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Right to Health and Medical Patent: A Human Right Perspective

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ABSTRACT

This research paper discusses aspects of two sets of law, one being Intellectual Property Rights and the other Human Rights. Although these two sets of law rarely coincide with one another, it is the increasing use of patents in the field of medicines that has led to the debate over medical patents violating the human right to health by making life saving medicines increasingly expensive and inaccessible for ordinary people. In the world we currently live in, having access to medicine which can save lives is extremely important, and the increasing number of patents on life saving drugs is making access difficult, especially for people living in developing countries. The objective of the research is to identify whether the growth of medical patents is making access to medicine difficult and thus conflicting with people's human right to health. The study intends to analyse whether the present framework of medical patents is at par with the needs of today's world, in which the greater part of the population lives in developing nations and does not have access to basic health products; and to understand what role the TRIPS Agreement plays in the evolution and regulation of medical patent law at the international level. It also studies the issues relating to generic medicines and the role they can play in improving global health, along with the legal issues relating to their use and legality. Finally, it studies the Indian medical patent framework and the role of the Indian judiciary in resolving disputes between patent rights and the human right to health.

Keywords: *Patents, Healthcare, Human Rights*

I. INTRODUCTION TO MEDICAL PATENTS

A. Introduction to Intellectual Property

It is an established fact that human intellect is the most important jewel of human civilisation and is essential to its survival; utmost importance should therefore be given to it and to the ways of protecting it. Intellectual property consists of any original creation of an individual's mind or human intellect, including any artistic, technical, literary or scientific creation. The legal rights given to a person for his creation or invention in order to protect his intellectual property are known as intellectual property rights. These are exclusive rights assigned to an inventor or creator, or to their representative, which authorise them to exercise complete authority over the

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invention or creation for a given period of time. Intellectual property rights play a very important part in recognising and protecting the rights of the creator or inventor; they provide a secure and motivating environment in which to work on a creation, with the assurance that the resulting rights will be protected. The cost of research and development is met through investment, which plays a very important role in the development of new technologies that in turn aid the development of human civilisation. The prospect of recovering the cost of research and development is important in order to encourage investors, and it is equally important to protect new technology from unauthorised use, at least for a period until its implications are clear.[1]

The protection of intellectual property rights not only ensures that a technology or creation does not fall into the wrong hands but also ensures the recovery of the investment made in research and development and of other costs incurred by investors, which in turn sustains continuous investment in research and development. Intellectual property rights are a robust mechanism protecting a creator's or investor's time, effort and money by conferring an exclusive right over the creation or invention. It can therefore be said that intellectual property rights assist in the economic development of a country by advancing healthy competition and industrial development.[2]

Like most bodies of law, the rules and procedures relating to intellectual property have their origins in fourteenth century Europe. England in particular was far ahead of its European counterparts in attracting artisans and inventors from other parts of the world on special terms that protected their rights and that contributed to the technological development of Europe. The first printing privilege of which we know was granted in Venice in 1469, and the first statutory patent system was the Venetian Patent Statute of 1474; the rest of the world followed that course. Patent legislation in India is more than 150 years old, the first Act having been introduced in 1856 on the model of the English system, although the statute now in force is the Patents Act, 1970.[3]

B. Scope of Intellectual Property

The scope of intellectual property has become wider with time. Initially intellectual property law protected only patents, trade marks and industrial designs, but it now extends to copyright, geographical indications and other subject matter. Intellectual property rights have to grow along with technological advancement, as the two go hand in hand. The reason is that

[1] RAGHUBHIR SINGH, LAW RELATING TO INTELLECTUAL PROPERTY vol. 1 (Universal Law Publishing 2004).
[2] V.K. AHUJA, LAW RELATING TO INTELLECTUAL PROPERTY RIGHTS 721-45 (2d ed., LexisNexis 2013).
[3] *Id.*

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intellectual property provides the encouragement and motivation for an inventor to create new technology, because it supplies a mechanism for dealing with infringement and piracy, which in turn results in technological development. The stronger the intellectual property regime of a country, the better its prospects of economic development.

