



## IMPACT OF PATENT SYSTEM ON HUMAN RIGHTS

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### Abstract:

*Human rights and patent rights are, to a large extent, fields of law that have evolved independently. On the one hand, patent rights consist of statutorily recognized rights, which provide incentives for the participation of the private sector in certain fields and seek to contribute to technological development. Patents are near monopoly rights. This monopoly is offered by society in return for certain concessions such as information disclosure and a limited duration of the rights granted. On the other hand, human rights are fundamental rights, which are recognized by the state but are inherent rights linked to human dignity. Different kinds of links between patent rights and human rights can be identified.*

### KEY WORDS:

Open Book Exam and Close Book Exam

### INTRODUCTION

Patent laws recognize that there is a socioeconomic dimension to the rights granted and that a balance must be struck between the interests of the patent holder and the broader interests of society. Patent rights also have direct and indirect impacts on the realization of human rights. For example, patent rights include economic and moral elements. The latter can be linked to certain aspects of human rights. Finally, human rights treaties recognize certain rights pertaining to science and technology. The links between patent rights and human rights have been acknowledged for many decades, as exemplified in the science and technology-related provisions of the Universal Declaration of Human Rights (Universal Declaration). Nevertheless, the main debates concerning the links between human rights and property rights focused for a long time on real property rights rather than intellectual property rights.

The adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and its implications for developing countries have fundamentally changed the nature of the debate concerning intellectual property rights and human rights. This shift is demonstrated in three ways. First, the possible impacts of the introduction or strengthening of intellectual property rights standards on the realization of human rights have been exemplified by the crisis over access to HIV/AIDS medicines. Second, there has been renewed debate over the introduction of intellectual property in fundamental bills of rights at the national or regional level. Third, at the UN level, there has been renewed interest in the science-

related provisions of Article 15 (1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR). This article analyzes a number of issues arising in the context of the direct and indirect patent system on human rights, as well as the broader issue of the possible future role of knowledge related human rights provisions. It examines issues related to the introduction of science and technology-related clauses in human rights instruments at the international level. It also briefly examines several specific regional and national case studies. It moves on to highlight issues concerning the relationship between existing intellectual property rights treaties and laws and the realization of human rights such as the rights to health and food. The third section first focuses on General Comment 17 on Article 15(1) (c) of the ICESCR adopted by the Committee on Economic, Social and Cultural Rights (ESCR Committee). It then suggests an alternative reading which takes a broader look at the meaning of knowledge-related provisions in human rights treaties and argues that provisions like Article 15(1) (c) should be seen in the context of broader intellectual property protection challenges such as questions related to traditional knowledge.

### CONCEPT OF PATENT

A patent is an “intellectual property right” in an invention. Intellectual property rights (IPRs) are rights given to a person or a corporation over mental creations, such as: an author's copyright in their book or the rights of musicians in their recordings; a company's distinctive trademark on its products; or a patent on a technological invention.

A patent gives its owner (the "patentee") the right to prevent others from making, using, importing, or selling an invention. In other words, patenting an invention gives the patent owner a monopoly over the invention. A patent is usually granted for a limited time, such as 20 years. A patent is granted under a country's domestic laws, which may be affected by international laws. A patent may come with conditions or exceptions, depending on what the law in a given country says.

What can be patented: A patented invention can be either an actual product or a new process for making a product. In order to qualify for a patent, an invention must satisfy three criteria: it must be something new, it must not be obvious but actually involve some sort of “inventive step”, and it must be usable. Medical drugs are inventions that can be patented.

Generic drug: A drug that is patented can only be made, used, imported/exported or sold by the patent holder. According to the World Health Organization's Action program on Essential Drugs, a drug that is patented is usually marketed under a proprietary or brand name reserved exclusively to its owner, i.e. the individual or firm granted a patent on that invention.

