According to her, anything less than (or different from) the internationally accepted standard medical care is unethical. All human beings have a right to receive that standard of care. Now this "standard care" usually means what is accepted in the US or western Europe. Is that necessarily the most desirable medical care? The desirability of a particular medical care is not based only on medical or technological reasons. Other issues, such as its appropriateness, acceptability, feasibility and affordability to people will influence the decision. Obviously in different socio-economic situations and cultures, different models will be more appropriate. These cannot be called sub-standard or "unethical". That position is absurd because it dictates to developing countries that even if they can't eat bread, they must eat cake and only cake. Oral rehydration therapy or community health workers may not be used in developed countries, but they are life-saving solutions for many developing countries.

7. The last question I wish to pose is: Is it ethical to evaluate and pass judgement against any study without completely and carefully studying the available information? The Gadchiroli trial had been extensively reported in 12 research articles published in 2005 in the supplement to the *Journal of Perinatology,* and these have been available on the Internet (10). These articles are not included in the references in the case study in this book published by the editors in 2007. If they had read these, their misconception – that we observed neonates with sepsis in the control area but did not treat them – would have been corrected. Shouldn't they at least verify the facts with the concerned person or organisation (as Zulfiqar Bhutta did by approaching us for certain clarifications) before passing an adverse judgement which reverberates internationally? This is an elementary part of journalistic ethics. Shouldn't the editors of a book on ethics accept this as the minimum standard of ethics?

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Impact of bioethics on patentability of inventions

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Abstract

This paper examines the impact of bioethics on patent claims. The increase in research activities involving human biological materials, and the rush to commercialise inventions derived from such biological materials, can at times result in unethical conduct of research. Questions arise as to whether patent law should concern itself with tainted research that has resulted in an invention or whether it should grant patent rights solely on the basis of the technical improvements resulting from such research. This paper highlights the significance of ethical practice in biomedical research, an issue that may influence the decision to grant patents on inventions. It explores the relation between morality, bioethics and patents from the perspective of the objectives of the patent system and current developments in the law on patents. The inclusion of the morality provision in patent law introduces a mechanism through which inventions derived from tainted research can be filtered at an early stage.

Introduction

The race for patents over inventions derived from human biological materials has given rise to concerns about the private control of human genetic resources. But a far more serious issue has surfaced in the wake of the South Korean stem cell fraud. South Korean scientist Hwang Woo-Suk is said to have coerced his junior colleagues to provide their gametes for stem cell research (1). Hwang fraudulently claimed success in creating human embryonic stem cells through somatic cell nuclear transfer but had inadvertently succeeded in deriving embryonic stem cells from parthenogenesis (1). While the scientist and his group of researchers have had to abandon further research, they have sought patents in various jurisdictions. The grant of a patent to Hwang and his group for this research would enable them to seek royalties and profit from immoral conduct.

The above account raises questions as to whether inventors should be rewarded with patents for inventions that are tainted by unethical behaviour. While patents are usually granted on meeting the technical criteria of novelty, non-obviousness and utility, there are provisions within the patent laws of various countries to deny patents on the grounds of "morality" (3). The United States, the European Union, Australia, New Zealand and India have provisions within their patent laws to deny patents to those inventions that are against public morality. The Andean community, consisting of Bolivia, Colombia, Ecuador, Peru and Venezuela, developed regional rules that require the inventor to show that s/he has obtained the voluntary consent of the people from whom the biological material is sourced (4). In doing so, the Andean community has moved in the direction of using patent law as a tool to filter unethical or immoral inventions. Further, the Italian patent law, through Article 5, requires the patent applicant to file a declaration that the person from whom the biological material is derived has expressed his prior informed consent for such use (5). The Italian Patent Office may refuse the patent application if this requirement is not met.

This paper looks at the patent system and how it has incorporated provisions to filter and prevent the grant of patents to inventions that are tainted by immorality. It explores the relation between morality, bioethics and patent laws. It attempts to illustrate the importance of ethical research, a value that could play a significant role in securing patent protection for new technology. While links between bioethics and patents are not so obvious, the exclusion clause based on morality may require patent offices across the world to seek information regarding the ethical sourcing of human biological materials when patents are claimed for inventions derived from them.

The patent system and morality

The patent system has often been portrayed as neutral and devoid of any moral or ethical values (6). Historically, the patent system originated in mainland Europe and was later on adopted by England in the form of "letters patent". The idea behind introducing monopoly rights through the patent system was to encourage the inventor to disclose his inventions to the public without fear of being copied by competitors (7). Monopoly rights protected the inventor's interests while at the same time the public disclosure mandated by the patent system enabled the public to learn about the invention and improve upon it in the future (7).