A range of intellectual efforts is protected by intellectual property law:[4]

Patents.

Industrial design right. This is a right which protects the visual design of a product or an object. It may cover any pattern used to produce a product, whether two dimensional or three dimensional, for example the shape of a Coca-Cola bottle or the design of a Mini Cooper.

Trade mark. This may be anything from a symbol or a logo to a word or group of words particularly associated with a brand and representing that brand or service. It is the means by which the brand is identified by the public, for example the logos of BMW, Audi and Jaguar, or the way in which the word Cadbury is written.

Copyright. This right is generally provided to protect artistic expression in literature, music, film or performance, and also computer software, for example a book or a painting.

Geographical indication. These are assigned to goods which originate from a particular geographical region and possess the quality and characteristics for which that region is reputed, for example Darjeeling tea and the Pashmina shawl.

A patent is granted to an invention that satisfies the requirement of global novelty and that provides a new way of doing something or offers a solution to a problem. A patent may be granted for a product or for a process which possesses the necessary uniqueness. A person who is granted a patent has the exclusive right to work the invention, and no one else may commercially exploit it. No one may use the product in any way except the patent owner or a person acting with the patent owner's consent.[5]

C. Patents

A patent is a monopoly right given to an inventor to exploit his invention for a limited period of time, after which it falls into the public domain. As the Madras High Court noted, citing HALSBURY'S LAWS OF ENGLAND, "the word Patent is used denoting a monopoly right in respect of an invention".[6] The monopoly right is given to the inventor as a reward for his innovation, so

[4] Vipin Mathur, *Patenting of Pharmaceuticals: An Indian Perspective*, 4(3) INT'L J. DRUG DEV. & RES. 27, 27-34 (July-Sept. 2012).
[5] Ahuja, *supra* note 2.
[6] *Bajaj Auto Ltd. v. TVS Motor Co. Ltd.*, 2008 (36) PTC 417, para. 27 (Mad).

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that he can enjoy its benefits and recover the cost incurred in developing it. A patent may be granted for a product as well as for a process. But not every product or process is patentable; in order to obtain that status it has to fulfil certain conditions:

New invention. An invention must be new or novel, that is, it must not already be in the public domain.

Inventive step. It is not enough that something has been made; the invention must also involve a technical advance over existing knowledge in that field, or have economic significance, or both.

Capable of industrial application. The product or process must be capable of being made or used in an industry.

Patents play an important role in the development and technological advancement of a country and its economy, because they provide the incentive for research and development work in various industries, without which no growth is possible.

D. Management of Patents in the Pharmaceutical Industry

Drugs and pharmaceuticals are considered to be among the most sensitive areas when it comes to the need for a strong intellectual property system. The pharmaceutical industry is essential to human well-being; it contributes a fair share to maintaining the health of people at large and to curing life threatening diseases. Given that a company may spend anywhere between USD 300 million and USD 1,000 million to bring a new drug to market, a strong intellectual property regime becomes difficult to negotiate away.[7] That is especially so in the times we are living in, with new viruses emerging and threatening human life. If we are to fight such pandemics it is essential to have strong research and development in the pharmaceutical industry, and that requires substantial investment and a legal guarantee that the resulting rights will be protected, which is what patents supply.

The pharmaceutical industry, unlike other industries, is driven more by scientific knowledge and new invention and less by factors such as manufacturing and advertising. The success of a pharmaceutical company depends largely upon its research and development capability. Investment in research and development is therefore, and rightly, significantly higher than in any other industry, and the share of research and development in total sales is correspondingly high. While competition in the pharmaceutical industry is in no way less than in any other

[7] Chandra Nath Saha & Sanjib Bhattacharya, *Intellectual Property Rights: An Overview and Implications in Pharmaceutical Industry*, 2(2) J. ADVANCED PHARM. TECH. & RES. 88, 88-93 (Apr.-June 2011), https://pmc.ncbi.nlm.nih.gov/articles/PMC3217699/.