Patented drug: A generic drug is a pharmaceutical product usually intended to be interchangeable with the original patented drug ("bioequivalent") because it does the same thing. Unless there is a prior agreement with the patent owner, a generic drug is usually made and marketed after the expiry of patent rights held by the patentee. A generic drug is marketed either under a non-proprietary or approved name rather than a proprietary or brand name. Generic drugs should not be confused with counterfeit drugs. “Counterfeit goods are generally defined as goods involving slavish copying of trademarks. According to WHO, a counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with incorrect quantity of active ingredients or with fake packaging.

### CLASSIFICATION OF PATENT

1. Process Patent: Process Patent means that when a substance is invented or produced, a patent is not granted to the substance itself but it is only the method or the process of manufacture of a substance that is granted a patent. Therefore the patent is granted to the process but not to the product, in this kind of patent.
2. Product Patents: In product patents, the patent is granted not to the method or process of manufacture of a substance but to the substance itself. Therefore in this kind of patent, it is the product that is covered and protected.

### EVOLUTION OF PATENT

Origin of patent is traceable to a Greek law in 510 B.C, which gave exclusive rights to those who created certain culinary delights. If a confectioner or cook invented any peculiar or excellent dish, no other

artist was allowed to make it for a year, but he alone was entitled to derive benefits from it during the period. But, the general policy of exclusive rights for inventions was debated and rejected. Aristotle disfavoured a proposed law that intended to entitle the people who made discoveries advantageous to their country to receive honors on the ground that it would lead to alterations to the constitution. He and Plato considered industrial and fine arts unimportant. Emperor Nero of Rome outlawed monopoly by any person over any material either by his own authority or by imperial sanction.

In the later part of the nineteenth century new inventions in the field of art, process, method or manner of manufacture, machinery, apparatuses and other substances, produced by manufactures were on the increase and the inventions became very much interested that the inventions done by them should not be infringed by anyone else by copying them or by adopting the methods used by them. To save the interests of inventors the then British rulers enacted the Indian Patent and Designs Act, 1911. Since then due to substantial changes in the political and economic conditions of the country, it was found desirable to enact compressive law on the subject. The Patents Bill, 1953 was introduced in the Lok Sabha on 7th December, 1949 but it lapsed on the dissolution of the First Lok Sabha. In 1965 the Patents Bill, 1965 was moved in the Parliament but could not be proceeded with for want of time and eventually lapsed with the dissolution of the Third Lok Sabha. The Patent Bill was again introduced in the Parliament in 1970.

Indian Patent system was developed largely through legislations. The Indian Patent Act, 1856 was the first Indian statute on the subject that corresponded to the English Act of 1852. After some changes in 1859 and 1872 it was consolidated in 1883 to keep pace with the development in English system. In 1911 the Indian Patents and Designs Act was passed and the patent administration was brought under the control of a controller. With the dawn of independence, review committees looked to the aspect of reforming the patent law. The Tek Chand Report 1949 revealed, "The Indian Patent system has failed in its main purpose. Keeping in mind the factors of economic development and public interest over the interest of inventor is implicit in the provisions for patentable invention, test for invention, term of patent, government control over patents in the form of acquisition etc. Three major amendments were brought to Act in 1999 and 2002 to render the Patent Act to confirm TRIPs Agreements. The 1999 Act removed the restrictions on Indian residents applying for patent outside Indian and created exclusive marketing rights for a period until 2005, for substances used for medicine or drug, concerning which process patenting is obtained.

### CONCEPT OF HUMAN RIGHTS

The expression 'Human right' is of recent origin. It denotes all those rights, which are inherent in human beings irrespective of creed, religion, sex, and nationality. Every individual (human being) is entitled to some basic rights, without which we cannot live as human beings. It is very difficult to give a precise meaning of the term human rights. All these rights, which are essential for the maintenance of human dignity, may be called as human rights. Human rights are the natural rights of the human race without which we cannot live as human beings. Therefore, human rights sometimes are also called as natural rights or basic rights or fundamental rights.

Louis Henkin, in his 'The Age of Rights' defines: "Human rights are rights of individuals in society. Every human being has legitimate, valid, justified claims upon his or her society to various 'goods' and 'benefits' they are defined, particular claims listed in international instrument deemed essential for individual well-being, dignity, and fulfillment, and that reflect a common sense of justice, fairness, and decency".