If not for a patent system, inventors and businesses would maintain secrecy about their inventions and new technologies (8). The lack of disclosure about the working of a technology or invention would affect the progress of science and technology related to the field (8) and the technological progress of a society. The patent system, by making it mandatory on the part of the inventor to publicly disclose the working of the invention, ensures that inventors provide public access to the working and development of their inventions, resulting in openness in the development of science and technology(8). Although downstream development of technologies in current times has been hampered by patent pools, non-commercial development of downstream technologies continues to be unhindered by the grant of patents.

The patent system was devised not merely to provide incentives to inventors so that the working of the invention is publicly disclosed, but also to benefit society (8). The question arises as to how the patent system confers benefit to society. The disclosure of a new technology is ultimately meant to benefit society as the invention falls into the public domain after the expiry of the monopoly period (20 years) which will allow anyone to commercially replicate the invention (9). Besides, this patent system also enables the government to use the invention during the monopoly period if it deems fit to do so. While monopoly over an invention does create a market imbalance, as is witnessed in developing countries, the provisions of compulsory licensing (i.e, the government may issue – without the voluntary consent of the patent holder – a commercial license to any enterprise to market the patented product for certain social benefit) serve to redress market imbalances (10). The idea behind having such safeguards in patent laws is primarily to ensure that the public benefits from such a system rather than be inconvenienced by it (11).

Given that the patent system was developed to incentivise the public disclosure of inventions, it would not seem to be at odds also if it came with a rider that it would grant a monopoly to fitting inventions that conformed with the current morals of society (2). After all, the monopoly granted to the invention is a mere privilege recognised by the governmental authority and it is only befitting that a privilege is granted to those inventions that lead to scientific progress without harming public morality. Granting monopolies to inventions that encourage offensive, immoral or anti-social behaviour would be against the larger interests of society and would therefore be against public policy (8). Issues of morality do not fall directly within in the patentability criteria of novelty, non-obviousness and utility. But it can be argued that it cannot be the objective of any state to encourage the diffusion of technologies that promote immorality within a society (8, 12). As a result the patent system has incorporated provisions that would prevent the introduction of a technology that is "frivolous or injurious to the well-being, good policy, or sound morals of the society". (13)

The issue of patents and morality arose in Darcy v Allen, an English case in which the courts determined that it cannot be the purpose of the patent law to encourage inventions that are contrary to law or morality. If indeed a person intends to seek patent monopoly, then the inventor has an obligation to comply with conditions imposed by society on him in exchange for the grant of the monopoly (14). This obligation on inventors arises from the understanding that the public does not endorse or promote actions of individuals that may cause harm to society or promote wrongful actions (5). Thus, patents were not granted to inventions that were tainted by immorality. It would be impossible to brush off claims that the patent system is linked to moral standards as it operates within a culture that subscribes to certain community values and shared economic and social interests (2).

Patent jurisprudence in the European Union has evolved to permit the challenge of patents that are against morality. Patents may be rejected on the basis of immorality if the invention is publicly unacceptable or abhorrent to the current morals of society (9). The recent decision of the Enlarged Board of European Patent Office (EBEPO) to deny patents to human embryonic stem cell compositions on the grounds of morality serves as a reminder that the patent office is required to find a balance between public policy and technological development (15).

TRIPS Agreement and the semantics of "morality"

In recent years, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), through Article 27.2, allows member countries to exclude from patentability those inventions, the commercial exploitation of which is necessary to protect public order or morality, protect human, animal or plant life or health or avoid serious prejudice to the environment. As per the agreement, member states have the right to refuse patents to those inventions that are against the public interest or against the prevailing morals of the member state. This provision is specifically included in the TRIPS Agreement so that the member states have the right to protect their public interests. The provision retains the tradition followed in the European countries which gave primacy to the prevailing morals in their countries rather inventions that could potentially harm the public interest (2).

The TRIPS provision specifically addresses the concerns of member countries as regards their right to exclude or deny patents to those inventions that threaten or damage the moral fabric or structure of society. The inclusion of morality as grounds for denying a patent was done with the objective of ensuring that an invention conformed to the prevailing moral principles or values in the country in which it is being patented (2). Thus, ethical or moral values within a member country hold the key if a patent is to be granted. Where an invention is derived from a tainted source which has the effect of breaching the moral or ethical values of a country, it could be excluded from being granted a patent.

