (GMOs) must have a designated investigator who is responsible for obtaining safety approval for the study and updating the IBSC on the progress and outcomes of the investigations. IBSC's duties include: 1 reviewing and approving project applications that fall within the restricted category in accordance with DBT rules. 2 Advising RCGM to approve studies with Category III risk or higher 3 adapting the biosafety programme to the level of risk analysis.

Staff Biosafety Training

Implementing Emergency Plans

The IBSCs play a crucial function since they are the only Statutory Committee that is located on an institution's grounds and may thus perform on-site evaluations, assessments, and monitorings of conformity to biosafety regulations. The applications filed by the researchers with IBSC clearance on the state of the project and its compliance with regulatory rules serve as the basis for the judgements made by the next higher body, the Review Committee on Genetic Manipulation (RCGM), which works from DBT. With the use of recombinant DNA technology, genes from unrelated species, such as microbes, as well as related plant species may be inserted into plants. Compared to conventional breeding, the development of transgenic plants is more accurate and selective. Recombinant technology is mostly used to create transgenic plants with improved yields, greater nutritional value, and enhanced resistance to pests. Many transgenic crops with significant economic potential, including maize, soyabean, tomato, cotton, potato, mustard, and rice, have been reported. Resistance against insects: By developing novel bio pesticides like microorganisms that are harmful to

specific crop pests but harmless to people, animals, fish, birds, or beneficial insects, biotechnology has opened up new possibilities for the protection of plants from nature[8].

Disease susceptibility: Plants are vulnerable to bacterial, viral, and fungal diseases. Transgenic plants that are virus-resistant have made significant development. For instance, it has been shown that the expression of a gene that produces the tobacco mosaic virus (TMV) coat protein makes transgenic tobacco plants resistant to TMV infection. Squash and potatoes are among the other plant species for which virus resistance has been developed. Improved produce quality: Using tomatoes, one of the most effective research projects to alter the properties of a plant's product was conducted. To ensure that the tomatoes are solid enough to resist mechanical handling and transit, they must be harvested when still green. Sadly, they don't acquire the same taste and texture as tomatoes that have fully matured on the vine. Human Health Risk: The new organisms'/products' toxicity, allergenicity, and antibiotic resistance are the primary risks of GMOs to human health. The type of the product whose synthesis is regulated by the transgene or changes in the metabolism and make-up of the organisms brought on by gene transfer may be directly connected to the risk of toxicity. Each GMO must undergo a rigorous assessment of its toxicity to both humans and animals. Most of these toxicity hazards may be evaluated statistically and qualitatively using scientific techniques.

GMOs' Effect on the Environment

The gene that was introduced into the organism or the offspring's products may really persist in the environment, posing environmental issues. Interest in potential interactions between other environmental creatures has grown as a result of the deliberate introduction of GMOs into the environment. A secondary effect of genetic alteration might be unintended genomic changes. Such modifications may result in the creation of novel proteins that may be harmful or allergic, disrupt or affect the metabolic pathways necessary for the GMO to function, or all three[9].

Flow of genes Pollen transfer may accidentally cross-pollinate traditional local varieties with GMO plants, contaminating them with GMO DNA and causing farmers to lose their traditional kinds. Target organisms' tolerance or resistance: Planting transgenic crops with insect resistance may have positive effects on crop damage and pesticide usage. Yet, the long-term effectiveness of insect resistance is seriously threatened by the natural capacity of insect populations to quickly adjust to environmental stressors. Insect and other pest adaptation to pest control measures may have negative effects on the environment and human health.

Higher Weediness

Weediness is the propensity of the plant to grow outside of the original planting area. There are worries that Transgenic crops will spread like weeds. For instance, a Transgenic crop that can tolerate salt may become a dangerous weed if it escapes into maritime environments. Superweeds, or weeds that have gained the herbicide tolerance gene by genetic tainting with a herbicide tolerance GMO through in-field cross breeding to related species or through horizontal gene transfer, are another concern. Reduced cultivars and loss of biodiversity There have been worries that the creation and worldwide dissemination of superior crop varieties brought on by the green revolution could reduce the genetic diversity of cropping systems. Farmers' adoption of monocultures instead of traditional variety has resulted in genetic loss. When more and more transgenic crops are released, which provide farmers with significant economic advantages, this is anticipated to become even more intense. When one

variety is utilised in a cropping system instead of many, the relative rate of sensitivity to any unanticipated diseases or harmful conditions rises.

Impact Evaluation Procedures

The technique of effect assessment is essential to the idea of risk management. The assessments required by national biosafety-related legislation, and particularly under the Cartagena Protocol, although exceeding the scope and detail of many Environmental Impact Assessment (EIA) procedures, offer a solid foundation on which at least some of a country's various decision-making, permitting, labelling, and other processes relating to GMOs could be based. The necessity for risk assessment is undeniable, but given that the introduction of GMOs is a relatively recent invention, it is unfortunate that the specific criteria of that inquiry are difficult to quantify in the biosafety field[10]–[12]. The main emphasis of investigation is often on the idea of "substantial equivalence," which compares GMO goods to the food they are intended to replace. Substantial equivalence may sometimes serve as the only basis for deciding whether a GM introduction requires a licence. In other words, if the GM product is sufficiently similar to the one it is replacing, it may be introduced with little administrative effort. 38 Nonetheless, in many more complex situations, considerable equivalence serves as the foundation for judgements about the security of planned GMO introductions. The significant equivalence method, according to the World Health Organization, is meant to account for both deliberate and unexpected changes in a plant or the meals generated from it39 by highlighting similarities and contrasts between the novel food and its traditional equivalent. The safety of detected variations regarding the replacement of the product, as food, is next evaluated by safety evaluations and risk/benefit analyses.

Next, risk managers do an assessment of this and create the best risk management strategies. Regrettably, very little of the dangers associated with GMOs that have been documented directly relate to this strategy. The reliance on the substantial equivalence test in the case of GMOs may serve as a diversion from the more serious need to consider other measures of the safety of GMOs and, as a result, to develop other mechanisms for managing those risks, despite its effectiveness in other areas (such as seed management programmes based on more traditional methods of new variety development). In this context, it's crucial to remember that the creation of agreed-upon risk management methods would be beneficial to both GMO proponents and the people and ecosystems who would be most impacted by the hazards. In general, the permit-holder is not responsible (or is held to a reduced level of culpability) for harm caused by the revealed risk if a government permission is provided on the basis of complete disclosure of risks and where the permitholder satisfies his risk management requirements.

So, the proponent has a safety net of protection against responsibility for "the inconceivable" but at the same time, local residents are better protected against such risks provided adequate and appropriate analytical models can be built for estimating the risk from an introduction. Still, there are unresolved issues that could affect how accurately the risks of GMOs can be identified and subsequently reduced or eliminated. These issues include the proper application of substantial equivalence and, in particular, the assumptions upon which both principles are founded and applied. Substantial arguments against "substantial equivalence" as a sign of safety or appropriateness are made about scientific uncertainty, which is the result of a small number of but very obvious technical issues. In response to these worries, it has been stated that: "The extent of [GMO-caused] disruptions is not currently known, as the contemporary biotechnology industry is not required to provide even the most basic information about the actual composition of the transgenic plants, to any regulatory agencies. In order to demonstrate, for instance, that the plant genuinely generates a protein with the

identical amino acid sequences as the original bacterial protein, no assays are necessary. Yet, this is the only means to demonstrate that the gene transfer produces the hypothesised outcome.

DISCUSSION

Changes in the ecology of the soil: Via their roots, many plants release chemical substances into the ground. There are worries that because of their altered DNA, transgenic plants may leak different substances than regular plants. According to theories, this might alter the functional content and biodiversity of the soil's ecosystem. It is quite complicated how plants and solid microorganisms interact since the bacteria that live around plant roots also secrete chemicals into the soil. The Cartagena Protocol and biosafety: The Cartagena Protocol on Bio-Safety, which was negotiated under the auspices of the Convention on Biological Diversity, is the first global regulatory framework for bio-safety (CBD). The Cartagena Protocol on Biosafety, so named after the Colombian city where the last round of negotiations began, lays out a thorough regulatory framework for guaranteeing the safe transfer, management, and use of Living Modified Organisms (LMOs), with an emphasis on transboundary mobility. The Protocol mainly deals with genetically modified agriculture products and LMOs that are intended to be purposely released into the environment (such as seeds, trees, or fish) (such as corn and grain used for food, animal feed or processing). It excludes items generated from LMOs, such as cooking oil made from genetically modified maize, and human drugs covered by other international agreements and organisations.

This body's primary duty is to evaluate how the Protocol is being applied and make the judgements required to support its successful functioning. In order to fulfil its commitments under the Protocol, MoEF has taken a number of actions, including improving the capacity of different stakeholders for the Protocol's successful implementation throughout the nation. In order to strengthen the regulatory framework, particularly with regard to the transboundary movement of living modified organisms (LMOs) and genetically modified organisms (GMOs), risk assessment and management, training and human resource development, and information sharing, the MoEF is implementing a GEF-World Bank funded capacity building project on biosafety.

Research on the hazards related to alternative activities is evaluated and compared via risk assessment. Risk assessment is a foundational part of risk management, which creates plans to avoid and manage hazards within reasonable bounds. It considers a number of aspects, including social values and economics, in addition to the scientific evaluation. In order to make the best decisions possible, risk communication entails a constant discussion about risk and risk management choices between regulators and the general public. Risk evaluation should be done on a case-by-case basis. While it is widely acknowledged that specific risk assessment techniques may differ from situation to case, the following logical steps must be taken:

GM crop risks

Transfer of genes from any creature into plants or other organisms is a component of genetic modification methods. Different cells in an organism may respond differently to the introduction of a novel gene. The insertion of a single gene may also change the pattern of gene expression. Hence, it is difficult to foresee the hazards associated with the release of GMOs into the environment. The genetic consequences of transformation, managerial effects, food safety, ecological implications, and socio-economic or bioethical concerns are some of the foreseen and unpredicted dangers.

Human and animal health biosafety

The transmission of poisons and allergenic compounds is likely to provide several risks to the health of people and animals. Food nutritional levels may change as well. It was widely reported in 1997 that after being sprayed with glyphosate, Roundup Ready Soybeans create a lot of phytoestrogen, which promotes breast cancer. The alien DNA in GM foods has a variety of negative impacts. Since promoters of viral origin are used, some genes will be activated by foreign DNA. Health concerns for people are raised. Cauliflower mosaic virus' 35S promoter, for instance, may be damaging if it infects human cells and activates certain genes. When antibiotics are taken with food, antibiotic resistance indicators such neomycin phosphotransferase (npt11) and hgromycin (hpt) will lessen their ability to combat illness. In a lab experiment, monarch butterfly caterpillars that consumed BT maize pollen perished.

Public Knowledge and Information Access Access to information for the general public is a crucial component of public engagement and one instrument that might aid in recognising the advantages and minimising the hazards of contemporary biotechnology. The Rio Declaration's Principle 10 and the newly passed rhus Convention on Access to Information, Public Participation in Decision-Making, and Access to Justice in Environmental Issues both recognise this idea. Capability and Transparency Yet, in the case of biosafety difficulties, simple "transparency" and "access" to pertinent papers may not be enough. It may be argued that the idea of access to information must in some manner also encompass access to the resources and knowledge needed to interpret that information.

In many developed nations with numerous highly specialised and active NGOs, simply granting "access" to the data will be sufficient; however, even in these nations, the balance of expertise is heavily skewed in favour of GMO proponents, who are frequently the organisations or companies that created the GMOs. Standardization, Labeling, and Certification However, in addition to the public's access to official records and procedures, there are other ways to promote public awareness and access to information. These include product labelling, food safety regulations, and general consumer protection laws. All of these are intended to raise public awareness and effectively convey public preferences to the commercial proponents of GMOs.

These methods may be successful if they are truthful, precise, easily understood, neutral, and based on the complete disclosure of all pertinent data by the GMO proponents. Labeling mechanisms, on the other hand, may lose their significance if they are permitted to become too general, written in an extremely technical way, or are known to be presented in an elitist manner. Regulations allowing for general declarations of hazardous and carcinogenic compounds in public spaces and consumer products effectively nullified a significant vote in California demanding such disclosures.

Trade secrets and private information: One of the biggest issues in this respect is the proponent's need to keep some material "private." Although it is true that confidentiality clauses are often utilised as a strategy of avoiding disclosures, it is also true that the fundamental realities of contemporary business plainly underline the necessity for secrecy. Labeling and other forms of information access are increasingly being addressed at the international and regional levels in response to the growing realisation that actions, particularly the introduction of species, in one country may have major effects on neighbouring nations. The UN Food and Agricultural Organization, whose Codex Alimentarius is one of the main platforms via which these challenges are being addressed, is a crucial organisation in this sector. Methods for Direct Public Involvement and Awareness: A limited number of nations, especially Denmark, the Netherlands, and New Zealand, are

leading the way in creating public awareness tools for direct public engagement in decision-making relating to biosafety. Legislative requirements in these nations call for very inclusive stakeholder mechanisms to handle certain facets of contemporary biotechnology, such as the dispersal of GMOs. These procedures aid governments and regulatory bodies in gathering information, generating discussion, gathering important data, and raising public knowledge of contemporary biotechnology.

GM Crop Biosafety

In order to avoid unintended exposure to infections and toxins or their unintentional release into the environment, biosafety refers to containment concepts, technologies, and procedures that are put into place. In other words, "safe use of biotechnology" is what biosafety refers to. Collective efforts are needed to achieve biological safety for a clean and safe environment. It refers to measures used to maintain environmental security throughout the creation and distribution of genetically modified organisms. Using GM material, biosafety experiments are an exercise in identifying the hazards to people, animals, and the environment. The risks are then controlled or reduced to acceptable levels using methods, techniques, equipment, and facilities. GMOs are quickly becoming highly significant instruments for solving many current issues, however the introduction of contemporary biotechnology goods must be tempered with sufficient biosafety precautions. It is important to do a case-by-case scientific risk assessment and cost-benefit analysis. Different parties involved should actively participate. The appropriate knowledge and information should be spread.

CONCLUSION

The safe transmission, processing, and use of any genetically modified organism arising from biotechnology is covered under the Convention on Biological Diversity (CBD). The CBD, which covers the conservation and sustainable use of biodiversity in all of its manifestations, including the genetic resources connected to it, places a strong emphasis on biosafety. The public's and the world's acceptance of the goods resulting from transgenic alteration via biotechnology depends critically on biosafety. A significant worldwide trade of biotechnology goods is anticipated to take place in the future. Nonetheless, there are doubts in the public's minds about how safe they are. The governing bodies must take the bio safety system seriously and reassure the general public that these new GM goods are completely safe. The greatest scientific information and experience must be used to address this problem in an open and transparent way. Risk assessment should simultaneously take into consideration cultural practises and public perception. Remembering that no generic predictions can be made about how a transgenic crop would behave in the open environment, it is crucial to evaluate the environmental effect on a case-by-case basis. The public's main concerns centre on how GM crops will affect nearby wild plants or other elements of biodiversity in the environment where they are introduced. This could result in genetic contamination and a possible loss of genetic diversity, the emergence of pests and diseases, as well as herbicide resistance, which could have an impact on human health via the food chain. In terms of risk assessments and bio-safety of GM crops and goods, social scientists and biotechnologists should collaborate to allay public concerns. By leveraging contemporary biotechnology techniques for the benefit of people, we may advance our country's growth and economic development.

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CHAPTER 6

LABORATORY FOR BIOSAFETY RISK EVALUATION DANGEROUS MICROORGANISMS

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ABSTRACT:

Risk assessment in biosafety labs is a dynamic and organized process. Evaluation of pathogenic microbiological risks, experimental activities, facilities and equipment, people, experimental techniques, etc. are all included in the assessment's purview. For hazard assessment, the four-level evaluation technique for pathogenic microorganisms is utilized. The danger of exposure to aerosols during experimental operations is the most prevalent. The foundation for a biosafety laboratory's secure functioning is its facilities and equipment. Risk analyses for laboratory biosafety should be carried out on a regular basis to guarantee the security of the lab.

KEYWORDS:

Genetically Modified (GM), GM foods, Recombinant DNA technology, Vaccines.

INTRODUCTION

Countries around the world have continued to study infectious diseases and invested in the construction of several high-level biosafety laboratories in recent years due to the constant innovation of biotechnology and the frequent outbreak of new infectious diseases. The biosafety laboratory is an essential location for conducting experimental research on pathogenic microorganisms and the prevention of infectious diseases.

It can prevent or regulate dangerous biological agents that might be damaging to humans and the environment via protective barriers and management techniques. In addition to affecting the lives and health of the experimental crew, the safe functioning of biosafety labs also has an influence on societal stability and public safety.

By performing risk assessments of biosafety labs and implementing the appropriate preventative and control measures, it is crucial to maintain safe laboratory operation, the safety of staff, and public safety.

Other biosafety risk assessment ideas

Biosafety

Biosafety is a crucial component of national security and broadly refers to the dangers and possible threats that diverse biological variables provide to the nation's social, economic, human health, and natural settings. A biological vector may provide current or prospective risks to people, animals, or plants by directly infecting or indirectly harming the environment[1]–[3]. This is what is meant more specifically by the term "biosafety."

Risk

Risk is the possibility of an unfavorable outcome or the total of a risky situation's chances and effects. People's perceptions of risk differ based on their past experiences, which can

affect how serious a risk is perceived by different individuals.Biological risk is the term used to describe the potential harm that certain pathogenic microorganisms and their associated operational procedures or experimental activities may cause to specific individuals, the environment, and larger society.

Risk evaluation

The ability to quantify the harm or loss brought on by a certain phenomenon is referred to as risk assessment[4]. Risk identification, analysis, and assessment are the three processes that make up the process of risk assessment, which serves as the foundation for risk management.

Identification of risks

Risk identification is the methodical, thorough, ongoing process of finding, illustrating, and summarizing risk variables utilizing pertinent information and techniques. To provide a foundation for future research and decision-making, the primary risk variables and the relationships between them have to be identified. Risk management begins with risk identification.

DISCUSSION

Risk Element

Epidemiological research must be integrated with aerosol exposure risk of microbial components and the variety of human illnesses linked to the microorganisms. The goal of the dose-response evaluation is to statistically describe the connection between the dosage and the likelihood that the exposed population would get an illness or a disease[5]. Acupuncture Blood sampling, tissue grinding, animal inoculation, and blood collection the probability of the intended pathogenic microbe infecting the populace is quite low. Assessment of exposure is an effort to determine. Pathogen culture, lyophilization of pathogens, sample preservation, tissue grinding, and animal culture. Identifying the microorganism, assessing high response and exposure, measuring the extent of public health concerns, and figuring out the confidence limitations of the dose-response model. The goal level of the biosafety laboratory may be defined by the risk assessment of pathogenic microorganisms.

Risk Assessment

To reduce the danger of biosafety breaches, microorganisms should be housed together with the necessary experimental standard operating procedures, laboratory management systems, and emergency treatment protocols. Understanding the nature of risk, providing information support for risk assessment, and determining the best risk management plan and approach are the three goals of risk analysis.

Risk Evaluation

The process of comparing the outcomes of a risk analysis with a predetermined risk criteria or the outcomes of a customized risk analysis in order to evaluate the risk and make a decision is known as risk assessment.

Risk assessment in biosafety labs: components and techniques

Pathogenic microbiological risks, laboratory activities, buildings and equipment, staff, laboratory procedures, natural catastrophes, fire protection, electrical appliances, hazardous chemicals and associated gases, etc. are all factors that go into a biosafety laboratory risk assessment[6]–[9]. Brainstorming, scenario analysis, pre-hazard analysis, hazard and operability analysis, fault tree analysis, event tree analysis, and other techniques of risk

analysis are examples of approaches that fall within the categories of qualitative and quantitative analysis. Often, matrix analysis or risk mapping are used to make a thorough evaluation of risk.

Risk Evaluation for Harmful Microbes

Risks of infectious illnesses in humans that are brought on by contact with harmful microorganisms have been around for a long time. The assessment of laboratory biohazards is described as follows in the national standard "General Requirements for Laboratory Biosafety" (GB 19489-2008): "When the laboratory activities involve infectious or potentially infectious biological factors, the assessment of the extent of the hazard should be carried out."

The degree of pathogenicity of the microorganisms, the transmission route, the stability, the infection dose, the concentration and scale of operations, the source of the subject, the availability of animal experimental data, and effective prevention and treatment should all be taken into account when assessing the microbiological hazard. Risk characterization, dose-response assessment, exposure assessment, and hazard identification are the four levels of evaluation that may be used in the assessment technique. The identification of hazards also involves

Evaluation of Experimental Activity Risk

The majority of the experimental tasks in the biosafety lab entail gathering, transporting, receiving, processing, operating, maintaining, and disposing of samples. With each activity, there is a chance that if control procedures are poor, infections may move beyond the lab and infect members of society or the experimental personnel. Cuts, acupuncture, direct skin, mucosa, and eye exposure to infectious microorganisms, animal bites, inhaling infectious aerosols, etc. are the primary causes of biosafety laboratory infections. 12 Aerosol infection is the most frequent of them since it is hard to see and occurs often during tests. The primary focus of infection prevention in biosafety labs is on laboratory personnel who are in high risk situations during testing.

Numerous experimental procedures have been shown to carry a risk of aerosol exposure, including high concentration suction and mixing, ultrasonic lysis, unintentional breaking of centrifuge tubes, unintentional spilling of freeze-dried powder, unintentional squirting when injecting an animal, animal dissection, etc.[10]. The challenged animal's accidental squirting results in the greatest aerosol concentration of any of these, which may approach 104 CFU/m3. Accidental aerosol exposure will also result from the drop of the culture container and the spill of the lyophilized powder.

The majority of aerosol particles are fewer than 5 lm of lung-accessible particles. Different experimental activities have different dangers. The sources of risk are identified via risk assessments of experimental operations, and matching personal protective measures are proposed to prevent unintentional injuries and exposure to pathogenic microorganisms, ensuring the safety of the experimental staff.

Facilities and Equipment Risk Assessment

A primary protective barrier (safety equipment) and a secondary protective barrier are the two kinds of hardware that make up the biosafety laboratory (facilities). There are four levels of biosafety protection, each of which is made up of different arrangements of safety tools and infrastructure. The foundation for a biosafety laboratory's secure functioning is the facility equipment. There is a safety risk if the laboratory's biosafety protection measures are

not satisfied. The purpose of the risk assessment of buildings and machinery is to evaluate and show that the current hardware is up to code. The danger will be lower if the facility equipment complies with security protection regulations. The danger will rise if the standards are not met. The protection efficiencies of biosafety cabinets, animal feeding isolators, life support systems, exhaust air efficient air filtration units, airtight doors, airtight enclosures, positive pressure protective clothing, etc. which are in use in some biosafety laboratories are all above 99.9%, satisfying the requirements of biosafety protection.

The daily inspection of facilities and equipment must be strengthened in laboratory management, important components must be replaced and maintained on a regular basis, instrument operation specifications must be strictly followed to ensure the normal operation of facilities and equipment, and risk points must be kept to a minimum.

Guidelines for risk evaluation in biosafety labs

The real hazard features of the experimental activities determine how difficult risk assessment and risk management procedures are in laboratories. The nature and severity of the risk sources should be taken into account while conducting risk assessment and risk control procedures. Hence, the principles of pre-assessment, integration with reality, entire process assessment, and scientific rationality should be followed in risk assessment. The experimenters collaborate with the accountable professional technologists.

The scope and timeliness of risk assessments in biosafety laboratories are set. It doesn't happen every single time, nor does it just happen once. Risk assessment is a dynamic process that reevaluates hazards as unique situations arise. The project's experimental activities should be evaluated before commencing a new pathogen experiment or making a substantial modification to the initial work plan. The background information should be updated as soon as it is discovered that the pathogen's pathogenicity, virulence, or method of transmission has altered, and the safety of the experimental operation should be reconsidered[11].

The safety of the protection should be evaluated whenever a facility unit, vital equipment, or standard operating procedures are expanded or considerably altered. The risk assessment should be reevaluated if highly pathogenic bacteria that were not included in the first assessment report are isolated during the experimental activities. When an event like an animal escape, a pathogenic microbial leak, or a personal illness happens while the experiment is being conducted, re-evaluation should be done very after. Reevaluation is necessary if a safety risk is identified during the experiment or if biosafety concerns emerge during the inspection and supervision phase. Reevaluation is required whenever applicable policies, rules, standards, etc. change. Every year while it is in operation, the biosafety laboratory should conduct at least a couple of systematic periodic risk evaluations.

Specified laboratory structural components, systems, and/or system components have been installed, inspected, functionally tested, and validated to satisfy national or international standards, as applicable. This procedure is known as laboratory/facility commissioning. These requirements are established by the design guidelines and design function of the relevant building system. In other words, the commissioning criteria for labs classified as Biosafety Levels 1-4 will vary and become more complicated. Geographical and climatic factors, such as geological fault lines, extremes in temperature or humidity, may also have an impact on the design of the laboratory and, therefore, the commissioning requirements. The relevant structural parts and support systems will have passed inspection when the commissioning procedure is through and will have been exposed to all possible operational scenarios and failure modes.

Early on in the building or remodeling project, ideally during the programming phase, the commissioning procedure and acceptability standards should be developed. Architects, engineers, safety and health staff, and eventually laboratory users will grasp the performance needs of the individual laboratory and create universal expectations for laboratory and/or facility performance by addressing the commissioning process early in the project. The commissioning procedure gives the organization and the neighborhood more assurance that the structural, electrical, mechanical, and plumbing systems, containment and decontamination systems, and security and alarm systems will function as intended to ensure containment of any potentially dangerous microorganisms being worked with in a specific laboratory or animal facility. Typically, commissioning operations start during the project's programming stage and continue through construction and the lab's or facility's following warranty term. In general, warranty terms should continue for a year after occupation. A commissioning agent who is independent of the architectural, engineering, and construction companies engaged in the design and construction should be hired, it is advised. The commissioning agent represents the institution building or remodeling the laboratory and should be regarded as a member of the design team; early participation by the agent in the project's programming phase is crucial. The institution could sometimes serve as its own commissioning agent. For more sophisticated laboratory facilities

Manual on laboratory biosafety

The institution could choose to hire a third-party commissioning agency with a track record of successfully commissioning sophisticated biosafety lab and animal facilities. The institution should continue to be a part of the commissioning team even when an independent commissioning agent is utilized. It is advised that the commissioning agent be joined on the team by the institution's Safety Officer, Project Officer, Programme Manager, and a member of the Operations and Maintenance staff. Depending on the containment level of the facility being refurbished or built, the laboratory systems and components listed below may be included in a commissioning plan for functional testing. This list is not all-inclusive. Of course, the complexity of the intended laboratory will be reflected in the actual commissioning plan.

The Laboratory Biosafety Manual formerly focused on conventional laboratory biosafety advice. The guideline places a strong emphasis on using adequate containment equipment, excellent microbiological work practices, correct facility design, operation, and maintenance, as well as administrative considerations to reduce the risk of worker disease or injury. By implementing these suggestions, the danger to the environment and the neighborhood as a whole is also reduced. It is now important to broaden this established method of biosafety by implementing laboratory biosecurity measures. Recent global events have made it more important than ever to safeguard labs and the materials they hold from being purposefully tampered with in ways that might be harmful to humans, animals, agriculture, or the environment.

The difference between "laboratory biosafety" and "laboratory biosecurity" must first be understood in order to determine a facility's laboratory biosecurity requirements. The containment concepts, methods, and procedures used to minimize unintended exposure to viruses and toxins, as well as their unintentional discharge, are referred to as "laboratory biosafety." In order to avoid the loss, theft, abuse, diversion, or purposeful release of viruses and toxins, institutions and individuals must take security precautions known as "laboratory biosecurity." The fundamental core of laboratory biosecurity efforts is the use of effective biosafety measures. During risk assessments, which are carried out as a crucial component of an institution's biosafety program, information is collected on the kinds of organisms that are

accessible, where they are physically located, who needs access to them, and who is in charge of them. This information may be used to determine if a facility has biological resources that would be alluring to individuals who might want to abuse them. National standards should be created that acknowledge and address the continuous duty of nations and organizations to safeguard samples, diseases, and poisons from abuse. For each institution, a unique laboratory biosecurity program must be created and put into place in accordance with the facility's needs, the kind of laboratory work being done, and the local environmental factors. As a result, laboratory biosecurity initiatives should take into account the institution's various needs and should solicit feedback from scientific directors, principal investigators, biosafety officers, laboratory scientific staff, maintenance staff, administrators, information technology staff, law enforcement agencies, and security personnel as necessary.

A thorough program of accountability for pathogens and toxins should serve as the foundation for laboratory biosecurity measures. This program should include an updated inventory with storage location, identification of personnel with access, a description of use, documentation of internal and external transfers within and between facilities, and any inactivation and/or disposal of the materials. A similar institutional laboratory biosecurity policy should be set up for recognizing, disclosing, looking into, and correcting laboratory biosecurity violations, including inconsistencies in inventory data. In the case of a security violation, the participation, duties, and obligations of public health and security authorities must be made explicit. All staff members should get laboratory biosecurity training, which is separate from laboratory biosafety training. Such training should include a review of relevant national standards and institution-specific protocols, and it should assist workers in understanding the necessity for protecting such resources and the justification for the particular biosecurity measures. Also, during training, policies detailing the duties and responsibilities of people in terms of security should be taught. Effective laboratory biosecurity efforts also depend on the professional and ethical fitness of all employees who regularly have permitted access to sensitive materials for dealing with hazardous diseases. In conclusion, just as aseptic methods and other safe microbiological procedures have become standard parts of laboratory work, security safeguards also need to be used.

The effective exchange of reference materials, clinical and epidemiological specimens, and associated information required for clinical or public health research shouldn't be hindered by laboratory biosecurity procedures. The day-to-day operations of scientific workers shouldn't be significantly hampered by competent security management, and neither should performing research. Important research and clinical resources must be legally accessible. Enhancing laboratory biosecurity may be accomplished via employee suitability reviews, security-specific training, and strict adherence to pathogen protection protocols. Regular risk and threat assessments, as well as frequent evaluation and update of processes, are required to develop and sustain all such initiatives. National guidelines for laboratory biosecurity should include checks for compliance with these protocols as well as explicit guidance on roles, duties, and corrective measures.

CONCLUSION

The goal of risk assessment is to carry out risk management, lower the risk of accidents, lessen their severity, and operate biosafety labs with the least amount of risk at the lowest possible cost. Each laboratory has a unique building structure, set of amenities, piece of equipment, and level of employees. The source, level, and preventative actions of dangers thus cannot be the same everywhere. The biological risk management system doesn't have any set procedures or modes. The laboratory should go forward with the real situation as a starting point, develop a risk assessment model appropriate for the laboratory in accordance

with specific guidelines, and construct and enhance the safety management system and standards. Only efficient management can safeguard workers, the general public's health, and the environment in addition to laboratory safety.

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CHAPTER 7

GMOS' ECOLOGICAL EFFECTS AND HOW THEY AFFECT BIODIVERSITY

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ABSTRACT:

Genetically modified organisms (GMOs) are one of the new threats to biodiversity offered by modern biotechnology. It is endangering our right to know what we consume and to make that decision for ourselves. Our seed freedom and biodiversity are under danger. Despite its rich biodiversity and indigenous knowledge base, India suffers from a lack of certain resources because of the Green Revolution technologies, which destroyed much of the country's biodiversity by turning mixed cropping systems into monocultures of cotton, wheat, and rice and by widely using herbicides that kill field greens. With a decrease in the insects that provide food for other types of species, such birds, the GM crops destroy biodiversity. The study discovered that Monarch butterflies' development was slowed and their mortality rate increased when they consumed leaves coated with GM corn pollen. Similar outcomes were obtained in a research that looked at pink bollworm fed on GM cotton. Another research looked at aphids that ate GM potatoes and discovered that the diet had a negative impact on ladybirds that fed on aphids.

KEYWORDS:

Genetically Modified (GM), GM foods, Recombinant DNA technology, vaccines.

INTRODUCTION

Environmental concerns are thought to vary from food safety issues in a number of ways, despite the fact that the worldwide debate against GMOs has often united divergent organizations concerned about both food safety and the environment.

It may take years or decades to fully comprehend the effects of novel biological components on ecosystems, according to experience gained through decades of environmental impact research. Ecological or genetic effects of newly introduced GMOs on the ecosystem might include:

- unexpected repercussions on non-target species, which may happen directly via predation or competition or indirectly through changes to land use or agricultural methods, on the dynamics of populations in the receiving environment;
- unexpected repercussions on soil microbial communities, which control the transport of nitrogen, phosphorus, and other vital elements, as well as unintended effects on biogeochemistry;
- The dissemination of introduced genetic material by pollination, mixed matings, dispersion, or microbial transmission to other domesticated or natural populations, also known as gene flow.

It is crucial to adequately manage and oversee all GMO introductions since these potentially harmful impacts have been seen in the wild with non-GMO species, and because the repercussions of these effects might be grave. Ecology field studies require months or years

to become reliable. Moreover, current information on GMOs in the field should be treated as site-specific, and extrapolations from lab or computer simulation to the field need to be done with caution.

Issues with the environment and GM crops

Almost 40 million hectares of transgenic crops have been planted commercially across six continents. Environmental concerns have turned their attention to these plantings since they are the largest-scale attempt to introduce GMOs into ecosystems. Concerned about the spread of GMOs into the ecosystem, activists have destroyed test plots on at least four different continents. This could demonstrate how deeply committed they are, but it also makes it impossible for anybody to benefit from the information that ought to have been gathered from those exams. Herbicide-resistant cultivars are used to cover the bulk of the land planted with GM crops. In large-scale arable crops, these herbicides are linked to a move toward reduced mechanical tillage, which lowers primary soil erosion[1]–[3]. Weed experts were among the first to recognize and research the environmental effects of introducing GM crops, particularly for weed management. An international scientific conference on the advantages and disadvantages of transgenic herbicide-resistant crops was held in 1998 and was sponsored by FAO.

Since there is a strong selection pressure on weeds to develop biotypes that are resistant to the herbicides associated with transgenic plants designed to be tolerant of those herbicides, repetitive use of one herbicide produces a change in the weed flora. The transfer of genes between related weed species and herbicide-resistant crops happens via outcrossing. The presence of this trait would not likely increase the strength of the weeds in the absence of the specific herbicide, but it would increase the weeds' strength when the herbicide is used, which might lessen the economic advantages of herbicide resistance. Areas of origin and diversification have greater gene transfer hazards. To prevent the transmission of herbicide-resistant genes from affecting native germplasm, especially relatives of weeds and wild crops, care must be taken.

Monitoring techniques and strategies for transgenic

Biochemical techniques may be used to find genetically modified organisms in food or feed. It may be qualitative, identifying the specific genetically modified organism (GMO) present, or quantitative, quantifying the level of a particular GMO's presence[4]. The ability to recognize a GMO is a crucial component of GMO labeling is necessary because, in the absence of detection techniques, documentation would be the only means of tracing GMOs.

PCR

A DNA fragment may be isolated and exponentially amplified by enzymatic replication using the polymerase chain reaction (PCR), a biochemistry and molecular biology technology that does not need the use of a live creature. Making millions of copies of a given genetic sequence allows it to recognize specific DNA strands. Simple visualisation methods may make the millions of copies of the target sequence—which are effectively photocopies—easily visible.

The technique works by combining the desired genetic sequence with primers, which are complementary DNA fragments with a particular design. The primers bind to the target sequence when it is present, which starts a chain reaction. Primer sequences serve as docking locations for DNA replication enzymes, which then begin duplicating the target sequences. The procedure is repeatedly carried out by sequentially heating and cooling until the target

sequence has been amplified several million times by doubling and redoubling[5]. The many identical particles are then colored, purified in a gel slab, and made visible by UV light. It does not easily get contaminated. Despite the great range of DNA analysis techniques, only PCR in its many forms has been extensively utilized for GMO detection and analysis and is typically regarded as sufficient for regulatory compliance. DNA-based detection techniques depend on the complementary nature of two DNA double helix strands that hybridize in a sequence-specific way. The operation of a GMO is controlled by a number of components in its DNA. The structural gene, the promoter sequence, and the gene's stop sequence are the elements.

DISCUSSION

Statistical detection

To quantify the amount of a PCR product, utilize quantitative PCR (Q-PCR) (preferably real-time, QRT-PCR). It is the technique of choice for determining how much transgenic DNA is present in a food or feed sample quantitatively. Q-PCR is often used to assess the quantity of copies of a DNA sequence contained in a sample as well as if it is there at all[6], [7]. Quantitative real-time PCR is the technique with the greatest degree of accuracy at the moment. Fluorescent dyes, like Sybr Green, or DNA probes containing fluorophores, like TaqMan, are used in QRT-PCR techniques to detect the quantity of amplified product in real time. A positive PCR test demonstrates the presence of a GMO in the sample if the targeted genetic sequence is specific to that GMO.