Section 2(1)(d) of the protection of Human rights Act, 1993 defines 'human rights' Human rights means rights relating to life, liberty, equality and dignity of the individual guaranteed by the Constitution or embodied in the international Covenants and enforceable by Courts in India.

### KINDS OF HUMAN RIGHTS

Under the United Nations system makes it clear that human rights are of two kinds namely;

1. **Civil And Political Rights:** civil rights or liberties are referred to those rights, which are related to the protection of the rights to life and personal liberty. Such rights include rights to life, liberty and security of persons, rights to privacy, home and correspondence, rights to own property, freedom from torture, inhuman and degrading treatment, freedom of thought, conscience and religion and freedom of movement. Political rights may be referred to those rights, which allow a person's to participate in the government of a state. Thus, rights to vote, right to elected at genuine periodic elections, rights to take part in the conduct public affairs, directly through chosen representatives are instances of political rights.
2. **Economic, social and cultural Rights:** Economic, social and cultural rights are related to the guarantee of minimum necessities of the life of human beings. In the absence of these rights the existence of

human beings is likely to be endangered. Right to adequate food, clothing, housing and adequate standard of living and freedom from hunger, right to work, right to social security, right to physical and mental health and right to education are included in this category of rights. These rights are included in the International covenant on economic, social and cultural Rights. These rights are based fundamentally on the concept of social equality.

### THE EVOLUTION OF HUMAN RIGHTS

The roots for the protection of the rights of may be traced as far back as in the Babylonian laws. Babylonian king Hammurabi had issued a of laws to his people which is called Hammurabi's codes, established fair wages, offered protection of property and required charges to be provided at trail. The codes, while often harsh in their punishment provided standards by which Babylonians could order their lives and treat one another. Assyrian law, hittiti laws and the Dharma of the Vedic period in India, also devised different sets of standards by which obligations of one was provided to another, jurisprudence of lao-Tze and Confucius in Chin also protected human rights. Thus, the world's all major religions have a humanist perspective that supports human rights despite the difference in the contents.

The concepts of Human right can be found as far back in time as age of the Greek philosophers Socrates, Plato and Aristotle. Their writings on the India of natural law contain many of the some principles that and associated with human rights. The Magna Carat (1215) is considered a milestone in the history of human rights and several great thinkers such as Grotius, Hobbes, Locke, Rousseau and Hant talk about the concept.

Some negative texts also are said to reflect the principles of the human rights. The Rig Veda promotes conduct that is based on equality. Even certain Bible passages have similar content. For instance, in the Old Testament, when the widwives of pharoah disobey his orders to will all male Babies, the do so on the basis of heighten and more fundamental laws that they felt bound to follow. The American and declarations of independence in the 18th Century were important promoting human rights that were universal, individual and national. In the 19th century, the abolition of slavery and increased debate open freedom from government intervention also further these principles. With the dwindling of colonialism development in the third world received more focus and adult suffrages, liberty, equality and justice come to be emphasized.

The term "Human Rights" was introduced in the United States Declaration of Independence in 1776 and the US Constitution embodied a Bill of Rights. In 1929, Institute of International Law, New York, USA prepared a Declaration of Human Rights and Duties. A Resolution was passed to this effect in the Inter American Conference seeking establishment of an International Forum for the furtherance of Human rights of Mankind. In India, the Protection of Human Rights, 1993, defined Human Rights Thus: "The rights relating to liberty, equality and dignity of the individual guaranteed by the Indian constitution as international Covenants.

### THE IMPACT OF PATENTS ON DEVELOPMENT

In practice the impact of patents on economic development is complicated by the fact that the potential gains in innovation must be offset against the short-term costs associated with patent protection, particularly the likelihood that relatively high prices will be charged for patented products, such as pharmaceuticals, in the absence of imitative products circulating in the market. Furthermore, in reality the extent to which patents will contribute to innovation and economic development will depend on local conditions and must be assessed on a case-by-case basis. Recent studies have considered this question in econometric terms.