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industry, the management of new innovation adds to the challenge. The risk associated with the failure of research and development is very high: most candidate drugs are unable to pass rigorous safety standards even after years of investment, and even when they do, it takes many years to recover the cost of development. Companies must also satisfy the safety requirements of different countries if they are to reach the global market. For these reasons companies were once reluctant to invest in the development of new drugs and new chemical entities. With the emergence of product patents in the drug industry, patenting became the main tool for protecting intellectual property, and drug companies concentrated on research and development to make new drugs for curing disease.[8]

Regulatory authorities have also made the process of approving new drugs more demanding. It is well known that any approval comes with a great deal of documentation and paperwork, which makes the process longer. In addition, the effective patent period has been reduced, which gives companies even less opportunity to recover their costs and reduces their profit margins. This has brought us to a crossroads: either the large drug companies will campaign for longer protection of drugs, harming the interest of the public at large, or governments, in order to secure the public good, will exercise more rigid price control, which would in turn require reduced costs of drug development, marketing and production so as to allow cost recovery over a longer period. That could also dampen investment in the pharmaceutical sector, since a smaller profit margin would be available. The pharmaceutical industry therefore has a difficult road ahead of it. Over the last two decades various efforts have been made to reduce cost, such as outsourcing research and development, but largely to increase the companies' own trade advantage rather than for the public good.[9]

E. Medical Patents

Medical patents are the soul of the pharmaceutical industry. The development of the pharmaceutical industry is heavily dependent upon the patent system. Just as patents generally play a very important role in providing an incentive to work on new technologies, in the pharmaceutical industry patents provide the means to invest in the research and development of new drugs which improve the healthcare system. Medical patents are a way to improve the quality of human life, because the more investment is made in the research and development of drugs, the greater the chance of finding treatment for life threatening diseases such as cancer and HIV/AIDS.

[8] Mathur, *supra* note 4.
[9] Marcia Angell, *The Pharmaceutical Industry - To Whom Is It Accountable?*, 342(25) NEW ENG. J. MED. 1902, 1902-04 (June 22, 2000).

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The term medical patent is not limited to medicines. There are several kinds of medical patent, and the law does not treat them alike:

Medical devices. Physical devices used by surgeons and other medical practitioners in hospitals may be patented. This category includes surgical tools, diagnostic instruments and the like, but such devices must also satisfy the conditions of patentability. Profit margins in this category are relatively low.

Information technology relating to health care. Software applications which aid in the medical care of a patient, for example by giving access to medical records or by managing appointments, may also be the subject of patent protection.

Medical and surgical methods. These are not patentable in India, however novel or efficient the method may be. Section 3(i) of the Patents Act, 1970 excludes from the definition of invention any process for the medicinal, surgical, curative, prophylactic, diagnostic or therapeutic treatment of human beings, and any similar process applied to animals. Article 27.3(a) of the TRIPS Agreement expressly permits members to make that exclusion. The instruments and compositions used in treatment may therefore be patented; the method of treatment itself may not.[10]

A patent works as a shield for a new invention by giving exclusive rights to its owner to sell and manufacture the patented product as he sees fit. The inventor has complete ownership of the invention and may work it as he pleases.

Pharmaceutical patents have become the core of the pharmaceutical industry, and with every new drug the importance attached to them increases. This is largely due to the commercial benefits attached to medical patents. The research and development of a new drug is an expensive process, and the pharmaceutical companies which invest in it expect to be compensated for their effort; patents provide that compensation along with the added incentive of exclusivity. The risks associated with research and development are also very high, as there is no guarantee of return and failure brings a heavy loss. Innovation in the pharmaceutical sector is therefore both the essence of the industry and a burden upon it.

i. The Importance of Innovation in the Drug Industry

A drug manufacturer's success is largely determined by its ability to obtain a patent for the products of its research.

[10] The Patents Act, 1970, No. 39 of 1970, sec. 3(i) (India); Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27.3(a), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C [hereinafter TRIPS Agreement].