Superior detection

Q-PCR and multiplex PCR are two methods that may be used to determine if a GMO is present in a sample. Using numerous, distinct primer sets inside a single PCR reaction, multiplex PCR creates amplicons of various sizes that are specific to various DNA sequences, or various transgenes. Several genes may be targeted at simultaneously, providing more information from a single test run than would be possible if just one gene were being tested. The amplicon sizes, or their base pair lengths, should be diverse enough to create discrete bands when seen by gel electrophoresis, and annealing temperatures for each of the primer sets must be adjusted to operate well within a single reaction.

Detection based on events vs detection based on constructs

Producers, importers, or regulators sometimes have no idea which GMOs to look for when testing a sample for the inadvertent presence of GMOs. EU officials, however The US government relies on construct-specific test methods because they favor an event-specific approach to this issue.

Detection of certain events

The DNA junction between the transgene and the organism's native DNA is often the target of an event-specific detection, which looks for its existence[8]. Using this method is the best way to accurately identify a GMO, however very identical GMOs won't be picked up at all. PCR is used for event-specific detection.

Identification of certain constructs

Both DNA and protein-based detection strategies may be used to identify certain constructs. A portion of the foreign DNA put into a GMO is what DNA-based detection seeks for. Many GMOs share certain DNA sequences due to technological considerations. Protein-based techniques are used to find transgenic products, including the Bt toxin. Construct-specific

detection may check a sample for many GMOs in one step since various GMOs may synthesize the same protein, but it cannot identify which of the comparable GMOs is present. The construct-specific technique uses protein-based detection, particularly in the USA.

Current detection techniques' shortcomings

As the DNA sequence of the transgene or the protein it produces must be known for detection, it is now very improbable that the presence of unanticipated or even unknown GMOs would be discovered. Even testing for known GMOs takes time and money since there is now only one GMO that can be detected at a time using accurate detection techniques. Hence, research initiatives. Improved and alternative testing techniques are being developed by companies like Co-Extra, such DNA microarrays.

Usage of pesticides and insecticide-resistant crops

Genetically modified (GM) crops that are insect-resistant (Bt) are designed to generate a toxin that renders the whole plant poisonous to certain insects, such butterflies and beetles. Between 1996 and 2011, Bt crops in the US reduced the usage of pesticides by 124 million pounds[9], [10]. The poison generated by the plant, however, could also have detrimental effects on the ecosystem. Bt crops only switch the application of pesticides from being sprayed on to being incorporated. In the US, Transgenic crops have resulted in an overall 403 million-pound increase in pesticide consumption (183 million kgs).

Weeds Resistant to Herbicide

Herbicide-resistant (HR) weeds, or "superweeds," have emerged and spread as a result of the increasing usage of certain herbicides alongside GM herbicide-tolerant crops. Some weeds become resistant to certain herbicides when they are used extensively and repeatedly. Herbicide-resistant weeds first appeared before GM crops. The development and widespread use of industrial agricultural practices and chemical pesticides in the 1950s led to the first reports of weeds resistant to herbicides. Herbicide-resistant weeds have become more prevalent and diverse as herbicide usage has grown. A huge portion of farmland is regularly sprayed with the same herbicide due to the introduction of herbicide-tolerant crops, notably glyphosate-tolerant "Roundup Ready" crops, which has been expedited and entrenched by GM crops. Currently, 37 different weed species exist in the globe that can tolerate glyphosate. There are five of these species in Canada. According to USDA estimates, glyphosate-resistant weeds invaded 28.3 million hectares of American agriculture in 2013. Moreover, herbicide-resistant weeds cost farmers money. In the US, the cost of controlling weeds in fields with infestations is 50–100% greater per hectare than it is in those without glyphosate-resistant weeds. Certain weeds have become resistant to several herbicides, making them even more difficult to eradicate. When RH weeds proliferate, herbicide usage rises as a result, creating a "pesticide treadmill" that has detrimental effects on both the environment and human health.

Differential detection techniques PCR-based detection improvement

The European research initiative Co-Extra has additional objectives, one of which is to enhance PCR-based GMO detection. Multiplex PCR techniques that may concurrently identify several distinct transgenic lines are now being researched. The growing use of transgenic crops with stacked characteristics is a significant obstacle. This is a term used to describe transgenic cultivars that are the result of crosses between parent transgenic lines that combine the transgenic characteristics of both parents. The GM maize variety MON863 x MON810 x NK603 includes three stacked characteristics and is now pending an approval

from the European Commission. It is immune to two distinct insect pests as well as a herbicide. A sample containing this GMO might have its real GM content tripled as a consequence of certain combination testing techniques.

Finding unidentified GMOs

Virtually all transgenic plants share a few structural components, making it simpler to identify unidentified GMOs. Finding a needle in a haystack may be compared to locating a new gene in a GMO, however it is much simpler since the needles are often identical. Scientists pair the gene they wish to introduce with something called a transcription promoter to start gene expression.

Several GMOs share the effective 35S promoter as a characteristic. Moreover, the NOS terminator is often the same as the stop signal for gene transcription in most GMOs. Now, scientists have compiled a list of genetic sequences that are typical of GMOs. After the genetic components that make up GMOs have been chosen, techniques and. Tools for finding them in test samples are created. Anchor PCR profiling and microarrays are two methods under consideration.

Fluorescence in the near infrared (NIR)

Based on the physical characteristics of the chemicals, near infrared fluorescence (NIR) detection is a technique that may identify the types of compounds that are present in a sample. When near infrared light strikes a sample, chemical bonds within the sample vibrate and emit light energy at a wavelength unique to that molecule or chemical bond. It is unknown at this time if NIR imaging will be able to distinguish between GMOs and regular plants. Despite the need for sophisticated equipment and data processing tools, a non-chemical method could offer certain benefits including cheaper costs, increased speed, and portability.

The Environment (Protection) Act of 1986 governs the Biosafety and Recombinant DNA Guidelines of India (1990). The DBT updated its prior regulations in 1994 when India ratified the Biodiversity Convention to account for the safe handling of GMOs in research, application, and technology transfer. This covers the purposeful release of GMOS plants, animals, and goods into the environment on a massive scale. Rules are also given for the importing and transportation of GMOs for lab research.

India has a well-established regulatory framework for the creation and assessment of GMOs and their byproducts. The two main regulatory organizations are the Department of Biotechnology (DBT) and the Ministry of Environment & Forests (MoEF). Since the government is responsible for both the creation and preservation of the environment, the MoEF announced rules under the Environmental Protection Act of 1986 (EPA) in 1989[11]. These regulations include the processes for the production, importation, usage, study, and release of GMOs as well as the goods created with these organisms. The rule's goal is to make sure that using these items or living forms is safe for the environment and advantageous for people. It has also been established who the relevant authorities are and how they would handle any matters relating to GMOs and their byproducts.

The Department of Biotechnology (DBT) released safety guidelines for biotechnology research, field tests, and commercial applications in 1990. Applications. Moreover, in 1998 and 1999, DBT released distinct guidelines for research on transgenic plants and therapeutic products. Other rules including the Medicines and Cosmetics Act (8th Amendment), 1988, the Drug Policy, 2002, and the National Seed Policy, 2002, also apply to activities using GMOs. There are now six competent authorities in the nation responsible for carrying out rules and directives:

India's regulatory structure or institutions

The hierarchy of competent authorities, as well as their makeup and roles, are described in the 1989 Regulations.

Advisory Committee on Recombinant DNA

The Department of Biotechnology oversees the Advisory Committee's operations. The Committee examines both domestic and foreign biotechnology advancements. It is required to periodically suggest "necessary and adequate safety measures" for GMO development and use. The Committee is tasked with creating a long-term strategy for research and development as well as educating researchers and professionals on the risks and preventative measures (1990 Guidelines).

Genetic Manipulation Review Committee (RCGM)

The Department of Biotechnology established the RCGM4 to oversee safety-related elements in active research projects and activities involving genetically modified organisms or microorganisms. The Committee also publishes guides on best practices for GMO research, usage, and application activities. The RCGM must examine any active study involving "high-risk category and controlled1 field experiments" to ensure strict adherence to proper containment and precaution. Subcommittees may be appointed by RCGM. The RCGM may establish guidelines that limit or prohibit the

GMO creation, distribution, importation, and application. Usage of GMOs or microorganisms is only permitted in labs or in places designated as such by the Environment Ministry. Experiments for educational purposes may be conducted elsewhere as long as they are under the supervision of the Institutional Biosafety Committees.

Genetic Engineering Approval Committee (GEAC)

The Ministry of Environment and Forests' GEAC is in charge of approving initiatives involving the extensive use of GMOs in research, manufacturing, and application. Only from an environmental perspective does the GEAC provide approval. The Committee approves the field testing and release of GMOs and goods into the environment. This implies that the GEAC alone must approve any large-scale trials beyond the purview of the RCGM. The GEAC must provide its approval before any dangerous GMOs are imported, exported, manufactured, processed, or sold. GMOs are often prohibited from being intentionally released into the environment or into nature for research reasons. But, in rare circumstances, the GEAC could approve such a release. For the manufacture, sale, import, and use of food, food components, and food additives, including processing and containing or consisting of GMOs, GEAC authorization is required. The GEAC must provide the occupier with instructions on the discharge of GMOs or microorganisms, as well as the ban of discharge and the appropriate safeguards. GEAC approvals must be renewed every two years and may last up to four years in the initial instance. The cost for covering expenditures (in whole or in part) incurred for approvals, exams, supervisions, and control may be set by the GEAC. Any new knowledge about the negative effects of GMOs, any harm to the environment, nature, or health that was not anticipated at the time of approval, and any incident of non-compliance with the requirements may lead to the revocation of GEAC licences[12]. Monitoring the terms' and conditions' implementation

The GEAC sets the approvals' requirements. The Committee may delegate the appropriate oversight to the State Biotechnology Coordination Committee, the State Pollution Control Board, the District Level Committee, or any other person. For environmental infractions, the Committee may take (or may authorize anybody to take) disciplinary action.

Committee for the State Biotechnology Coordination (SBCC)

Via the nodal department, the State Pollution Control Board, the Directorate of Health or Medical Services, and other agencies, the SBCCs have the authority to "inspect, investigate, and take disciplinary measures" against statutory infractions. The Committee will conduct regular evaluations of the safety and control procedures in businesses and institutions.

Fifth District Committee (DLC)

The district-level DLCs are responsible for keeping an eye on the safety laws in place. To prepare for any emergency, the DLC or its representatives must visit the site and assess the dangers and risks there. They are required to create off-site emergency plans and make frequent reports to the GEAC or the SBCC.

CONCLUSION

An occupier or any anyone engaging in research activities while handling GMOs must establish an IBSC. The Committee will be made up of the institution's leader, a medical specialist, a scientist knowledgeable on DNA research, and a DBT candidate. According to the manual or RCGM standards, the occupier or research institution is required to create an updated on-site emergency plan (with the assistance of the IBSC). Copies of the plans must be sent to the GEAC, State, and District Level Committees. Every research institution should have a designated Principal Investigator (P.I.) who will inform the IBSC about the nature of experiments are being conducted. If the risk is of a higher category, the Investigator should get approval from the IBSC or the RCGM (via the IBSC).

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CHAPTER 8

NATIONAL BIOSAFETY POLICIES AND LAW

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ABSTRACT:

The Indian Biosafety Rules and Regulations were created with the intention of making it easier for researchers employing cutting-edge biotechnology technologies to conform to the legal requirements. In a laboratory context, it's crucial to use biosafety concepts and procedures to minimize the health risks connected to handling infectious agents, poisons, and other biological hazards.

KEYWORDS:

Biosafety, genetically modified organisms (GMOs), Genetically Modified (GM), GM foods, Recombinant DNA technology, vaccines.

INTRODUCTION

In the food and agriculture sectors, humankind has used biotechnology concepts for ages. Biotechnology, which is defined as technical applications that employ biological processes and live creatures to create or change goods for human use, has led to improvements in the creation of foods, pharmaceuticals, fabrics, and other goods we use on a daily basis. Contemporary biotechnology has evolved from conventional cross-breeding of closely related species as a result of scientific advancements like the discovery of DNA technology. Using in vitro nucleic acid procedures, modern biotechnology enables the utilization of genes from any class of organisms as well as the creation of genetically engineered creatures.

New genetically altered plant or animal life forms are constantly being created via research in modern biotechnology for application in horticulture, agriculture, the food business, medical research, the pharmaceutical sector, etc. The hazards associated with the use of these genetically modified organisms, or GMOs, must be carefully assessed and handled even if they have the potential to improve human growth. These dangers include potential extinctions of species, hazards to the health of people, plants, and animals, as well as the socioeconomic fallout from releasing GMOs and their byproducts into the environment or the market. The method of controlling these dangers is known as biosafety. National biosafety regulations, the Biosafety Protocol of Cartagena, the World Trade Organization, and other international accords. Many laws are now in effect that have an impact on various areas of biosafety. The national policies, legislation, and regulations listed below are pertinent.

Biosafety Rules

This regulation puts restrictions on plant pests and governs the importing of certain plant species. The Act gives the Minister the authority to prohibit the importation of any plant, object, or thing from any nation where he is certain that plant pests may be brought into the island in addition to quarantine procedures. Any GMO that may be categorized as a "plant pest" would fall under this[1]–[3].

The only existing piece of legislation that specifically addresses biosafety concerns is this one. This legislation was passed in 1997 and changed in 2005. The National Biosafety

Committee is mandated by these rules to oversee the importation of any plant, seed, cutting, or slip that has been genetically modified and brought into Jamaica for experimental purposes. As a result, the NBC has been keeping an eye on both the importation of transgenic material and the experimental transgenic experiments being carried out in Jamaica. This law mandates a quarantine period for any imported birds, reptiles, mammals, and insects. A 1991 law known as the National Resources Conservation Authority (NRCA) Act

This Act creates the NRCA, whose duties include the ability to manage Jamaica's physical environment in a way that ensures the preservation, protection, and efficient use of its natural resources. Its legislative authority is sufficiently wide to encompass biosafety concerns and potential GMO effects on biodiversity and human health. The NRCA monitors how the environment is affected by industry via the Environmental Permit and Licence system. The NRCA is consequently obligated to control a variety of activities, including the introduction of new species of flora, animals, and genetic material into the ecosystem. The Wildlife Protection Act of 1945 and the Endangered Species (Protection, Conservation, and Regulation of Trade) Act of 2000 are two related pieces of legislation.

The 1975 Food and Pharmaceuticals Act

This legislation governs the selling, labeling, packaging, advertising, and importing of food and medicine items. The importation or sale of GMOs in the form of medicinal goods may be prohibited under this legislation and the Pharmacy Act of 1975.

The 1975 Pesticides Act

The use of GMOs for pest management may be impacted by this regulation, which controls the importation, production, sale, labeling, and usage of pesticides.

DISCUSSION

Biotechnology for Socio-economic Development: Policies

A Jamaican Policy (Draft, 2006): This policy is only concerned with biotechnology, including R&D activities. Public consultations are now taking place on the draft biotechnology policy.

Technology and Science Policy (1990)

According to this strategy, biotechnology is a top priority, notably in terms of agricultural, crop, and animal production as well as R&D efforts[4]. It acknowledges the need of controlling the use of the island's biological resources and expanding biotechnology capabilities. Now, the Science and Technology Policy is being updated to reflect contemporary concerns.

Act governing national biosafety (proposed)

To go along with this approach, drafting guidelines for biosafety legislation are now being developed. A biosafety framework is indirectly impacted by other laws and policies in addition to those that are already mentioned. These laws and the agencies in charge of carrying them out or enforcing them.

Biological Diversity Convention (CBD)

The United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro in 1992 resulted in the adoption of the Convention on Biological Diversity (Biodiversity Convention, CBD). There are now 193 Parties to the Convention. Switzerland

approved it in 1994. The signatories to the CBD pledge to protect biodiversity on their own soils, support suitable conservation and sustainable use initiatives in developing nations, and fairly control who has access to and uses genetic resources. The CBD Parties committed to reducing the pace of biodiversity loss considerably by 2010 in April 2002[5], [6]. Sadly, the goal of drastically slowing down the existing pace of biodiversity loss by 2010 was not met. The 20 Aichi Biodiversity Goals, often known as the Aichi Biodiversity Objectives, and the worldwide Strategy Plan for Biodiversity 2011-2020 were established during the Conference of the Parties in Nagoya in October 2010. The strategic plan and objectives call for actions such as the abolition of counterproductive incentives, enhanced protected area connectivity, and sustainable use of areas with an economic purpose.

On behalf of the Federal Council, the Department of Environment, Transport, Energy and Communications (DETEC) created a national biodiversity policy to guarantee the long-term preservation of biodiversity. On April 25, 2012, the Federal Council approved it. By the end of 2017, the related action plan should be finished. In order to secure the long-term protection of biodiversity in Switzerland, it will specify specific steps for each of the 10 strategic objectives.

The Biosafety Protocol of Cartagena Introduction

The Convention on Biological Diversity was completed in Nairobi in May 1992, and on June 5, 1992, it was made available for signing at the UNCED conference in Rio de Janeiro. It becomes effective on December 29, 1993. The Convention is now the primary international tool for addressing biodiversity-related challenges. It offers a thorough and all-encompassing approach to the preservation of biological variety, the judicious and equal distribution of the advantages resulting from the utilization of genetic resources, and the sustainable use of natural resources. One of the topics covered by the Convention is biosafety[7]–[9]. This idea alludes to the need to safeguard the environment and human health from potential risks posed by contemporary biotechnology goods. At the same time, it is acknowledged that contemporary biotechnology has considerable promise for enhancing human wellbeing, especially in addressing pressing needs related to food, agriculture, and healthcare. These two features of contemporary biotechnology are expressly acknowledged by the Agreement. On the one hand, it allows for the transfer of technologies, such as biotechnology, that are important for the preservation and sustainable use of biological variety, as well as access to such technologies.

The Convention's overarching objective is to lessen any possible dangers to biological variety while also taking into consideration the hazards to human health. On the other hand, it ensures the creation of proper processes to increase the safety of biotechnology. The Conference of the Parties to the Convention created an Open-ended Ad Hoc Working Group on Biosafety at its second meeting in November 1995 with the goal of creating a draft protocol on biosafety that would specifically address transboundary movement of any living modified organism resulting from contemporary biotechnology that could have a negative impact on the conservation and sustainable use of biological diversity[10]. The Protocol, also known as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, was finally completed and ratified in Montreal on January 29, 2000 during an extraordinary meeting of the Conference of the Parties after many years of talks. The completion of the Biosafety Protocol has been welcomed as a major step forward since it offers a worldwide regulatory framework to balance the interests of commerce and environmental protection with regard to the biotechnology industry, a sector of the global economy that is expanding quickly. The Protocol thereby fosters an atmosphere that is favorable for the ecologically

sound implementation of biotechnology, allowing for maximum gain from the technology's potential and minimal potential harm to the environment and human health.

An international agreement on biosafety as a supplement to the Convention on Biological Diversity has been in operation since 2003 under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. With the help of contemporary technologies, genetically modified organisms offer possible threats to biological variety, which the Biosafety Protocol attempts to safeguard. The use of genetically modified, living creatures raises environmental and health concerns, which are addressed by the Cartagena Protocol, an international legal agreement. It is intended to guarantee the secure handling and application of living things that have undergone biotechnological modification, which might endanger the preservation and sustainable use of biodiversity. The Biosafety Protocol makes it clear that new technology-based goods must adhere to the precautionary principle and enable poor countries to weigh economic advantages against public health considerations. It would, for instance, permit nations to prohibit the importation of GMOs if they believe there is insufficient scientific proof that the product is safe and mandate that exporters identify shipments containing GMOs, such as cotton or maize.

Agreements connected to the WTO

An incredibly significant advancement in the worldwide regulation of genetically modified organisms (GMOs) and genetic engineering is the Cartagena Protocol on Biosafety. For the first time, genetic engineering and GMOs are officially regulated by international law.

Various WTO (World Trade Organization) Agreements pertaining to biosafety, which are enforceable by its Members. It evaluates the prospects for ensuring biosafety as well as the most important pertinent requirements included in these agreements. Measures taken by WTO Members that adhere to their rules, directives, and suggestions are assumed to be WTO-compliant. The WTO could have the effect of establishing a legal hierarchy through its decisions with regard to United Nations agreements because it is the only international organization with a formal and enforceable dispute settlement system. This was not the intention of the nations that negotiated the trade agreements and the creation of the WTO.

The 1994 GATT (General Agreement on Tariffs and Trade)

In essence, WTO regulations are limitations on Member States' freedom to conduct acts that have an impact on commerce, including freedom to control biotechnology and enact biosafety regulations. GATT 1994 is a set of rules that apply to any actions affecting any product involved in international commerce between WTO Members, including genetically modified (GM) goods. It must be studied with GATT 1947. Three clauses include the essential disciplines:

According to Most Favoured Country, Article I, any benefit, privilege, or immunity given to a product coming from or headed for another nation must be given promptly and unconditionally to a "similar product" coming from or headed for the territory of all other Members.

WTO Members are forbidden from adopting actions that directly or indirectly discriminate between similar goods based on their place of origin under Article III (National Treatment).

According to Article XI (Quantitative Limitations), WTO Members are not permitted to enact or continue to use prohibitions or quantitative restrictions (such as quotas or import licenses) on the import of goods from other WTO Members. Regulation of biosafety is affected by two significant and unresolved questions over how to interpret these Articles.

Secondly, it has not been determined if conventional goods and GMOs and GM products are "like items" (e.g. GM soya and conventional soya). Second, there is disagreement among Members on the existence and scope of WTO Agreements regulation of production and processing methods (PPMs). The inclusion of PPMs generally in the WTO concerns developing nations that are WTO members since they may be a cover for trade protectionism.

According to the biosafety argument, genetic engineering is a manufacturing technique that differs fundamentally from a traditional technique and has possible dangers built into the former. In contrast to a variety grown traditionally, a soybean variety generated by genetic engineering may be subject to trade limitations required for biosafety. The majority of poor nations advocated for the Cartagena Protocol on Biosafety from this stance. PPMs, however, are still a controversial topic in both legal theory and WTO policy. In any case, the GATT's Article XX offers a number of broad exceptions to these rules, including one that permits trade-restricting measures.

Application of Sanitary and Phytosanitary Measures Agreement (SPS Agreement)

A WTO Member must abide by the Agreement on the Application of Sanitary and Phytosanitary Measures if they seek to implement trade restrictions to safeguard the lives or health of people, animals, or plants. Sanitary and phytosanitary measures that "may, directly or indirectly influence international commerce" are included under the SPS Agreement. These actions take the form of laws, rules, specifications, guidelines, and decrees.

The SPS Agreement is basically an expansion of the guidelines for implementing GATT 1994's sanitary and phytosanitary measures regulations, particularly those included in Article XX (b). Definitions on the sanitary or phytosanitary character of a measure are included in the SPS Agreement. Any of the following measures is considered sanitary or phytosanitary:

- To guard against risks associated with the introduction, establishment, or spread of pests, diseases, disease-carrying organisms, or disease-causing organisms inside the Member's territory.
- To guard against hazards associated with additives, pollutants, poisons, or disease-causing organisms in foods, drinks, or feedstocks within the Member's territorial jurisdiction.
- •To prevent or minimize other harm within the Member's territory caused by the entrance, establishment, or spread of pests.
- To safeguard human life or health within the Member's territory from dangers originating from illnesses carried by animals, plants, or products thereof; or

Agreement on Trade-Related Technological Barriers (TBT Agreement)

The Agreement on Technical Barriers to Trade regulates trade restrictions that are technical rules and technical standards (including packaging, marking, and labeling requirements) and are not sanitary or phytosanitary measures as defined in Annex A of the SPS Agreement. It applies to all industrial and agricultural products. The TBT Agreement aims to prevent unneeded trade barriers from being created by the rules, criteria, testing, and certification processes (which differ from country to country).

It permits a WTO Member to have national regulations, which should not restrict trade more than is required to achieve a legitimate objective, such as national security, the avoidance of dishonest business practices, the protection of human health and safety, animal or plant life, or the environment.

WTO Members may take the necessary actions to guarantee that their own standards are upheld. Members are not obligated to modify their level of protection as a consequence, although they are urged to do so when applicable international standards are available.

The TBT Agreement includes I the creation of technical rules by governments, which are required; (ii) the creation of standards by government standardizing organizations, which are optional; and (iii) the processes used to evaluate or ascertain compliance with these laws and standards.

GATT, SPS, and TBT Agreement Connection

Although there is some debate regarding how the GATT, SPS, and TBT Agreements interact, it is evident of the SPS Agreement ("Nothing in this Agreement shall affect the rights of Members under the Agreement on Technical Barriers to Trade with respect to measures not within the scope of this Agreement") and Article 1.5 of the TBT Agreement ("The provisions of this Agreement do not apply to sanitary and phytosanitary measures") that TBT measures that are not covered by the GATT, SPS, and TBT Agreements are

Further international Treaties

The Convention on International Trade in Endangered Species of Wild Fauna and Flora is one such agreement (CITES). The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), sometimes known as the Washington Endangered Species Convention, was adopted in Washington in 1973. On July 1st, 1975, it became law in Switzerland. In Geneva, there is a CITES secretariat. The Federal Food Safety and Veterinary Office is in charge of CITES in Switzerland (FSVO).

Convention of Bern

The Council of Europe ratified the Convention for the Protection of European Animals and Natural Habitats in Bern in 1979. It is the first agreement to govern biodiversity conservation on a European level. The Bern Convention aims to foster cooperation between European nations in the protection of biodiversity as well as the preservation of wild flora and wildlife and their ecosystems. Endangered and extremely sensitive species must get special consideration in this situation. Several of the global objectives outlined in the Convention on Biological Diversity (1992) are implemented at the regional level via the Bern Convention.

Plant Genetic Resources for Food and Agriculture:

On February 20, 2005, Switzerland ratified the 2001 Rome-adopted International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). The Federal Office for Agriculture FOAG is the body in Switzerland in charge of the ITPGRFA.

CONCLUSION

In order to ensure user and environmental safety when using genetically modified organisms (GMOs) and their products in research, the Environment (Protection) Act 1986 and Rules 1989's biosafety procedures, rules, and guidelines are being made easier to implement under the Biosafety Research Program. Institutional Biosafety Committees (IBSC) at the Institute or Company; the Review Committee on Genetic Manipulation (RCGM) in the Department of Biotechnology; and the Genetic Engineering Approval Committee (GEAC) in the Ministry of Environment & Forests (MoE&F) are the three levels of the mechanism for approving research and development activities on recombinant DNA products, environmental release of genetically engineered (GE) crops, and monitoring and evaluation of those activities. The RCGM looked at applications in the pharmaceutical and agricultural sectors for the import,

export, transfer, or exchange of genetically engineered materials, including GE seeds, conducted pre-clinical toxicity studies, evaluated pre-clinical study reports, and made recommendations to DCGI for the proper phase of clinical trials of new drugs or similar biologics, conducted confined field trials on GE crops, etc. Appropriate decisions were made. RCGM has made a number of policy choices on agricultural, biopharmaceutical, and industrial product biosafety research.

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CHAPTER 9

CROSS BORDER MOVEMENT OF GERMPLASM

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ABSTRACT:

Germplasm is a priceless natural resource that offers information about a species' genetic make-up and is essential for preserving plant variety. In addition to saving plant species that are in danger of becoming extinct, germplasm conservation measures work to maintain all vital plants, which are necessary for the existence of all creatures. Genetic resources must be carefully gathered, stored, analysed, documented, and exchanged in order to be used effectively. Some methods for conserving germplasm include slow growth cultures, cryopreservation, pollen and DNA banks, botanical gardens, genetic reserves, and farmer's fields. Although the use of in-vitro methods that even have a remote chance of causing genetic instability could result in the total destruction of the substance, a better understanding of the fundamentals of regeneration biology would undoubtedly increase the capacity to regenerate new plants, increasing the range of possible selections. For future procreation and development, germplasm conservation aims to protect fragile and endangered plant species around the globe. It is also the cornerstone of agricultural output.

KEYWORDS:

Cryopreservation, Economic, Genetic Resource, Genetically Modified (GM), GM foods, Recombinant DNA technology, vaccines.

INTRODUCTION

Around 10,000 years ago, humans began to understand the economic value of plants and began domesticating wild species. Even when moving from place to place, they began to save seeds or vegetative plant propagules from one season to the next. In certain regions of India and China as early as 700 BC, the practice of seed saving was taught and practiced. Due to natural hybridizations with wild and weedy cousins and spontaneous mutations, this has played a significant role in the global growth of agriculture and the introduction of genetic diversity into populations. Humanity depends on a varied pool of plant genetic resources being continuously available for use in agriculture to provide both nutritional and financial security. Global food security depends on crop wild relatives (CWRs) pre-breeding to capture natural and existing genetic diversity. Their untamed natural selection produced a wealth of advantageous variants that may be bred into crop plants to serve as a foundation for future alterations. The CWRs are essential for preserving healthy agro-ecosystems in addition to serving as an important source of germplasm for enhancing agricultural productivity. Hence, it is essential for preserving and using germplasm resources to understand the pattern of variation and the locations where it exists[1]–[3].

Plant genetic resources (PGRs) are the totality of all allelic sources that affect a crop's spectrum of attributes, while germplasm is the genetic material handed down from one generation to the next. This genetic diversity may have been derived from closely related wild plant species, which are the immediate or indirect ancestors of cultivated species, currently domesticated or semi-domesticated cultivars, as well as their component cultivars, which are either still in use or have been rendered obsolete, or landraces or historic varieties.

Despite their availability, there aremajor obstacles to using these allelic resources in a sustained and efficient manner. Despite the fact that there are several gene banks in existence today, only roughly 30 nations have chosen to store their germplasm there for secure long-term preservation due to a lack of long-term maintenance facilities for such gene banks. Also, the 7.5 million accessions in these gene banks include predominantly landraces and diverse wild relatives of crops that are important for human and animal nutrition. Nonetheless, there are underused species and locally significant crops that need protection.

Since human interference has resulted in the erosion of genetic diversity by increasing favored genes and completely eliminating the less desirable, having an effect on the extinction of the historic genetic material, germplasm conservation aids in the preservation of knowledge about extinct, wild, and other living species of a crop plant. By gathering the propagules of each taxon, it primarily focuses on assuring the safe handling and correct storage of the germplasm of economically important plants. PGRs for food and agriculture (PGRFA) and PGRs for non-food utilization, such as medicinal plant species, wood and fuel plant species, ornamental species, and recreation and amenity species, are a few applications of germplasm protection that include plant breeding and habitat regeneration of ecosystems for livestock, horticulture, and forestry. The use of readily accessible genetic resources for agricultural enhancement is, however, being disregarded. For each given crop species, there is a considerable discrepancy between the amount of germplasm that is actually used and the number of collections that are accessible in gene banks. Hence, as plant breeders continue to heavily rely on fewer, closely related parents and their derivatives in crop improvement efforts, the whole purpose of generating large germplasm banks is defeated. One method of creating crops that are more tolerant to changing climatic circumstances is the introduction of beneficial traits from wild relatives into high yielding cultivars. The germplasm accessions are crucial resources for understanding how genes operate and how plants grow, even if they seem to be genotypic twins.

There is a significant danger of disease and pest dissemination while moving plant germplasm or any other raw plant material. The International Plant Protection Convention (IPPC) include viruses, bacteria, fungi, weeds, and even animal pests like insects among the harmful and potentially dangerous biotic agents. In other cases, the target plant may truly be or may become a pest, which would impede its ability to traverse borders in a way that would be dangerous.

There are laws in several nations that control the importation of plant material. Even the internal movement of plant materials is governed by certain rules. The laws are an attempt to reduce the spread of plant diseases and pests. Hence, those programs planning to transport plant germplasm both domestically and abroad must be aware of and compliant with the relevant regulatory requirements. A phytosanitary certificate stating that the requirements stipulated by the importing country have been satisfied must be included when plant material crosses international boundaries. The criteria are specified in plant import licences in the majority of nations. Adherence to phytosanitary rules helps to ensure the quality of the germs being exchanged in addition to preventing the transmission and spread of pests and illnesses[4], [5].

According to the 1998 amended rules for transgenic plant research in India, the RCGM will provide the relevant importer application approval for the import of transgenic material for research purposes. After reviewing the paperwork pertaining to the material's safety and the necessity for the country, the RCGM will issue an import certificate. The RCGM will take into account the importer's facilities for in-soil testing on the transgenic material. An acceptable phyto-sanitary certificate issued by the organization in the exporting nation may

be imported with the transgenic material by the importer. Nevertheless, based on the import authorization provided by the RCGM of DBT, such import may be done via director NBPGR.

DISCUSSION

The Legal System

The UN Convention on Biological Diversity and the International Treaty on Plant Genetic Resources for Food and Agriculture both provide the legal basis for crop biodiversity. The first discusses the genetic variety of animals, plants, and bacteria, while the second focuses on the safety of the world's food supply. Instead of seeing genetic variation and germplasm as the common legacy of humanity, the Convention on Biological Diversity places more emphasis on the creation of bilateral agreements that involve benefit sharing among nations that own or are interested in genetic resources. While the US hasn't joined the Convention on Biological Diversity, it has sometimes taken part in bilateral germplasm exchange agreements with other nations. Nevertheless, in contrast to other germplasm repositories throughout the globe, the US National Plant Germplasm System primarily aims to make germplasm freely accessible to any and all requestors. The 64 crops covered by the International Treaty on Plant Genetic Resources for Food and Agriculture are the only ones whose plant genetic resources are utilized to generate food. The nations who ratify this agreement and agree to utilize the genetic resources solely for plant breeding and research activities that benefit food and agriculture would have free access to a pool of genetic resources.

During the last 25 years, plant germplasm patents have also had a significant impact on the diversity landscape. Changes in US legislation made it possible to patent cultivars, genes, plant breeding techniques, and related technology, while asexually propagated species were the only ones eligible for patents prior to 1980[6]. Utility patents covering extensive breeding practices and the cultivars they developed have sometimes been granted. The adoption of the Plant Variety Protection legislation in the 1970s enhanced the possibility of protecting agricultural species that are transmitted by seeds. The Plant Variety Protection Act, which is significant, did not prohibit breeding with cultivars that were legally protected in this manner, but cultivars that were patent-protected could not be utilized without a permission from the owner.

Plant breeding must consider the effects of these two accords as well as the growing trend of plant patents on biodiversity. At an earlier period, plant breeders openly traded germplasm on the assumption that it was the common heritage of humanity. Public sector plant breeders often developed "codes of ethics" or guidelines that stipulated crediting other breeding programs' germplasm where appropriate. Free trade, however, was the norm rather than the exception. Public institutions with breeding programs have been looking for ways to make money out of the germplasm that their researchers have created since the 1980s[7]. This was first done by individual breeders who wanted to use the royalties from germplasm sales to fund their breeding efforts. However, due to public funding reductions and a widespread movement in the 1990s to find new sources of funding for public institutions, many of them sought to formalize germplasm licensing contracts that required licensees or buyers to pay royalties to the institution's technology transfer division.

Several organizations wanted legal protection for plant germplasm, just as a commercial business would. It may be too soon to determine if this component of technology transfer has been a successful model since it has only been used for around 20 years in the US. Nonetheless, there is some anecdotal evidence that the protection provisions in germplasm agreements have decreased the sharing of germplasm across breeding groups. On the other hand, there is some indication that royalties collected have supported public breeding

initiatives, which may not have survived without public assistance. The contradiction in this institutional approach is clear: public breeding programs that are in risk of extinction are more dependent on royalty generation, which has the potential to further restrict breeding operations, inhibit the flow of germplasm, and impede genetic gain. Lately, some have proposed open-source germplasm distribution patterns akin to those used by the computer software sector Open Plant Breeding Foundation, website. These methods may serve to reassert the public character of public breeding programs, although funding for these initiatives remains a challenge.

Rules for Importing Plants

Plant import rules are divided into three categories: those that are authorized (low risk), those that are forbidden, and those that need quarantine. There is little chance of pest introduction from the approved imports. This may change depending on the kind of plant and the locality. Materials with a high risk of introducing hazardous pests and illnesses are subject to quarantine upon import. Some plants may not show any symptoms, yet they nevertheless contain pests. Such a material must be imported with a "Q" designation, and depending on how serious the danger is, it must be cultivated in a quarantine station or in an open/provisional quarantine[8], [9]. Due to the high danger of pest introduction, some plant materials and even imports from specific countries may be forbidden.