Gould and Gruben (1996) related economic growth rates across countries to a simple index of patent strength and other variables. They found no strong direct effects of patents on growth but noted a significantly positive effect when the index was interacted with a measure of openness to trade. In particular they found that strengthening the patent regime in open economies was likely to raise growth rates by 0.6 per cent on average. For Gould and Gruben, therefore, trade liberalization in combination with stronger patent protection and enforcement enhances growth because it improves the competitive nature of markets and increases access to foreign technologies. Park and Ginarte (1997) focused on the extent that patents affect investment in capital and R&D, as well as economic growth. As with Gould and Gruben's study, they found no direct correlation between patent strength and economic growth. However, Park and Ginarte did generate empirical evidence to suggest that patents can have a powerful and positive effect on investment and R&D spending, which in turn can have indirect positive effects on economic growth.

#### Medical Patents and the Human Right to Health

General considerations concerning the impacts of existing intellectual property rights on human rights highlighted above are better analyzed by focusing on specific rights. In recent years, one of the most controversial debates has focused on the impacts of medical patents on the realization of the human right to health in developing countries. The right to the “enjoyment of the highest attainable standard of physical and mental health” is specifically protected under the ICESCR. Core obligations of member states include the necessity to ensure the right of access to health facilities, especially for vulnerable or marginalized group's case of primary health care; this includes the provision of essential drugs. In the case of HIV/AIDS more specific elaborations of these obligations have been given. The UN Human Rights Commission adopted resolutions indicating that access to medication in the context of HIV/AIDS is one fundamental element for achieving the full realization of the right to health. In other words, accessibility of medicines and their affordability are two central components of the right to health. Medical patents have direct impacts on accessibility and affordability. They have the potential to improve access by providing incentives for the development of new drugs as well as to restrict access because of the comparatively higher prices of patented drugs.

In practice, access to drugs is governed by a number of factors. Their price is one important factor. Therefore, the fact that patented drugs are nearly always more expensive than generic drugs is a relevant consideration. Other factors that influence access include situations where there is only limited competition between generic producers, local taxes, and mark-ups for wholesaling, distribution, and dispensing. Improving access can thus not be limited to bringing prices down through competition but must also include further measures such as public subsidies, or price control measures. Fostering better access to drugs can be approached from the point of view of medical patents or the right to health. The dichotomy is unavoidable insofar as each relevant legal framework is largely insulated from the other, but both need to be considered jointly because, in practice, a solution focusing on medical patents that ends up constituting a denial of the right to health would not be acceptable. From the standpoint of the TRIPS Agreement, the question of health is one that can be tackled through some of the exceptions provided in Section 5 of TRIPS or through the two general clauses of Articles 7 and 8. This, however, falls short of providing a reasoned argument concerning the relationship between TRIPS and human rights. From the human rights perspective, the realization of the right to health does not imply an outright rejection of medical patents. Nevertheless, several points need to be highlighted. Patent protection does not ensure that the most common diseases will attract the greatest amount of research. This implies that even if patent protection can be justified in markets where all consumers can afford to pay directly or indirectly the price of patented drugs, this is not so in other situations.

The central issue is that the realization of human rights must be judged according to the level of implementation among the most disadvantaged. The issue is not, therefore, whether certain countries can afford patent rights, but whether the poorest in any given country stand to benefit from the introduction of medical patents. In certain situations, the introduction of medical patents is likely to restrict access to drugs even further than now because price hikes will further limit the number of persons who can afford to purchase medicines.<sup>60</sup> In a situation where compliance with commitments under the TRIPS Agreement leads to reduced access to drugs, this raises the question of a substantive violation of the ICESCR. Indeed, while Article 2 of the Covenant does not require immediate full implementation of the right to health, it obliges states to take positive measures towards the fulfillment of the right. Thus, the repeal of legislation which is necessary for the continued enjoyment of the right to health, or the adoption of legislation incompatible with pre-existing domestic or international legal obligations in relation to the right to health, would constitute a violation. In this specific case, the introduction of medical patents could be construed as a “deliberately retrogressive” step if no measures are taken to limit the impacts of TRIPS compliance on access to medicines by, for instance, providing that all essential medicines should remain free from patent protection.