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Innovation, where it succeeds, yields a high rate of return on investment. Although the costs of designing and marketing a new medicine are significant, the return on approved products may be considerably greater than the cost of bringing the drug to market.

While the risk associated with drug development is high, creativity allows for greater profitability, so that for a successful product the benefits outweigh the costs.

Innovation matters to these companies because a great deal of money is spent on the research and marketing of candidate drugs. If those drugs do not reach the market, the time and money spent are lost. Innovative approaches must therefore be taken to determine how such companies can obtain a return on their investment without losing too much money.

While the cost of bringing a new drug to market can be high, drug companies can also increase profits by marketing existing drugs so as to enhance the success of those products which they are currently manufacturing and which are already on the market.

II. THE MEDICAL PATENT REGIME AND THE HUMAN RIGHT TO HEALTH

There has never been a deep and settled relationship between intellectual property law and human rights law; the two have rarely been linked to each other. One of the main reasons is that intellectual property systems are not, in their design, governed by socio-economic concerns. But in recent times the extension of intellectual property rights into areas of basic human need, such as health, has made it necessary to rethink the relationship between the two. The importance of a healthy life is undeniable. That is why it has been recognised at both the international and the national level by accepting health as a human right. One of the major instruments which gives the most detailed version of this right is the International Covenant on Economic, Social and Cultural Rights, which recognises the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The right to health includes not only the availability of safe and adequate food and water but also access to treatment for common diseases and injuries and the availability and affordability of essential drugs.[11]

The main aim of intellectual property rights, and of patents in particular, is to provide the necessary encouragement for research and development. A patent gives the developer a monopoly right for a certain period of time.[12] The purpose of granting such an exclusive right is to reward the inventor. In the case of medical patents the aim is to encourage the development

[11] International Covenant on Economic, Social and Cultural Rights art. 12, Dec. 16, 1966, 993 U.N.T.S. 3 [hereinafter ICESCR]; COMMITTEE ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS, General Comment No. 14: The Right to the Highest Attainable Standard of Health, U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000).

[12] Philippe Cullet, *Patents and Medicines: The Relationship Between TRIPS and the Human Right to Health*, 79(1) INT'L AFF. 139, 139-60 (Jan. 2003).

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of more drugs capable of saving lives. Medical patents work as an incentive for inventors to develop life saving drugs, which in turn contributes to improving the health of the population.

Intellectual property law and human rights law have developed separately. But in recent times, because of the increasing reach of patents in the health sector, the connection between the two has become increasingly evident and direct. That is all the more reason to reconsider the relationship between patents and medicines, and to study them from a fresh perspective. This is especially so for developing countries such as India, whose healthcare systems are already under strain, because as the use of patents in the pharmaceutical business has increased so has the price of medicines, and highly priced medicines cannot be reached by everyone.

From the legal point of view there are two main areas of concern. First, access to drugs and medicine is an indispensable part of the human right to health, as the International Covenant on Economic, Social and Cultural Rights makes clear. Second, there is the question of the accessibility of drugs and its relationship with intellectual property rights, and whether or not medicines should be patentable at all; the increasing use of patents in the pharmaceutical sector is evident from the TRIPS Agreement.

Issuing patents in the health sector has two aspects. On the one hand it encourages and gives an incentive to companies to invest more in research and development so that they can develop drugs. On the other hand the grant of an exclusive right to the inventor may lead to limited availability of a drug and to an increase in its price.[13] This produces a standing tension between the pharmaceutical companies, which want to recoup their investment, and governments, which try to contain the cost of health care.

The most fundamental component of the human right to health is access to medicine. Accessibility here means that medicines should be available at an affordable price, so that people in developing countries can buy them. Where medicines are patented, access is restricted, because patented drugs are generally higher in price, and price is one of the principal barriers for developing countries and above all for those living in poverty.[14] Generic medicines are plainly available at lower prices than patented medicines, so people in developing countries who cannot afford patented medicine tend to turn to generics, which raises a further set of questions about the legality of their use.