The pests connected to the source plant species of the target plant species must be understood by institutions or programs engaged in plant germplasm exchange. When sourcing the plant germplasm, the national regulatory body may be contacted if in doubt. These risk-mitigation measures make it simpler for the regulator to determine whether to provide a phytosanitary certificate or to provide guidance on the most suitable treatment plan. Before obtaining germplasm, the collector should have a list of pests and illnesses connected to the target plant species in a specific area.

International Phytosanitary Measures Standards (ISPM)

These plant protection standards were approved by the IPPC of the FAO. The goal and duty of IPPC-ISPMs is to ensure widespread and efficient actions to stop the spread and introduction of pests of plants and plant products, as well as to promote the right controls. The phytosanitary criteria for exchanging plant materials depend on the species of the plant, where it came from, and the laws in effect in the importing nation.

The crop-specific technical criteria created by IPGI should also be included, particularly for small, specialist consignments like those for research, conservation, and fundamental plant breeding programs When germplasm is transported abroad, the technical standards include pertinent information on disease indexing and other measures that serve to assure phytosanitary safety.

Importation and Exportation of Plant Germplasm

In general, the safest source should be used to get plant germplasm. True seed of germplasm, if available, should be selected for the transfer since seed provides a low risk of migrating and introducing pests. When actual seed is unavailable, germplasm should be transferred as pathogen-tested in vitro cultures. If it's not feasible to do this, strict quarantine regulations must be followed until the seed or vegetative material is cultivated in a dish.

It is important to check in vitro material for viruses that are known to harm crops in the germplasm's place of origin. It is important to record indexing processes and outcomes, for instance in a germplasm health statement. A sample copy of this publication is provided at

the conclusion. In conjunction with the appropriate indexing laboratory and quarantine authorities, the transfer of germplasm should be carefully arranged.

The import and export of healthy plant germplasm depends on the actions that follow.

Importation of plant genetic material

- Submitting a statement of intent to import to the National Plant Protection Organization (NPPO) specifying the kind, amount, use, and source of the plant material.
- Act 324 contains the import regulations for Kenya, with a distinct order outlining the specifics for each plant or plant species.
- New source: Information from a pest risk analysis (PRA) is required to create import criteria when plant material is supplied for the first time.
- The NPPO transmits import requirements, describing the standards that the in question plant material must meet, to the source nation through the application (importer).
- The nation of origin: The NPPO assesses and verifies that the plant materials adhere to the requirements of the importing nation.
- The nation of origin: If the import requirements are satisfied, the NPPO creates a phytosanitary certificate.
- The phytosanitary certificate issued by the source country and the original PIP granted by the receiving country must be included with the shipment of the plant material. In nations that do not issue PIPs, this can be different.
- At the entrance point, all plant materials must be disclosed to NPPO.
- At the point of entry, the NPPO of the importing nation validates the documents and examines the plant material.
- Plant materials that are prohibited or non-compliant are processed at the importer's expense, destroyed, or returned to their source.
- Verified distribution of clean, healthy plant material to the owners
- After the examination, owners are given access to the authorized, legal plant materials.

Depending on the risk levels, plant materials imported under the "Q" designation are either brought to quarantine stations or placed in open or temporary quarantine for further inspection. These materials are only provided if they are clean or after cleaning and indexing. Non-conforming materials may, if possible, be cleaned and indexed at the owners' expense prior to release.

In Kenya, the Kenya Standing Committee on Import and Exports must also approve the import of regulated goods including bio-control agents (KSTCIE). If the in issue plant germplasm is transgenic, the National Biosafety Committee (NBC) of the National Council for Science and Technology must assess the application (NCST). If the variety in issue is protected, importers of plant germplasm also need to respect the rights of plant breeders. The breeder's approval is necessary for the transaction. The variety release system must be updated with any new varieties that are subject to mandatory certification.

Exporting plant genetic material

The applicant outlines the import regulations of the destination nation.

- In cases where certain circumstances may only be verified during active growth, it is best to include the NPPO as early as possible to facilitate the compilation of the phytosanitary certificate.
- Protected plant varieties, CITES, and pharmacological materials are examples of other plant materials whose export may be prohibited.
- By inspection and/or laboratory testing, NPPO confirms that the import requirements of the importing nation are being met.
- Then, the NPPO would only create phytosanitary certifications for plant materials that complied.
- In addition to phytosanitary certifications, seeds of crop species may also need certification labels and certificates if commercial quantities are involved.
- Kenya Wildlife Service certification under CITES regulates the transportation of endangered plant species listed in the appendices of CITES (KWS).
- Only after KWS has obtained a CITES certificate will the NPPO issue a phytosanitary certificate.
- In certain circumstances, a Material Transfer Agreement (MTA) involving the exporting institution, the community where the target plant germplasm occurs, the scientist, the exporter, and the importing party may need to be prepared and signed.

Containment concerns in risk management

In order to reduce, monitor, and control the likelihood or effect of unpleasant occurrences or to optimize the realization of possibilities, risk management involves the identification, appraisal, and prioritizing of risks. This is followed by the coordinated and efficient use of resources. The process of choosing suitable containment methods to guarantee that biohazards are appropriately handled is known as biosafety risk management[10], [11].

The complete risk assessment and management process determines where, how, and by whom a biohazard will be handled from the time it is first purchased until it has been safely stored or deactivated once the task is over. The possible danger to workers must be considered at each stage of the work process. Evaluate the area where biohazards will be handled at work. Make sure no one else who uses the place will be exposed.

Research on the hazards related to alternative activities is evaluated and compared via risk assessment. Risk assessment is a foundational part of risk management, which creates plans to avoid and manage hazards within reasonable bounds. It considers a number of aspects, including social values and economics, in addition to the scientific evaluation. In order to make the best decisions possible, risk communication entails a constant discussion about risk and risk management choices between regulators and the general public. Risk evaluation need to be done on a case-by-case basis.

CONCLUSION

Germplasm is the main focus of agricultural production. In order to get a solid understanding of plant variety, the environment, and the socioeconomic and cultural components of farming, germplasm collecting necessitates the use of theoretical and empirical community sampling expertise. By restoring natural variety and fostering crop diversity for agricultural crop cultivation, it supports global efforts to assure future food security. The repair of damaged lands, the maintenance of ecological resources throughout the landscape, forestry, and horticulture are all dependent on it. The management and use of plant genetic resources have tremendously benefited from biotechnology. In vitro culture techniques, cryopreservation, and molecular markers have all helped plant germplasm survive, and they

provide a useful alternative to plant diversity research and genetic resource management. It is especially helpful for plant species that generate refractory seeds or reproduce asexually. In vitro culture technique is utilized to expand the quantity of germplasm specimens in gene banks all over the globe. To fully benefit from cryopreservation, modifications to gene bank procedures would be required. For collection, recovery, and sequence comparisons, better and reliable data management procedures are essential. The collection and preservation of genetic resources has become more urgent in recent years since germplasm is the starting point for breeders to create a variety of crops. With these initiatives, a "knowledge bank" based on genomics, digital phenotyping, and technical advancements will progressively be created, enabling a more data-driven adoption of crop variety.

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CHAPTER 10

IMPACT ON ENVIRONMENT: HEALTH ASPECTS, TOXICOLOGY, ALLERGEN CITY, ANTIBIOTIC RESISTANCE

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ABSTRACT:

One of the most important discoveries of the 20th century, antibiotics significantly altered how a wide range of illnesses were treated. A significant quantity of antibiotic residues have been exposed to bacterial populations and ecosystems as a result of increasing use. This chapter seeks to provide a succinct review of the main factors influencing the environmental prevalence of antibiotics. The author have made an effort to sum up how antibiotic residues behave in the environment and why it's important to find and measure them. They also provide up-to-date information on environmental antibiotic discharge and risk analysis for both human and environmental antibiotic use. The author suggest reducing environmental antibiotic contamination by first controlling the factors that contribute to it, and then moving on to regulate antibiotic discharge and risk assessment. The identification and measurement of the antibiotics as well as the description of their activity in the environment are some crucial intermediate stages that might inform future regulatory choices.

KEYWORDS:

Antibiotics, Cloning, contamination, environment, risk assessment.

INTRODUCTION

Antibiotic usage patterns that are often used to treat bacterial illnesses and to produce animals have led to the formation of antibiotic residues in the environment. According to statistics, animal husbandry uses antibiotics far more often than human medicine.

Optimizing and/or regulating antibiotic usage are essential components in lowering environmental contamination since antibiotics used in human and animal treatment are dispersed in urine and excreta. Depending on the medication class, between 40 and 90% of the antibiotic dosage delivered is excreted in the urine and feces as the parent compound, which is the active form. This parent molecule ultimately enters the environment and contaminates soils, waterways, plants, etc. By applying contaminated manure as fertilizer to agricultural fields and watering crops with wastewater, among other methods, the overuse of antibiotics in animal husbandry may pollute agro-ecosystems. The inappropriate disposal of unwanted medications by flushing them into sewage systems raises another issue.

Once in the environment, antibiotic residues can harm both human health and biota at various trophic levels by contaminating food and water, contributing to the growth of the population of resistant bacteria, and maintaining the selective pressure that leads to the development and/or spread of resistance in various environmental compartments.Antibiotic residues may be taken by plants, interfering with physiological processes and perhaps having ecotoxicological consequences, in addition to the possibility of promoting microbial antibiotic resistance. Numerous chronic and acute toxicity tests have been conducted to highlight the negative effects, and the results showed that antibiotics have an adverse effect on photosynthesis (chloroplast gene expression, cell proliferation, and oxidative stress

response in plants), which is likely explained by the bacterial origins of chloroplasts and mitochondria[1]–[3]. Moreover, the amounts of antibiotics present in agricultural soils may cause germination delays or biomass reductions, which may have a detrimental impact on the output of farms treated with contaminated manure. Moreover, antibiotic residues may change the human microbiota and result in health issues including allergic responses, long-term harmful consequences, and disruptions of digestive system processes. The key causes of antibiotic occurrence in the environment, such as rising antibiotic usage and antibiotic discharge, were the initial focus of this research. The behavior of antibiotic residues and the impacts of environmental pollution were thoroughly analyzed in order to achieve the second goal. Last but not least, an update on scientific and regulatory information about the risk assessment of environmental and human antibiotics was provided.

Antibiotic use and environmental antibiotic contamination

It has been noted over the decades since the discovery of antibiotics that the use of antibiotics in human medicine, veterinary medicine, and agriculture is connected to the contamination of the various environmental compartments (such as surface water, groundwater, drinking water, municipal sewage, soil, vegetables, and sludge), which in turn contributes to the rise in antibiotic resistance and has a negative ecological impact. Moreover, the use of antibiotics promotes the growth of bacteria or genes that are resistant to them, increasing the risk of transmission to people from the environment. Increased use of antibiotics is thought to contribute to infections brought on by bacteria resistant to them, lengthening of sickness, and an increase in morbidity and death.

According to recent statistics, 33,000 individuals in the EU pass away each year as a result of infections with bacteria resistant to last-line antibiotics like carbapenems and colistin. In 39% of these instances, the cause of death was an infection with bacteria. Similar circumstances exist in the US, where more than 35,000 individuals pass away and 2.8 million people have an illness that is resistant to antibiotics each year[4]. Antibiotic-resistant illnesses, however, are very expensive for both the economy and the healthcare system. The reason for the price rise is because last-line antibiotics, which are far more costly than first- and second-line antibiotic treatment, are needed to treat these illnesses. Also, a patient with illnesses that are resistant to antibiotics may need to stay in the hospital for an additional 6.4 to 12.7 days. According to estimates, infections with antibiotic-resistant bacteria cost the EU and the United States a combined total of $55 billion annually in lost productivity and healthcare expenditures.

According to one of the most recent comprehensive analyses of human antibiotic use, the consumption of antibiotics, expressed in defined daily doses (DDD), increased by 65% between 2000 and 2015, with a particularly rapid increase of last-resort antibiotics like glycylcyclines, carbapenems, oxazolidinones, and polymyxins. If no modifications are made to the policy, we may also anticipate a rise of up to 200% until 2030[5], [6]. Unnecessary antibiotic usage has been linked to problems with patients, healthcare professionals, and healthcare systems (e.g. expectation that a physician visit will lead to antibiotic prescription, poor knowledge of microbiology, underuse of available guidelines, lack of availability of local guidelines or lack of access to diagnostic tools etc.). Also, a variety of societal and cultural variables impact attitudes regarding the prescription and usage of antibiotics as well as the abuse of antibiotics. Nonetheless, the primary actions that should be taken to ensure a responsible and sensible use of antibiotics continue to be better hygiene, sanitation, immunization, and access to diagnostic tools. Limiting the use of wide spectrum antibiotics, vitally necessary drugs, and forbidding the release of antibiotic waste into the environment are other crucial steps. One important contributing reason to the introduction of antibiotics

into wastewater systems may be improper drug disposal, such as when medications are flushed down the toilet in homes. Patients and doctors must receive focused education on the negative environmental impacts of inappropriate medicine disposal due to a lack of suitable disposal methods. Another significant source of antibiotic residue contamination is hospital effluents. For instance, ciprofloxacin prescription volume and antibiotic residual levels in hospital wastewater were shown to be positively correlated.

Antibiotic use patterns are connected to how much antibiotics contribute to the emergence and maintenance of clinically relevant antibiotic resistance. The creation of targeted interventions and policies to optimize and encourage the responsible use of antibiotics would be aided by a better knowledge of the relationship between the emergence of antibiotic resistance and the usage of antibiotics[7]. Putting in place monitoring mechanisms to evaluate the effectiveness of laws and regulations tailored to the unique circumstances of each nation may also be helpful. Monitoring antibiotic usage is thus crucial to gathering information on antibiotic resistance trends and drawing connections between antibiotic use and resistance.

The purpose of legislation is to define the obligations of governments and other stakeholders in the battle against antibiotic resistance, including the use and disposal of antibiotics into the environment. Despite the fact that rules "are vital, but not always simple to influence in all areas or nations" and "not always obeyed," some steps might be helpful in circumstances thought to be high risk. 17 potential policy options to lower human antibiotic usage were found in a recent comprehensive analysis, although most of the proposals have not actually had their effects on antibiotic use assessed[8]. High levels of particular legislation have been shown to be strongly connected with decreased antibiotic usage in 20 countries within the WHO European Area. Genes from unrelated species, including microorganisms, as well as related plant species, may be put into plants using recombinant DNA technology. The creation of transgenic plants is more precise and selective than normal breeding. Transgenic plants with higher yields, more nutritious ingredients, and superior insect resistance are often made using recombinant technology. Many transgenic plants have been recorded, including maize, soyabeans, potatoes, mustard, tomatoes, cotton, and rice.

Insect resistance

By creating innovative bio pesticides, such as microorganisms that are harmful to certain agricultural pests but not to humans, animals, fish, birds, or beneficial insects, biotechnology has made it feasible to protect plants naturally.

Plants are susceptible to bacterial, viral, and fungi-related illnesses. There has been substantial advancement in virus-resistant transgenic plants. For instance, it has been shown that transgenic tobacco plants become resistant to TMV infection when a gene that creates the tobacco mosaic virus (TMV) coat protein is expressed[9], [10]. Other plant species for which viral resistance has been developed include potatoes and squash. One of the most successful studies to change the characteristics of a plant's produce was carried out using tomatoes. Tomatoes must be picked when still green in order for them to be sturdy enough to withstand mechanical handling and transportation. They unfortunately do not have the same flavor and texture as tomatoes that have completely ripened on the vine.

Danger to human health

The main hazards of GMOs to human health are the toxicity, allergenicity, and antibiotic resistance of the new organisms/products. Risk of toxicity may be directly correlated with the kind of product whose synthesis is controlled by the transgene or changes in the metabolism and make-up of the organisms brought about by gene transfer. Each GMO must go through a

thorough evaluation to determine how hazardous it is to both people and animals. The majority of these toxicity risks may be quantitatively and statistically assessed using scientific methods.

Allergenicity

Allergy reactions to GM crops may sometimes be a concern. It is estimated that certain proteins found naturally in foods including milk, eggs, wheat, fish, tree nuts, peanuts, soybeans, and shellfish are to blame for up to 90% of food-related allergies. The issue is that either a protein from one of these food types was added to a food where it is not often present or a gene from one of these food types was put into crops, which may produce protein that causes allergies. The WHO states that there is a possibility that eating GM food might cause an allergic reaction, albeit this risk is comparable to that of eating food from traditional farms. Each newly discovered gene has the risk of producing proteins that cause allergies. When a gene is introduced, or a new allergen is added, the number of allergens in an organism may increase above the range seen naturally in convectional diet. Since a gene's primary progeny

It is probable that any new proteins introduced to a plant might induce allergies since expression is a protein and the majority of food allergens are also proteins. While the majority of people do not respond allergic to the majority of foods, those who do may have an extremely strong reaction to certain dietary proteins[11]. As a result, the primary concern throughout the development of GM crops has been the introduction of new allergens, which is the subject of a detailed food safety evaluation. For instance, the idea of introducing a Brazil nut gene into soybeans was abandoned because to worries that it would result in an unforeseen allergic reaction. Bean crops that had been genetically modified to increase the concentration of cysteine and methionine were destroyed after it was revealed that the produced protein of the transgene was severely allergenic. Testing of GM foods could be required to safeguard consumers against the harm caused by food allergies.

Toxicity

Toxicology refers to the change of an organism's metabolic and genetic make-up. The effects of GM potatoes on the digestive tracts of rats were assessed in a research that appeared in the journal Lancet. Moreover, potatoes were given a gene known to be harmful to animals, the snowdrop flavor lectin. Despite the possibility of naturally occurring harmful chemicals in food, when it is consumed or cooked appropriately, these substances often exist at levels that are safe for humans. Concerns concerning the possible introduction of new hazardous substances or an increase in naturally occurring toxins that are harmful to human health have been raised in relation to GM foods. Liavoga sought to draw the conclusion that the source of the gene is often reviewed to ensure that the gene product itself has no adverse toxic effects because the number of naturally occurring toxins is not raised over the usual level. The safety assessment of hazardous hazards assessed this possibility using both qualitative and quantitative methods. Transnational gene transfer GE foods may transfer genetic material to human body cells or

According to recently highlighted concerns from the WHO and bacteria in the gastrointestinal system, DNA from GM crops may be transmitted to soil microbes. Since the DNA from eaten GM foods is not completely eliminated after digestion and might be found in different regions of the digestive system. So, by a DNA fragment being absorbed by the somatic cells of the intestinal lining cells or the gut microbiota, a gene may be passed horizontally. Whereas it has been believed by scientists that the absorption of GM DNA into the cells of the gastrointestinal system won't have any biological consequences since this DNA will be

broken down in the cells, this idea has not been supported by any evidence[12]. Nonetheless, this could cause digestive problems in others. Moreover, the spread of antibiotic marker genes may result in rapid and widespread acquisition of the trait of antibiotic resistance in both humans and animals. Due to their presence in these three places, antibiotic resistance genes might spread to bacteria in the soil, the environment, and the food that humans and other animals eat.

Many bacteria have the capacity to take up genes from their surroundings and pass them on to new bacterial species, including genes that are resistant to antibiotics. Such genes may eventually find their way into pathogenic bacteria, causing antibiotic resistance and complicating medical therapy, or they might create infections that are resistant to antibiotics in animals. The bacteria in human mouths, which are able to absorb and express DNA containing antibiotic resistance flag genes, may actually make the spread easier, according to research. It is necessary to establish a rigorous, demanding, and mandatory pre-market approval procedure that evaluates the safety of GM crops for both human and environmental health.

DISCUSSION

GMOs and the Environment: Impacts

The inserted gene may really remain in the environment and cause environmental problems in the organism or its offspring's products. The purposeful release of GMOs into the environment has increased interest in possible interactions with other environmental species. Unintentional genomic alterations might be a subsequent consequence of genetic modification. These alterations may disrupt or change the metabolic pathways required for the GMO to operate, produce new proteins that may be harmful or allergenic, or cause all three of these effects.

Movement of genes

Pollen transfer has the potential to unintentionally cross-pollinate local traditional varieties with GMO plants, infecting them with GMO DNA and costing farmers their traditional variations. Pollen and seeds may carry genes. This migration might result in GM contamination in a number of ways, including perhaps as a result of human error. The 2015 investigation showed how over the preceding 20 years, genetic material from GM crops had interbred with non-GM foods and crops.

Cross-pollination between GM crops and related species or wild relatives is possible. The study found that at distances of 200 m and 400 m, respectively, gene flow in transgenic rapeseed resistant to herbicides ranged from 0.0156% to 0.0038%. The threat to biodiversity is enhanced by the potential for gene flow to relatives in the wild or to species that are similar to them, which might lead to unpredictable changes in the ecosystem as a whole. By assessing each incident separately or by conducting interdisciplinary biosafety studies starting with the first phases of the development of GM crops, this should end.

Tolerance or resistance of the target organisms

Transgenic crops with insect resistance may reduce crop damage and pesticide use when planted. Yet, the ability of insect populations to swiftly adapt to environmental stresses poses a severe challenge to the long-term efficacy of insect resistance. For the environment and human health, insect and other pest adaptation to pest management tactics may be harmful. The tendency of a plant to spread outside of its initial planting area is known as weediness. Transgenic crops are feared to grow uncontrollably like weeds. For instance, if a transgenic

crop escapes into a marine environment, it may turn into a harmful weed. Superweeds, or weeds that have acquired the gene for herbicide tolerance by genetic tainting with a GMO for herbicide tolerance or through horizontal gene transfer in the field, are another issue.

Lack of biodiversity and fewer cultivars

There have been concerns that the green revolution's development and global adoption of improved crop types could lessen the genetic diversity of cropping systems. Genetic diversity has been lost as a consequence of farmers' choice of monocultures rather than conventional variation. This is projected to intensify even more when additional transgenic crops, which provide farmers huge economic benefits, are made available. The relative incidence of susceptibility to any unforeseen illnesses or adverse situations increases when one variety is used in a cropping system rather than many.

An interruption in the food chain

Another issue is the possibility of a drop in big pests and an increase in tiny pests as a result of insect-resistant plants. It is likely that in this situation the pest population may shift from species that are frightened off by the changed plants to other, unaffected species. This alteration in turn may result in a broad disruption of the whole food chain due to new predators for the new insect species and so on up the food chain.

The disturbance might also go the other way, with herbicide or insect-resistant plant residues negatively affecting neighboring species of bacteria and fungi that live in the soil.

A change in the soil's ecology: Many plants discharge chemical compounds into the ground via their roots. There are concerns that since transgenic plants have changed DNA, they may leak different compounds than natural plants. Theories suggest that this might change the ecosystem's functional makeup and biodiversity. As the bacteria that reside around plant roots also emit chemicals into the soil, the relationship between plants and solid microorganisms is highly complex.

Risks associated with employing bacterial resistance genes to create GM plants. There are both direct and indirect risks when bacterial AR genes are inserted into a commercial cultivar to produce GM plants. Plant tissue that is poisonous when swallowed by anybody or anything directly poses a risk (cf. the native crop that is non-toxic). Indirect hazards are risks to human health that arise from the cultivation of GM crops but are unrelated to toxicity, such as damage to the environment or to the standard of living of people.

Direct risks

Introducing a plant with a damaging DNA sequence (i.e. the particular section of DNA is toxic to man). Since everyone on the planet consumes significant amounts of DNA every day as a crucial component of food without experiencing any negative effects, and since it is generally accepted that all DNA sequences behave chemically in the same way, and since no DNA fragment has ever been known to be toxic to humans or any other animals;

When bacterial genes are expressed, toxicity is created (toxic RNA or risky proteins are produced from the bacterial DNA sequence). Creation of a toxic chemical caused by the bacterial gene's progeny in the plant.

Indirect risks

One of these is the spread of resistance genes from genetically modified (GM) crops to other plants, and another is the increased likelihood of AR genes spreading across bacterial illnesses that impact both people and animals (actual or potential).

Environmental impact and the behavior of antibiotic residues

Antibiotics are made up of heterogeneous compounds with different functional groups that are responsible for very different physicochemical properties and behaviors in the ecosystem. They are classified as "persistent or pseudo-persistent substances" because their rate of entry into the environment is higher than their rate of elimination. The pharmacokinetic profile of antibiotics also affects whether antibiotic residues are present in the environment. Several kinds of antibiotics exist, including those with low oral bioavailability, those given parenterally and eliminated via the gastrointestinal system, and those utilized in animal collective therapy. For instance, due to their unabsorbed portion, certain antibiotics, such as tetracyclines, which typically have limited oral bioavailability, may persist in the gastrointestinal tract and expose commensal bacteria for longer than the therapy time. The unabsorbed portion is later expelled into the environment, where it may have biological effects.

The bioavailability of antibiotics and how they interact with other environmental factors like pH, the amount of organic carbon in the soil, the kind of water present, the type of organism present, etc. determine the biological activity of antibiotics in various environmental matrices. Hence, it is both necessary and very difficult to offer information about the bioavailable fractions and how they affect the environment, particularly when it comes to analytical results. In this instance, there may be a discrepancy between laboratory-based analytical data and the bioavailable percentage in the environment.

Given that the effects of antibiotic residues on aquatic and terrestrial ecosystems are still not completely known, understanding antibiotic degradation in the environment is crucial. Numerous processes can degrade antibiotics in the environment, including biotic processes like bacterial and fungal biodegradation (microbial degradation) and/or non-biotic processes like hydrolysis, photolysis, oxidation, and reduction, depending on the physicochemical characteristics and environmental factors like temperature and light. The active chemicals may also be dissipated by other mechanisms such volatilization, adsorption, and the production of non-extractable residues. Under anaerobic settings, transformation takes longer than in aerobic conditions, and higher temperatures encourage compound breakdown, which may have an impact on the makeup of the microbial population.

Studies examining the fate of chlortetracycline, oxytetracycline, and metabolites during anaerobic digestion found that iso-chlortetracycline metabolite concentrations doubled as compared to the initial concentration due to increased metabolite solubility, while those of chlortetracycline and the epimer 4-epi chlortetracycline decreased. Due to matrix binding, the oxytetracycline and its metabolites were only present in low amounts. In a research on the persistence of macrolides, identified the half-lives in soils, which ranged from 5 days to more than 120 days. Tylosin was mineralized or permanently attached to solid soil particles, according to research on the mobility and sorption of tylosin in soils conducted in a lab setting. The half-life of the parent chemicals (erythromycin, azithromycin, and tylosin) and the photo degradation products, which varied from 0.2 minutes to 200 minutes, were examined in a photo-induced degradation research under UV irradiation. The authors suggested UV irradiation as an effective technique for getting rid of macrolides from water.

The majority of fluoroquinolones have strong chemical stability and are not quickly destroyed by hydrolysis or elevated temperatures. They thus move quickly from the water into the soil and sediments. Owing to their environmental durability, it has been shown that high concentrations of ciprofloxacin (25 g/L) and norfloxacin (5 g/L) may alter Salmonella typhimurium bacterial strains and have genotoxic effects on aquatic species. Penicillins and

cephalosporins are very susceptible to hydrolysis, which may happen over few days in more alkaline systems and within a few weeks in most surface waters. Moreover, they are less likely to bind to soil elements, but they may combine with cations to create complexes that build up in sediments and sewage sludge. This might help to explain the cephalosporin-resistant bacteria seen in sewage treatment facilities.

CONCLUSION

As a result, antibiotics that have a high capacity for adsorption on soil tend to collect and remain in this matrix, whereas those with a lesser potential for adsorption are more readily transferred into aquatic environments. Furthermore, breakdown byproducts may be produced. These products have the potential to be further converted into bioactive molecules that are persistent and mobile in the environment, perhaps more hazardous than their parent compounds, and significantly affect living things and microbial populations.

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CHAPTER 11

REGULATION OF BIOSAFETY IN POOR NATIONS: ADVANTAGES AND PROBLEMS

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ABSTRACT:

Now, a growing portion of the globe is very concerned about the fast growth of biotechnology. It has developed into one of the most promising industries that delivers advantages to society and guarantees profits to enterprises. The first concern that comes to mind when discussing biotechnology is the safety of the technology from top to bottom, or the safety of biotechnology's products, how they may be used on people and animals, and their impact on the environment. This essay's goal is to compare emerging nations' regulatory demands and sufficiency to those of wealthy nations. Governments have implemented the necessary legislation to address these worries, guarantee the safety of biotechnology goods, and safeguard not just the environment but all living things. This essay will go through such laws, particularly as they have been accepted by emerging nations, as well as their effects. It is believed that the report would address the industrialized country's lack of restrictions.

KEYWORDS:

Biosafety,Cryopreservation,Cloning, Economic, Genetic Resource.

INTRODUCTION

Emerging technologies often have a lot of promise. Yet, they must also be thoroughly monitored to guarantee their safety, as well as that of the environment and society. While genetic engineering or genetically modified organisms (GMOs) are advantageous to society, worries about the potential threats they represent to human, animal, and environmental health nevertheless exist. However, there are several socioeconomic factors that should be taken into account, especially in emerging nations. Biotechnology is the use of scientific methods to modify and improve the genetic material of plants, animals, and microbes in order to increase their value. On the other hand, significant biotechnology issues are more related to environmental and human health issues. It's critical to distinguish between traditional and contemporary biotechnology. According to Zepeda and Cohen (2006) and Abraham (2009), tissue culture, marker aided selection, breeding, and mutagenesis are not covered by the biosafety law since they are not contemporary biotechnology products. Along the road, as we consider GMOs, we come to understand what GM goods might really look like and how GM crops may benefit the developing world. The first commercially successful genetic engineering goods were plants that were immune to pesticides and weed killers, according to several researchers who verified the claim. Some important concerns need to be addressed when we consider GMOs. In this context, studies have indicated that the first commercially successful products of genetic engineering were weed- and pest-resistant plants.

According to (2005), farmers are the biggest beneficiaries. Nonetheless, a lot of scholars in Europe. New items are now being created in different regions of the globe that are intended to directly benefit customers[1]–[3]. As was previously said, the effectiveness of the GM goods itself has a significant impact on customer acceptability and image. If consumers thought GM goods were more troublesome than helpful, they would choose to ignore them. Furthermore, fostering consumer confidence in GM goods requires a favorable attitude

toward biotechnology. Research decisions are often made in poor nations based on local objectives and are frequently driven more by need than by choice. The major justifications cited by GM proponents, according to the author are increased food quality, a longer shelf life, and food security.

They think that GM crops will help the environment as well as consumers, farmers, and the agricultural industry for the following reasons. Yet, even while GM crops may provide excellent opportunities for improving food security, there may also be unfavorable effects. Also, consideration should be given to not just the safety of the customer but also to how well they comprehend GM technology[4], [5]. It is quite concerning because access to important information is far more challenging in developing nations than it is in wealthy nations. So, there are both possible benefits and drawbacks to using GM technology to improve agricultural results for small-scale subsistence farmers in developing nations. However, there are several socioeconomic factors that must be taken into account, especially in emerging nations.

If contemporary biotechnology is not adequately controlled and regulated, it might have a significant influence. Several studies claim that there isn't enough evidence to prove that using biotechnology harms people's health or the environment. Nonetheless, restrictions are being created as a preventative step against any potential threats that GMOs may pose to human health and the environment, as well as to engender public trust prior to the release of the GMOs into the environment. The release of a GMO into the environment should be of more concern, even if the phrase "biosafety" itself is always employed in regard to the hazards connected with the products of contemporary biotechnology.

GMOs' introduction has raised questions about environmental safety, and those questions are understandable given that it is impossible to predict how those GMOs may affect the ecosystem in the long run (Lu, 2008). GMO environmental releases fall into two basic categories: The introduction of genetically modified organisms (GMOs) into the environment for experimental reasons, sometimes referred to as field or clinical trials. These kinds of releases are often conducted for research, study, demonstration, and the creation of new varieties. It is investigated how GMOs operate in a natural setting and how they interact with other creatures and the environment. These releases are referred to as Part B releases under the law.

Release of GMOs into the environment by selling them for commercial use; if the experimental release's outcomes are promising, the corporation may elect to sell the GMOs and make them accessible to other parties for a price or for free. The GMOs may be sold for industrial product development, importation, or for use in agricultural production. These releases are referred to as Part C releases under the law.

Contested Risks and Benefits

While biotechnology advancements may be beneficial, it is equally important to consider the hazards that come with them consideration. Of fact, not all items produced by contemporary biotechnology pose concerns. Notwithstanding the stark differences in opinion on the advantages and disadvantages of genetic modification (GM), Pretty (2001) asserts that GM is not a single homogeneous technique. For various interested parties, each application includes a particular set of risks and rewards.

If strict measures are not taken to characterize plant and animal species at the molecular level in order to assess their production potential and disease and environmental stress resistance and to ensure long-term conservation, developing countries could end up being the largest

hosts for agricultural activity. There are both benefits and drawbacks to the ecosystem from the widespread cultivation of GMOs. Its immediate effects may be observed in the species that consume the crops, and their wider effects can be seen in the food chains that are generated as a result of increases or declines in the populations of other organisms[6]. Although using other GM crops without those herbicides has actually improved biodiversity, using other GM crops in conjunction with them has been shown to be detrimental to biodiversity.

For whatever reason, the quick development of this technology could benefit underdeveloped nations. On the other hand, unless strict plans and actions are taken to characterize these plant and animal species at the molecular level to assess their production potential and disease and environmental stress resistance or to ensure long-term conservation, developing countries could be the greatest host for agricultural activity. The widespread development of GMOs has both favorable and unfavorable consequences on the ecosystem. Organs that eat the crops directly experience the impacts. Increases or losses in the number of other creatures have broader implications on food chains. Although utilizing some GM crops without these pesticides boosted biodiversity, using certain GM crops with long-lasting herbicides decreased biodiversity.

Pretty (2001) adds that there were strongly divergent opinions about the advantages and hazards of the first GM crops immediately after their creation. Despite the fact that some claim that GMOs are secure and essential to society, others assert that they pose too many hazards and are thus not beneficial to it. While opponents claim that scientists, for-profit companies, and regulators are downplaying risks in order to maximize profits, proponents of GMOs contend that media manipulation and scare tactics are preventing the development of useful technologies. Both points of view are incomplete for one obvious reason[7]. GMOs are not a single, homogeneous technology, as rightly noted by Pretty (2001), since each application and product has diverse advantages for various stakeholders and has unique health and environmental hazards.

The initial generation of technologies entered the market in the late 1990s and tended to provide few clear advantages to consumers. As these technologies tend to primarily benefit the firms that manufacture them, the advantages to farmers and the environment have only seldom materialized. For instance, herbicide-tolerant soya forces farmers to purchase the herbicide made by the company that sells the GM seed. Bt cotton and maize allow farmers to use less pesticides, which saves them money. However, businesses presently recoup a large portion of the margin by raising seed prices.The technologies in the second generation are those that have previously undergone development and testing but have not yet been made available for commercial use due to possible environmental issues or questions about the technology's stability as a whole[8], [9]. A variety of medical applications are among those that will undoubtedly benefit the public and consumers more than others. The third generation of technologies are those that have not yet reached the market but often call for a deeper comprehension of whole gene complexes that regulate features like salt- or drought-tolerance and nitrogen fixation. Again, they are probably going to provide more obvious consumer advantages than the previous generation.

According to our assessment, the usage of GMOs may potentially result in negative effects and problems, such as those related to socioeconomics and sociocultural difficulties, as a result of the increased capital investment. To avoid advance insect lines that are resistant to the plants, for instance, the command of the used seed from genetically modified has higher costs, which lead to necessity of particular expertise in using insect-resistant plants. In addition to socioeconomic considerations, GMOs may be considered as one of the dangerous

elements that might have a significant economic impact on small farmers in constrained agricultural environments. Despite these adverse consequences, there are also advantageous ones. Nanda (2000) claims that the improvement of crops with specific beneficial qualities and the expansion of the global food supply are two ways that the process of genetic modification adds value. For instance:

The biggest manufacturer of GM seeds, Monsanto, makes insect-resistant maize and roundup-ready soybeans that are resistant to the herbicide roundup. The threat to biological diversity, economic considerations, intellectual property issues, ethical and religious concerns, risks to human and animal life or health, the right of consumers to know, and food security are some of the major substantive issues associated with the development, use, and trade in GM products. The security interest might be impacted in a number of ways, including the greater concentration of power in a few major companies over food production techniques, the overuse of pesticides due to crops' rising herbicide resistance, and a decline in crop variety.

A GM crop may also be advantageous or have a favorable effect in at least two different ways, it has also been noted. According to Madsen et al. (2003), it might be "profitable for the producer or through meeting significant social demands." Moreover, when the general population insists that GM crops are valuable, it may provide a second definition that shows its need to suit social demands[10]. The public's opinion of and readiness to embrace GM goods tend to be adversely impacted by debates about GMOs, it should be highlighted. Acknowledges that politics and obstruction of national biosafety are the main reasons why GM crops are not used in underdeveloped nations. Due to the commercialization of the rights to deploy and use the technology, another issue is that the technologies could not reach the poor farmers.