#### THE IMPACT OF THE PATENT SYSTEM ON INVENTION

The patent system has been transformed over the past twenty-five years by an unusually large number of significant changes, says Steve Merrill of the National Academies. “Some of these changes are legislative,” he says, “and even more of these changes are from the courts, applying the law to new circumstances.” Collectively, the impact on invention has been dramatic. These and other developments have contributed to a general expansion of rights and benefits for patent holders, says Merrill. He agrees that it's much easier and more common in IP law to expand rights rather than take them away. Intellectual property protections tend to be “a one-way ratchet,” as it may be unconstitutional to take away a legitimately expected right without just compensation, says Rochelle Dreyfuss this expansion of rights may

have contributed to the simultaneous surge in patents applied for and issued, adds Merrill. The U.S. issued between 60,000 and 70,000 patents per year from 1965 through 1983. Then there was a sharp spike upwards, leaping to about 170,000 per year by the late 1990. During this time, we've also seen higher renewal rates and a more frequent asserting of patent rights. Since 1988, the number of patent lawsuits filed in U.S District courts have doubled, and overall patent litigation rates have increased tenfold over the past two decades.

Anthony Breitzman, vice president and chief technology officer at CHI. Research Inc., says that the increased rate of patenting has naturally favored large multinational corporations who can best afford to file and assert large numbers of patents. Foreign corporations now receive nearly half of U.S. patents, up from about 40 percent in 1980. About 41 percent are now received by U.S. corporations. Individually owned patents have declined slightly over this period, to about nine percent. Only about two percent of patents are university owned, and one percent is owned by government. Not surprisingly, patenting is highly correlated with R&D spending. About 100 companies account for 70 percent of the R&D in the United States, and about 20 universities represent a very substantial portion of academic R&D, according to CHI. But we're also seeing increased patent productivity among big firms. "The number of patents yielded on dollars of R&D spent is increasing within large firms," Breitzman says. This concentration is spreading to large government and university laboratories too. About two-thirds of all patents now are being granted to about 1,500 organizations. However, Breitzman also revealed a surprise. In terms of high-impact inventions, the field is "concentrated, but not as much as you might think," he says. "Against the odds, there's still a substantial amount of independent and small company invention. A lot of the individual inventors are in small companies and so small companies are actually pretty big in this pecking order." The next question, he says, is "where do small companies patent?" The data show real barriers to entry in aerospace, motor vehicles, oil and gas, computing, and plastics. More than 97 percent of the patents in each of those areas are being issued to large corporations. Small companies, meanwhile, are showing strength in biotechnology, pharmaceuticals and medical electronics. About 25 percent of patents in these industries are being issued to small companies and individuals. "There are areas where small companies are really competing," Breitzman concludes. Numbers, of course, only tell a part of the story. "The actual number of patents doesn't mean much," he says. Numbers of patents correlate with money spent on R&D. And on a macro level, you can even correlate patents with country by country GDP. But since only a small number of patents – an estimated one percent – turn out to be valuable or have a high impact on the marketplace, the sheer numbers don't tell you much about where these high-impact patents are being generated.