"Morality" provision and biotechnology

Rapid innovations in the field of biotechnology have meant that inventors and companies invested in biotech research place emphasis on protecting their inventions through patents. While the patentability criteria set for biotech inventions remain controversial, it is all the more important to ensure that patents are excluded for inventions that are regarded as repugnant to the values within a country.

Whole organs and tissues have been excluded from being patented on the grounds of morality and the failure to meet the criteria for patentability (16-19). But biotech patents granted to human biological materials such as isolated and purified or synthetic genes and DNA have already resulted in arguments that granting private monopoly over the common heritage of humankind could be detrimental to the future of humankind as it puts control of key components of human life in the hands of a few private companies (16, 17). While these concerns remain, the move by the EBEPO in November 2008 to deny patents to human embryonic stem cells derived from the destruction of an embryo has raised concerns regarding the need to exercise caution in seeking patents from inventions that may be regarded as immoral within a society (15).

Concerns also arise when patents are sought for biotech inventions that are sourced unethically. Unethical sourcing of biological materials used in an invention could raise issues of morality. It raises concerns about respecting the autonomy of the tissue provider. Respecting the autonomy of the tissue provider includes a moral obligation not to interfere with the body of a person (20). Interfering with the body or mind of the person amounts to treating humans as objects and impinges on people's freedom to decide for themselves (21). Doing something without individuals' consent would amount to forceful overriding of their autonomy.

The right to self-determination relies on the notion that freedom must be the overriding value in our body politic and respect for human dignity must be the ultimate concern of every society (21, 22). The human dignity of each individual is respected by allowing autonomous individuals to determine what they shall do, and allow or permit others to do, with their bodies or minds (22). Thus, people should have ample freedom to decide whether they must agree, withhold, or deny access to their biological materials (23). If human dignity is to be fully respected, then individuals should also have the freedom to decide whether the biological materials extracted or derived from their bodies can be used for specific purposes (23). This could be vital given that certain communities and religious groups may not agree on the use of biological materials for research that may advance better techniques for, say, abortion, or xenotransplantation or for fusing human and animal genetic material (24). The value of a life depends wholly on the value that individuals give to their lives through their choices. Therefore, individuals from whom human biological materials are sourced must be allowed to determine their choices without coercion or undue influence from researchers or medical practitioners who are involved in sourcing and inventing a biotech product.

Compromising the autonomy of a person strikes at the very root of the existence of a liberal society and results in harming society if human beings are treated as mere means to an end (17). When patents are claimed for inventions that are derived from a tainted source, as in the case of Hwang and his colleagues, the patent office may have to take into cognisance the unethical sourcing of the human biological materials from which the invention is derived. In the case of Hwang, coercing junior colleagues to provide tissues for research would amount to lack of respect for the autonomy of his junior colleagues. This in itself can be regarded as immoral and abhorrent to the ethical values or moral principles prevailing in a society. Thus the patent offices in various countries could refuse to grant patents to tainted inventions on the ground of immorality.

In India, the Patent Act of 1970 provides for moral and ethical considerations in granting patents to the inventor, thus

establishing a link between invention and morality. Section 3(b) of the Patent Act 1970 states that "an invention, the primary or intended use or commercial exploitation of which would be contrary to public order or morality or which causes serious prejudice to human life, or plant life or health or to the human environment are not inventions within the meaning of the Act". Section 3(b) is listed under chapter II of the Patent Act and relates to exclusion of inventions that may have otherwise qualify as patents (25). Thus, in India the Patent Act provides room for excluding inventions that may be contrary to public order or morality. Under current practice, it is not an explicit requirement for the inventor to disclose to the Patent Office that he has respected the autonomy of the tissue provider at the time of sourcing the biological materials. But, it is implicit within the language of the Act that patents may be refused if the inventor approaches the Patent Office with unclean hands. The Patent Office could deny the inventor to benefit from his tainted act. The lack of well developed jurisprudence in the Indian case will leave inventors uncertain as to the exact meaning of the provision. But the Patent Office could be guided by the interpretations of the European Patent Office which has in the recent past dealt with issues of patents and morality.

Conclusion

While the patent system is devised mainly to examine the patentability of an invention it has, over the years, evolved to look at issues of morality. Issues of morality of an invention have become more relevant in the era of biotechnology where patents are being sought for inventions that have been derived from tainted sources. Requiring patent applicants to furnish information about the ethical sourcing of the human biological material does not necessarily digress from the primary objective of the patent law. The morality provision in the patent law acts a filter to discourage patents for inventions that are derived from tainted sources. (26).

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