Additionally, it was stated that in order to reduce the evaluation of GMOs to a simple question of how much risk a society is willing to take in exchange for the potential benefits of the technology, the methods used in risk assessment are crucial in determining whether or not the GMOs pose a threat to human health and the environment. Consequently, there are significantly more consequences of GMOs than the risk/benefit connection shows. Studies are keenly studied on both sides because of the issue surrounding GMOs. On the one hand, studies demonstrating nutritional equivalence or the absence of health risks are used to support commercialization and approval by decision-makers. On the other hand, studies indicating health or environmental risks have been used by environmental NGOs to criticize positions in favor of GMOs.

DISCUSSION

Institutions and scholars have stressed the need to quicken the pace of orphan crop investments and knowledge generation. From the perspectives of regulation and biotechnology innovation, this implies a sizable knowledge gap regarding orphan crops in general as well as potential protocols and processes used in gene manipulation and extraction to meet particular needs of developing world, including those found in tropical climates[11]. As a result, only a small number of GM crops (all commercial) have received approval for usage in underdeveloped nations at this time. There have been a lot of arguments made about the advantages and negative effects of agricultural biotechnology, particularly in relation to genetically modified (GM) crops and, more recently, emerging techniques in plant breeding like genome editing. This is typical when new technologies are introduced to society. Beginning in the 1980s, early worries about genetic modification prompted the development of regulatory mechanisms for assessing environmental risk and ensuring the safety of food

and feed. Like with other areas of safety regulation, national biosafety systems in Africa were often very recently developed by governments, and the work of developing science-based standards and enforcing them has proven challenging. The Cartagena Protocol on Biosafety, which was adopted in 2003 as an addendum to the Convention on Biological Diversity (CBD) and aims to address the environmental impact of transboundary movement, management, and safe use of genetically modified organisms, has established the starting point for the majority of them (GMOs).

The implementation of regulatory standards for biosafety and food/feed safety should be seen as a component of a larger, evolving international regime that has an increasing impact on the usage and accessibility of genetic resources for agricultural and food production. This international system has a significant impact on scientific freedom and autonomy: As access to vital research inputs (such as genetic resources or protected technology) and the release of research outputs (such as new crop varieties) are slowed down or stopped by overly restrictive regulations, the development and deployment of new agricultural technologies become increasingly regulated and frequently hampered. Obviously, international law has now solidified the reality of sovereign rights over a nation's natural resources, including genetic resources. Historically, genetic resources for agriculture were regarded as a shared inheritance of humanity, and there was often unrestricted access to all biological materials worldwide. Over time, it was believed that this situation led to an imbalance between nations with abundant genetic resources, who typically provide these resources for free, and nations without significant biological resources, who nevertheless used those resources for R&D and protected the research findings as intellectual property. The Cartagena Protocol on Biosafety, which was inspired by the CBD, altered this idea and strengthened state sovereignty over their biological resources via "access and benefit sharing" (ABS) regimes.

Nevertheless, as a result of research done by developing nations and their cooperating partners, new GM crops and animal products have been produced, this situation is gradually changing. All of these items need to be reviewed and approved by biosafety regulatory agencies in the meantime.bBiosafety regulation is described by Zepeda and Cohen as the legal framework and additional risk analysis controls intended to guarantee the environmental, agricultural, and human health safety of current biotechnology applications. This definition of biosafety states that it is a philosophy that moderates the adoption of new technology with careful consideration of its possible consequences on all stakeholders and the environment. The regulatory systems in industrialized nations and those in emerging nations are different from one another. Regulation is intended to guarantee that GMOs are authorized and meet the necessary standards in industrialized nations.

Evidently, the degree of economic stability and progress of the relevant nation determines the quality of regulation. Even while they work very hard to accomplish the goal of advising against the anticipated impacts of GMOs, regulation is still in its infancy for the majority of developing nations. Throughout time, emerging nations have used the regulatory frameworks and procedures of established nations as models for creating their own national regulatory systems, especially those with less complex regulatory systems. The protocols outline the requirements and clauses that need to be in the rules. Countries with existing procedures often need to examine them and bring them into compliance with their more standardized equivalents.

A good regulatory framework should cover a wide range of issues. Gregory (2010) said that such a system must thoroughly cover a range of topics, from the various phases of creation via laboratory research and field tests to goods that are readily accessible on the market and consumed by people and/or animals. It should address both food safety problems and the

environmental challenges raised by the biosafety standard. Finally, it should include transgenic animals as well as plants that have been genetically altered to generate compounds other than food or feed.

When it comes to environmental and food safety concerns relating to genetically engineered plants and animals in the laboratory, when they are tested outdoors, and when they are turned into commercial products consumed by humans and/or animals, regulation in some developed countries can be quite thorough. This is in contrast to the scenario in many developing nations, which is not yet as extensive and not now desirable given the lack of GMO field experiments in such countries.

They did not address food safety, focusing exclusively on environmental problems. As a result, there are huge differences in how extensive biosafety regulation regimes are in developing nations. A further point made by Gregory (2010) is that "many developing nations are concentrating their biosafety systems on environmental problems surrounding the release of GMOs into the environment and have not developed clear paths for the foodsafety evaluation and clearance procedure around GMOs.

The degree of comprehensiveness is merely one way in which the regulatory systems of industrialized and developing nations vary from one another. In terms of decision-making competence in science. In contrast to poor nations, which need external specialists to evaluate, analyze, and appraise data owing to inadequate technological ability, industrialized countries have expert scientists inside the government who undertake the analysis. Because to this restriction, several developing nations have created expert scientific advisory committees that are tasked with reviewing applications pertaining to GMOs and advising the government on their safety, or lack thereof.

Yet this work shouldn't be entirely left to the hands of scientists. To ensure that the regulatory system is comprehensive, members of the public should also be held accountable. Without a question, the general public and consumers have a significant role in the introduction and acceptance of GMOs.

People must be properly informed about GMOs. In modern nations, the media, official publications, and the internet are essential instruments for educating the populace about their rights to participate. In contrast, the execution of public participation standards is severely hampered in developing nations by budgetary limitations, linguistic hurdles, and the absence of effective communication channels.

While biosafety is a serious issue, there is still a dearth of knowledge in Malaysia about the problem and the necessary safety precautions. According to this report, only Malaysians with a necessary awareness and a good knowledge foundation in the scientific and technological fields. Hence, even if technological development is at a very advanced stage, concerns about safety and awareness should also be taken into consideration. Malaysians need more exposure to these issues, hence necessary knowledge must be made available via suitable education. Biosafety problems, for instance, might be included into school curricula as a minor topic of general knowledge and as part of public awareness initiatives.

There are other methods that may be employed, including seminars, workshops, and small advanced discussion groups. Every strategy used should be as realistic as feasible, and the organizers should have the necessary qualifications. The methods used at the secondary and tertiary levels must likewise exhibit excellent standards. It is recommended that biosafety may be presented as a significant topic at the tertiary level. Especially so, considering that biosafety is one of the most significant problems with contemporary biotechnology and that

not all the outcomes of this procedure may be entirely safe. Hence, biosafety education may be a valuable way to teach students and other young people in advance about the problems presented by contemporary biotechnology and GM products, acting as a significant preventative strategy.

CONCLUSION

In conclusion, the safety regulations of industrialized and developing nations vary from one another. Notwithstanding the variances, the primary. The same aim is to guarantee that the environment of each nation is protected from any damage caused by the release of GMOs. In other words, stronger tools and rules should be made available to ensure that the necessary safety standards are met in order to address this scenario. Farmers in particular may gain greatly from the use of GM technology if they attempt to embrace the methods and applications related to GM crops. Genetically modifying food is necessary and advantageous, but it should only be done under circumstances that minimize any hazards. Before any new genetically altered organisms or foods are released, time and effort must be committed to field testing.

To determine GM goods' impacts on human health, agricultural pests, and the environment, a thorough evaluation should be conducted over an extended period of time. To prevent potential environmental and safety issues, which might compromise the anticipated advantages of this new research, caution and the appropriate legislation are required. Although while GM technology has the potential to expand the field of biotechnology, the technology itself cannot be transferred or disseminated without carefully and realistically taking into account the aforementioned factors and issues. In other words, the government should rebuild public and consumer trust and acceptance to comprehend the legislation, while stakeholders like policy makers and academics, especially in developing nations, should carefully examine the risk and danger. Leaders in the commercial and public sectors should also be aware of the public's degree of knowledge of the new items. They will be able to use it to develop an efficient advertising strategy for new GM foods and goods.

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CHAPTER 12

AN OVERVIEW OF INTELLECTUAL PROPERTY RIGHTS AND THEIR CONSEQUENCES FOR THE PHARMACEUTICAL INDUSTRY

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ABSTRACT:

Ideas, innovations, and creative expressions on the basis of which there is a public desire to grant the status of property are referred to as intellectual property rights (IPR). In order for the inventors or developers of that property to profit commercially from their creative endeavors or reputation, IPR provide them certain exclusive rights. There are several forms of intellectual property protection, including trademark, copyright, and patent. An innovation that fulfills the requirements of universal novelty, non-obviousness, and industrial use is given a patent. IPR is a requirement for improved innovation or creative work identification, planning, marketing, and protection. According on its area of specialization, each industry should have its own IPR policies, management style, strategy, and so on. The IPR strategy used by the pharmaceutical sector is currently changing, and a better focus and strategy will be needed in the future**.**

KEYWORDS:

Biosafety,Cryopreservation,Cloning, Economic, Genetic Resource.

INTRODUCTION

Every original work of the human mind, including those in the arts, sciences, literature, technology, or other fields, is considered to be the subject of intellectual property (IP). The term "intellectual property rights" (IPR) refers to the legal privileges granted to the inventor or creator to safeguard their work for a certain amount of time. These legal rights allow the inventor or creator, or his assignee, the only right to fully exploit their idea or creativity for a certain amount of time. It is widely acknowledged that IP is essential to the contemporary economy. Also, it has been unequivocally shown that the intellectual work connected to the invention ought to be given the respect it deserves in order for it to serve the greater good. The price of research and development (R&D) has skyrocketed, and so have the capital needed to get a new technology to the market. As the stakes for technology developers have increased significantly, it is now imperative, at least temporarily, to safeguard information from unauthorized use in order to guarantee recovery of R&D and other related expenditures as well as sufficient earnings for ongoing investments in R&D. As it gives the inventor or creator of an IP an exclusive right to exploit his invention or product for a certain length of time, IPR is a powerful weapon for protecting investments in time, money, and effort. By enabling healthy competition, industrial progress, and economic expansion, IPR thereby contributes to the economic development of a nation. The current study provides a succinct summary of IPR with a focus on medicines.

History

The administrative processes and rules governing intellectual property (IPR) originated in Europe. Throughout the fourteenth century, patents were more common. England was technologically more sophisticated than other European nations in various areas, which it

utilized to entice artists from outside Europe with favorable conditions[1]–[3]. Italy is where copyrights were originally recognized. As Venice was the first place in the world to create laws and institutions governing intellectual property, it may be said that Venice is the birthplace of the IP system. Other nations soon followed. The Indian Patent Act dates back more than 150 years. The first was the 1856 Act, which was modeled after the British patent system and established the 14-year patent period. Many further acts and modifications followed.

Intellectual property types and descriptions

Initially, the word "Industrial Property" only applied to patents, trademarks, and industrial designs, but now, the definition of "Intellectual Property" is far broader. The following ways that IPR advances technology:

- As all kinds of IP are disclosed, with the exception of trade secrets, it (a) offers a framework for managing infringement, piracy, and illegal use; (b) it gives a pool of knowledge to the general public.
- A range of intellectual endeavors may be protected by IP, including
- Industrial designs refer to characteristics of any form, arrangement, surface pattern, composition of lines, and color applied to a product whether it is 2-D, like a cloth, or 3-D, like a toothbrush.
- Trademarks are any name, mark, or logo used in commerce to identify the maker of a product or service and to facilitate trade in such product or service. You may purchase, sell, and license trademarks. A trademark is only as good as the reputation of the item or service it represents.
- Copyright pertains to the expression of ideas via the use of material, and this includes computer software, audio recordings, and literary, musical, dramatic, and aesthetic works.
- Geographical indications are indicators that place a good's quality, reputation, or other attribute primarily due to its geographical origin in the territory of a nation, a region, or locale within that area.

When an invention fulfills the requirements of general novelty, non-obviousness, and industrial or commercial use, a patent is granted. Products and methods are eligible for patent protection. According to the Indian Patent Act of 1970, a patent had a period of 14 years from the date of filing, with the exception of preparation techniques for medications and food products, for which the term was either 7 years from the date of filing or 5 years from the date of the patent, whichever came first. Drugs and food products were not the subject of any product patents.

A copyright created in one of the Berne Convention's signatory nations immediately enjoys protection in all other signatory nations without the requirement for registration. India is a party to the Berne Convention and has excellent copyright regulations that are on par with those of any other nation. In nations that are not Berne Convention members, the copyright will not, however, be accessible immediately. Copyright may not be regarded as a territorial right in the strict sense as a result. IPR may be given, sold, or transferred just like any other property. The Use of Confidential Knowledge in Intellectual Property

While it is perhaps the most significant kind of protection for businesses, R&D institutions, and other organizations working with IPR, protection of concealed knowledge is both the least understood and least discussed by IPR stakeholders. Unreleased information encompasses any formula, pattern, compilation, program, gadget, method, technique, or

process. It is often referred to as trade secret information or confidential knowledge. Preservation of trade secrets and concealed information is nothing new for humans; throughout its history, individuals have developed strategies to keep sensitive information hidden, often by limiting access to their immediate family. In India, laws governing all types of IPR are in various levels of implementation, but there is no specific legislation that just protects private or concealed information.

Throughout the 1950s to 1980s, the pressures of globalization or internationalization were not very severe, and many nations, like India, were able to survive without using a robust IPR system. R&D spending has increased as a consequence of the globalization led by the chemical, pharmaceutical, electronic, and IT sectors[4], [5]. The product cycle, length, and significant risk of rival reverse engineering are characteristics of this method. Industries eventually understood that trade secrets were insufficient to protect a technology. Without standard laws and regulations governing patents, trademarks, copyright, and other intellectual property rights, it was impossible to profit from breakthroughs. IPR rose to prominence inside the World Trade Organization in this way (WTO).

Reason for Patent acknowledges the kind of IP that manifests in innovation. Under the rigorous examination and opposition procedures outlined in the Indian Patents Act, 1970, patents are granted for patentable inventions that meet the requirements of novelty and utility. However, there is not even a prima-facie presumption as to the validity of the patent that has been granted. [9] The majority of nations have put in place national frameworks to safeguard the IPR that fall within their purview.

Except in the case of copyrights, the inventor's or creator's protection is limited to the area where protection is sought and is not applicable in other nations or regions, such as India or the European Union. [1] As an example, a patent issued in India is only valid for India and not the USA. The main goal of patenting an invention is to profit from exclusivity, which entitles the inventor or his assignee to a monopoly if two conditions are met: the inventor created a significant invention while taking into account customer modifications; and the patent agent accurately described and claimed the invention in the drafted patent specification. The patentee has two options for exercising his exclusivity: either by using his own marketing channels or by granting a third party a license.

The following wouldn't be considered to be patents

A frivolous innovation or one that makes claims that are evident or go against well-established natural law.

An innovation whose main or intended usage would violate morals, the law, or the interests of the public health (ii) A discovery, a scientific theory, or a mathematical technique (iii) The bare use of a known process, equipment, or apparatus (unless such usage results in the production of a new product or uses at least one new reactant), or the sheer discovery of any new property or application for a known material (iv) A simple arrangement, re-arrangement, or replication of a recognized device, each of which functions independently of the others in its own manner. (iv) A material created by a simple mixing that just aggregates the attributes of its components. (vii) Any procedure for the medical, surgical, curative, prophylactic diagnostic, therapeutic, or other treatment of humans or any procedure for the similar treatment of animals to make them disease-free or to increase their economic value or that of their products. (vi) A method of agriculture or horticulture a discovery using atomic energy (viii); a discovery that is essentially conventional knowledge (ix).

DISCUSSION

Reasons for the License

A license is a legal agreement that grants the licensee the right to carry out tasks that would otherwise be illegal. For instance, in a patent license, the patentee (licensor) grants the licensee certain rights to use in connection with the patent. The result is that the licensee is granted the ability to carry out actions that would otherwise be illegal; in other words, a license makes legal what would otherwise be illegal.

Together with the patent right, the licensor may additionally include in a licensing agreement "know-how" relevant to the execution of the licensed patent right, such as data, a method, or a device that occurs or is used in a commercial endeavor[6], [7]. Examples of know-how include: Technical information includes formulas, operating processes, and techniques, whereas commercial information includes customer lists, sales statistics, marketing, and professional and managerial practices. In fact, any kind of information technical, economic, trade, or otherwise can be protected.

Advantages for the licensor

Helps overcome the difficulty of establishing the technology in various markets, particularly in foreign nations, by lowering costs and risk and saving on distribution and marketing expenditures. Advantages to the licensee include: I Savings on R&D and the removal of risks related to R&D; quickly addressing market demands before interest dwindles; and (iii) ensuring that goods are the most recent.

Patent Cooperation Treaty's Function

In 1978, the global Patent Cooperation Treaty (PCT) came into effect. By designating the countries of interest in the PCT application, an inventor from a member country contracting state of PCT can simultaneously obtain priority for his or her invention in all or any of the member countries without having to submit a separate application in each of the countries of interest. The Geneva-based World Intellectual Property Organization (WIPO) oversees the coordination of all PCT-related operations.

It is necessary to submit a separate patent application in every nation of interest in order to get priority in those countries and protect an invention there. In certain situations, this must be done within a certain amount of time.

This would need a significant financial outlay within a short period of time to cover expenditures for filing fees, translation, legal fees, etc. Also, it is believed that the choice about whether or not to submit a patent application in a certain nation may not be properly justified owing to the limited time available for doing so[8]. On the other hand, inventors from PCT contracting nations may concurrently get priority for their ideas without having to submit separate applications in the countries of interest, saving them the initial costs associated with filing fees, translation, etc. Also, the method offers considerably more time for member nations to file patent applications.

According to the Paris Convention, you have 12 months from the date of your original filing to get priority in other nations. The period allotted under the PCT might range between 20 and 31 months in length. The search report created under the PCT procedure also helps an inventor to confirm if the claimed invention is new. To be extra certain that the invention qualifies for patent protection, the inventor may choose to have a preliminary examination performed before filing in other nations.

Intellectual property management in the pharmaceutical industry

Drugs and medicines, more than any other technology field, best fit the criteria of globalization and need a robust IP infrastructure. No company would want to take the chance that its intellectual property would become public property without receiving adequate compensation, given that the price of introducing a new drug into the market could cost a company anywhere between $ 300 million and $1 billion along with all the risks associated at the developmental stage. The development, acquisition, protection, and management of IP must be integrated into company operations in a similar way as resource and capital acquisition[9]. The information revolution, which we will undoubtedly see, will call for IP to be given particular consideration and treatment across the whole decision-making process.

The success of a corporation will mostly rely on its R&D activities since scientific understanding rather than industrial expertise drives competition in the global pharmaceutical sector. As a result, R&D spending in the pharmaceutical sector is highly high as a share of overall revenues; some estimates put it as high as 15%. The management of creative risks while attempting to obtain a competitive edge over competing businesses is one of the major problems in this sector. With the development of possible medications that are unable to fulfill the strict safety criteria, being abandoned, sometimes after many years of investment, there is a large cost associated with the risk of failure in pharmaceutical R&D. From the time the molecule was originally produced, it takes roughly 8–10 years for medications to go through development barriers. Drug firms will have to adjust their emphasis of R&D away from creation of new procedures for manufacturing existing pharmaceuticals towards development of a new drug molecule and novel chemical entity as product patents emerge as the primary instruments for protecting IP (NCE). After a period in which many illnesses with short durations were effectively treated, the R&D emphasis switched to long duration (chronic) disorders in the 1980s. One must be sure to satisfy the needs of various regulatory agencies while searching for a worldwide market.

It is acknowledged that in the last 10 years, the number of papers that must be presented to regulatory agencies has practically quadrupled. In addition, it currently takes regulatory agencies a lot longer to approve a new medicine. As a consequence, the duration of patent protection is shortened, necessitating more work to generate sufficient income. In the case of pharmaceuticals created using biotechnology, particularly those involving the use of genes, the situation may be worse. It is anticipated that the developed world will soon begin advocating for extended medication protection[10], [11]. Also, it's probable that many governments may implement more and more price controls in order to achieve their objectives. This would highlight the need for lower medical research, manufacturing, and marketing costs while also requiring planning for lower profit margins in order to recoup expenditures over a longer period of time. It follows that it is evident that the pharmaceutical sector must navigate a maze of competing regulations. During the last 10 to 15 years, a wide range of solutions have been developed for cost reduction and trade advantage. R&D outsourcing, creating R&D collaborations, and forging strategic alliances are a few of them.

The Pharmaceutical Industry's Nature

The rush to discover the human genome's mysteries has resulted in a flood of scientific information and sparked the creation of novel technologies that are changing the economics of medication development. Everyone will have their own genome mapped and saved on a chip, therefore biopharmaceuticals are likely to have a particular role in the future with tailored therapies as the end objective. Doctors will examine the data on the chip(s) and provide prescriptions if necessary. The security of such personal information databases would

be the key IP problem involved. More and more pharmaceuticals created using biotechnology will enter the market. Such pharmaceuticals will have a somewhat different protection process than those ordinary drugs that have not undergone biotechnological development. It is necessary to include the microbial strains utilized while creating a medicine or vaccination in the patent document. The situation is straightforward if the strain is well-known and has been described in the literature that scientists typically review[12]. The Budapest Treaty requires that many novel strains be lodged with international depository authority as they are continually identified and created. The databases of these depositories should also be checked when conducting a novelty search. Businesses often don't publicize their work, but it's a good idea to make it a rule to hold off until a patent application has been submitted before disclosing the innovation via publications or seminars.

It is crucial when dealing with microbiological innovations to deposit the strain with one of the reputable depositories who would then provide the strain with a registration number that should be cited in the patent specification. This eliminates the need to describe a living form in writing. Depositing a strain also costs money, although if one is not working with, say, cell lines, this is not much. Also, as has been the case in the past, the sequences must be stated in the patent specification for innovations involving genes, gene expression, DNA, and RNA. The partnerships may be formed to achieve a variety of goals, including pooling resources for research and development (R&D), employing marketing networks, and sharing manufacturing facilities. It is always advisable to enter into a formal agreement before beginning an R&D alliance to address issues like IP ownership across borders, cost sharing for acquiring and maintaining IP, revenue generated by it, ways to protect trade secrets, accounting for IP owned by each company prior to the alliance and IP created during the project but not covered in the plan, and dispute resolution. Remember that an alliance would be advantageous if your IP portfolio is stronger than the partner in question. There may be several other components to this agreement. Soon, many pharmaceutical businesses will contract with academic institutions, commercial R&D firms, and government-funded R&D facilities in India and overseas. All of the aforementioned factors will be helpful. The secrecy of the study must be maintained with special care.

IPR are being unjustifiably reinforced and misused at the cost of competition and customer welfare, according to the status of the pharmaceutical sector today. The pharma industry's lack of innovation and risk-taking highlights the injustice that is happening at the cost of the common good. It is an injustice that cannot be resolved only by legislative change. Antitrust law must adequately intervene, even while legislative attempts to plug gaps in existing laws and new legislation to stop more unfair commercial practices by the pharmaceutical sector may provide some alleviation. Although the pharmaceutical industry's commercial activities, such as mergers and acquisitions and agreements not to compete, have been carefully reviewed by antitrust laws, there are still a number of additional practices that need attention. Antitrust law can help maintain the equilibrium between rewarding innovation and preserving competition in a number of situations, including the granting of patents on insignificant components of outdated medications, reformulating outdated medications to obtain new patents, and using advertising and brand name development to raise barriers for generic market entrants.

Traditional medicine using organic botanicals plays a significant role in providing healthcare for people in both developed and developing nations, boosting its economic worth. The global market for these medications has grown at a pace of 5% to 15% annually, reaching US $ 60 billion. People often assert that only medications based on conventional knowledge are eligible for patent protection. After making minor modifications, researchers or businesses

may also claim IPR over biological resources and/or traditional knowledge. This tendency is abundantly seen in the rapid increase of herbal medicine-related patent filings. The IPR regulations of each nation are applied to the patent applications for natural goods, traditional herbal remedies, and herbal medical items as suitable within the categories of food, pharmaceuticals, and cosmetics. As they have attracted the attention of the worldwide organized herbal medication and cosmetic industries, medicinal plants and allied plant products are significant targets of patent claims.

Some Unique Features of Drug Patent Specification

Drafting patent specifications requires a high level of professional ability that must be developed over time and requires a strong balance of legal, technical, and scientific understanding. Every patent specification's claims are what give the patent its essential legal proprietary status. A known substance cannot be patentable when a new property is discovered in it. A practical use of the property qualifies as an innovation that could be eligible for patent protection. A railway sleeper built of the material may very easily be copyrighted, but the finding that a known substance can tolerate mechanical stress would not be patentable. Even if a material may not be new, a new property has been discovered in it. If it is combined with some other known compounds and produces a novel outcome, it could be feasible to patent the combination. The cause is because no one has ever utilized that combination to create a pesticide, fertilizer, or medication in the past. It's very feasible that someone has invented a novel molecule whose exact structure is unknown. The description of the chemical, together with its qualities and the process used to create it, will be crucial in this situation.

If two substances have a functional connection when mixed, the creation of valuable goods from their combination may be the subject of a patent. No chemical reaction occurs in this situation. It merely offers a sliver of protection. Any use of individual components of the combination by third parties is not covered by the patent. An aqua regia patent, for instance, won't prevent anyone from combining the two acids in various ratios and gaining new patents. Treatment modalities for people and animals are not patentable in the majority of nations (the USA being an exception), since they are not seen as having practical industrial applications. Writing claims for a novel pharmacological use of a well-known drug requires caution since they shouldn't suggest a particular course of therapy. The majority of applications deal with pharmaceuticals, including natural medicines. There are just a few uses in engineering, electronics, and chemistry. Drugs and medicines are mentioned in over 62% of the applications.

CONCLUSION

It is clear that managing IP and IPR requires a variety of activities and techniques, all of which must be in compliance with local laws as well as international conventions and standards. It is no longer only influenced by a national viewpoint. The market's demands, its reaction, the expense of converting IP into a business enterprise, and other factors have a significant impact on IP and its related rights. In other words, the administration of IPR must take into account issues relating to trade and commerce. Various IPR forms need distinct management, planning, and tactics, as well as the involvement of people with a variety of subject-matter expertise, including science, engineering, medical, law, finance, marketing, and economics. Depending on its area of specialization, each industry should have its own IP rules, management practices, strategies, etc. A developing IP strategy is now used by the pharmaceutical business. Antitrust law must thus intervene to prevent the wrongful assertion of invalid IPR in order to create and sustain illegitimate, if temporary, monopolies within the

pharmaceutical business, given the greater likelihood that certain IPR are illegal. In this context, there are still a lot of issues to be handled.

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CHAPTER 13

INTELLECTUAL PROPERTY RIGHTS

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ABSTRACT:

Ideas, innovations, and creative expressions on the basis of which there is a public desire to grant the status of property are referred to as intellectual property rights (IPR). In order for the inventors or developers of that property to profit commercially from their creative endeavors or reputation, IPR provide them certain exclusive rights. There are several forms of intellectual property protection, including trademark, copyright, and patent. An innovation that fulfills the requirements of universal novelty, non-obviousness, and industrial use is given a patent. IPR is a requirement for improved innovation or creative work identification, planning, marketing, and protection. According on its area of specialization, each industry should have its own IPR policies, management style, strategy, and so on. The IPR strategy used by the pharmaceutical sector is currently changing, and a better focus and strategy will be needed in the future.

KEYWORDS:

Drug, Intellectual Property, License, Patent, Pharmaceutical.

INTRODUCTION

Intellectual property includes creative thoughts, innovations, industrial models, trademarks, music, books, symbols, names, and brands, among other things. Similar to other property rights, intellectual property rights are a kind of property. They enable the owner to fully profit from the creation of the thing that began as a concept and eventually crystallized. They also provide him/her the right to stop others from using, interacting with, or interfering with his/her product without first getting their consent. In reality, he or she has the right to sue them, order them to cease, and have them pay for any damages. The term "intellectual property rights" (IPR) refers to the ownership rights that individuals have over the works of their creative minds. Typically, they provide the inventor a time-limited, exclusive permission to utilize his or her work. Intangible works of human creativity are included in the category of property known as intellectual property (IP). Many nations recognize different kinds of intellectual property to varying degrees. The most well-known categories include trade secrets, patents, copyrights, and trademarks. In the 17th and 18th centuries, England was where the modern idea of intellectual property first emerged. While the concept of "intellectual property" was first coined in the 19th century, it wasn't until the late 20th century that it was widely accepted in the majority of the world's legal systems [1]–[3] .

Encouragement of the production of a broad range of intellectual commodities is the primary goal of intellectual property legislation. To do this, the law grants individuals and organizations ownership rights to the knowledge and intellectual products they produce, often for a certain amount of time. This provides an economic incentive for their development by enabling individuals to profit from the knowledge and intellectual products they produce and by enabling them to safeguard their ideas and prevent piracy. Depending on the level of protection provided to inventors, these economic incentives should encourage innovation and advance technology in nations.As compared to conventional property like land or things,

intellectual property's intangible character offers challenges. Intellectual property is "indivisible" in contrast to conventional property since it may be "consumed" by an infinite number of individuals without being exhausted.

Investments in intellectual property also face appropriation issues: unlike landowners, who can fence in their property and hire armed guards to protect it, creators of information or literature typically have little control over how easily their first customer will copy their work and resell it for less.

Modern intellectual property law's main goal is to strike a balance between rights that are strong enough to promote the development of intellectual products but not so strong that they restrict their widespread use.

Included under intellectual property rights are:

Copyright, industrial design, plant variety, trademark, trade dress, and geographical indication rights. A vast collection of intellectual property rights, such as patents, trademarks, industrial designs, utility models, service marks, trade names, and geographical indications, are frequently referred to as "industrial property."

Organization for World Trade

The World Trade Organization (WTO) is the sole international body that deals with international trade regulations. It was created in 1995 as a result of an international agreement ratified by the General Agreement on Tariffs and Trade member nations (GATT). Making ensuring that commerce moves as easily, productively, and freely as possible is the WTO's declared goal. Geneva, Switzerland serves as the WTO's administrative center. Activities of WTO

The WTO's primary duties include: managing WTO trade agreements; serving as a platform for trade discussions; resolving trade disputes; observing national trade policies; providing technical assistance and training to developing nations; and cooperating with other international organizations.

Organization for Global Intellectual Property

The World Trade Organization established the World Intellectual Property Organization. WIPO was established in 1967 with the goals of "encouraging creative endeavor and advancing the protection of intellectual property globally. WIPO now has 192 member countries, is based in Geneva, Switzerland, and oversees 26 international treaties.

The three main duties of WIPO are:

- Registration procedures
- Promotion of substantive activity and intergovernmental collaboration
- Aspects of intellectual property rights that are trade-related (TRIPS)

There are minimal requirements for several types of intellectual property (IP) rules for all WTO members under this international agreement, which is managed by the WTO. The TRIPS agreement, the most comprehensive international agreement on intellectual property to date, was the first to integrate intellectual property law into the framework of global commerce[4]. Thus, the government has been supporting programs to foster innovation, creativity, and entrepreneurship via measures like

Maximum Period of Protection of Various IP Rights

- 20-year PATENT (renewed every year)
- PLANT VARIETIES: 15 and 18 years (renewable after the sixth and ninth years)
- Geographical indications: unrestricted (renewable every ten years); trademark: unrestricted (renewed every 10th year)
- COPYRIGHT: For as long as the author is alive or 60 years after the work was published.
- DESIGNS FOR INDUSTRIES: 10 + 5 years (renewed after 10th year)

A patent is their successor-in-title, granting the owner the right to exclude others for a set period of time in exchange for the public disclosure of the invention. An invention is a technological breakthrough that satisfies the following criteria: it must be novel, inventive, and not previously known. It is required of patent holders to make useful information about their innovations public in order to advance knowledge and foster innovation.

Categories of Patents: Plant Patents, Design Patents, and Utility Patents

Every novel and useful technique, apparatus, production, composition of materials, or novel and beneficial innovation is granted a utility patent. Valid for twenty (20) years starting with the earlier of the priority dates or the filing date[5].

The look of an object of manufacturing, or its innovative, non-obvious, decorative design, is protected by a design patent. From the date of issuance, a patent is valid for about fourteen years. Plant patents are granted for novel plant kinds that have undergone asexual reproduction. The plants found in nature cannot be patented, and the new variety must be original, different, and non-obvious.

Standards for Patentability

- Must be practical must be fresh or unusual It must not be clear
- The advantages of patent protection
- Protects against invention theft
- Increases market share
- Higher margins of profit
- Promote Agreement
- Fewer competitors

A Model for a Patented

Glyphosate was first marketed by Monsanto in 1974 under the brand name Roundup, and the company's last commercially viable United States patent expired in 2000.

Traditional Information (TK)

Traditional knowledge is the knowledge that has been continuously created, acquired, applied, practiced, communicated, and maintained by groups and/or people through generations (TK). Traditional information, including current oral knowledge, cannot be protected in India under the terms of the IPR laws / acts now in effect, as stated above.

Traditional Knowledge Bio-Piracy

The commercial exploitation or monopolization of biological or genetic material, such as therapeutic plant extracts, often without paying the indigenous peoples or nations from where the material or pertinent knowledge was derived.

Geographical Markers

Geographical Indications are meant to identify the caliber of a product, showcase brand identification, and safeguard cultural traditions. It is a term or symbol that is put on certain items and designates their origin or connection to a particular place (e.g. a town, region, or country).

India's Geographical Indications

The Geographical Indications of Products (Registration & Protection) Act, 1999 was passed by India as a member of the World Trade Organization (WTO), and it became effective on September 15, 2003. The Geographical Indications Registry has been created by the Central Government of India with jurisdiction over all of India in Chennai[6], [7]. The Controller General of Patents, Designs, and Trade Marks, who is also the Registrar of Geographical Indications, is in charge of overseeing it.

The trademark

In layman's terms, a trade mark, also known as a brand name, is a visual symbol that may be a word signature, name, device, label, numerals, or combination of colors used by one company on goods, services, or other articles of commerce to distinguish them from comparable goods or services coming from another company.

Registration of Trademarks

Product trademarks include the following sorts of trademarks under Indian trademark law: are those that are attached to items to identify them. Services that are employed in conjunction with it in the course of business and have verified quality or other unique attributes Collective trademarks: are registered under the names of organizations, associations, or pursuits to signify participants' affiliation with the group.

The benefits of registering a trademark

Safeguards the reputation you have worked so hard to build. Prevents your name or brand from being utilized by any other company firm in a same or identical manner, discouraging others from profiting from your carefully developed reputation. Confers the designation of "branded goods" to your items. Gives clients the idea that the business is offering some conventional goods or services. The only right to use the trademark in connection with the products or services for which it has been registered. To get compensation for trademark infringement (misuse by third parties). Ability to transfer (assign) the trademark to other parties for consideration

Copyright

An author's legal ownership of a creative work is known as a copyright. Examples of these creative endeavors include literature, paintings, sculptures in three dimensions, and musical compositions.

"Original works of authorship preserved in any physical form of expression currently known or subsequently created, from which they may be viewed, reproduced, or otherwise transmitted, either directly or with the help of a machine or mechanism.

Copyright Conditions

Work must be original: The work of another author cannot be just duplicated or reproduced as original authorship. It must be fixed in a physical form: must be transmitted from the

author's imagination to a definite, physical medium, such as a written piece, a sculpture, a musical composition, etc. Regarding the industrial designs to which the design is applied, a declaration of uniqueness (However, when registering wallpaper, lace, or textile items, a declaration of uniqueness is not necessary); and full payment of the relevant filing cost.

The Preservation of Plant Variety and Farmers Right Act, 2001 (PPVFR Act) was passed by the Indian Parliament in order to provide an efficient system for safeguarding plant variations, farmers' and plant breeders' rights, and to promote the creation and propagation of novel plant varieties. On October 30, 2001, the President of India gave his approval to this law.