#### **IMPACT OF PATENTS ON R&D AND EMERGING PATENTING STRATEGIES OF INDIAN FIRMS**

Under the new Indian patent regime, biomedical research tools are patentable in India. There are two exceptions to this. Firstly, there is a research exemption for patented inventions, which can be interpreted to be applicable for both academic and commercial research. Secondly, medical, diagnostic and therapeutic kits/ tools are not patentable only when they are for the treatment of human beings or animals or plants. Legal and economic literature on the impact of stronger intellectual property protection has pointed out that stronger intellectual property protection can, instead of promoting innovative activities, limit access to knowledge that is necessary for society to indulge in innovative activity, by restricting access not only to inventions but also to research tools and processes. There is evidence of firms creating patent portfolios and holding up research in cases where progress is dependent on access to their inventions. These concerns have been deepened by strong patent rights acquired by firms that cover not only inventions related to genes, but also genes and proteins themselves and fundamental research tools, apart from entire living organisms. Empirical evidence on this topic is limited and controversial, although some studies have been conducted on the topic in the recent past, albeit mainly in developed countries. The topic assumes at least as much importance in the context of developing countries, especially those that are trying to/have been able to develop significant local capacity in the pharmaceutical and also biotechnological sectors. Will India's full-scale TRIPS compliance result in restricting access to technologies to the local pharmaceutical industry to test this, the survey posed the question whether firms face increased difficulties in accessing new technologies that are required for their activities after India started its phased compliance with the TRIPS Agreement over the past few years. A total of 43 firms felt that access to new technologies have become more difficult after India started implementing its compliance with the TRIPS Agreement.

#### **INTELLECTUAL PROPERTY RIGHTS AND THE REALIZATION OF HUMAN RIGHTS**

Patent rights largely evolved as a distinct field of law for most of their history. This was due in part to the perception that rights like patents made a specific contribution towards economic and technological

This has two important implications. First, there is no equality of rights between the different actors in presence. Second, patent laws have only made insignificant contributions to the understanding of the potential impacts that they can have on the realization of human rights. The relative isolation of intellectual property rights from broader debates concerning their impact on the realization of human rights or on environmental conservation has ended following the adoption of the TRIPS Agreement, whose main impact has been to substantially raise intellectual property rights standards in a majority of developing countries. In the context of a majority of developing countries, and probably all least developed countries, the implementation of the TRIPS Agreement has the potential to have significant impacts on the realization of human rights. The link between patent protection and the realization of human rights is not new per se, but it has been made much more palpable following the adoption of the TRIPS Agreement. Most developing countries have had and are having to quickly adopt intellectual property rights standards which have the potential to trigger significant socioeconomic disruption. This was probably never so visible in developed countries, where the strengthening of patent protection has largely been incremental.

The links between patent rights and the realization of human rights in developing countries exist with regard to a number of human rights. They are easily visible in the case of the rights to food and to health. With regard to the human right to health, the link has become apparent in the relationship between medical patents and the realization of the right to health, particularly in the context of the HIV/AIDS epidemics. To the fact that a number of drugs used to alleviate HIV/AIDS are protected by patents. There is, therefore, a direct link between patents, the price of drugs, and access to drugs. With regard to the right to food, there are links between patents in the field of genetic engineering, the limitation of farmers' rights, and access to food. While the link between patent rights and human rights has been made, in other words, there remains to date a visible imbalance insofar as the language of human rights has not penetrated intellectual property rights institutions, while the language of intellectual property rights is now regularly addressed in human rights institutions. At the UN level, this has been the case of the Sub-Commission on the Promotion and Protection of Human Rights (Sub-Commission) and the ESCR Committee. The Sub-Commission specifically debated the question of the impact of patent rights on the realization of human rights.

## CONCLUSION

Currently, most debates focus on the place of patent rights in a human rights context and on the impacts of patent on rights human rights. In view of the importance science and technology in the twenty-first century, it is imperative to move beyond exiting patent rights when addressing the issue from a human rights perspective. This due to the fact that Article 15 (1) (c) does not refer to patent rights and to the fact that a human rights perspective cannot be limited to certain types of intellectual contribution. Intellectual property rights instruments have never directly addressed impacts on the realization of human rights. Yet, the adoption of the TRIPS Agreement and its progressive implementation in developing countries has been associated with certain specific difficulties. Problems identified in the context of medical patents and the human right to health indicate that measures must be taken to ensure that the progressive strengthening of intellectual property rights does not contribute to limiting access to drugs, something which would directly go against the commitments taken by states under the ICESCR with regard to the progressive realization of the human right to health.

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