[13] Cullet, *supra* note 12.
[14] ICESCR, *supra* note 11, art. 12.

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The legal arguments about the relationship between human rights and intellectual property rights have forced us to recognise the existence of conflicts between the introduction of patents on drugs and the realisation of the human right to health.[15]

A. The Right to Health as a Human Right

A healthy life is one of the most basic needs of an individual and is recognised as such at both the national and the international level. Various international instruments treat health as a human right, but it is often regarded as merely another socio-economic right and is subjected to a good deal of criticism for being vague and for overlapping with other rights.

One of the first mentions of the right to health is found in the Constitution of the World Health Organization of 1946, which states that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition". This covers all aspects of health, including mental and social well-being and not merely physical health. The right was mentioned again in 1948 as part of the right to an adequate standard of living in Article 25 of the Universal Declaration of Human Rights.[16]

Although the right to health was recognised by these instruments, it was not until 1966 that it was recognised as a human right in the International Covenant on Economic, Social and Cultural Rights. The independent committee responsible for monitoring the Covenant has given a broad reading to Article 12, which provides:[17]

that all States parties to the Covenant must ensure the right of everyone to the enjoyment of the highest attainable standard of physical and mental health; and

that States parties must take a series of steps towards the full realisation of that right, which include:

provision for the reduction of the stillbirth rate and of infant mortality and for the healthy development of the child;

provision for the improvement of all aspects of environmental and industrial hygiene;

provision for the prevention, treatment and control of epidemic, endemic, occupational and other diseases; and

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[15] WORLD HEALTH ORGANIZATION, *Globalization, TRIPS and Access to Pharmaceuticals*, WHO Policy Perspectives on Medicines (2001).

[16] Universal Declaration of Human Rights art. 25, G.A. Res. 217 A (III), U.N. Doc. A/810 (Dec. 10, 1948); Constitution of the World Health Organization pmbl., July 22, 1946, 14 U.N.T.S. 185.

[17] ICESCR, *supra* note 11, art. 12(2).

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the creation of conditions which would assure to all medical service and medical attention in the event of sickness, so that no one is left behind.

The Covenant identifies and gives great importance to the individual's highest attainable standard of physical and mental health.[18] Like all other rights, this one is to be protected by the State; it is the responsibility of the State to take appropriate steps to guarantee the right to its citizens by making appropriate legislative provision and by ensuring administrative measures towards its realisation.

The Covenant framework emphasises the role of international cooperation, along with domestic measures, in the full realisation of this right. The wealthier countries have a duty to assist poorer countries to develop and to facilitate the fulfilment of the right to health, so that people all around the world have access to basic health facilities. This includes ensuring the availability of medicine at an affordable price.[19]

On the principles laid down by the Committee on Economic, Social and Cultural Rights, the main components of the right to health include ensuring the availability of primary health care such as safe drinking water, adequate food and nutrition, immunisation against major diseases, proper sanitation and the provision of basic medicines, especially to vulnerable groups. Beyond accessibility and affordability, the right to health also requires the government to take appropriate steps of a broader kind.

The right to health is a broad and inclusive right. It includes not only access to health care but also the other factors which determine the health of society at large, such as access to safe drinking water, sanitation, proper food and nutrition, healthy working conditions and a safe environment; educating people and spreading information about safe and healthy habits is also considered part of the human right to health. The human right to health has been recognised by almost all nations, and nearly every State is party to some international human rights treaty which recognises it as a basic right.[20]

B. Access to Drugs and the Patent Regime

Intellectual property rights, and patents in particular, are a means of providing the motivation and incentive for research and development. They are sometimes regarded as an exception to the idea of free trade, because they confer exclusive rights on the inventor of a product. The

[18] General Comment No. 14, *supra* note 11, paras. 11-12.
[19] Cullet, *supra* note 12.
[20] Laurence R. Helfer, *Pharmaceutical Patents and the Human Right to Health: The Contested Evolution of the Transnational Legal Order on Access to Medicines*, in TRANSNATIONAL LEGAL ORDERS 311, 311-39 (Terence C. Halliday & Gregory Shaffer eds., Cambridge Univ. Press 2015).