DISCUSSION

It has been deemed necessary to recognize and protect the rights of the farmers in respect of their contributions made at any time in conserving, improving, and making plant genetic resources available for the development of new plant varieties in order to facilitate the establishment of an effective system for the protection of plant varieties, the rights of farmers, and plant breeders. The Indian government adopted a sui generis approach when it passed "The Preservation of Plant Varieties and Farmers' Rights (PPV&FR) Act, 2001[8]–[10]." The laws of India are not only compliant with the International Union for the Preservation of New Varieties of Plants (UPOV), 1978, but they also provide enough protections for farmers' and public sector breeding institutes' interests. The law acknowledges the roles played by farmers and commercial plant breeders in plant breeding activities and calls for TRIPs to be implemented in a way that advances the unique socioeconomic interests of all parties involved, including the public and private sectors, academic institutions, and farmers with limited resources.

- To create a framework that effectively protects plant varieties, farmer and plant breeder rights, and to promote the creation of new plant varieties.
- To acknowledge and defend farmers' rights with regard to their ongoing efforts to preserve, enhance, and make accessible plant genetic resources for the creation of new plant kinds.
- Protecting the rights of plant breeders would help the nation's agricultural growth along with encouraging public and private sector investment in research and development to create new plant types.
- Encourage the development of the nation's seed business, which will guarantee that farmers have access to high-quality seeds and planting supplies.

Rights granted by the Act

Breeders' Rights: The protected variety may only be produced, sold, marketed, distributed, imported, or exported by breeders. Breeder may designate an agent or licensee and pursue a legal action in the event that their rights are violated.

Researchers' Rights: Under the Act, researchers may conduct experiments or conduct research using any of the registered varieties. This includes using a variety as a starting point for the development of another variety, but recurrent usage requires prior consent from the registered breeder.

Agriculture Rights

A farmer can save, use, sow, re-sow, exchange, share, or sell his farm produce, including seed, of a variety protected under the PPV&FR Act, 2001, in the same manner as he was entitled before the coming into force of this Act, with the caveat that the farmer shall not be

entitled to sell b) any product that is derived from a variety protected under the PPV&FR Act, 2001, or that is derived from a farmer's

Actualization of the Act

The Protection of Plant Varieties and Farmers' Rights Authority was founded by the Department of Agriculture, Cooperation and Farmers Welfare, Ministry of Agriculture and Farmers Welfare, on 11 "2005 November. The Authority's Chief Executive is the Chairman. According to a notification by the Indian government, the Authority comprises 15 members in addition to the Chairman (GOI). Among these, eight are ex-officio members who represent different groups[11]. The Central Government nominates departments/ministries, three from SAUs and the State Governments, one representative for farmers, tribal organizations, the seed industry, and women's organizations involved in agricultural activities. The Authority's ex-officio Member Secretary is the Registrar General.

CONCLUSION

It is clear that managing IP and IPR requires a variety of activities and techniques, all of which must be in compliance with local laws as well as international conventions and standards. It is no longer only influenced by a national viewpoint. The market's demands, its reaction, the expense of converting IP into a business enterprise, and other factors have a significant impact on IP and its related rights. In other words, the administration of IPR must take into account issues relating to trade and commerce[12]. Various IPR forms need distinct management, planning, and tactics, as well as the involvement of people with a variety of subject-matter expertise, including science, engineering, medical, law, marketing, finance, and economics. Depending on its area of specialization, each industry should have its own IP rules, management practices, strategies, etc. A developing IP strategy is now used by the pharmaceutical business. Antitrust law must thus intervene to prevent the wrongful assertion of invalid IPR in order to create and sustain illegitimate, if temporary, monopolies within the pharmaceutical business, given the greater likelihood that certain IPR are illegal.

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CHAPTER 14

INTELLECTUAL PROPERTY AND BIOETHICS

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ABSTRACT:

Patents, trademarks, copyrights, and trade secrets are all examples of intellectual property and are all types of legal mechanisms used to safeguard original ideas, innovations, and other intangible property. Intellectual property laws aim to strike a balance between artists' and inventors' moral and financial rights and the broader interests and demands of society. The idea that providing incentives and rewards to innovators would benefit society is a key argument for patents and copyrights. The term "intellectual property rights" (IPR) refers to the legal privileges granted to the inventor or creator to safeguard their work for a certain amount of time. These legal rights allow the inventor or creator, or his assignee, the only right to fully exploit their idea or creativity for a certain amount of time.

KEYWORDS:

Copyrights, Intellectual Property Rights, Patents, Trademarks,Trade Secrets.

INTRODUCTION

Recent advances in the life sciences, such as genetic cloning, cell line modification, and the exploitation of genetic resources, have spurred a heated discussion concerning the moral implications of these novel technologies. The causes are simple to pinpoint. Research in the life sciences directly addresses concerns of life and death. Biotechnology aims to meet fundamental human needs like food, health, as well as a safe environment. It also touches on fundamental ideals like human dignity as well as the genetic integrity of humanity. However, it can also raise issues related to human rights, such as access to health care and the benefits of scientific advancement. It also raises questions about fair distribution of the benefits of new technologies, informed consent from research participants, and environmental protection. The ethical ramifications of safeguarding biotechnological ideas via the intellectual property (IP) system are one of many topics and policy groups that are touched by the ethical component of the life sciences. The complicated interaction between the domains of bioethics and intellectual property is systematically outlined in Part I of this topics paper. The relationship between IP and bioethics is outlined in Part II in general terms. The four major groups of arguments are examined in Part III. These are difficult and intricate problems. In order to help individuals who want to actively participate in a significant set of discussions about bioethics, biotechnology, and intellectual property, this article clarifies the concerns rather than offering any preset or favored answers to today's complex challenges in these areas. In a background research, which examines several of the prominent examples mentioned briefly in this article, these concerns are covered in greater detail[1]–[3].

Intellectual Property and Bioethics

Bioethics: What is it?

The study of ethics is the science that examines what is good or evil, right or wrong. It contains both theoretical and useful components. In order to create norms or standards of behavior (normative ethics), and to examine the foundations of moral judgements, ethics (descriptive ethics). The use of theoretical ethical instruments and ethical rules to address real

moral decisions is known as applied or practical ethics. The ethical ramifications of biological research as well as its biological and medicinal applications are discussed in bioethics. In discussions about the dignity of the human being, beginning-of-life and end-of-life issues, consent to medical treatment, freedom of research, the consent of the donor of human genetic material, access to health care and resource distribution, equitable access to the results of biological research, animal protection, and environmental ethics, specific bioethical issues come up. Morality vs ethics while the terms "ethics" and "morality" are often used synonymously, they do have some differences.

In the area of intellectual property, some patent laws relate to innovations whose commercialization would be against the public good or morality, while some trademark laws refer to trademarks that are against the public good or morals. In this sense, "morality" might be used to describe a group of people's shared values, which could vary from one group to another. Ethics vs the law while they are distinct from one another, law and ethics are intimately intertwined. Certain legal actions could be seen as unethical[4]. For instance, lying is often immoral but only sometimes constitutes a genuine crime. While there may be much overlap and coherence between ethical standards and expectations and the legislation governing human rights, to see the latter as just providing ethical advice would actually diminish the legal significance and legitimacy of the former. Legislators sometimes decide not to enact laws on certain topics because of a purposeful decision to let ethical concerns in communities guide conduct rather than legal requirements. Others could argue that certain sorts of stem cell research are unethical even if they don't necessarily violate local laws.

What is protection of intellectual property? Legal rights deriving from intellectual work in the sectors of industry, science, literature, and the arts are referred to as intellectual property. IP systems provide authorized right holders with restricted rights to prohibit others from using the protected content in specified ways, protecting well-defined subject matter. Yet, the ownership of an IP property does not provide the possessor the right to use or commercialize a product. IP rights are often generated, managed, and used individually under each nation's national laws. They only have legal significance within the boundaries of the states in which they have been granted. General legal and administrative norms are outlined in a number of international treaties[5], [6]. Yet, these international standards may be used in a variety of ways and must be implemented via national legislation. Certain issues that could be of interest to the bioethics community are seldom ever addressed at the international level and are instead allowed to be decided by national or regional authorities. They include the meaning of the fundamental term "innovation," as well as the principles of "morality" and "ordre public" that need to guide the application of patent law.

Patents provide legal protection for some types of biological innovations (the exact scope of protectable inventions varies from one national system to another). The form of IP that is most relevant to biotechnology and is most often addressed in the context of bioethics is the patent. But, a variety of other types of intellectual property can also be regarded as relevant, for example: In general, with the exception of additional breeding, plant breeder’s rights or plant variety rights regimes provide Property rights over new plant varieties. Access to genetic information may have ethical ramifications for copyright and sui generis database rights. When it comes to fake medications, for instance, trademarks may assist guarantee ethical business operations. The ethical requirements to preserve personal genetic information, for example, may be impacted by laws governing confidentiality and the preservation of information that has not been released. Due to the public interest role of this information and worries about duplication of trials involving human or mammal subjects, bioethics concerns regarding clinical trials and informed consent questions may be relevant to

the protection of test data regarding the safety and efficacy of chemical entities. International IP law contains a broad mandate to prohibit conduct that is "contrary to honest business practices" in the area of unfair competition[7]–[9]. The moral foundation for IP policy In theory, effective IP protection seeks to further governmental goals that are in line with generally acknowledged ethical standards.

Nonetheless, there are several approaches to delving into the moral foundations of IP legislation. There is a claim that certain intellectual property laws and concepts are based on 'natural rights,' reflecting an innate right to equitable compensation and acknowledgement for one's intellectual and creative achievements. On the other hand, IP law and policy also have a strong utilitarian bent, acting as a deliberate instrument to advance societal welfare. An action's moral worth would be determined by its contribution to the general societal utility or welfare under a utilitarian theory of ethics. The present discussion of IP as an instrument of public policy is placing more and more emphasis on this utilitarian ethic.

The protection and enforcement of IP rights should "contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations," according to the TRIPS Agreement, which is a reflection of this idea.

The four overarching principles transparency, prior informed consent, fair benefit-sharing, and pluralism are covered in this section. Transparency Access to information and transparency are fundamental values that support bioethical concerns and make it easier to evaluate new technologies from an ethical perspective. The UDBHR (Universal Declaration on Bioethics and Human Rights) encourages the quick and broad dissemination of information on advances in medicine, science, and technology. The patent system must, in theory, encourage the timely flow of knowledge about innovative technology. A novel biotechnology is often initially and completely revealed to the public via the patent system. The names of the inventors, businesses, governments, and academic institutions engaged in the development of certain inventions are also made public in patent filings. Patent information systems provide insight into the creation of technologies that may have significant bioethical concerns early on. They might be used to keep an eye on: broad trends and patterns in the development of important technologies for example, the trends in patenting gene sequences.

State-of-the-art and recent advancements in a particular technical field such as recent advancements in stem cell technology, as well as the research and patenting efforts of certain businesses, institutions, and people for instance, the activities of government agencies or a university foundation. So, the openness of the patent system encourages moral examination of biotechnology and may contribute to a more informed discussion on bioethics. Nonetheless, it may be challenging for decision-makers and other discussion participants to make better use of patent information due to the vast amount of information given via the patent system. This raw patent data may require more distillation and analysis in order for policymakers and others interested in ethical concerns to understand the consequences on a larger scale.

But, having access to knowledge via the patent system does not provide you the freedom to utilize it in actual technology, for the simple reason that a patent grants you exclusive rights to that technology in the nations where it is enforceable. There may also be an ethical component to how such exclusive rights are acquired and used, which is covered below.

Consent

The use of particular inputs in biotechnological research has often included consent, which has bioethical ramifications. There have been instances when research projects using genetic components extracted from human bodies resulted in innovations that were later granted patents. This has prompted inquiries concerning the need of obtaining the approval of the relevant human subjects in advance and if consent extends to the patenting of research products. The link and limits between the legal and ethical elements of permission to utilize genetic inputs in research might be usefully explored. Consent is a fundamental problem in bioethics[10]. Concerns about research using human subjects in general may intersect with the problem of recognizing the rights of the contributor of human genetic material. Whether agreement to participate in medical research or get medical treatment extends to consent to the acquisition of IP based on that study may need to be made explicit. The need of study participants' agreement is stressed in several books. Scientific research should only be conducted with the prior, free, explicit, and informed permission of the individual involved, according to UDBHR Article 6(II).

Other genetic resources, such as genetic resources collected via bioprospecting, that are then employed in research to generate new technologies for which patent protection may be sought, are also subject to a similar argument. Access to genetic material of plant, animal, or microbial origin is subject to prior informed permission, which is mandated by the Convention on Biological Diversity (CBD). Prior informed consent is defined under the UDBHR in terms of individual autonomy and dignity, but the CBD connects it to national resource sovereignty, indigenous rights, and local community interests. fair distribution of benefits another subject is how to distribute the rewards of research and what it means to do so in a fair manner. This subject may have legal and ethical implications. Human rights legislation, as stated in the International Declaration on Human Rights, affirms that everyone has the right "to the preservation of the moral and material interests" deriving from their scientific achievements, as well as the right "to partake in scientific development and its advantages." Several legal mechanisms give voice to this fair balance of interests. For instance, the CBD defines the equitable sharing of the benefits from the exploitation of genetic resources as an international legal concept.

The UDBHR also calls for "equitable access to medical, scientific, and technological developments as well as the greatest possible flow and the rapid sharing of knowledge regarding those developments and the sharing of benefits, with particular attention to the needs of developing countries," explicitly in a bioethics context. A multilateral system of benefit-sharing for the utilization of plant genetic resources is established by the FAO International Treaty on Plant Genetic Resources for Food and Agriculture. The IP system, particularly the patent system, may have a potential auxiliary function in assisting with the generation, clarification, and equitable distribution of gains from biotechnological research. It's still debatable how to identify what constitutes an equal distribution of benefits and how to strike this balance between competing interests. That is yet another instance where ethical notions of what is just or equitable may conflict with or have an impact on formal legal requirements. This may include more than just allocating financial return shares; it might also mean giving people preferential access to technologies. For instance, several research institutions are creating "humanitarian licensing" policies that ensure access to life sciences technology to meet the requirements of poor nations. Although these policies are not required by law, some adhere to them out of moral obligation[11]. Inevitably, these values vary from society to society, as will the moral foundations for ethical decisions. If a technology is deemed unethical in one nation, it could be seen ethically acceptable and even beneficial in another. This group includes certain stem cell research's facets. This raises the issue of how

the IP system should handle these various value systems, such as in the interpretation and use of patent law's exclusions for morally repugnant technologies.

DISCUSSION

IP and Bioethics: Four Essential Aspects

The discussion of biotech IP rights raises a broad variety of ethical issues. These inquiries may sometimes have more to do with the technical area than they do with the Intellectual rights pertaining to a certain technology. Ethics may be applied to decisions made by the State or by government officials as well as to the actions of people, businesses, or organizations. Clinically, these problems are not separate from one another. Despite this, it might be useful to make certain philosophical, legal, and ethical distinctions given the intricacy of the concerns. Hence, organizing the ethical dilemmas into four groups might help in working through them: the moral implications of a technology in general (such as whether or not research on embryonic stem cells should be approved); The moral considerations that go into national governments giving exclusive Intellectual rights over a technology (for instance, is it wrong to patented a genetically modified mammal? What ethical factors must to be taken into account?) ; The moral ramifications of a person, business, or organization pursuing exclusive intellectual property rights over a technology (could a publicly supported organization patent its research findings, for instance? When is it immoral to do so, such as when no essential permission has been obtained?) ; The moral considerations that should guide an IP right holder's exercise of exclusivity over a technology (for instance, should the owner of a patent on a fundamental research tool provide it an open or a restricted license? From a clearly humanitarian standpoint, are governmental entities morally obligated to license medical technology?). These four elements may be shown and distinguished using the examples below:

Ethical ramifications of technology in general

This component relates to moral evaluations of several aspects of technology, including genetic engineering, research methods, and research involving human beings and genetic materials. Regardless of whether these inventions are patented, bioethical concerns may still exist. Even before any study results that may or may not be copyrighted, important bioethical concerns, such prior informed consent, apply to the very process of research. There is a lot of ethical discussion around stem cell research, especially that using embryonic stem cells. In contrast to whether the results of such research should be eligible for patent protection, the issue of whether to enable stem-cell research at all is separate and may have ethical implications of its own. As yet another illustration, some have argued that genetic use restriction technologies (GURTs), which forbid farmers from using harvested seeds for future crops, may be immoral or, alternatively, ought to be made illegal; others, however, contend that it is a legitimate technology with a valuable commercial function. A patent on a GURT does not give its owner the right to actually use the technology, and revocation of the patent on the technology does not stop it from being used. These ethical problems, however, are totally unrelated to the question of whether a patent should be awarded over such technologies. Certain actions may be deemed immoral and unethical, and as a result, they may be outright forbidden. Yet, such ban alone does not automatically bar the issue of patents linked to this information. Not every nation has the same moral or legal limitations. On the other hand, biotechnological research in most cases is not only allowed, but actively encouraged by society, such as the development of new pharmaceuticals. Many patent laws explicitly forbid the grant of patents where the exploitation of inventions is thought to be contrary to ordre public or morality (such laws are therefore relevant to the following aspect). Several technologies have a good ethical component, and other technologies may be used in

both ethical and immoral ways. Even drug research that starts out promising but ends up failing could be praised and accepted by society as having a good ethical character. Nonetheless, without the required regulatory permission, which comes after the successful completion of significant clinical studies, it is often unlawful to commercialize a new medicine.

Ethics Of Providing Exclusive Intellectual Property Rights To A Technology

Considering the kind of innovations over which national authorities should issue patent rights is a different ethical or moral concern. As we have said, certain innovations (like novel surgical techniques) are seen as ethically good yet are nonetheless not protected by patents in some nations. In other instances, patent protection may be refused in certain nations precisely because commercializing the invention would be immoral (say, methods of cloning human beings). National patent laws often define some types or categories of technology as "unpatentable subject matter," making them ineligible for patent protection. International negotiators, national lawmakers, patent authority, and courts have all been engaged in setting and enforcing laws in this area. This issue has a lengthy history in the field of patent law.

Some groups of innovations that might ordinarily qualify for patent protection are excluded by several national legislatures. Within a larger context of public policy issues, ethical concerns may have an impact on these decisions. For instance, some nations have opted to ban medical treatment techniques from patentability, even if they would otherwise be deemed novel, creative, and beneficial, due to a variety of public policy issues, including ethical concerns. This exclusion is, of course, based on the decision of public policy not to include such technologies within the patent system and not due to any unethical assessment of innovative medical therapies that may have significant societal benefits. Some nations, on the other hand, choose to permit the patenting of medical treatment procedures, presumably believing that doing so has mostly favorable ethical and policy implications. The morality of patenting living things, especially higher life forms like genetically altered animals, has been the subject of intense discussion on par with that surrounding the ethics of genetically modified organisms. Several approaches have been taken by national governments to address these problems; these approaches are related to various societal ideals and ethical viewpoints.

The patenting of genes or DNA sequences, particularly without revealing any specific recognized application, is still up for debate. Is it ethical for society to award exclusive property rights on human genome-derived nucleotide sequences when there isn't a clear use for the patented sequence? Is there a moral difference between human genes and other nucleotide sequences, both generally and with regard to patents? Others have claimed that the raw data included in human genome sequences shouldn't be copyrighted for a variety of ethical, legal, and policy reasons. Others emphasize the advantages for society of establishing explicit property rights over beneficial genes that have been removed from their natural environments in order to encourage the allocation of funds toward the development of novel diagnostic and therapeutic procedures. The ethical implications of the sequencing of the human genome as a whole, which has been warmly embraced, are not at issue in this argument, however. The decision of how to define and apply the ideas of morality and ordre public directing the application of certain exclusions to patentability based on these criteria is another one that policymakers and, in individual circumstances, the patent authority, must make. For instance, the European Biotechnology Directive (98/44/EC) outlines the idea that innovations should not be granted patents if doing so would be against the public good or morals. It lists "technologies for changing the genetic identity of animals which are likely to cause them misery without any meaningful medical benefit to man or animal, and also

creatures originating from such procedures" as an example of technology that is not patentable on the grounds that it is immoral.

Ethics of pursuing exclusive intellectual property rights over a technology

We recently looked at the ethical considerations that went into the judgments made about national law to establish that certain innovations should not be patentable. Individual choices and acts, however, also have an ethical component. Therefore, even if an invention as a whole would be legally eligible for a patent under national patent law, there may be ethical considerations in the decisions made by an individual actor - a firm, a research institution, or a university - regarding whether or not to pursue a patent for a specific invention. The line between the legal and ethical concerns is again hazy. As a result, some contend that there need to be restrictions on applying for a patent for an invention that is based on genetic resources or traditional knowledge that was acquired without prior informed permission and without an equitable benefit-sharing arrangement. Even though the claimed invention would ordinarily qualify for patent protection, this objection may still be raised. Nevertheless, are these restrictions moral, legal, or both? Should moral restrictions become legal ones? In reality, there are already certain national laws that address these issues, and there are even proposals for international law. As a result, this problem has been addressed legally under both international and domestic law, but it could also continue to have an ethical component. What if, for instance, the traditional knowledge that inspired an innovation was acquired entirely lawfully that is, no laws were committed but the acts of the patent applicant in acquiring and applying for that information were deemed unethical? Some laws place restrictions on acquiring or using patent rights that have been acquired unfairly.The moral ramifications of claiming exclusive control of a technology certain ethical issues emerge with how a patent holder decides to exploit the rights provided by a patent, rather than the ethics of a technology as a whole or whether that invention should be patented. In rare circumstances, the proper use of a patent by its owner may raise ethical concerns. When a patent holder acts within their legal rights and nevertheless draws ethical attention, it might be claimed that some ethical restrictions still hold true.

Protections for the public interest apply to the licensing and use of intellectual property. The market's ability to exercise Intellectual rights is constrained by legal limits. Included in this are prohibitions against unfair licensing activities, general competition principles, and the use of specialized patent law remedies (such as compulsory licensing). Yet, the moral, "best practice," and regulatory standards for licensing important technology may also have an impact on how one decides to utilize their intellectual property rights. Examples include a rising trend for university technology offices to include sample humanitarian clauses in their technology licensing agreements and a set of OECD Guidelines for the Licensing of Genetic Inventions that advocate for a somewhat lax licensing policy, notably for genetic diagnostics. Other licensing systems may also be used to develop access to the advantages of scientific research. In the life sciences, for instance, the BiOS movement describes open source licensing as follows: "Typically, licenses for patented technology place tight requirements on the user, sometimes requiring fees or royalties for use of the materials or techniques or both. The creation of goods is often prohibited by Material Transfer Agreements (MTAs), which normally impose the restriction that the technology may only be utilized for certain purposes. In a BiOS-compliant agreement, the user must consent to terms that promote collaboration and the advancement of the technology in order to get the right to use the technology as opposed to royalties or other restrictions that discourage the development of goods. These requirements state that licensees are not permitted to use the "kernel" of the technology and upgrades only for their own benefit. The original technology is still the property of the

organization that created it, but advancements can be shared with others to support the creation of a protected commons around it. Those who accept the same terms of sharing gain access to advancements as well as other information shared by other consenting parties, such as regulatory and biosafety data. In other words, in order to continue having legal access to the technology, you must consent to allowing others who have accepted the same conditions to use it and any advancements made in the creation of new goods.

CONCLUSION

This chapter doesn't address every facet of the relationship between IP and bioethics and doesn't provide any clarification on the issues posed. Instead, it only aims to spark additional discussion and investigation and to support a methodical approach to the issues highlighted. The following are a some of the more general inquiries that arise: And what distinguishes life science technologies from other types of technology? How to define the links between IP law and policy on the one hand, and bioethics and humans rights legislation on the other: particularly, how can the IP system be employed constructively to react to bioethics concerns and to encourage recognition of human rights?

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CHAPTER 15

DEVELOPMENT OF TRIPS COMPLIED REGIME IN INDIA

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ABSTRACT:

Since 1995, the country's system of intellectual property rights has undergone a number of legislative changes. As India had a ten-year transition period (1995-2005) to make its domestic law compliant with TRIPs, the WTO's TRIPs agreement became enforceable from that point on. The most extensive international agreement on intellectual property to date is the TRIPS Agreement, which went into force on 1 January 1995. The statute promoted the creation of substitute methods for goods with foreign patents as well as reverse engineering. The first thorough drug policy in India was The Drug Policy, 1978. Up until the 1990s, the policy's fundamental structure remained substantially in place.

KEYWORDS:

Biosafety,Cryopreservation, Cloning, economic, genetic resource, Intellectual property (IP).

INTRODUCTION

Intellectual property (IP) refers to works of art, literature, and other creative works as well as trademarked symbols, names, and logos. Industrial property, which includes inventions (patents), trademarks, industrial designs, and geographic indications of origin, and copyright, which includes literary and artistic works like novels, poems, and plays, films, musical compositions, artistic creations like drawings, paintings, photographs, and sculptures, and architectural designs, are the two categories of intellectual property. Performers' rights in their performances, phonogram makers' rights in their recordings, and broadcasters' rights in their radio and television broadcasts are all covered by copyright laws. By granting creators ownership rights over their works, intellectual property laws safeguard their interests[1]–[3].

Yet, the most obvious distinction between intellectual property and other types of property is that the former is intangible, meaning that it cannot be described or recognized by its own physical characteristics. To be protectable, it must be stated in a recognizable manner. The term "intellectual property" is often used to refer to four independent and distinct categories of intangible property, namely trade secrets, copyrights, patents, and trademarks. Yet, as fresh forms are added to the intellectual property portfolio, the meaning and scope of intellectual property are always changing. Geographical indications, plant variety protection, semiconductor and integrated circuit protection, and confidential information have all recently been included within the definition of intellectual property.

Intellectual Property: A Notion

The notion of intellectual property is not new since Renaissance northern Italy is regarded to be the origin of the Intellectual Property system. Inventions were first systematically attempted to be protected by a kind of patent under a Venetian Statute from 1474, which for the first time gave a person an exclusive right. The first copyright system in the world was created in the same century with the creation of moveable type and the printing machine by Johannes Gutenberg about 1450.

More creative manufacturing techniques helped spark widespread industrialization towards the end of the 19th century, which was accompanied by an increase in transoceanic commerce, rapid urbanization, the development of railway networks, and capital investment. Several nations developed their contemporary intellectual property laws as a result of new industrialist values, the rise of larger centralized governments, and nationalism[4]. With the establishment of the Paris Convention for the Protection of Industrial Property in 1883 and the Berne Convention for the Protection of Literary and Artistic Works in 1886, the International Intellectual Property system also began to take form at this time. The fundamental tenet of intellectual property has always been that ownership of innovations and creative works results in recognition and incentives, which in turn spur on additional imaginative and creative effort, which in turn spurs economic progress.

Ideas and information have grown in importance as commerce throughout time, especially in the context of the modern corporate paradigm. The amount of invention, creativity, research, design, and testing that goes into high-tech goods and novel medications accounts for a large portion of their worth. Videos, music records, books, computer programs, and online services are all purchased and sold for the knowledge and creativity they impart, not often for the plastic, metal, or paper that went into their creation[5]. Several items that were formerly considered low-tech goods or commodities, such designer apparel or novel plant species, now have a bigger share of innovation and design in their worth. So, creators are granted the right to forbid the use of their ideas, designs, or other works. Intellectual property rights are the name given to these rights.

The TRIPS Agreement strives to harmonize, reinforce, and provide for effective enforcement at both the national and international levels. It embraces, in theory, all types of intellectual property. It discusses the terms of international IP agreements as well as the general GATT principles' application (Part I). It defines guidelines for the accessibility, range, and application of intellectual property rights (Part II), as well as for their acquisition and upkeep (Part IV). It also discusses relevant conflict prevention and resolution methods (Part V). Parts VI and VII of the Agreement, which cover institutional and transitional arrangements, respectively, deal with formal stipulations.

The most extensive international agreement on intellectual property to date is the TRIPS Agreement, which went into force on 1 January 1995. Its scope of intellectual property includes the following areas:

- Copyright and associated rights (i.e., performers', sound recording producers', and broadcasting organizations' rights).
- Trademarks, such as service marks.
- Geographical cues, such as appellations of origin;
- Industrial designs.
- Patents, which provide protection for novel plant kinds;
- The topographies (layout designs) of integrated circuits;
- Unreleased data, including test results and business secrets.
- Indian Intellectual Property Law

As previously mentioned, the Venetian Ordinance, which was initially implemented in 1485, was the first mechanism in history to safeguard intellectual property. The Act of Monopolies in England, which expanded patent rights for technological inventions, came after this. Patent laws were first adopted in the US in 1760. Between 1880 and 1889, most European nations created their own patent laws. In India, the Patent Act was first passed in 1856 and was in effect for more than 50 years before being changed[6], [7]. The "Indian Patents and Designs

Act, 1911" was passed, revised, and named. The Patents Act, 1970, a comprehensive law on patent rights, was passed in the years after Independence.

Just limited types of intellectual work were protected by specific legislation; until recently, only four types were. Copyright, patent, design, and trademark grants served as the protection. The Copyright Act of 1957, the Patents Act of 1970, the Trade and Merchandise Marks Act of 1958, and the Designs Act of 1911 all governed intellectual property rights in India.

A number of new laws for the protection of intellectual property rights were established in India in response to the creation of the WTO and the country's membership in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). They included the Trade Mark Act of 1999, the Designs Act of 2000, which superseded the Designs Act of 1911, the Copyright (Amendment) Act of 2012, which was the most recent change to the Copyright Act of 1957, and the 2005 revisions to the Patents Act of 1970. Also, new laws governing geographical markers and plant types were passed. They are referred to as the Farmers' Rights Act of 2001, the Protection of Plant Varieties Act of 1999, and the Geographical Indications of Products (Registration and Protection) Act of 1999, respectively.

Intellectual property rights have developed to the point that they now significantly influence the growth of the global economy during the last fifteen years. Several nations tightened their rules and regulations in this field unilaterally in the 1990s, and many more were prepared to follow suit. The World Trade Organization's (WTO) successful completion of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) raises the protection and enforcement of IPRs to the status of a serious international commitment at the multilateral level. Stronger IPR protection is believed to boost incentives for innovation and raise returns on foreign technology transfer in the context of a globally competitive market.

The Government passed the Protection of Plant Varieties and Farmers' Right Act in 2001 with the intention of establishing an Authority to provide an effective system for protecting the rights of plant breeders and farmers, to promote the development of new plant varieties, and to give effect to the provisions of the TRIPS Agreement. By assuring adequate returns on such investments, this Act aims to encourage investment in research and development for the creation of novel plant types in both the public and commercial sectors[8]. In order to guarantee that Indian farmers have access to high-quality seeds and planting supplies, it also aims to encourage the development of the nation's seed industry via local and international investment. By recognizing them for their contribution via benefit sharing and defending the farmers' traditional rights, it also acknowledges the role of farmers as cultivators and conservationists as well as the contribution of traditional, rural, and tribal groups to the nation's agrobiodiversity. In order to produce novel plant varieties and advance the rights of farmers and breeders, the Act also allows for the establishment of the Protection of Plant Varieties and Farmer's Rights Authority.

Act of 2000 Concerning Semiconductor Integrated Circuits Layout Design

One of the industries with the quickest growth rates and one that has contributed significantly to the global economy is electronics and information technology. The development of electronics, computers, and telecommunications is mostly to blame for this. Microelectronics, which primarily refers to Integrated Circuits (ICs) ranging from Very Large Scale Integration (VLSI) to Small Scale Integration (SSI) on a semiconductor chip, has rightly been recognized as a core, strategic technology on a global scale, especially for Information Technology (IT) based societies. Depending on the intricacy, integrated circuit design involves a lot of knowledge and work. Thus, it is crucial to safeguard the Intellectual Property Rights (IPR)

that are built into layout designs in order to stimulate continuing expenditures in R & D that lead to breakthroughs in the technology of microelectronics.

The techniques of copyright and patent protection were not sufficient to adequately address the needs of intellectual property rights protection for integrated circuit layout designs. This was done because originality—whether it be a "novelty or not"—is of the highest importance in the context of layout designs. Since the copyright law is too vague to account for the original ideas of scientifically created Layout-Designs of Integrated Circuits, the patent law stipulates that the concept must be both unique and innovative. Given the above, it was decided that Layout-Designs of Integrated Circuits needed to be protected in order to reward and promote a sufficient level of investment of human, financial, and technical resources[9], [10].

The majority of nations that value the protection of IP rights in semiconductor integrated circuits have a sui generis method of protection for integrated circuit layout-designs, which is often covered by a separate Act. The WTO Trade Related Intellectual Property Rights (TRIPS) Agreement comprises provisions relating to the establishment of standards on the availability, scope, and use of intellectual property rights, geographical indications, integrated circuit layout-design, etc. In order to preserve semiconductor integrated circuits, the government passed the Semiconductor Integrated Circuit Layout- Designs Act, 2000. Layout-Designs through the registration process, a method for identifying Layout-Designs that can be protected, regulations to prevent the registration of Layout-Designs that are not original and/or that have been commercially exploited, a period of protection, provisions regarding infringement, payment of a royalty for registered Layout-Designs, provisions for dealing with willful infringement by way of punishment, appointment of a Registrar for registering the Layout Designs, and more.

In conclusion, India's endeavor toward a new IPR regime to better position itself for the global trade competition can be seen in the many adjustments and amendments to prior Intellectual Property Laws.

Commerce Secrets

An organization may get a competitive advantage from secret business knowledge. They are often business secrets as well as manufacturing or industrial secrets. They include of production procedures, lists of suppliers and customers, sales techniques, distribution techniques, consumer profiles, and advertising plans. Trade secrets are protected without registration, in contrast to patents[11]. A trade secret may be kept indefinitely, but there must be a significant amount of secrecy such that finding the knowledge would be difficult unless inappropriate techniques were used. Given the abundance of traditional knowledge in the nation, the protection provided by this will be essential for obtaining the advantages of this kind of information.

Useful Models

A utility model is an exclusive right awarded for an innovation that permits the right holder to bar others from utilizing the idea for commercial purposes without his permission for a certain amount of time. A utility model is comparable to a patent in terms of its fundamental concept, which may differ from one nation (where such protection is allowed) to another. In fact, utility models are often known as "innovation patents" or "petty patents." Utility model protection is only offered in a small but considerable number of nations and areas. India does not yet have any utility model laws.

The following are the primary distinctions between utility models and patents:

A utility model may be acquired with less restrictions than a patent. Although "novelty" is a condition that must always be satisfied, "inventive step" and "non-obviousness" requirements may be much less stringent or nonexistent completely. In reality, incremental advances that may not fulfill the requirements for patentability are often sought after for utility model protection. Utility model protection lasts less time than patent protection and varies from nation to country (usually between 7 and 10 years without the possibility of extension or renewal).

Most nations that provide utility model protection do not require applications to be substantively reviewed before registration with the patent office. This implies that the registration procedure, which normally takes six months, is considerably sped up and simplified. Utility versions are substantially less expensive to buy and keep up[12]. Utility model protection is only available for goods in specific nations, not processes, and only for specified technological disciplines. Utility models are seen to be especially useful for SMEs that modify and adapt current goods in "minor" ways. The main applications of utility models are in mechanical advancements. After thorough investigation into the requirements of small and medium-sized businesses, the "Innovation patent" was developed in Australia a while ago with the goal of offering a "low-cost entry point into the intellectual property system."

BIODIVERSITY & IPR

Simply said, biodiversity is the variety of different living forms found within the Biosphere. The cornerstone of life on Earth is biodiversity. It is essential for the health of ecosystems that provide us the goods and services we need to survive. We have a significant impact on both human health and the health of all other living things when we alter biodiversity. Biodiversity is often divided into three main areas.

DISCUSSION

India's Development of a TRIPS Compliant Regime

In order to institutionalize the global framework of commerce, the creation of the WTO necessitates the harmonization of numerous facets of Indian law pertaining to intellectual property rights. The TRIPS agreement established baseline requirements for IPR rights protection as well as a deadline by which nations had to amend their legal systems in order to provide the necessary level of protection. In light of this, India has recently made steps to alter and revise the different IP Acts.

1970 Patents Act

The Patents Act, 1970 was amended in the years 1995, 1999, 2002, and 2005 to comply with the TRIPS agreement after India became a signatory. The TRIPS agreement is a component of the Agreement establishing the World Trade Organization (WTO) and aims to reduce trade distortions and obstacles while promoting effective and adequate protection of intellectual property rights. The Patents Act has been updated to take into account India's growing technical capacity as well as the need to harmonize the nation's intellectual property laws with those of other countries. The changes were made in order to satisfy India's international responsibilities under the TRIPS Agreement and to modernize, harmonize, and make the Act easier to use while still protecting national and public interests.

The Patent Act's regulations were subsequently modified, and these changes took effect in May 2003. With effect from January 1, 2005, the Patents (Amendment) Regulations 2005

have further altered these regulations. As a result, the Patent Amendment Act of 2005 is now fully effective. The law of trademarks is also now modernized under the Trademarks Act of 1999. A trademark is a special. In India, trademarks have been protected by the terms of the Trade and Merchandise Mark (TMM) Act of 1958 for more than 40 years. India joined the WTO as a member right away. The agreement relating to intellectual property rights is one of the agreements (TRIPS). India became a party to the Paris Convention in December 1998.

In the meantime, efforts to update the Trade and Merchandise Marks Act of 1958 were made while taking into account recent changes to business and trading practices, the growing globalization of trade and industry, the need to promote investment flows and technology transfer, the need to simplify the trademark management system, and the need to implement significant judicial decisions. The Trademarks Bill was proposed in 1994 to fulfill these goals.

The Bill indicated the improvements that the Government of India was thinking about and considering, however it expired in 1994. The previous regulations were thoroughly reviewed in light of changes in trading and commercial activities as well as the growing globalization of commerce and industry. The Trade and Merchandise Mark Act of 1958 was replaced by the Trademarks Bill of 1999, which was approved by Parliament and got the President's assent on December 30, 1999. It expands the definition of trademark infringement to include legal action against the unauthorized use of a mark that is confusingly similar, not only in relation to the goods and services covered by registration, as was the case previously, but also in relation to goods and services that are so similar that there is a likelihood of deception or confusion.

If a trademark is comparable to a registered trademark that is widely recognized in India and the owner's interest is likely to be harmed, an action for infringement would also be possible against the unauthorised use of the trademark in connection to unrelated products. The new legislation further strengthens the remedy for trademark infringement by giving police the authority to confiscate infringing goods without a search warrant.

The 2000 Designs Act

The Designs Act of 2000 is the successor of the Designs Act of 1911. A more effective legal system for the protection of industrial designs was felt to be necessary in light of the significant advancements in science and technology in order to ensure that registered designs are effectively protected as well as to promote design activity to highlight the design element in a product. In light of this, the Designs Act, 2000 was passed primarily to strike a balance between these interests and guarantee that the legislation does not needlessly extend protection beyond what is needed to encourage creative activity while reducing barriers to the unrestricted use of existing designs.

As the new Act conforms to TRIPS' standards, it has immediate bearing on global commerce. The original design or aesthetics of an industrial product are the subject of industrial design legislation. A typical industrial product has either artistic and utilitarian features, or elements of both art and craft. The operational components of an item are not covered by the design legislation, which only protects those that are aesthetically pleasing. For instance, a teacup's design must have a handle and a hollow chamber for storing tea. These features are functioning but cannot be registered. But, if it had a unique form or decoration, it would be registrable. A table, for instance, has a flat top that can accommodate other things. This is what makes it work. Nonetheless, if it is distinctive and innovative, its form, color, and how it is supported by legs or otherwise fall within the category of design or creative aspects and are thus registrable.

The following are the key components of the Design Act, 2000: (a) Extending the definition of "article," "design," and adding a definition of "original."

a) Extending the definition of "previous publication."
b) Making provisions for the transfer of the Controller's authority to other officers and outlining the mandated obligations of examiners.
c) Identification of designs that are not registrable.
d) Allowance for applicant replacement prior to design registration.
e) The replacement of the Indian classification system with a system of classification that is used worldwide.
f) A provision for the addition of a computer-maintained registry to serve as a Register of Designs.
g) A provision for the revival of abandoned designs.
h) I Provisions for appealing Controller orders to the High Court rather than to the Central Government
i) (j) The two-year term of a registered design's confidentiality being revoked.
j) (k) Include language requiring the mandatory registration of any document transferring ownership of a registered design.
k) (l) Adding new grounds for cancellation and allowing cancellation procedures to be started before the Controller rather than the High Court.
l) (m) Increase in the amount of the fine for violating a registered design.
m) A clause that allows cancellation reasons to be used as a defense in infringement proceedings in any court that is higher than the Court of District Judge.
n) (o) Increasing the original registration term from five to ten years, with a further five-year extension.
o) With the exception of the United Kingdom and other Commonwealth Countries, (p) provides for the provision of preference to other convention nations and countries belonging to the group of countries or intergovernmental organizations.
p) (q) A provision to prevent the imposition of certain stringent restrictions for the prevention of anticompetitive behavior in licensing agreements.

CONCLUSION

Industrial design is becoming a crucial component of consumer culture, as competing products vie for consumers' attention. Giving a unique industrial design proper protection has so become crucial. Separating a final product's appearance from its purpose is not always simple. But, according to the law, only the visual appeal or the design element may be registered and protected. For instance, while creating furniture, whether for export or otherwise, one must ensure that no one else has a design right in that specific design before copying it from a catalogue. Be sure the furniture design is not already registered as a patent or design in the exporting nation, especially when exporting furniture. Otherwise, the exporter can get entangled in pointless legal battles and perhaps be subject to damage claims. Contrarily, if ethnically inspired furniture is being exported and the design satisfies the criteria for what constitutes a "design" under the Designs Act, it would be worthwhile to register the design in the country where the product is being sold so that others cannot copy it and deny the designer of the design the financial benefits of his creation.

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CHAPTER 16

CONCEPT OF PATENT

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ABSTRACT:

There are many ways to preserve the creative work of the human mind, and the major reason for doing so is because doing so is a clear way to stimulate the creative process. Several different types of creative activity protection have emerged, including some that are particularly relevant to industrial growth. In general, a patent is a monopoly award that gives the inventor control over the production and, up to a certain point, the price of the patented goods. The patent system's primary economic and commercial argument is that it encourages investment in industrial innovation. The upkeep and expansion of a country's portfolio of valuable, tradable, and industrial assets are facilitated by innovative technologies.

KEYWORDS:

Biosafety,Cryopreservation, Cloning, economic, genetic resource, Intellectual property (IP), Patent.

INTRODUCTION

It is possible to date the earliest patent award to 500 B.C. It was the gaurmand-dominated city that granted what is now known as a patent right to promote culinary art, making it perhaps the first. Because it granted exclusive sales rights to any confectioner who created a delectable dessert first. When the practice spread to more Greek towns, as well as to other industries and goods, it was given the term "monopoly," a Greek portmanteau word made from the words mono (alone) and polein (sale).

Evidence of exclusive property rights being granted to private persons by monarchs and other authorities goes back to the 14th century, but their uses have changed through time. History demonstrates that monopoly rights for inventors were routinely used in Venice throughout the 15th century to promote innovation. The invention's usefulness and novelty were key factors in determining whether to issue a patent privilege. The inventors also had a deadline by which they had to exploit their innovation commercially. The German rulers of the 16th century gave prizes to those who created new arts and devices while also taking into account their usefulness and originality. Early regulations in the American colonies were largely intended to provide protected domestic markets to foreign manufacturers in order to encourage them to start new businesses there[1]–[3].

During the late 15th century, the English monarchs had begun to employ monopoly privilege more often to reward royal favorites, to maintain allegiance, and to maintain control over the industry, but not to promote innovations. The inventors patent was recognized as a legitimate monopoly in 1623 by the English Parliament, which also created a Statute of Monopolies to set it apart from other monopoly rights. The giving of monopoly powers was prohibited by the Statute, with the exception of the first and genuine inventor of a new product. By the 16th and 17th centuries, the inventor's patent of monopoly had grown in significance across England. The laws recognizing the patent monopoly extended throughout Europe and North

America from the middle of the eighteenth century to the middle of the nineteenth century, but these advantages were not given without struggle.

The Act of 1856 that granted inventors special rights is the source of the Indian Patent System. The Patents and Designs Act, 1911, which provided provisions for both product and process patents, regulated the patent system at the time of Independence. Yet, it was widely believed that the patent legislation had not done much to benefit the populace of the nation. Foreigners profited from the Act's design significantly more than Indians did[4]. It hindered Indians' ability to be imaginative and creative, and it did absolutely nothing to further scientific research or industry in the nation. In order to conduct a thorough examination of the operation of the 1911 Act, a committee headed by Justice (Dr.) Bakshi Tek Chand, a retired judge of the Lahore High Court, was established shortly after Independence in 1949. On August 4, 1949, the Committee delivered its interim report, and the

50 suggestions were made in the final report for preventing the exploitation or misuse of patent rights in India. It also suggested that the Patent Act clearly state that food, medicine, and surgical and curative equipment must be made accessible to the general public at the lowest cost possible while yet providing the patent holder with adequate recompense. The 1911 Act was updated in 1950 (by Act XXXII of 1950) to address the functioning of innovations, including compulsory licensing and patent revocation, in accordance with the committee's recommendations. A subsequent modification (Act LXX of 1952) was enacted to allow for obligatory licensing of food, medicine, pesticide, germicide, or fungicide, as well as any innovation pertaining to a technique for generating substances or surgical or curative instruments[5], [6]. The government introduced a measure (Bill no. 59 of 1953) in Parliament in response to the committee's suggestion, but the bill was not pushed and was allowed to expire.

A new committee was established in 1957, headed by Judge N. Rajagopala Ayyangar, to examine the patent law from a fresh perspective and reformat it entirely so that it would best serve the requirements of the nation at the time. In particular, patents for chemical innovations and patents for inventions pertaining to food and medicine were covered in Judge Ayyangar's findings[7]. The Patents Act, 1970, which replaced the Patents and Designs Act, 1911, entered into force on April 20, 1972, and was largely based on the recommendations made in Justice Ayyangar's thorough Report on Patent Law Revision, which was submitted in September 1959. However, the 1911 Act continued to apply to designs.

DISCUSSION

1970 Patents Act

The Patents Act of 1970 remained in effect until December 1994 for almost 24 years without any modifications. The fundamental tenet of the Act, which is a turning point in India's industrial growth, is that patents are granted not just to give the patentee a monopoly on importing the patented item into the nation, but also to encourage inventions and ensure that they are quickly implemented on a commercial scale. The aforementioned philosophy is being put into practice through compulsory licensing, registration of only process patents for food, medicine or drug, pesticides, and substances produced by chemical processes, which include items like alloys, optical glass, semi-conductors, inter metallic compounds, etc. in addition to chemicals as they are typically understood. Nevertheless, it should be remembered that some goods, such as those used in agriculture and horticulture, atomic energy discoveries, and all living creatures, are not subject to patent protection. So, it was anticipated that the Patents Act of 1970 would strike a suitable balance between the advancement of

technology, the public interest, and the unique demands of the nation, on the one hand, and the necessary and effective protection of patents, on the other.

WTO was established as a result of the GATT discussions in Uruguay. India was thereby forced by contract to update its Patents Act to comply with TRIPS's requirements. On January 1st, 1995, India had to adhere to the first set of conditions. As a result, on December 31, 1994, an Ordinance was enacted that made certain adjustments to the Act but only lasted for six months. Another Ordinance was then published in 1999[8], [9]. The Patents (Amendment) Act, 1999, which went into effect retroactively on January 1, 1995, later superseded this Ordinance. While such patents were not permitted, the modified Act allowed for the submission of applications for product patents in the fields of medications, pharmaceuticals, and agrochemicals. However after December 31, 2004, these applications were only going to be reviewed. If certain requirements are met, the applicants may be granted Exclusive Marketing Rights (EMR) to sell or distribute certain items in India.

The Patents (Amendment) Act, 2002, which was passed in India in 2002, revised the Patents Act once again, extending the patent period to 20 years for all technologies and reversing the burden of proof. The older Patents Regulations, 1972 were replaced by the new Patent Rules, 2003, which went into effect on May 20, 2003.The Patents (Amendment) Ordinance, 2004, which took effect on January 1, 2005, brought the third modification to the Patents Act of 1970. It included provisions for the awarding of product patents in all technological domains, including chemicals, food, pharmaceuticals, and agrochemicals. The Patents (Amendment) Act 2005, which went into effect on January 1, 2005, eventually took the place of this Ordinance. It was passed on April 4, 2005.

Rule for Patents:

The Central Government is authorized to create regulations for implementing the Act and managing patent administration under the requirements of Section 159 of the Patents Act, 1970. As a result, on April 20, 1972, the Patents Regulations, 1972, were announced and implemented. These Regulations were periodically updated until May 20, 2003, when the 2003 Patents Rules took effect and repealed the 1972 Rules. The Patents (Amendment) Rules of 2005 and the Patents (Amendment) Regulations of 2006 further modified these regulations. The most recent changes become effective on May 5, 2006.

The Patents (Amendment) Regulations 2005 include four schedules. The First Schedule stipulates the fees to be paid, and the Second Schedule lists the forms and their texts that must be used in conjunction with different operations under the Patents Act[10]. These forms should be used whenever necessary, and they may be changed if necessary with the Controller's approval. The Third Schedule specifies the kind of patent that must be granted upon patent grant. The Fourth Schedule specifies the expenses that must be awarded in certain Act-related cases before the Controller.

Salicy Elements of the Act

An exclusive right to produce, use, sell, and market an invention is known as a patent. This right is awarded by a nation to the inventor, providing the creation complies with specific legal requirements. Exclusivity of right means that the innovation cannot be created, used, manufactured, or marketed by anyone else without the patent holder's permission. This privilege is only accessible for a brief length of time. Yet, additional regulations of the nation that granted the patent may have an impact on how it is used or exploited.

These laws may deal with things like food, security, safety, and the like. Existing patents in a related field may likewise be a hindrance. According to the law, a patent is a property right and may be given, inherited, sold, transferred, or leased[11]. Even if the patent has already been sold, licensed, produced, or marketed, since the right was granted by the State, it might still be canceled by the State in very limited situations. The patent right is territorial in nature, thus inventors and their assignees must submit separate patent applications in the nations in which they are interested, together with the required fees, in order to be granted patents there.

A patent is a legal document issued by the government to an inventor that enables him to prevent anybody else from financially exploiting his creation for a certain time period, now 20 years. According to the Supreme Court, the goal of patent law is to promote innovative research, cutting-edge technology, and economic development. A limited-time grant of the only right to own, use, or sell a patented technique or product encourages the development of new commercially useful ideas. The disclosure of the invention at the Patent Office is the cost of the monopoly grant; when the predetermined amount of time has passed, the innovation reverts to the public domain. Patents give incentives to people by giving an exclusive right, rewarding them financially for their commercial ideas and recognizing their talent. In order for others to benefit from the new information and advance the technology, the inventor must appropriately reveal the patented innovation to the public in exchange for the exclusive right. So, the disclosure of the invention is a crucial factor in any process for getting a patent.

Patents for goods and processes

Only process patents may be granted for certain types of innovations under Section 5 of the Patent Act of 1970. As an example, the Patent Act of 1970 states that in every other product and process. Patents may be granted and already have been. The Paris Agreement has left it up to each state to decide how to address this problem in its own laws.

With the exception of the exclusion specified in Article 27.1 of the TRIPs Agreement, all innovations, whether goods or processes, in all disciplines of technology, should be eligible for patent protection.The TRIPs agreement allowed for the 2002 amendment of the Patent Act of 1970. According to Section 5 of the Patents Act of 1970 (as it stood after the 2002 changes), only patents covering the production processes of such substances may be granted for innovations that were claimed to relate to food, medicine, pharmaceuticals, or chemicals.

The Section 5 explanation revealed that biochemical, biotechnological, and microbiological processes are included in the definition of "chemical process." The Patents (Amendment) Act, 2005, which went into effect on January 1, 2005, later repealed Section 5 of the Patents Act, 1970, opening the door for the creation of product patents[12].This intentional policy of excluding pharmaceutical ideas from product patent protection may be traced back to the Ayyangar Committee Report, which served as the fundamental inspiration for the Patents Act of 1970. The Committee discovered that between 80% and 90% of Indian patents were controlled by foreigners, and that more than 90% of these patents were not even developed in India. The Committee came to the conclusion that multinational corporations were abusing the system to gain monopolistic control over the market, particularly in respect to essential sectors like food, chemicals, and medicines.

The Patents Act has been updated to take into account India's growing technical capacity as well as the need to harmonize the nation's intellectual property laws with those of other countries. The Act has been updated in order to appropriately defend national and public interests and to satisfy India's international responsibilities. The Act has also been harmonised, modernized, and made more user-friendly.

Length of Patents

According to Section 53, the term of any patent issued after the start of the Patents (Amendment) Act, 2002, as well as the term of any patent that has not yet expired or ceased to be in force on the date of such start, must be twenty years from the date of filing of the patent application.The explanation to Section 53(1) makes it clear that the term of a patent in cases of international applications submitted under the PCT designating India must be twenty years from the date given under the Patent Cooperation Treaty as the international filing date.

If the renewal fee is not paid within the specified time or within any extended period that may be imposed, the patent will expire when the period for payment of the renewal fee expires. Also, the subject matter covered by the stated patent shall not be entitled to any protection upon termination of the patent right owing to non-payment of renewal fee or upon expiration of the term of patent.

According to Rule 80, in order to maintain the validity of a patent, the renewal fees listed in the First Schedule must be paid at the end of the second year following the date of the patent, or at the end of any succeeding year, and they must be submitted to the patent office prior to the end of the second or any succeeding year. The Patents (Amendment) Regulations, 2005's Sub-rule (1A) states that if a request for an extension of time is submitted, the term for payment of renewal fees may be extended to a period not exceeding six months. With the payment outlined in the First Schedule, in Form 4. It is necessary to specify the patent's number, expiration date, and the year for which the fee is being paid when paying the renewal fee. It is possible to pay the yearly renewal costs for a period of two or more years in advance.

PATENTABLE SUBJECT MATTER Patentability Criteria

As previously mentioned, a patent may be issued for an innovation that is connected to any method or item. A discovery is not the same thing as an innovation. Something that had been discovered was something that had previously existed. Not every innovation is eligible for a patent. The criteria for patentability are standards that an invention must satisfy. According to Section 2(1)(j) of the Patents Act of 1970, a "invention" is defined as "a novel product or technique incorporating an inventive step and capable of industrial application."

The innovation must be the subject of the patent, not a finding. The basic tenet of patent law is that only innovative and beneficial inventions are eligible for patent protection. It must thus be both unique and useful. It is crucial for a patent to represent the inventor's original discovery rather than just a confirmation of what was previously known at the time the patent was filed. It is crucial to keep in mind that an improvement on something previously known or a combination of several already known things must be more than a simple workshop improvement and must independently fulfill the test of invention or a "inventive step" in order to be patentable. The combination or improvement must provide a new outcome, a new item, a better or less expensive article than before for it to be patented.

The term "new invention" refers to any invention or technology that has not yet been used in the country or elsewhere in the world or anticipated by publication in any document as of the date of filing of a patent application with complete specification, meaning that the invention has not yet become common knowledge or is not already considered to be among the state of the art. In Raj Prakash v. Mangat Ram Choudhary (AIR 1978 Del. 1), it was determined that invention as is commonly known means to learn something or make a discovery that hasn't been made before. The innovation does not have to be very difficult. The most important factor is that the innovator used it initially. The underlying idea is that any basic innovation

that is claimed is an invention as long as it is something fresh or new, and the claims and specifications must be interpreted in that context. Hence, novelty, inventive step (non-obviousness), and industrial application are the requirements for patentability (utility)

Novelty

A new invention is one that hasn't been previously disclosed in the prior art, which refers to anything that has been published, exhibited, or otherwise made publicly known as of the patent application date (The prior art includes documents in foreign languages disclosed in any format in any country of the world.) The disclosed knowledge must not be found in the "prior art" in order for an invention to be considered innovative. This implies that before the "priority date," which is the date on which the application is originally filed, there should be no previous publication of any material included in the patent application (anywhere in the public domain, either written or in any other form, or in any language).

CONCLUSION

An invention is a product or a technique that, in general, offers a new way of doing something or presents a new technological solution to a problem. A patent is an exclusive right awarded for an invention. Technical details concerning the innovation must be made public in a patent application in order to get one.

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CHAPTER 17

TRADE MARKS

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ABSTRACT:

The ability to carve out one's own niche and position one's brand as distinct and superior is crucial for sustainability as well as future growth in India's highly competitive business environment, where there are numerous local players and an increasing number of multinational corporations entering the country. In this case, intellectual property infringements becomes a significant danger, and trademark infringement and protection are increasingly being given attention. However, a significant amount of trademark infringement involving brand name and brand positioning occurs in the consumer goods sector, which includes both consumer durable and non-durable goods. In India, the pharmaceutical, information technology, and entertainment industries are the ones that receive the most attention for their intellectual property violations. This essay seeks to analyze several case studies of trademark infringement incidents from the consumer goods industry that occurred in India.

KEYWORDS:

Brands, Biosafety,Cryopreservation, Cloning, economic, genetic resource, Intellectual property (IP), Patent, Infringement, Patent, trademark.

INTRODUCTION

An organization's success is recognized to rely on its profitability and capacity to advance shareholder values; brands play a significant part in this. Brands may be an organization's most valuable asset, yet they can also a trademark, also known as a trade mark or trade-mark, is a kind of intellectual property that identifies goods or services as coming from a certain source and sets them apart from those offered by other companies. The owner of a trademark may be a person, a company, or another legal body. A trademark could be found on the product itself, on a label, a voucher, or a box. Sometimes trademarks used to distinguish services are referred to as service marks [1]–[3] .

During the rule of Henry III of England, the first law governing trademarks was enacted in 1266, mandating all bakers to adopt a distinguishing symbol for the bread they sold. The late 19th century saw the emergence of the first contemporary trademark regulations. The world's first complete trademark system was established in France in 1857. The system was altered by the Trade Marks Act of 1938 in the United Kingdom, which allowed registration based on "intent-to-use," established an examination-based procedure, and established a mechanism for application publishing. Other innovative ideas included in the 1938 Act, which served as a template for similar laws worldwide, were "related trademarks," a permission to use system, a defense mark system, and a non-claiming right system.The symbols TM (the trademark symbol) and ® (the registered trademark symbol), which may only be used by the owner of a trademark that has been registered, are used to denote trademarks.

Usage

A trademark identifies the company that owns the brand for a certain item or service. Under licensing agreements, trademarks may be used by third parties. For instance, Bullyland

secured a license to create Smurf figurines, the Lego Group bought a license from Lucasfilm to launch Lego Star Wars, and TT Toys Toys is a producer of licensed ride-on replica automobiles for kids. Brand piracy is the illegal use of trademarks in the manufacture and sale of imitation consumer products.

A trademark's owner has the right to file a lawsuit to prevent infringement. For this kind of action to be pursued, official trademark registration is often a need. Common law trademark rights are acknowledged by the US, Canada, and other nations, which enables legal action to be taken to defend any unregistered brand that is already being used. Yet, compared to registered trademarks, common law trademarks often provide the possessor with less legal protection.It is common legal advice that trademark owners should always use their trademarks as adjectives modifying a generic product name, set off with capitalization or a distinctive typeface, as a safeguard against the trademark becoming the generic name of the product, as the purpose of the trademark is to identify a particular source of the product rather than the product itself.

Hence, rather than "some Lego" or "Legos," say "LEGO bricks." The producer's name itself may be used as a noun and is a "trade name" as opposed to a trademark[4], [5].The Trade Marks Act of 1940 established legal protection for trademarks in India, which was followed by the Trade and Merchandise Act of 1958 and, eventually, the Trade Marks Act of 1999, which is now in effect, in order to keep up with key advances on the world stage. Trademarks show that a company's goods have unique qualities, generating a significant amount of income year after year. In other words, a company's trademark for its goods and services is vital to its existence. It is not required to register a trademark in India, however it does rely on how well-known or reputable the brand is, and it may not be a registered one to demonstrate its uniqueness. The suffix TM is used to simply indicate that a mark is held by a firm and not to indicate that it has been registered; it may also be used to indicate that registration of the mark is in progress. The only right to use a trade mark for the products and/or services is granted to the trade mark holder upon registration.

The sign is put next to the trademark if it has been registered. Anybody who uses a mark, name, sign, or symbol to portray the products or services of another as their own is breaking the law. A civil wrong known as passing off results from this portrayal. While there are millions of instances of trademark infringement, we have sought to analyze it here using a few significant case examples.The Supreme Court clarified the difference between a trade mark and a property mark in the case of Sumat Prasad Jain v. Sheojanam Prasad and Ors., AIR 1972 SC 413. The difference between a trade mark and a property mark, according to the Apex Court, is that the former indicates the manufacturing or quality of the items to which it is connected, whilst the latter indicates ownership of those things. In other words, a trade mark is concerned with the products, but a property mark is concerned with the owner[6]. Even if a portion of a person's moveable property leaves his possession and ceases to be his, a property mark linked to it remains.

There is no need for proof of earlier use of the mark under India's "first-to-file" system of trade mark law. A trade mark application may be submitted based on the mark's "planned to be used or intent-to-use" status or on evidence of usage. Under the Trade Marks Act of 1999, the word "use" has taken on a wide definition and is no longer limited to the actual presence of the products in India. The use of a trademark in India is also regarded to occur when it appears on the Internet and is published in foreign periodicals with a readership in India. The "Whirlpool case" [N. R. Dongre v. Whirlpool Corporation, 1996 (16) PTC 583], one of the first significant rulings in this area, established that a rights holder may pursue a passing-off lawsuit against an infringer based on the reputation of its trade marks abroad and that the

presence of the goods or actual use of the mark in India is not required. If the rights holder has established a reputation and goodwill for the mark in India via marketing or other methods, it would be sufficient.

Descriptions of Key Terms Used In the Trade Mark Act Of 1999

Trade mark

A trade mark is any term, phrase, symbol, or design, or a combination of words, phrases, symbols, or designs, that is used in commerce to identify and differentiate the source of products or services provided by one firm from those of other businesses.As previously mentioned, the definition of "trade mark" under Section 2(1) (zb) has been expanded to mean a mark that can be represented graphically and that can distinguish the goods or services of one person from those of others. This definition now encompasses both goods and services and may include the shape of the goods, their packaging, and a combination of colors.The term "mark" refers to any design, brand, heading, label, ticket, name, signature, word, letter, and number, form of the product, packaging, or combination of colors. Article 2(1) (m). Due to the broad nature of the term, any mark that may be graphically depicted and can identify one person's products or services from those of others will be included in the definition of trade mark[7].

Service

The addition of the new definition of "service" is intended to benefit businesses that provide services like banking, communications, education, finance, insurance, chit funds, real estate, transport, storage, material treatment, and processing as well as businesses that provide boarding, lodging, entertainment, amusement, construction, repair, or the dissemination of news or information. The only difference between a service mark and a trade mark is that a service mark is used to identify and differentiate the provider of a service rather than a product. A mark for products often appears on the item or its packaging, whereas a service mark typically appears in advertisements for services[8].The term "registered trade mark" as used in Section 2(1) (w) now refers to a mark that is genuinely listed on the Register and is still in use. Instead of every seven years as required by the current Act, a trade mark's registration should be renewed every 10 years.

Assurance Trade Brand

"Certification trade mark" refers to a mark that can distinguish between goods or services that it is used in connection with and that are certified by the mark's owner in terms of origin, material, mode of manufacture of goods or performance of services, quality, accuracy, or other characteristics, from goods or services that are not so certified and are registrable as such under Chapter IX in respect of those goods or services in the name, as owner.

The introduction of "collective mark" will benefit the traditional Indian family trade marks. The new definition of "collective mark" has been supplied for the advantage of members of an association of individuals (but not partnerships) [9] . A trade mark used to differentiate the products or services of members of an organization of people (not a partnership within the definition of the Indian Partnership Act, 1932) that is the mark's owner from those of others is referred to as a "collective mark" under Section 2(1) (g) of the Act.

Trade Specification

Trade description, as defined by Section 2(1)(za), refers to any description, statement, or other indication, whether direct or indirect, that relates to any of the following: I the number,

quantity, measure, gauge, or weight of any goods; (ii) the standard of quality of any goods or services according to a classification that is generally accepted or used in the trade; or (iii) the fitness for use, strength, performance, or behavior of any goods, being a "drug," as.

The Trademark Process

Searching & Planning

Forming a solid conception of the mark you wish to register is the first step. Remember that a trademark must be used or intended for use in commerce in order to be considered legitimate. With your mark in mind, give us a call or fill out our online form, and we'll do a preliminary search at no charge for you. This will enable us to check for any potential contradictions or chances of misunderstanding[10], [11]. With our simple search, you avoided paying the nonrefundable filing costs if your mark is already in use and cannot be registered as a trademark. Also, we will provide suggestions on how you may improve or amend your mark depending on the results of our search.

Finding Products and/or Services

A list of the products and/or services that will be used with the mark must be included when registering a trademark. They are the products or services that will bear, exhibit, or otherwise be connected to your trademark. The class or classes with which your trademark will be registered will be determined using this list (read more about Trademark Classes).

Show your Mark

If your mark consists of more than just words or has a distinctive design, you must provide a precise description of it. One of two forms must be used when submitting a trademark:

- Standard character format: This format is used for text-only markings without any indication of the font's style, size, color, or other design component.
- Gives you more freedom to use your mark in any way by giving you greater rights to do so.
- Stylized/Design format: This format is for marks that you would want to protect that have a design element, a certain style/appearance, or a color.

Providing a Sample

To prove that your mark is being used in commerce, you must provide a sample of usage. The specimen should show your mark being used on the linked products and/or services. For further information, see the Samples of Usage page.

Legal Review and Publication

Your mark will be authorized for publication after your application has been received and the USPTO examining attorney has determined there are no grounds to reject the mark. Any business or person will have 30 days after publication to submit objections. The USPTO will either submit a Certificate of Registration or a Notice of Allowance if an opposition is not filed or is defeated [12] .

Notification of Allowance or Certificate of Registration

If your application was submitted under the heading "use," your trademark will be registered and a certificate will typically be granted 12 weeks following the date of publication.

A Notice of Permission will typically be issued 12 weeks following the publication date if your application was submitted with the "intent to use" defense. After receiving the Notice of Allowance, you have six months to submit an allegation of use and a specimen (read about Intent to Use vs In Use for more details).

After Registration

With the right use of an Affidavit of Use, your trademark will be granted a 10-year term. At the conclusion of each term, you have a continuous 10-year renewal option for your trademark.

DISCUSSION

Trade between nations has significantly increased since the onset of globalization. A rise in unfair commercial rivalry between businesses and between nations is the downside, however.By infringing on trademarks and deceiving consumers, this illegitimate commerce has significantly increased.

These examples make it clear that businesses today that assume they have registered trademarks and that no one else may use their mark for any reason without authorization are mistaken. If a trademark is protected by law, there are ways and means to violate that trademark as well. We believe the following four factors are the primary causes of trademark infringement: To promote a business using another person's reputation in order to make quick money; to damage the reputation of a competitor or the owner of a trademark; to distribute counterfeit, subpar goods in the market under the name and trademark of an already established good in order to make money quickly.

Formerly, the definition of passing off only applied to misrepresenting products. Nevertheless, it currently covers a wide range of unfair business practices and unfair competition, and is usually understood to occur when one person's or company's actions harm the reputation connected to those of another person's or company's actions. Both a cause of action for passing off and a cause of action for infringement are ways to protect intellectual property against illegal use of a mark that is seen to be confusingly similar to someone else's trade mark. The extent of the inquiry in an action for passing off differs from that in one for trademark infringement, however. A common law remedy known as a "passing off action" involves a person misrepresenting his own property as belonging to another person. An action for infringement, on the other hand, is a legal remedy given to the registered owner of a registered trade mark to uphold the exclusive right to use the mark in connection with certain products.

The Trade Marks Act of 1999 does not define passing off, however it is mentioned in certain of the Act's provisions. The provisions of the Act are unaffected by the rights of action against any person for misrepresenting products or services as belonging to another person or as services rendered by another person, according to Section 27(2) of the Act. No suit for passing off arising from the defendant's use of a trademark that is identical to or misleadingly similar to the plaintiff's trademark, whether registered or unregistered, shall be instituted in any court inferior to a District Court having jurisdiction to try the suit, according to Section 134(1)(c) of the Act. The remedies for passing off resulting from the use of a trademark are described in Section 135. The plaintiff in a passing off lawsuit must demonstrate that the defendant is passing off his products as the plaintiff's and that there is a likeness in the trade names or markings. The "Classical trinity" of passing off refers to the three components—goodwill, deception, and damage that make up the tort of passing off. Damages or an injunction are two possible remedies.

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CHAPTER 18

COPYRIGHT

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ABSTRACT:

The court has granted the inventor of an invention an exclusive legal right known as copyright, which is a subset of intellectual property rights. As the creator, he, she, or the group has the legal right to receive financial and other advantages related to the work. A violation of copyright laws might result in a number of legal repercussions. Yet, libraries are legally allowed to utilize copyrighted content for research and scholarly purposes without the copyright holder's consent. Also, the Copyright Act makes any infringement or violation of fair use of library materials illegal. In this article, an effort has been made to comprehend copyright concerns in connection to library resources and to emphasize protection, infringement, fair dealing, and limits under the 1957 Indian copyright legislation. In addition, highlighting the roles and duties of librarians in relation to copyright legislation.

KEYWORDS:

Biosafety,Copyright, Cryopreservation, Cloning, economic, genetic resource, Intellectual property (IP), Patent.

INTRODUCTION

The primary goal of intellectual property law is to encourage the development of a wide range of intellectual resources. To do this, the law grants individuals and organizations property rights to the knowledge and intellectual products they produce, often for a certain period of time. They can, thusget profit from them, providing economic incentive for their development. Depending on the level of protection provided to inventors, these economic incentives are expected to promote innovation and advance the technological development of nations.

Copyright may be a privilege that gives the creator of a particular work the only authority to control how it is used and distributed. Usually, this is only available for a short period of time. The exclusive rights do not seem to be unrestricted; rather, they appear to be constrained by copyright law's restrictions and exceptions, as well as by simple usage. One major drawback of copyright is that it only protects the unique presentation of ideas, not the underlying concepts.

Academic research is the careful examination of a certain issue, subject, or crisis in order to ascertain its facts or guiding principles. The question of copyright emerges when there is scholarly study.

We discover that certain literary works, such as articles, are protected by copyright while others are not when we look for them. The copyright for an author's works may or may not exist. The world may utilize a work that is not copyrighted for its own advantage, but some writers limit the use of their works for personal gain by copyrighting their creations [1]–[3] .

The 1957 Copyright Act

India's copyright laws are governed by the Copyright Act of 1957. Using Copyright. Act became operative in India on January 21, 1958. India's history with copyright laws dates back to the British Empire's colonial rule. The first copyright law passed in India after independence was the Copyright Act of 1957, which has subsequently undergone six amendments. The Copyright (Amendment) Act 2012, which was passed in 2012, was the most recent amendment. The Universal Copyright Convention of 1951, the Berne Convention of 1886, the Rome Convention of 1961, and the Agreement on Trade Related Aspects of Intellectual Property Rights are among the important international treaties regulating the area of copyright law that India is a party to1 (TRIPS). Yet, neither the WIPO Performances and Phonograms Treaty nor the WIPO Copyright Treaty include India as a signatory.

Section 3: Publication's intended audience

Except as otherwise expressly provided in this Act, the following are not included: I in the case of a literary, dramatic, musical, or artistic work, the subject of copies of the work to the people in adequate quantities; (ii) in the case of a cinematograph film, the sale or hire or offer for sale or hire of the film or copies thereof; and (iii) in the case of a record, the issue of records to the public in adequate quantities.

Section 13. Works protected by copyright:

The following types of works are subject to copyright protection under the terms of this act: (a) Original literary, dramatic, musical, and artistic works; (b) Cinematograph films; and (c) Recordings.

"Foreign Works in India" Protection

The Indian Copyright Act of 1957 grants overseas writers and owners of works the same

According to the Act, Indian nationals are entitled to security in India. The Copyrights Act of 1957 introduced significant changes and brought the copyright law in the nation in line with advancements in the IT industry, whether it be in the field of satellite broadcasting, computer software, or digital expertise. This was done in order to keep pace with the need for global harmonization. The revised legislation includes safeguards to protect the rights of performers as outlined in the Rome Agreement.Along with participants in the industry through associations and organizations like National Association of Software and Service Companies (NASSCOM), National Initiative against Piracy and Counterfeiting (NIAPC), etc., the government is also taking action to combat piracy in the software, movie, and music industries.

Copyright in the Classroom

The learning process depends on the utilization of resources that are subject to copyright restrictions. There are educational materials in every media that copyright law recognizes as "works." The legislation has a variety of exceptions that allow for the use of all forms of copyright work for certain educational purposes, which lessens the burden on educators and students who want to utilize copyright materials as part of their teaching and learning process.

It does not follow that you may ignore copyright if you are utilizing resources for educational purposes. What it does imply is that one must be aware of when it is OK to utilize a work without asking permission or purchasing a license and when doing so requires permission or a license. For instance, the Educational Recording Agency will need a license from a school

or institution if it wants to record television programs for use in the classroom[4]. Every educational institution typically has a person in charge of copyright matters. Find out who is in charge of that position at your place of study or employment as a starting step. They should be able to explain to you whether or not a relevant licensing scheme applies or if your use of a work is permitted under an exemption. In general, it's important to remember that copies made for educational reasons may not be used for commercial purposes.