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reason for granting the exclusive right is to reward the inventor for his effort. That right is limited in time, and the inventor must eventually disclose the invention so that society at large may benefit from the scientific advance.[21]

Human rights, by contrast, protect the basic entitlements of individuals which belong to them as members of the human race. Enshrined in two United Nations covenants, human rights are guiding principles of State action at both the domestic and the international level. While implementing international rules of intellectual property, therefore, States must bear their human rights obligations in mind.[22]

The pharmaceutical industry argues that patents are an indispensable part of the industry, because it spends more than any other industry on research and development and is highly exposed to copying. On this view the patent system acts not only as an incentive to research and development but as a condition of survival. The risk of failure associated with the industry makes patents more important still. Industry representatives argue that charging higher prices for a limited period not only helps to recover cost but also keeps control of the research in responsible hands.

Although the pharmaceutical industry puts forward convincing arguments in favour of the patent regime, many countries have historically been reluctant to allow patents on drugs on grounds of public policy, especially developing countries, while patents on drugs have long been the norm in developed countries such as the United States. The Uruguay Round of trade negotiations played an important role in pharmaceutical patent protection, because before it developing countries either did not allow patent protection for drugs or gave only partial protection, most of them taking the view that the health sector formed part of the basic needs of citizens and should therefore not be fully commercialised.[23]

Accessibility of drugs is one of the most important components of the human right to health. The introduction of patents into the world of medicine has a twofold implication: it may improve accessibility by motivating further research and development, and it may restrict access by raising the price of drugs and making them available only to a privileged section of society. Accessibility refers to the idea that the policies made by government should cater to the needs of all those who require them, which means that health policy should be such that medicine is made available to patients at an affordable price. This idea highlights the link between poverty

[21] Emmanuel Kolawole Oke, *Incorporating a Right to Health Perspective into the Resolution of Patent Law Disputes*, 15(2) HEALTH & HUM. RTS. 97, 97-109 (2013).
[22] Oke, *supra* note 21.
[23] Cullet, *supra* note 12.

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and health care.[24] A large part of the world's population lives in poverty and without access to basic drugs, and Asia and Africa are the most affected. Given that price is the most important factor in the availability of medicines, patented drugs fall on the more expensive side, which places them beyond the reach of a great many people. Patents cannot be blamed entirely for problems of access, since governments can also provide subsidies and implement price control measures, but they play a major role.

The conflict between pharmaceutical patents and universal health has had a considerable impact and has led to a conflict of interest between the aim of pharmaceutical companies to recoup their investment and the aim of governments to control the cost of health care so that it can reach all sections of society. This continuing conflict has prompted the search for alternative approaches.[25] There is an urgent need to make the patent system more friendly to universal health, in such a way that the existing system is not dismantled but arrangements are made within it to serve health goals.

i. The TRIPS Agreement

The Agreement on Trade-Related Aspects of Intellectual Property Rights played the most important role in introducing medical patents in developing countries. It was negotiated during the Uruguay Round, which ran from 1986 to 1994, and is administered by the World Trade Organization. Its main aim is to ensure that all member countries provide a minimum level of intellectual property protection for copyright, trade marks, patents, geographical indications and other subject matter. In practice this required all member countries to accept intellectual property standards close to those of the developed countries, which enjoy great influence in the WTO. As for patents, the TRIPS Agreement specifies that inventions of products or processes in all fields of technology must be given patent protection. The Agreement is directed to protecting the interests of intellectual property right holders and does not itself address the wider implications of intellectual property. It is mostly concerned with facilitating international trade, but it certainly has consequences beyond trade and commerce, including for environmental protection and human rights. Yet the WTO framework gives little prominence to matters beyond international trade.

The TRIPS Agreement is a very important international treaty, especially for developing countries, which received it as part of a package deal at the close of the Uruguay Round.