Copyright Concerns in the Classroom

Copyright concerns in education are a frequent occurrence that may be studied in two ways:

Public Domain 1.

The term "public domain" refers to the condition of belonging to or being completely available to the public, especially without being constrained by copyright or other legal restrictions. Any artistic creations to which no intellectual property rights apply are included in the public domain. Such rights might be incorrect, out of date, forfeited, or explicitly waived. Public domain works are creative creations that are not covered by copyright. These contains works that have endured for a sufficient amount of time[5]. Moreover, it includes government-produced works that are not protected by copyright. Even if anybody may use or even sell a work that is in the public domain, the original author must still be given credit.The rights of the original inventor are not entirely abolished by public domain. Always give credit, but feel free to make major changes to the original work.

Copyright and Licensing When someone creates a work, they are the exclusive owners of the copyright, which gives us the sole ownership of that work. He has control over who else can use the work and how. So, in order to use a work protected by copyright, a license must be granted by a relevant body.

There may be a variety of restrictions and requirements for copyright and license assignments. Restrictions may include restrictions on the kind of use that the work may be put to, the amount of time for which a license is valid, and payment obligations[6]. It is usually a good idea to put the specifics of a license in writing, whether you are giving or obtaining one. Also, it is a good idea to date and have both the licensor and licensee sign the written record of the license.

Fair Use in Research and Education

According to the fair use doctrine, you are permitted to use copyrighted material in some circumstances without first getting permission from the copyright owner[7], [8]. One of the restrictions on copyright, known as fair use, seeks to strike a balance between the rights of copyright holders and the public interest in the distribution and use of creative works by permitting certain limited uses as a defense to accusations of infringement.

Faculty have a huge chance to make sensible, constrained usage of copyrighted materials thanks to fair use. Several behaviors that are common at the university, such as copying, pasting, uploading, publishing, and many others, may violate intellectual property rights or may be considered fair use. Examples include:

- Copying and pasting content into cutting-edge teaching tools
- Publishing educational resources.
- Creating databases of works protected by copyright for study.
- Distributing books, articles, and other resources among students.
- Establishing online libraries.
- Setting copies aside in libraries.

To determine whether your usage is lawful, you must do a fair use analysis. Use of copyrighted material for academic purposes:

Benefits and Disadvantages

The usage of copyrighted materials for academic purposes may have both advantages and disadvantages.

1. **Pros:** It is undeniably advantageous for both instructors and students when a copyrighted material is utilized for academic purposes. The copyrighted works almost always include some useful and significant elements that reveal little-known truths and enhance student learning while also assisting teachers in their instruction.
2. **Drawbacks:** While fair use of a copyrighted work can be advantageous, it can also be detrimental if faculty members and students use it in their own names rather than in a fair manner, giving the impression that the author's rights have been violated. This will immediately violate the author's right to be protected.

DISCUSSION

Ownership of Copyright in India

Chapter 17 Initial copyright holder: Section 17 of the Copyright Act states that a person is the owner. The publisher of a newspaper, magazine, or similar periodical shall, absent any agreement to the contrary, be the primary owner of the copyright in any literary, dramatic, or creative work created by the author during the course of his employment by the publisher under a contract of service or arrangement for the purpose of publication in a very newspaper, magazine, or similar periodical.

It has two components:

(a) When on the job - It is generally accepted that the creator of a work is the only owner of the copyright to that work. Nonetheless, if three requirements are satisfied, a company may have rights over an employee's works:

1. The continuation of an employment contract.
2. The creation of a work while doing job-related duties
3. The lack of a contract that makes alternative arrangements.

(b) Not in the course of employment - When a person is not working for anybody, he or she will be the sole proprietor of the work they have produced.

When using protected works infringes on intellectual property.

Section 51 states that the following situations constitute infringement of copyright in a work: (a) When a person, without a license granted by the owner of the copyright or the Registrar of

Copyrights under this Act or in violation of the terms of a license so granted or of any condition imposed by a competent authority under this Act— I does something for which the owner of the copyright is granted a special right by this Act, or (ii) permits payment for use of any location for communicating the work to the public where such communication constitutes a violation of the copyright in the work, unless he wasn't aware an infraction had occurred[9].

(b) Any violating copies of the work that are made for sale or rent, sold, rented, or offered for sale or rent via trade displays, distributed for commercial gain or to the extent that the owner of the copyright is harmed, shown through commerce in public, or imported into India are prohibited.

When using copyrighted materials doesn't violate their rights

The provisions of S. 52 of the Copyright Act of 1957 allow for some conduct that would not constitute a copyright infringement, that is, simply engaging with a literary, dramatic, musical, or artistic work that is not, for the purposes of, a computer program.

Use of copyright in educational institutions (Limitations)

The sole purpose of the copyright material utilized in educational institutions is to benefit the students. It is copyrighted to the point that it can only be accessed from a certain institution. Despite so, it can only be utilized with institutional internet. It is done in order to keep data properly guarded and prevent any other institution or individual from using it unjustly[10]. When a resource is only available on campus, it may sometimes be a problem for students since they may not always be able to do their work there. But, if the resource is available everywhere, it makes the task much simpler.

For instance, manupatra is a website that provides comprehensive legal information, but the institution must first purchase a membership before students can access it outside of the institution's campus and internet. This presents a problem because students cannot access the website from anywhere else. Teachers and students are only allowed to use the campus, where it is not always feasible to complete all of the work, and are prohibited from using from their homes.

New Threats to the Traditional Copyright Regime at Academic Institutions

In India, educational institutions are using Technology more and more. At practically all educational levels, the internet and intranet have been included into the teaching-learning process. Virtual learning environments are already a reality. Nowadays, distance learning is a quick procedure. Students may at their leisure access information saved on any website, anywhere in the globe. Without having the pupils in front of them physically, teachers may still instruct. Blackboards have been replaced with computer displays. Instead of being transmitted on paper, notes and resources are now shared over computer networks. The effects of all these advances on copyright concerns in educational institutions are significant. Although some of the old problems have taken on new dimensions, whole new problems have also emerged.

In the context of digital technology, ownership of works produced for and by educational institutions is expected to give rise to new concerns. Even though academicians may continue to own the rights to the books and papers they write on the subjects they teach, the ownership of the copyright in any course materials or other teaching materials they produce while performing their duties as university employees may give rise to legal disputes between the institutions and the authors[11]. For instance, if a professor created and taught a certain course at a university, continued to do so for a while, then left that organization and joined another, it may become problematic for him to teach the same course at the new organization without violating copyright. The paradigm of job production at the educational institution has also changed as a result of technological advancements. The creation of multi-media education kits, which are utilized primarily in distance learning, often involves collaboration and association of a number of people from the faculty and staff.

One area where the ownership problem can take on a new dimension is computer education. As part of a class project, the professors and students may develop new software applications that may subsequently be used for commercial purposes. There is no reason to believe that the program that was produced was their original idea, yet it was made using classroom time, materials, and institutional resources. Such circumstances leave up the possibility of ownership issues between the institution and the writers.

- Copyright law remedies for violation of rights
- In India, there are two different sorts of remedies available for copyright violations:
- Two options: civil and criminal remedies
- Civil Redress for Copyright Violations

According to Section 55 of the Copyright Act of 1957, the following legal remedies are available:

1) Interlocutory Orders

The granting of an interlocutory injunction is the most important remedy. In the majority of cases, the application submitted is for interlocutory relief, albeit sometimes the issue progresses beyond the interlocutory stage. The following three conditions must be met in order for an interlocutory injunction to be granted.

The criteria established by the Agreement on Trade-Related Aspects of Intellectual Property Rights are equivalent to the copyright law of India (TRIPS). The Berne Convention for Protection of Literary and Artistic Works, 1886, and the Universal Copyrights Convention have both been clearly reflected in the Copyright Act of 1957 (the Act), which has undergone multiple changes.

The Act efficiently aligns Indian copyright law with technological advancements in order to comply with international standards for organization and harmony. The Act outlines the minimal requirements for protecting writers' rights and for fostering and rewarding their creativity. The creativity of authors, actors, singers, architects, and other creatives is given protection.

Ownership and Authorship:

Any individual may be granted full or partial ownership of the copyright to an existing work or future work at the owner's discretion and free choice. The person who is transferring the rights, or any of his authorized representatives, must make the assignment in writing. The granted rights, as well as the length and the scope of its geographical authority, must be specified in the assignment document. Together with any limitations, extensions, and terminations on the conditions and contractual terms agreed upon, it must also include the compensation that the assignee must pay to the assignor.

Rules for registering:

Copyright status is established as soon as the work is produced. It is assumed that the person who really developed the work is its owner and author, hence formal acquisition is not necessary. Nonetheless, the copyright authorities stress that the "work" is legitimately registered and that the data in the copyrights register must have probative value.

Validity of copyright:

According to Indian Copyright Law, a copyright interest lasts for 60 years. The length of the copyright for original literary, musical, and theatrical works is based on the year after the

author's death. The period is measured starting from the date of publication for cinematograph films, photographic films, publications, and other works created by international organizations.

Civil action for infractions:

Before taking legal action against the infringement, there are a few crucial factors to take into account. These are the prerequisites:

1. Evidence that the copyrighted material belongs to you
2. A striking resemblance between the copied work and the genuine one

The Copyright law requires and stipulates a step-by-step process to begin and proceed in the following way:

1. A legal notification that should be given to the accused infringer
2. Section 55 of the Act allows for the filing of a civil lawsuit against the accused, and the court has the authority to issue a preliminary injunction to stop the infringement of any sort.
3. In accordance with Sections 55 and 58, a pecuniary remedy may be awarded in cases where a claim is made for profits obtained via illegal activity, conversion damages, or compensating damages.
4. In addition, the Anton Pillar Order would forbid the accused from handling the counterfeit products or even from destroying them. It enables the owner to enter the property, search it, and remove any items that are in their possession. The offender must provide precise information on the buyers and suppliers of the items that have been infringed upon, as ordered by the court.
5. In addition, the Mareva injunction serves as a directive that allows the court to secure standby possession of the counterfeit items in order to stop disposal.
6. To find and acquire crucial information from a third party source, the Norwich Pharmacal Order might be obtained.

Copyright Organizations:

A recently evolved idea is collaborative management of copyright. In this case, a society or group of owners is in charge of managing and protecting the copyright work. It should be highlighted that an owner cannot monitor how his copyrighted work is being used. The copyright owner has the power to monitor consumption of the work after joining a society or an international organization. The likelihood of the copyright owner being a member of international treaties and having agreements with similar conventions in other nations is high. The greatest way for owners to ensure greater protection and achieve the most effective use of the copyrighted work and profits from it is to join such organizations. One kind of legally recognized collective administration created by a grouping of copyright owners is a copyright society. For doing business in relation to one kind of work, there is only one registered society.

The first case is R. G. Anand v. Deluxe Films [AIR (1978) SC 1613].

It is crucial to note that the Hon'ble Supreme Court of India in this case decided that the play and the film were surrounded by same topic. Yet, it is widely accepted that a straightforward concept should not be treated as the subject of copyright. In this instance, the narrative presented two interpretations of the topic. Also, it addressed the problems brought on by dowry and caste prejudice.

Given that there was just a passing similarity to the original play and that it was not a faithful reproduction, it was determined that there had been no copyright infringement. In this case, the court declared that the differences outweighed the parallels more. As a result, if the play and the movie were seen side by side, a wise person would not get the conclusion that they are comparable. All of the elements—including the finale, representation, and each scene's breakdown are vastly different from how they are shown in the play. Ultimately, the circumstances of this case did not constitute copyright infringement.

Eastern Book Company and Others v. D.B. Modak and Others [(2008) 1 SCC 1]

In this instance, Eastern Book Company ("EBC") was a partnership company that had been established specifically to print legal literature. Respondent-defendant Spectrum Business Support Services Ltd. introduced software that was made available on CDs. EBC said that the material and case laws on the CDs were organized and formatted exactly like those in the legal volumes it had produced. The defendant-respondent was given permission to use the CDs throughout the pendency and term of the appeal after EBC applied for an interim injunction, which was dismissed. The Supreme Court ultimately ruled that the respondents were permitted to sell the judgment texts on CDs, but they were not permitted to use the editorial annotations, headnotes, or footnotes that appeared in the plaintiff's journal. It was also ruled that the defendant may not utilize the altered version's paragraphs as internal references. According to the Supreme Court, the High Court's decision should be changed in proportion to the already-granted temporary remedy.

CONCLUSION

As a copyright registration acts as the first line of ownership documentation, it is essential to safeguard the work from unauthorized use or replication. Moreover, it enables the registered copyright owner to increase the work's worth via licensing, assignment, and fund raising.The Copyright Act of 1957, the Copyright Regulations of 1958, and their subsequent changes aim to safeguard both the rights and interests of those who create and possess intellectual property as well as the general public's interests.It should be highlighted that the Act is a thorough law that is built on the tenet that the owners' creations cannot be stolen. The English and American intellectual property laws have been taken into consideration while writing this Act. The goal of this law is to protect both the owner and the "work." In India, copyright is seen as an architectural creation that can only be used in India, the nation from where it originated.

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CHAPTER 19

PATIENT-REPORTED OUTCOME MEASURES, COPYRIGHT OR TRANSLATIONS

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ABSTRACT:

There are concerns about how copyright protection applies to PRO equipment in general and even to their translations in particular as patient-reported outcome (PRO) assessment expands. The main goals of this reflection paper are to: 1) aid PRO instrument authors in understanding the fundamental laws of intellectual property as well as copyright that safeguard the integrity of their instruments as well as derivatives; and 2) offer suggestions to PRO instrument authors and users to help prevent misuse or abuse. As PRO devices are works of imagination, both national intellectual property (IP) rules and the international Berne Convention are completely applicable. As a result, the person or legal organization that owns the copyright of a PRO document, also known as the copyright holder, owner, or claimant, is given exclusive rights that are broken down into two primary categories: moral rights and economic rights. The three main moral rights are: the right of attribution (or right of paternity), which is the right to claim authorship of the work; the right against false attribution; and the right to integrity, which is the right to protest any mutilation, distortion, or change of the work. The exclusive rights of the author to create or provide permission for reproduction, the creation of derivative works, distribution, and public communication are known as economic rights.

KEYWORDS:

Copyright, Intellectual Property, Patent, Patient-Reported Outcome.

INTRODUCTION

The Translation and Cultural Adaptation Special Interest Group (TCA-SIG) has three main goals: to identify and advance research methods and patient-reported outcome (PRO) instrument cultural adaptation; to provide an evidence database on translation and cultural adaptation of PRO instruments; and to increase awareness of cross-cultural issues in the creation and application of PRO instruments in ISOQOL. The TCA-copyright SIG's subgroup has concentrated its efforts on problems relating to the copyright of original works and their derivatives, such translations[1]–[3]. The main goals of this reflection paper are to: 1) assist PRO instrument authors in understanding fundamental copyright and intellectual property laws in order to safeguard the integrity of their instruments and derivatives; and 2) offer suggestions to PRO instrument authors and users in order to prevent any abuse or misuse.

Definition and legal implications of copyright

Any original works of authorship that are permanently fixed in a physical medium of expression are protected by copyright, according to the US Copyright Act. The term "original work" refers to a piece of work that has not been given to another person, copied from their work, or is based on it, and at least demonstrates a minimal degree of ingenuity.

A "derivative work" is a work "based upon one or more preexisting works, such as a translation, abridgment, condensation, or any other form in which a work may be recast, transformed, or adapted. Copyright is a group of exclusive rights that grants the owner of the copyrighted work the exclusive right to I reproduce the work in copies; (ii) prepare derivative works; and (iii) distribute. National copyright laws and the Berne Convention for the Protection of Literary and Artistic Works, as updated in Paris on July 24, 1971 (hence referred to as the "Berne Convention"), govern copyright on a global scale. Each time a member nation ratified the Berne Convention and therefore became a party to it, that nation put it into effect. For instance, the USA implemented and joined the Berne Convention on March 1, 1989 after ratifying it on October 31, 1988, by passing the Berne Convention Implementation Act of 1988[4]. On December 5, 1887, it was adopted by a number of other nations, including Belgium, France, Germany, Italy, Spain, Switzerland, and the United Kingdom. The World Intellectual Property Organization (WIPO) website has a list of the countries that have ratified the Berne Convention, together with the dates when each of those countries put the agreement into effect.

The Berne Convention seeks to effectively and uniformly safeguard authors' rights in their creative, scientific, and literary works on a global scale. The copyright is said to be automatic (belongs to the "author" of the work; no registration is required) and grants the copyright holder minimal exclusive rights that are split into two primary categories: moral rights and economic rights.Moral rights include the following:

1) The right to claim authorship of the work (right of attribution or right of paternity),
2) The right against false attribution, and
3) The right to object to any mutilation, deformation, modification, or derogatory treatment of the work, which constitutes any act related to a work that is in any way harmful to the author's honor or reputation.

The term "economic rights" refers to the only ability of the author to profit commercially from the use of his or her creations and to provide permission for their public communication, distribution, and replication. In contrast to economic rights, moral rights safeguard non-economic interests and cannot be sold, given away, or otherwise disposed of[5], [6]. Nevertheless, the restrictions of use of an instrument and related payments are established entirely by the copyright holder. Even though the work is protected by copyright, the copyright holder has the right to determine whether it may be accessed without payment or just by a certain group of people.

The copyright has a temporal restriction. Copyright typically lasts for the author's lifetime and ends 50 or 70 years after his or her death (depending on national laws).A piece of art is said to be in the "public domain" if it is not covered by copyright or any other kind of intellectual protection such as a trademark or patent. This may be the result of the copyright having run out or the decision of the original author to forego copyright and allow the public to freely use, edit, and adapt their work.

How do patient-reported outcome (PRO) instruments fall under intellectual property laws?. PRO tools provide proof of the patient's claimed health condition[7], [8]. They are often used to gather information during clinical studies and to reveal the patient's perception of the effectiveness of the therapy. As PRO instruments are used to gather health data, regulatory agencies like the Food and Drug Administration and the European Medicines Agency place a premium on the validity of their content (instructions, items, and answer categories) as well as their measurement capabilities. Each content change must be justified and recorded

according to these agencies' guidelines and revisions often call for further proof to back up the instrument's content validity[9].Regardless of whether they fall within the category of scientific works, PRO instruments are considered literary works that are protected by copyright because they are original works of the intellect that were expressed in a permanent, physical form. Hence, PRO instruments are subject to all applicable national IP laws as well as the Berne Convention on a global scale. As a result, the copyright claimant of a PRO instrument is the owner of the work's moral and financial rights, as stated in the chapter above section. The integrity of the PRO instruments is safeguarded by the moral rights, which is crucial for regulatory reasons, as previously noted.

The identification of the copyright owners, however, might be difficult if they are not expressly identified on the instrument[10]. This can result in infringement as well as misuse or abuse of the instrument. Several organizations (such as a researcher, sponsor, or institution) may be eligible for copyright ownership in certain circumstances. The issue of copyright ownership may also come up again at the moment of publishing or distribution of the work since the publishers or the journal may get some or all of the economic rights.To prevent any future doubt or argument over ownership, it is crucial to clearly identify the copyright holder (via a copyright notice) immediately on the instrument and to establish a contract from the creation phase through the derivative phase.

DISCUSSION

Copyright for PRO instrument translations

Laws and accepted guidelines

As previously said, only the original instrument's copyright owner has the authority to permit the creation of a translation. The organization doing the translation, which creates a derivative work, is responsible for first securing the required authorization from the original's owner of the copyright; otherwise, the translation would be seen as a copyright infringement. Making ensuring that the translation is accurate to the original is another duty of the translator (or Translation Company)[11], [12]. A moral right of the original author will be violated if the translation does not accurately reflect the original or changes or modifies the original in any way.Copyright laws may provide protection for translators as the "author" of their translations.

For instance, Article L. 112-3 of France's "Code de la Propriété Intellectuelle" (Intellectual Property Law) stipulates that translation writers are entitled to the same rights as authors, without affecting the rights of the original author (on the condition, of course, that the copyright holder of the original work gave its authorization). For instance, translations may fall under the definition of a "work made for hire" in the USA if the parties expressly agree in a written agreement that the work shall be regarded as a work made for hire. Similarly, a work prepared by an employee while performing work-related duties may also fall under this category. The commissioning party is regarded as the legal author in this situation. This is an exception to the usual rule that the author of a piece is the person who actually produces it. Internationally, the United Nations Educational, Scientific and Cultural

Organization (UNESCO) has adopted a recommendation that states: "Member States should accord to translators, in respect of their translations, the protection accorded to authors under the provisions of the international copyright conventions to which they are parties and/or under their national laws, but without prejudice to the rights of the authors of the original works translated.We provide a number of guidelines to PRO instrument developers and users in order to avoid disputes, misuse, and abuse of PRO instruments:

Safeguard your copyright

PRO instruments are "de facto" legally protected in nations that have accepted the Berne Convention, which is a considerable improvement in copyright protection. While not required in some nations, copyright registration is advisable, particularly in the event of a possible copyright violation. Proof of possession a posteriori is never simple. The safest approach to demonstrate the author's ownership and anteriority on the instrument is to register copyright with local copyright offices or by any other means, notwithstanding the seeming contradiction.

Hence, in order to prevent a dispute over ownership and to safeguard the integrity of the work, authors are urged to register their works with the local copyright office in their country of residency or seek help from private practices or businesses that specialize in copyright protection. The copyright claim becomes public information after registration.

Write a contract

Ownership of PRO instruments and their derivatives should be spelled out in a written agreement and determined from the very beginning (during the instrument development phase). Copyright ownership should be considered at every stage of the questionnaire's existence.

Use caution while publishing

In a scholarly publication, you shouldn't publish the instrument in extenso (in its entirety). Just release excerpts of the instrument, if at all feasible. If not, it must be specified in the contract between the author and the publisher that the author owns the copyright to the actual piece of music.

Establish rules

Consider the use restrictions for your tool (such as the licensing agreement, translation agreement, data use restrictions, fees, etc.) and have them documented in writing. It is important to stress that copyright should not be seen as a barrier to simple access and usage; access to a work protected by copyright need not involve paying a royalty; access may even be free.

Be sure to display your copyright notice

Even though the copyright notice is not required, it is nonetheless advantageous to let the reader or user know that the work is protected to reduce copyright infringement. The word "copyright," a "c" in a circle (), the date of publication, and the name of the person who owns all copyright rights in the published work should all be included in a copyright notice.

Provide special copyright holders access to original works and derivatives. To unify and make conditions of access and usage easier, a PRO instrument's copyright should be controlled by a single copyright holder, preferably the original creator. This includes translations and electronic versions.

Centralize the supply chain

To (a) make questionnaires more accessible, (b) maintain accurate information about them in accordance with regulatory requirements, and (c) control their use, for example, by avoiding multiple translations for the same language, the distribution should be centralized, ideally by the original author.

Seek advice

Getting legal advice for the administration and distribution of your instruments as well as legal protection for those instruments may seem costly and unneeded, but it will likely end up saving you a lot of trouble in the long run. You may register your copyright and prepare the necessary agreements with the aid of a legal professional who specializes in intellectual property. Specialist PRO groups May also help with the process by bridging the gap between copyright rules and PRO best practices.

Older PRO Instruments

The goal is to abide by these suggestions and establish distinct intellectual property on a new PRO tool throughout its development. Therefore, it is the author's duty to ascertain the copyright position for legacy instruments that were created without taking such factors into account by exercising due diligence. The author will make contact with all parties involved in the creation and dissemination of the instrument (universities, hospitals, for-profit businesses, co-authors, publishers, etc.) in order to discuss and determine the best means of preserving the integrity of the instrument by combining the intellectual property rights in one person (whether natural or legal). After these negotiations, a contract between the parties should be drafted to resolve the ownership of the music's copyright. The author may register the copyright on the instrument when due diligence has been completed and the issue involving intellectual property has been resolved. Once again, certain PRO firms are experts in this kind of copyright management and may assist the author in carrying it out.

A violation of copyright occurs when works are used improperly. That implies that without first acquiring the necessary authorization, you CANNOT duplicate, distribute, exhibit, or create derivative works. Additionally, just because an item doesn't have a copyright notice on it doesn't imply it isn't protected. As a result, copyright holders must always be sought out and the terms of access to PRO instruments must always be confirmed with the instruments' writers before usage.Nonetheless, the user must make sure that it is authorized to use the instrument when there is no copyright notice. The user will be responsible for doing the required due diligence by getting in touch with the individuals involved in the instrument's creation if the author has not done so. The user may also get assistance from specialist businesses with in-depth industry expertise for this purpose.

If you wish to utilize a particular instrument, you should plan on the fact that locating the copyright owners and creating a licensing agreement may take some time. Given that all clinical outcome assessments (COAs), including performance outcomes (PerfOs) instruments, clinician-reported outcomes (ClinROs) instruments, observer-reported outcomes (ObsROs) instruments, and observer-reported outcomes (ObsROs) instruments, are based on the same scientific principles and human inventions, these recommendations ought to be applied to all COAs.

CONCLUSION

Simple standards should be followed even if copyright and intellectual property laws governing PRO instruments or their derivatives might be complicated. The use of the original instrument writers' surveys should be a core and important consideration as copyright holders. These should serve as the basis for any requests for usage, modification, adaption, and translation. The questionnaires may be used and accepted more widely and be given more credence by the scientific community if copyright ownership is anticipated at every step of the instrument's life cycle (i.e., development, communication, or derivatives).

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CHAPTER 20

THE CODE OF CONDUCT, BIOSECURITY AND BIOSAFETY

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ABSTRACT:

Although biosafety focuses on preventing unintentional exposure to biological agents, biosecurity works with preventing abuse of diseases, poisons, as well as other biological materials via loss, theft, diversion, or purposeful release. A worldwide applicable code of conduct with a focus on biosecurity has been created, together with instructions for how to carry it out in practice. This is done in order to address the laws controlling the possible dual use of biological materials, information, and technology, as well as to lessen the likelihood of their harmful use. It is the duty of scientists doing research and exchanging microorganisms to avoid abuse of those that are intrinsically hazardous, i.e., those that produce toxins or are pathogenic. With a focus on microorganisms specifically, the code of conduct described here is based on best practice guidelines for scientists and their institutions dealing with biological resources. It strives to safeguard researchers, their facilities, and stakeholders while bringing attention to the need for regulations.

KEYWORDS:

Biosafety, Copyright, Cryopreservation, Cloning, economic, genetic resource, Intellectual property (IP), Patent.

INTRODUCTION

Current biology and biotechnology provide honorable methods for modifying fundamental living processes.Human genetic research has greatly benefited humanity by producing medicines, vaccines, diagnostic tools, and other information that will help with improved health and illness management. Crop productivity has grown and animal health has improved as a consequence of genetic research in agriculture. Yet, the genetic manipulation of microbes may be exploited to produce new species that are more virulent, resistant to antibiotics, or capable of causing environmental instability.Even with increased understanding of bio-safety and containment procedures, handling pathogenic microbes still puts lab workers at risk for infection and even death. There have also been cases of illness secondary transmission to the general population, perhaps as a result of environmental or human resource pollution. Accidental misuse of harmful biological agents and toxins is attributed to inadequate adherence to the recommended guidelines, a lack of understanding of the recommended laboratory procedures, inadequate training of laboratory staff, inadequate preparation of pathogens with low levels of biosecurity, and improper disposal of contaminated materials[1], [2].

We have seen a string of mishaps and security lapses at bio-containment facilities in the US (West Nile Virus, Tuberculosis, and Anthrax), UK (FMD), USSR (Anthrax), Singapore (SARS), and China in recent years (SARS). Recent incidents in the US, including the accidental contamination of a relatively harmless flu sample with a dangerous H5N1 bird flu strain, the export of potentially infectious live anthrax bacteria samples to laboratories unprepared to handle them, and the leaving of several vials of smallpox in a cardboard box in an unused storage room, have exposed the researchers' laxity and carelessness in adhering to

bio-safety and bio-security measures. In the US labs between 2003 and 2009, there were 400 incidents that included the possible release of specific agents, according to a report by the University of Minnesota. These incidents were mostly caused by containment issues, spills, needle sticks, and/or other sharp injuries[3].

These incidents, which occur even in a developed nation like the US where numerous public and commercial entities focus on different crucial areas of bio-safety, biosecurity, and bio-containment, have raised major questions about the execution of laws at a global level. If such poor management is allowed in the USA, there is a chance that researchers elsewhere will disregard the rules and endanger the environment and the welfare of people. To ensure that only authorized scientists have access to lethal organisms and supervise potentially hazardous research with dual use implications, managing the risks requires effective policies and a globally ratified system of controls and regulations that can be implemented at the international level.

India's biosafety

In order to safeguard the health of researchers, the general public, and the environment, biosafety procedures make sure that such research is carried out in line with the highest standards.

To safeguard personnel, the general public, animals, and the environment from mishaps, laboratory bio-safety often focuses on preventing inadvertent or unintentional exposure to or discharge of diseases and toxins[4], [5]. The biosafety industry consists of biotechnology and manufacturing, control testing, food, agricultural, and veterinary testing, environmental testing, and reaction to known or suspected acts of biological warfare, bioterrorism, or other associated criminal activity. Promoting safe laboratory methods, protocols, and the appropriate use of equipment and facilities for containment, risk assessment and management, GMO evaluation, etc.

With the development of science and technology, India has a well-conceived notion of bio-security and bio-safety that is measured against the emergence of new bio-security threats. The Environment (Protection) Act, 1986 (Rules of 1989), which lays out guidelines for the production, import, usage, testing, and release of genetically modified organisms and their products, is the foundation of India's biosecurity regulatory framework.

The control of GMOs under the EP Act is justified by their apparent potential to be hazardous chemicals or environmental pollutants. GMOs are classified as dangerous microorganisms. The Directorate of Biotechnology (Ministry of Science and Technology) and the Ministry of Environment and Forests (MoEF) work together to execute the regulatory framework, with necessary assistance from the Ministries of Agriculture and Health and Family Welfare[6].

The National Health Research Policy (2007) of the Indian Council of Medical Research ensures that the requirements of the National Health Policy (2002) are met, including that research is conducted with adequate levels of bio-safety so that novel, exotic, and dangerous organisms can be handled without posing any threat.

Genetic Engineering Research

India has some of the strictest biosecurity laws in the world governing genetically altered goods. The following activities are coordinated to form the biosecurity system's institutional framework:

RDAC, or the Recombinant DNA Advisory Committee: The Department of Biotechnology's RDAC periodically makes recommendations for relevant and adequate safety laws for recombinant research, its usage, and its applications. To provide advice to the government on matters of policy, the Committee studies both domestic and foreign advancements in biotechnology.

The Institute of Biosafety Committee (IBSC): ISBCs play a key role in the development, assessment, and management of a biosecurity regime. In accordance with the manuals and rules of the Review Committee on Genetic Manipulation, it is required for all research institutes, universities, and businesses that work with microorganisms and genetically modified organisms to establish IBSCs for specific study areas (RCGM). This committee investigates every facet of biosafety, such as containment and experimentation concerns. Currently, there are roughly 320 IBSCs operating throughout the nation[7].

RCGM: The Department of Biotechnology-managed RCGM keeps an eye on the elements of ongoing research projects involving dangerous microorganisms and genetically modified organisms that are linked to safety. The Committee also publishes manuals that provide recommendations outlining the regulation process for operations falling under the high-risk category and controlled field studies. Although the Drug Controller General of India, the Central Drug Regulatory Authority, performs bio-security review of agricultural goods, the Indian Council of Agriculture Research grants bio-security approval to medicinal items.

The MoEF's Genetic Engineering Approval Committee (GEAC) reviews requests for the release of GMOs and products into the environment as well as activities involving the extensive use of potentially dangerous recombinants and microorganisms in research and industrial production. An event-based approval system has been in place since June 2006 to quicken the procedure. State Biotechnology Coordination Committee (SBCC): The Committees inspects, investigates, and takes disciplinary action in case of violation of legislative restrictions. An "event" refers to a particular gene construct that may be inserted in a number of current hybrids or types.

District Level Committee (DLC): This Committee inspects, investigates, and reports to the SBCC or the GEAC about r-DNA guidelines compliance or non-compliance or EPA violations. It also serves as a nodal body at the district level to evaluate any harm caused by the release of GMOs[8].The Monitoring-Comprehension-Evaluation Committee (MEC) conducts field trips to examine the experiments and trials and to gather data throughout the restricted open field trials. Additionally, MEC gathers data on the comparative agronomic benefits of transgenic crops, evaluates and provides advice on the risks and advantages of using transgenic plants, aids in gathering, combining, and analyzing field data to assess the environmental risks posed by transgenic plants, and recommends to RCGM and GEAC those transgenic crops that are determined to be both environmentally sound and commercially viable.

In order to increase public trust in the use of GMOs, the National Biotechnology Regulatory Authority (NBRA) was suggested by the M.S. Swaminathan Task Group in 2003. The task group also recommended that the GEAC's responsibilities be limited to bio-safety and environmental safety until the NBRA is established. It has been recommended that the MEC report to the GEAC.

DISCUSSION

The Prevention of Food Adulteration (PFA) Act and Regulations, which were passed in 1954 and 1955, respectively, had the dual goals of promoting ethical business practices and

ensuring the quality and safety of food. No one is allowed to produce, market, store, or distribute contaminated products under the guidelines.Or misbranded food items that do not meet the required standards, whether they are manufactured locally or abroad[9], [10]. The PFA Act and Regulations' requirements must be monitored and put into practice by the state governments and the union territories. The Essential Commodities Act of 1955 was passed to safeguard the interests of the general public by regulating the production, distribution, and sale of certain commodities. The legislation gives the federal and state governments the authority to enact control orders that limit the quantity, quality, transportation, and licensing of critical goods.

The Export (Quality Control and Inspections) Act, passed in 1963, established the Export Inspection Council of India, which advises the national government on how to implement quality control and inspection procedures in respect to export-related goods. This law established the Bureau of Indian Standards (BIS) Act, 1986, which is a legally independent organization. It offers quality certificates for goods and management practices that guarantee customers' satisfaction with words like quality, reliability, and safety. Mandatory certifications are needed for drinking water, food colors, and additives. Via Quality Management Systems, Environmental Management Systems, Occupational Health and Safety Management Systems, and Food Hygiene - Hazard Analysis and Critical Control Point System, the effectiveness of an organization's management systems is evaluated.

Animal Welfare

Concerns about the preservation of animal health, particularly the health of domesticated animals and the health of wildlife in sanctuaries and wildlife parks, are within the purview of the MoEF and the Ministry of Agriculture (MOA). The MOA also offers export certification and controls the import of cattle and associated goods. The responsibility of overseeing and organizing numerous organizations involved in animal health falls to the Department of Animal Husbandry and Dairy.

The national government gives notices and instructions on epidemic outbreaks and also creates ad hoc monitoring bodies, although each state government is responsible for protecting the health of animals within its own borders. The Wild Life (Protection) Act of 1972 aims to safeguard ecological and environmental security by protecting wild animals, birds, and plants. The Act forbids the use of any chemicals, explosives, or oher anything that might harm or threaten any species. According to an amendment to the Act made in 2000, the Chief Wildlife Warden must take action to immunize cattle housed in sanctuaries or within five kilometers of them against infectious illnesses.

The Livestock Importation Act of 1898, as revised in 2001 by the Livestock (Importation) Amendment Law, governs the import of cattle that may be afflicted by infectious diseases or communicable conditions. The Act gives the central government the authority to control, impose restrictions on, or outright forbid the importation of any livestock product into the areas covered by the Act that may have the potential to endanger the health of people or animals. Moreover, it gives the state governments the authority to enact laws governing the inspection, sanitization, and/or destruction of imported animals.

Plant farming and quarantine

The Preservation of Plant Varieties and Farmers' Right Act of 2001 calls for the creation of an effective system to safeguard plant varieties, farmers' and plant breeders' rights, and to promote the growth of new plant kinds. This law permits a fair and equal distribution of the advantages resulting from the use of and inventions based on genetic resources in India.

The Biological Diversity Act of 2002 establishes guidelines for the preservation of biological variety, the sustainable use of its elements, and the equal distribution of the advantages associated with their utilization. The Act calls for the creation of an executive National Biodiversity Access to the nation's plant and animal genetic resources is governed by authority, state biodiversity boards, state biodiversity management committees, and a biodiversity registry. In order to safeguard the interests of various stakeholders in India from the effects of OECD legislation that permits the patenting of genetically modified organisms and life-forms, the Patents Act and Intellectual Property Rights Amendment, 2002 expressly prohibits the patenting of traditional knowledge and life forms. The introduction and movement of any insect, fungus, or pest that may be damaging are subject to regulations under the Dangerous Insects and Pests Act of 1914.

Guidelines for preventing and controlling the import into India of agricultural commodities and products that are likely to create biosafety issues are provided by the Plant Quarantine (Regulation of Import into India) Order, 2003 of the MoA. According to the classification of plants into three categories species that are prohibited from being imported, species that are restricted from being imported, species that require additional declarations and special conditions, and plant material imported for human consumption or industrial processing—the order regulates the imports of agricultural products into India. For these categories, import procedures have been established, which include phytosanitary certificate requirements, permission requirements, requirements for GMOs with plant origin, and compliance requirements with the International Plant Protection Convention (IPPC).

In order to fulfill India's commitment under the IPPC to create a central regulatory body for plant protection, the Plant Quarantine Bill, 2004, requires the establishment of the Plant Quarantine Authority of India (PQAI). The bill aims to provide a thorough regulatory framework for the control of the local and international spread of pests under quarantine.

Biosecurity

The Bio-Security Program entails the creation of regulations addressing life sciences research that produces data or technology that might be abused to endanger the public. National security or health. Laboratory bio-security includes, among other things, safeguards against the theft, abuse, or discharge of biological materials on purpose. The Biosecurity Program assures that guidelines for the management and conduct of ethical life sciences research are being developed. The most common biosecurity legislation are as follows: The Prevention of Terrorism Act, 2002 is applicable to terrorist acts that use bombs, explosives, inflammable materials, firearms, lethal weapons, poisons, noxious gases, other chemicals, biological agents, or other dangerous materials in such a way as to threaten the unity, integrity, security, or sovereignty of India or to terrorize the general public or any section of the general public.

The Weapons of Mass Destruction and Their Delivery Systems (Prohibition of Unlawful Activities) Bill, 2005, expands the regulatory framework governing controls over the export of WMD-usable materials, chemicals, organisms, equipment, and technologies by outlawing unlawful activities relating to WMD and their means of delivery. The export of Special Chemicals, Organisms, Materials, Equipment and Technologies (SCOMET), which includes bacteria, fungus, parasites, viruses, rickettsial, plant pathogens, and GMOs, has been under Indian regulation. The Foreign Trade (Development and Regulation) Act of 1992 states that exporting certain SCOMET products needs a license. The Medicines and Cosmetics Regulations of 1988 were announced on September 21 by GSR No. 944 (E).

The requirements of the activities for enabling the import or manufacture of biological and biotechnological products, the manner of conducting clinical trials in India and their

presentation, or the method of presenting clinical trial data generated elsewhere, were described in detail by the Ministry of Health and Family Welfare in 1988. The Drug Control Authority must approve the importation or local production of any new medications intended for commercialization.According to Drug Policy 2002, specific cell/tissue targeted formulations, bulk drugs made using rDNA technology, bulk drugs requiring in vivo use of nucleic acid as the active principles, and bulk drugs produced using rDNA technology all require an industrial license, approvals for foreign investments, and foreign technology agreements.

The Water (Prevention and Control of Pollution) Act of 1974 sets forth provisions for the prevention and control of water pollution as well as for maintaining or restoring the wholesomeness of water. It also calls for the creation of Boards for the prevention and control of water pollution and the granting of authority and responsibility for prevention of water pollution to such Boards.

The Air (Prevention and Control of Pollution) Act of 1981 and its rules from 1983 set down the procedures for preventing, controlling, and reducing air pollution as well as for creating boards and granting them authority over related issues. For the management and handling of biomedical wastes produced by hospitals, clinics, and other institutions for scientific management of biomedical waste, the Biomedical Waste Management & Handling) Regulations, 1998 are in place. Under State Pollution Control Boards, these activities are regulated by law.

In order to tackle risks of bioterrorism from pests and weeds, the Agricultural Biosecurity Bill, 2013, which was tabled in Lok Sabha in 2013, proposes to develop an integrated national bio-security framework spanning plant, animal, and marine challenges. The Cattle Importation Act of 1898 and the Destructive Insects and Pests Act of 1914 are both repealed by the Bill. In order to I regulate the import and export of plants, animals, and related products; (ii) prevent the introduction of quarantine pests from outside India; and (iii) carry out post-entry quarantine procedures, it is advised that an Agricultural Biosecurity Authority of India (Authority) be established.

The regulatory structure in India is strong and stringent, and it offers the necessary protections and restrictions for biosafety and biosecurity policies. Nevertheless, there is not enough technically skilled labor or sufficient equipment to firmly implement the regulatory framework. Thus. The urgent need for technical needs and capacity development should be addressed. From the standpoint of public policy on health, the environment, and sustainable development, biosecurity must be regarded more generally. A quality control program in hospitals in general and labs in particular may help ensure laboratory safety in India as part of an overall safety program in hospitals.

All labs should be given grades based on how well they perform in comparison to a set of preset criteria, and accreditation must be made mandatory. There is a discussion in the nation about imposing security-related limits on the funding and publishing of research conducted in areas of dual use concern. In order to identify the implications of projects with dual use research concerns at the time of presentation to the IBSCs, peer review by experts at the time of proposal consideration for funding, or by the journal editorial system to identify them at the stage of peer review/publication, suggestions are circulating.

Scientific collaboration between various institutions involved in biomonitoring and other bio-security programs would be facilitated by a cogent bio-security strategy for healthcare research and microorganisms, agricultural crops, farm animals, living aquatic resources, and agriculturally important microorganisms that involves education and social mobilization of

regulatory measures. Within the confines of their separate responsibilities, protection and promotion of biosecurity would result from a coordinated effort among the relevant authorities and adequate legislation. Regulators should work to align their policies with those of other nations.

The problems with bio-safety and bio-security processes were discussed on a panel at the International Conference on Host Parasite Interactions on July 15, 2014, at the National Institute of Animal Biotechnology in Hyderabad. The group recommended that the government take the initiative in developing standardized guidelines for all laboratories working with BSL 2/3 or 4 microorganisms; technical guidance documents for technical / administrative staff in laboratories working with exotic organisms; and establish an agency for Biorisk Management at the center of academia, industry, civil society, and the legal profession for biological disaster management, global collaboration, and risk mitigation strategies.

CONCLUSION

The experts correctly emphasized the importance of knowledge and awareness, as well as the application of rules and regulations, outreach and education, capacity development, risk assessment, and risk management. The purpose of capacity development should be to improve the legal system and operational processes. The establishment of a specialized centralized autonomous body or center with a mandate to develop human resource in biorisk management may give India an advantage in the biotechnology sector. This is in line with recommendations made by various expert bodies, and it will increase awareness and training on safety and security in research institutes, academia, and industry. In order to maximize the advantages of life sciences research, it would encourage a culture of appropriate bio-safety and bio-security practices via efficient monitoring, teaching and training, information distribution, and knowledge exchange. In the end, this will also encourage the researchers' culture of accountability.

Such a body may provide specialized courses in bio-risk management, related policies, relevant laws, audits, and inspections; handle the possibilities and problems linked to facility risk assessment; and arrange conferences, seminars, symposia, and short-term training programs. It is equally important to create specific guidelines for medical surveillance and evaluation systems, secure aquatic resources, agriculturally significant microorganisms, and plants, animals, and other resources, update safety manuals, biosecurity plans, safe practices, and standard operating procedures, and emergency response plans, and widely disseminate and reach out to a large number of beneficiaries through electronic media and periodic newsletters. It would be crucial to keep track of all biosafety lapse episodes, build databases for the individuals responsible, and record all possible mitigating measures.

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CHAPTER 21

ETHICAL IMPLICATIONS OF CLONING

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ABSTRACT:

The science of therapeutic and reproductive cloning has sparked contentious ethical discussions. Some of the concerns and anxieties are unfounded; yet, some of them are genuine and significant. If the direct physiological hazards associated with cloning are reduced, it could be morally feasible to do reproductive cloning. But only in a study setting with comprehensive monitoring and following of kids and families, to the level of existing assisted reproductive technologies. The ethical implications of therapeutic cloning are many and interconnected. The loss of unborn human life, its connection to reproductive cloning, and the treatment of egg and cell donors are a few of them. While none of these problems warrants banning therapeutic cloning research, researchers working on it should be aware of the morally contentious character of their work.

KEYWORDS:

Cloning, Reproductive Technologies, Reproductive Cloning.

INTRODUCTION

There are several cultural roots to these anxieties and concerns. They primarily result from the perceived danger that cloning poses to the sanctity of human life. A person's ability to be replicated implies that each person is a replaceable component, much like the machine components in an industrial system. Many concern that life will become disposable in a future where people may be simply copied. Thus, cloning is seen as paving the path for human degradation such as slavery, murder, and other atrocities. Some individuals see cloning as a means of technical "immortality" in opposition to these concerns. Some regard cloning as a means of preserving their own life or the existence of a loved one in a brand-new, cloned body. Such expectations are based on the fallacious notion that people with the same genotype will be the same person.

These worries and inflated expectations cannot be ignored in an ethical consideration of human cloning. But, such a study must be supported by facts from science and society, not by fantasy. The major concerns raised concerning human cloning are critically examined in the paragraphs that follow. The quest to create a human person via cloning technology is the subject of reproductive cloning, which is the first section of this topic. The use of cloning technology to create isogenic immunologically compatible stem cell lines for the treatment of illness or trauma is covered in the second half along with some of the concerns it raises.

Reproductive Cloning

Knowing a few key characteristics is useful when addressing reproductive cloning. The first is between blastomere-based cloning (embryo splitting) and SCNT technique cloning, or somatic cell nuclear transfer. In the former, a genome is purposefully duplicated by splitting or multiplying the individual cells of an early embryo. The latter involves replicating a person's DNA using a somatic cell nucleus from a living (or even a dead) human. Since embryo splitting makes it feasible to produce many genotypes that are identical, it is a reason

for worry. The question of replicating a live thing's genome is brought up by SCNT cloning. In reality, there isn't a huge difference between these two kinds of cloning. It is feasible to create the identical twin of a person born decades earlier via blastomere separation and embryo freezing. By beginning with many copies of a somatic cell, SCNT cloning may likewise be utilized to mass-produce identical genomes. The most difficult ethical issues are brought up by SCNT cloning since technology enables the intentional replication of an adult or offspring's DNA and may potentially be utilized for mass reproduction. SCNT is the subject of the discussion that follows[1]–[3].

It is also helpful to differentiate between the primarily procreative applications of this technology and its purposefully replicative uses when discussing reproductive cloning. The former, for instance, may include the use of SCNT by individuals who are unable to otherwise produce a kid who is biologically related to them. When just one spouse has gametes and a heterosexual pair doesn't want to employ artificial insemination or egg donation to bring a third party into their relationship, this may happen. It can also happen when only one partner has gametes.

Lesbians or homosexual males may find this kind of procreative SCNT technology appealing. For instance, some lesbian couples are reluctant to utilize donor insemination out of concern that the sperm donor may eventually claim parental rights. Those who want to prevent sexual reproduction from passing on a significant genetic illness may also be drawn to procreative SCNT. This may be the case when a condition is implicated, for which not all mutations are known and for which prenatal screening is ineffective in preventing. In each of these situations, the goal is to create a healthy kid who is connected to the parents biologically, not so much to copy an existing genotype.

Contrarily, replicative reproductive cloning purposefully seeks to duplicate or multiply an existing genome. Replicative cloning may be used, for instance, by couples looking to replace a lost child or to create a "twin" appropriate as a tissue donor for an already-born kid. Replicative cloning may also be used for profit in the selling of "celebrity" genomes for use in reproduction. Ultimately, it may be used by governments or other groups to create a variety of desirable genotypes for military or other uses. Compared to procreative SCNT cloning, replicative SCNT cloning directly tries to produce a person with chosen genetic features, which poses additional moral concerns. One such scenario, as shown in the films "Multiplicity" and "The Sixth Day," depicts current people as losing their unique identities or rights as a result of the instantaneous (and potentially uninformed and covert) manufacturing of copies made by cloning them.

All of these possibilities overlook the fact that cloning just creates a genotypically identical human embryo, which still has to go through the whole gestational period as well as infancy, youth, and adolescence. Even if "genotype = phenotype," which is not true (see below), were true, it would still take decades to create the cloned version of any adult[4]. We do not have to take these hypothetical situations seriously since they are based on completely speculative technology of instantaneous reproduction of body and mind.In a parallel scenario, despots would mass-produce subservient legions of "superwarriors" via cloning. This vision also has a number of flaws. For starters, it assumes that cloning technology can be used to identify and create in large quantities a phenotype that is appealing to the military. Yet as recent experience in the Gulf and Balkan Wars has shown, military technology may advance

significantly in the few decades it takes for a person to reach adulthood[5], [6]. Hence, a tyrant may see his cloned superwarriors being wiped out on the battlefield after years of work and effort by a small group of able-bodied yet skilled computer experts sitting miles away

from the fight. In addition to this, it should be clear at this point that the presence of a tyrant eager to exploit biotechnology for aggression and reproductive enslavement is what is really frightening about this scenario. If our civilization ever reaches a stage in which such an event may materialize.

There is little reason to anticipate that many people would decide to start their families using commercially accessible cloned embryos in the absence of significant societal change or pressure. Moreover, there would be no overall effects on society if a small number of individuals adopted cloning for reproductive or procreative objectives. It would be reasonable for society to set a cap on the number of people that could be produced from a single genome in order to further prevent this from happening and to avoid the potential confusions caused by the existence of many individuals with the same genotype and physical characteristics.

DISCUSSION

Important Ethical

A significant factor in the moral assessment of reproductive cloning is the possibility that some individuals may gain from it. The majority of ethical theories agree that we should safeguard human liberty and the pursuit of pleasure unless doing so poses a disproportionate risk of damage to people and society[7]. Cloning is likely to be sought and utilized by a limited number of individuals who would not otherwise be able to produce children, similar to other aided technologies. So, the pertinent ethical issue is whether this tiny gain is likely to offset the negative effects brought on by the technique of cloning. An array of purported harms are frequently identified and evaluated in discussions concerning cloning.

Physical Damage to Children

The potential hazards to any child created by the cloning method are the set of ethical issues that need to be addressed most immediately. Physiological dangers are at the top of the list. There is general agreement that we should strive to prevent purposefully and intentionally subjecting our kids to birth abnormalities, lifelong sickness, or early death[8]. Here, the potential born children of cloning are the main topic.

Only those who think these early recreated embryos are moral beings are directly concerned about the significant loss of these embryos that has historically been frequent in cloning processes (a matter that is addressed below in connection with therapeutic cloning). The high prenatal loss rate is concerning for those who are less concerned with the destiny of the early embryo since it suggests that cloning may result in long-term physiological issues.

There is compelling scientific evidence that SCNT cloning is not yet secure enough for use in clinical settings as an assisted reproductive technique. We do not yet fully understand the process of epigenetic reprogramming that takes place in a reconstructed cloned embryo and cannot guarantee that the process will be completed successfully in most cases[9], [10]. This is evidenced by the high ratios of transferred embryos to live births in the majority of animal species experimented on up to this point, as well as the frequent occurrence of perinatal deaths and birth defects.

Complex problems about the possibility of passing on somatic cell mutations or short telomeres to the progeny remain unanswered. Long-term postnatal survival are thought to be more likely to have small epigenetic flaws that, while they don't endanger viability, might nonetheless cause major health issues later in life.

Even if chance achievements like Dolly are optimistic in the long run, they cannot now support the therapeutic use of this technology.

Psychological Harms

Clone-related psychological hazards for children are a contentious topic because of allegations that are sometimes very speculative and hard to evaluate. This urges prudence but does not lessen their importance as causes for worry. Prior to these claims serving as the foundation for ethical or policy judgments, further study is advised.

Compared to replicative cloning, procreative reproductive cloning seems to provide less issues. While the parents may want some of their children to share some of their genes, they are not seeking to have a kid with a particular genetic feature. By doing this, the dangers of placing expectations on the youngster are diminished. Even reproductive cloning, however, brings up fresh ethical issues. We have never previously had families with the type of parent-child identical twins that cloning makes conceivable, despite the fact that sibling identical twins are very frequent. There are some grounds for thinking that these concerns could be exaggerated. One reason is because there are already various levels of such closeness between parents and their sexually produced offspring, and this is not usually seen as a morally questionable practice. So, these worries may not be important enough to support a ban on the first cloning efforts[11]. Nonetheless, they advise intensive pre-therapy for anyone who use this technology for reproduction, as well as continuous counseling for both parents and kids. They also recommend that any first efforts at cloning be made in a scientific setting with thorough observation and documentation of physiologic and psychological changes.

A fundamental tenet of developmental biology is that organisms continuously evolve from conception to death. This development is the particular result of the interactions between the genes in their cells, the temporal dynamics, and the spatial dynamics. The organisms go through a series of habitats, and random biological processes decide whether cells live, die, and undergo changes. As a consequence, even identical twins' fingerprints are unique. Despite the concerted attempts of many parents to impose as much likeness as possible, their temperaments, mental processes, skills, life choices, sickness histories, and deaths undoubtedly vary.The ramifications of this knowledge for human cloning are many. Secondly, it warns us that parents who utilize cloning to try to mimic the virtues of a famous person are probably going to be let down. These truths must be explained to the youngster in order to keep their disappointment from becoming a burden. The most effective method to avoid these negative effects is by education and information, not by outlawing this technology. Second, it shows us that long-term cloning usage has less risks than previously thought. Contrary to popular belief, human clones won't be lifeless replicants made in a factory. They will be discrete people with unique physical and psychological traits, much like identical twins.

In fact, it's possible that cloned kids vary more from one another than monozygotic twins do. Unlike to cloned offspring, monozygotic twins share the same environment from conception on and have 3% of their genetic makeup made up of mitochondria. In other words, misunderstandings that may best be dispelled by good parental selection and a rigorous informed-consent procedure are the main cause for concern here not cloning.

Social Damages

Ethics experts dispute whether there may be damages done to society as a whole in addition to those caused directly or indirectly to individuals. Without concluding this argument, it is obvious that harmful alterations to cultural norms or institutions brought on by cloning should be considered since, in the end, they may lower many people's quality of life. Of course, not every alteration to established institutions or cultural norms has to be detrimental.

It may be difficult to distinguish between legitimate worries about changes that could be bad for individuals and worries stemming only from a fear of change.

Many people are against the idea of reproductive cloning because they believe it would harm the structures of marriage and family. Unquestionably crucial to the wellbeing of people they foster are these institutions[12].Yet, when an embryo must be produced from scratch for a stem cell research methodology, like in the case of therapeutic cloning research, this restricted acceptability of hES or hEG cell research disappears. This makes this study very problematic.

It may be claimed that since an egg activated via nuclear transfer is not the product of fertilization, it is not an "embryo" in the meaning of the word used traditionally. Nonetheless, given that this creature has the same developmental potential as a naturally fertilized egg, it is reasonable to assume that the majority of people who think life starts at conception also have the same opinion about it. The fact that current federal restrictions in the United States forbid government financing of embryo research and define an embryo as "any creature... that is generated by fertilization, cloning, parthenogenesis, or any other method from one or more human gametes" is a testament to this way of thinking. In addition to this sizable group of opponents, some people who disagree with the notion that life starts at conception are against any study in which intentionally generated and killed embryos are used. Some opponents worry about the symbolism involved in the purposeful production and eradication of a kind of human existence. They are concerned that these activities might lead us down a slippery road toward the damaging, unauthorized usage of other types of study subjects.

Responses to These Arguments

The idea that human existence starts at conception in a moral sense is not widely accepted. According to the "developmental perspective," fetal life gains moral significance during pregnancy and doesn't achieve complete equality with other humans until very late in the process or at delivery. Several factors that are relevant to the very early embryo support this opinion and undermine the argument that it should be accorded significant moral weight. For instance, practically all theories supporting the idea that human existence starts at conception argue that this is the time when a brand-new, individual human being is created. Nonetheless, it is dubious that one can talk about human identity at this point since twinning and chimerism are still conceivable throughout the early stages of development. Developmental uniqueness is not reached until gastrulation, when the body axis (primitive streak) starts to develop.

The early embryo is not able to think, feel, or have experiences since it does not yet have all of its organs. It is incapable of feeling hurt or regretting the chance it had to grow. So, the only factor that would support assigning it major moral weight is its potential for becoming a human being. How much this possibility should be considered, however, in defending its preservation is unclear. Whether cloning is ever likely to be safe enough to be employed in human reproduction, future research on animals and human embryos will disclose. IVF and other modern reproductive technologies set the bar for safety. No attempt is made to reproduce unless the scientific community has reasonable confidence that this requirement can be reached, cloning can be done ethically. If and when this happens, the first cloning attempts should be conducted in research settings and be subject to close supervision and follow-up.

A separate but connected set of ethical questions are raised by therapeutic cloning. These concerns range from whether it is acceptable to create embryos with the goal to kill them to advancing the possibility of reproductive cloning and promoting a market for human oocytes

for scientific study. Here, it is claimed that none of these problems is sufficient to morally forbid study of therapeutic cloning. These findings stand in stark contrast to the exceptional level of public hostility against the concept of cloning. A large portion of this hostility stems from an ignorance of the relevant science. Part of it may be attributed to the newness of this field of study and the perceived danger it poses to conventional cultural and familial values. We may assume that part of this hostility will lessen if reproductive cloning turns out to be medically and psychologically safe, as has been the case with other modern assisted reproductive technologies. Yet, researchers in this field should be cognizant of the contentious character of their work at all times. By taking extra care to ensure that all facets of their work adhere to the highest standards of research on human subjects, they may contribute to lessening public anxiety.

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CHAPTER 22

INTELLECTUAL PROPERTY AND THE HUMAN GENOME

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ABSTRACT:

The original researcher or firm is the sole party with the exclusive right to utilize the GMO under IPR (intellectual property rights). Using a variety of IPRs, such as trade secrets, patents, copyrights, geological indications, and breeder's rights, one might prevent unlawful use of their goods. The Human Genome Project aimed to achieve two objectives. The scientific objective was to map and sequence the human genome, and the social objective was to improve human health and wellbeing. Although the first objective is nearly finished, the second one is not quite there yet. This is mostly due to the fact that it will take some time for the benefits to be applicable and useful, but it is also a result of the project's inherent character. There was little doubt that the HGP also had an economic component, which had a big influence on its social component. Human DNA may now be patented thanks to the intellectual property right, which functions in the center of these three dimensions. Alternatively, to put it another way, implementing the HGP necessitates the commercialization of genetic data, which might be perceived as a threat to humanity's genetic heritage.

KEYWORDS:

Biotechnology,Disease, Intellectual Property, Human Genome, Patent.

INTRODUCTION

Concerns concerning intellectual property in the area of life sciences have increased over the last 20 years as a result of breakthroughs in genetics and molecular biology. In the 1970s, a burgeoning and expanding U.S. biotechnology industry as well as U.S. academic scientists, especially those who were active in promoting academic-industry links, filed an increasing number of patent applications on biological molecules with potential as new products, biologically-based processes, and genetically modified organisms. Currently, patent applications for nucleic acids (RNA and DNA), proteins, cell lines, genetically modified microbes, transgenic animals, and plants are submitted by academia researchers, public sector scientists, and commercial researchers. This is due to how widespread the application of intellectual property has grown in the biological sciences and certain specialized disciplines of biotechnology. Yet, there has been much debate and discussion over how intellectual property rights for the biological sciences should be created. The best illustration of this is the human genome project. In the next 10 years, patenting is expected to increase significantly in the field of genomics, which studies the structure and function of human, plant, animal, and microbial genomes. The current issues raised by the use of intellectual property rights in research and development connected to human genome analysis are covered in this chapter, along with the implications for public policy.

Gene-Modified Animals

These are creatures whose DNA has been altered to express an extra (foreign) gene. While mice make up more than 95% of transgenic animals, transgenic rats, lambs, rabbits, pigs,

cows, and fish also exist. Why did these creatures need to be created, and how would these changes help us? Let's examine a few typical causes.

- Explore related areas such as Biotechnology and Its Uses.
- Biotechnology's Use in Agriculture
- Biotechnology's Use in Medicine
- Normal Development and Physiology

We can research how genes impact the body's development and regular activities thanks to transgenic mice[1], [2]. They also aid in our understanding of how the body controls gene expression. For instance, we may learn more about the biological function of a factor in our body by adding genes from other species that affect the synthesis of the factor and by researching its biological impacts.

Study of Disease

Also, transgenic animals help us better understand how genes affect disease development by acting as models for human disorders. They also enable the investigation of novel disease-treating strategies. Several human illnesses, including Alzheimer's, cancer, rheumatoid arthritis, cystic fibrosis, etc., have transgenic models available today.

Biological Products

Some human disorders necessitate the use of biological product-containing medications, which are often costly to produce. It is also possible to produce these biological products using transgenic animals.

Transgenic organisms will produce a specific biological product when the product's genes are included[3]. Human antitrypsin is one example, which is used to treat emphysema. The first transgenic cow, named Rosie, was created in 1997 and is the most notable example. Compared to normal cow milk, the milk from this cow had a better nutritional value for human infants since it included human -lactalbumin.

Safety of Vaccines

Vaccines are first evaluated for safety on transgenic mice before being administered to humans. Now, transgenic mice are being used to examine the safety of polio vaccinations. Transgenic mice will replace monkeys as the primary animal used to evaluate the safety of these vaccinations if the test is reliable and successful.

Testing for Chemical Safety

Transgenic animals are also used to investigate the toxicity and safety of chemicals. Transgenic animals are made for this purpose by introducing genes that increase their sensitivity to the harmful material being researched[4], [5]. They are then exposed to the poison, and the consequences are investigated. Results from toxicity testing using transgenics are available quickly.

Ethics Concerning Transgenic Animals

Gene-modified mice Using Wikipedia Commons as a source

Ethical Concerns

What do you believe will occur if human genetic modification of living things is left unchecked? Not only will it result in the exploitation of the species, but it will also negatively affect our ecology. Both morally and biologically, it is wrong! This is why moral guidelines are necessary to control how humans manipulate living things.

GEAC

The Genetic Engineering Approval Committee has been established by the Indian Government in relation to genetically modified organisms (GMOs) (GEAC). This group decides if studies involving GMOs are reliable and discusses the security of GMOs that have been made available for use by the general population.

Rights and Patents

Recently, several businesses received patents for goods and innovations using genetic material or other resources created and used over many years by residents of a particular location. Several individuals have been enraged by this. Basmati rice, which was created by Indian farmers over a long period of time, is a recent example. The US Patent and Trademark Office granted a US corporation the patent rights to Basmati rice in 1997[6]. This patent not only enables this business to profitably market and sell novel varieties of basmati rice, but it also prevents others from doing the same. Similar efforts to patent Indian natural treatments have also been tried. Thus, individuals and nations need to exercise caution and oppose patent applications that make use of locally produced goods and technological innovations.

Ethics Concerning Transgenic Animals

Field of basmati rice in Punjab, India Using Wikipedia Commons as a source

Bio piracy

The use of bio resources by multinational corporations without the necessary consent or payment to the people or nation in question is referred to as bio piracy. The majority of established, monetarily wealthy countries lack biodiversity or traditional knowledge, but it is the opposite for underdeveloped countries. As a result, conventional knowledge is used to create cutting-edge, profitable applications that save their creators time, money, and effort. People are increasingly conscious today of the unfairness and inadequate compensation and benefit-sharing between wealthy and underdeveloped countries[7], [8]. As a consequence, numerous countries now have laws that prohibit the use of their traditional knowledge and bio resources by other countries. The second amendment to the Indian Patents Bill, which addresses the problem of bio piracy, was recently approved by the Indian Parliament.

DISCUSSION

Throughout the 1970s and 1980s, the genetic engineering of living things created new opportunities for innovative goods and procedures. Direct insertion of synthetic or foreign genes into an organism allowed scientists to think about the development of innovative human gene-based medicines, crops with improved qualities, and genetically modified (GM) animals for use in science and agriculture. Due to these early breakthroughs, the economic potential of genetic alteration and the need of suitable intellectual property protection were quickly recognized. Finding, describing, and patenting biological molecules has become a key area of study, especially in the pharmaceutical industry.

Previous to these advancements, medical equipment, chemical compounds, and chemical processes were the main categories of pharmaceutical advances covered by patents. The courts have not encountered any specific challenges when it comes to biological molecules fitting eligibility requirements. These substances are primarily chemical in nature, hence the extremely broad case law for chemical substances that dates all the way back to the previous century has been relied upon. While nucleic acids are given a unique status as the biological

molecules that constitute the foundation of "life," they are nevertheless considered chemical entities for the purposes of patentability.

It is now well acknowledged that intellectual property rights (lPR) are crucial to innovation in the medical sciences. The creation of biological research tools, products, and processes requires the use of two different forms of intellectual property. Patents and trade secrets exist. Prior to the invention and utilization of genetic engineering, neither the biological sciences nor the academic research community had used patents extensively. Among the first to employ intellectual property rights in the rapidly developing biological environment were pharmaceutical corporations, who were already familiar with the value of intellectual property in innovation in their respective industries. While their assets were (and still are) heavily weighted in terms of the strength of their patent portfolios as well as their product pipeline, biotechnology businesses were also quite active in filing for many earlier patents in the 1970s and 1980s.

The public sector has shown a growing interest in patent applications since the middle of the 1980s. In an effort to increase its external revenue from royalties, government research institutions and universities, notably those in the US, have been seeking patents in the life sciences. Two factors have led to this. First off, a large portion of the fundamental and practical research that has supported molecular biology and biotechnology has been done in the public sphere. From the beginning of biotechnology, there have been a lot of academic-industry connections between public sector institutions and business, including major and small organizations that specialize in the field. Second, the increased focus on wealth creation via investments in fundamental research and the overall drop in government funding on science in industrialized nations have both contributed to the expanding use of intellectual property by public sector scientists. Decreasing resources have given institutions a strong incentive to supplement their government financing with other revenue sources.

Life Sciences Patent Controversies

Even though patenting is already well-established in the biotechnology industry, there have been several legal issues between businesses and government agencies. All three of the criteria novelty, originality, and utility required for patentability have given rise to disagreements. In terms of life science patents, all three requirements have been significant. For instance, there have been several disputes over the novelty of biological compounds that have been extracted from their natural source[9].

The Human Genome Project: A Comparison of Theory and Reality

We may genuinely consider whether the Valencia Declaration on the Human Genome Project (24 October 1988) still holds true now, twelve years later. It is still possible to sustain the hope shown by those in attendance. The first tenet of the Declaration stated: "Those present believe that the information gained from the mapping and sequencing of the human genome may significantly improve human health and welfare. Participating scientists take responsibility for ensuring that genetic information is only used to enhance human dignity and to promote public discussion of the ethical, legal, and social concerns surrounding the use of genetic information in this respect.

If the Declaration's contents are carefully examined, several inferences about the project's stated goals may be made; one is directly scientific, "the mapping and sequencing of the human genome," and the other is social, "to significantly improve human health and well-being." In addition, scientists emphasize that in order to achieve this aim, they are dedicated to making sure that genetic information is utilized exclusively to enhance human dignity and

to promote public discussion of the related ethical, legal, and societal challenges. Such lofty goals would undoubtedly make people in our nation and even all scientists across the globe smile at the statement; yet, the proclamation's good intentions did not calm the conscience of a segment of the public, which is not at all anti-science but competent to analyze the data.The Declaration, as well as others of a similar sort that followed, looked only partially genuine because of the circumstances in which science grows and the many "counter-aims" or undesirable impacts that science imposes onto every aspect of the reality within which it functions and is applied. The idea that such eminent scientists would ignore the commercialization of science or the project's relationship with biotechnology is obviously the furthest thing from our minds[10]. These issues, on their own, further exacerbate the already challenging anthropological and social issues that genetic research raises, issues I would even go so far as to label "bio-political."

Acts, colloquia, and seminars organized by scientists around the globe that were funded by governmental or private organizations followed the Declaration. We attended these events hungry for knowledge and prepared to support any action that may improve "hwnan dignity." We may now address such a complicated issue without needing to be geneticists or even professionals in the area of natural science thanks to such facts, together with the considerable literature that has followed and the occurrences themselves.

The Watson and Crick discovery of DNA's double helix marked the beginning of a sequence of genetic discoveries that culminated with the acknowledgment of the anatomy and topography of the hwnan genome via the Hwnan Genome Project. R. Dulbecco, an Italian scientist, recommended the comprehensive mapping and sequencing of the genome in an editorial that appeared in Science magazine in 1986. The National Research Council Committee was established in the US in the same year. It acknowledged the project's viability and, two years later, chose to support the Hwnan Genome Project by providing $200,000,000 per year for fifteen years. The NIH's management would be in charge of overseeing the program[11]. The project was started virtually simultaneously across Europe. European governments supported it enthusiastically, contributed to its funding, and established HUGO as a watchdog organization. The Hwnan Genome Project began as any other scientific endeavor would, that is, as a continuation of applied genetics research as is customary; the novelty lay in the fact that for the first time in science's history, an expansive, global project that was primarily supported by public funds had been established. The project's first phase had two clear objectives.

The "Hwnan chromosomal map" was created, and the "linkage" included sequencing the DNA of the genes contained in the physical map. The improvement of fundamental knowledge in the fields of biology and genetics as well as other knowledge relating to clinical application affecting health matters, which cover areas as different as the identification of diseases, prevention, and genetic therapies, were among the objectives that various approaches, some of a theoretical-cognitive nature and others of a practical-applied nature, were taken into consideration in order to achieve these goals. With this money and these objectives, the project adopted the organizational format of a global scientific corporation where the traditional line between basic research and applied research was blurred or unclear.

At the moment, all that is required to claim inventorship and get exclusive rights over any and all future uses of the "new" is to explain the chemical make-up or the function of a small portion of genetic material.An inherited trait. Some patents are so wide that they cause disputes inside the corporations itself. Take the case of W.R. Grace, a global corporation that was granted a monopoly patent on all types of genetically modified cotton. 8 Similar circumstances may be seen in the example of the multinational corporation from Europe,

Monsanto, which was refused a patent 9 that would have given it exclusive control over all genetically modified plants with insect resistance.

For many individuals, it is ethically wrong to extend the "intellectual property" right to industries that are essential to providing for basic necessities like food and medicine. The issuing of patents on human beings is immoral, especially in cultures like our own where the concepts of "private property" and "intellectual property" comprise an unassailable set of norms.

This is true whether the subject is DNA or the methods by which life is transferred. It is undeniable that the Community Guidelines still state that "the human body cannot be patented," but including this phrase in such declarations is merely a rhetorical ruse intended to hide the fact that the Human Genome Project's "other" goal is financial gain, without pausing to consider the procedure's potential for reifying people. Since the genetic systems of the species are at stake here rather than the full human "body," it is now a matter of how to behave with the human body, which has been trivially reduced to DNA threads. This is obviously inappropriate as holding a property right in the form of a monopoly over a specific live creature and its whole descendent is in no way the same as "possessing slaves." Moreover, the privilege that a patent bestows with relation to living things extends beyond a single act and is comparable to stealing both the unique ability for regeneration of people as well as the life-sustaining systems of the whole species.

The Human Genome Project has given the scientific community information and technology—genetic engineering—that may interfere with biological processes and change a person's genetic makeup and inheritance. Despite this capacity, the person who uses it does not suddenly become a "creator." He or she is only a nature's discoverer and manipulator. No matter how much biotechnology enables us to reproduce and reassemble the intricate "parts" of the instrument that is life, living creatures are a creation of nature, not a human construct. A major shift in how we think about and approach biodiversity is implied by expanding the patent system to human beings. This might result in a decline in genetic variation, turning biodiversity into a simple "resource" available for commercial exploitation.

CONCLUSION

The monopoly of biological resources and genetic knowledge, as well as the entry of powerful pharmaceutical firms eager to get the greatest number of functioning genes for themselves. The competition for patents poses a significant threat to biomedical research. Examples of the complexity of the issue include the Biocyte patent on umbilical cord blood cells, which are essential for bone marrow transplants, or the Human Genome Science patent application on the genetic sequence that codes the CCR5 receptor, which plays a significant role in the infection of immune system cells with the AIDS virus and represents a well-founded hope that a cure will be discovered. However, drawing that conclusion would be incorrect and would result in the following paradox: If the right to intellectual property and patents and their guaranties are responsible for what is happening with genes and their commercialization.

Even though one should be cautious when using the word "rights" in the strict sense of the Greek word phronesis, which means "as if donned with the capacity to pass judgment when no mechanical rules, that can be objectified, exist in order to do so" 18, as long as no other more fitting term is found, we cannot throw everything overboard. This is because we are aware that this speech is frequently used to justify all forms of trafficking as some people's tool of oppression.

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