[24] Helfer, *supra* note 20.

[25] Michael Krennerich, *The Human Right to Health: Fundamentals of a Complex Right*, in HEALTHCARE AS A HUMAN RIGHTS ISSUE: NORMATIVE PROFILE, CONFLICTS AND IMPLEMENTATION 23, 23-54 (Sabine Klotz, Heiner Bielefeldt, Martina Schmidhuber & Andreas Frewer eds., transcript Verlag 2017).

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Although the Agreement does not directly protect the interests of developing countries, it does contain broad safeguards, although their implementation requires flexibility and differential treatment. TRIPS affects fundamental human interests such as food and health. As regards the human right to health, it significantly changed the health sector of those countries where medical patents were not previously allowed or which had rejected the commercialisation of the health sector before the Uruguay Round. It significantly changed the position in countries such as Brazil, where no medical patents were allowed before TRIPS, and in India, where it altered the orientation of the pharmaceutical industry.[26]

Despite the fact that on its face the TRIPS Agreement provides a strict legal regime for the protection of intellectual property, it leaves room for exceptions which can be used by States to advance public policy goals such as making essential drugs accessible to all. One of the most important features of the Agreement is that it signals to all member States that intellectual property protection should be so applied that technological advancement and innovation run parallel to social and economic welfare rather than against it. Another feature is that it recognises limitations on intellectual property rights by emphasising the need for a balance of rights and obligations. Article 8(1) also states that members may adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the Agreement.[27]

Apart from these general clauses in Articles 7 and 8, the patents section of the Agreement contains important exceptions which can be used by States to pursue their public health goals:

Article 27.2 permits members to exclude from patentability inventions the prevention of whose commercial exploitation within their territory is necessary to protect ordre public or morality, including to protect human, animal or plant life or health. The exception is narrow: it is available only where prevention of commercial exploitation is itself necessary, and it may not be invoked merely because the exploitation is prohibited by domestic law.[28]

Article 30 allows members to provide limited exceptions to the exclusive rights conferred by a patent. It gives States the power to regulate the way in which a patent holder may use his patent, and it reflects the same balance that informs Article 7. The permission is a qualified one. The exceptions must be limited; they must not unreasonably conflict with the normal exploitation

[26] Md Monirul Azam, INTELLECTUAL PROPERTY AND PUBLIC HEALTH IN THE DEVELOPING WORLD ch. 3, 89-148 (Open Book Publishers 2016).
[27] TRIPS Agreement, *supra* note 10, arts. 7-8.
[28] *Id.* art. 27.2.

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of the patent; and they must not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.[29]

Article 31 supplements the exceptions mentioned above. It is essentially the regulatory provision for compulsory licensing. The compulsory licensing regime of TRIPS is accompanied by strict conditions: the proposed user must ordinarily have made efforts to obtain authorisation on reasonable commercial terms, unless there is a national emergency or other circumstance of extreme urgency or the use is for public non-commercial purposes; the scope and duration of the licence must be limited to the purpose for which it is granted; the licence must be non-exclusive and non-assignable; use must be predominantly for the supply of the domestic market; and the right holder must be paid adequate remuneration in the circumstances of the case. The Article is a tool with which developing countries can control at least some of the effects of introducing patents into areas they were unwilling to commercialise, such as the pharmaceutical sector.[30]

From the point of view of public health there are certain openings in the Agreement. There is no limitation on the grounds upon which a compulsory licence may be granted, which gives member States a reasonable opportunity to shape public health and other public policies. Article 31(a) requires each authorisation to be considered on its individual merits, so the mechanism operates case by case rather than by a blanket licence over an entire class of products. The concept of a national emergency has also been left to States to determine, so that they may decide for themselves what situation constitutes one.

The exception provisions have given a measure of flexibility to the TRIPS regime, especially with respect to health emergencies. The usefulness of these provisions in resisting pressure from developed countries has nevertheless been questioned, in part because they are seldom actually invoked and are often used merely as bargaining tools in negotiations with pharmaceutical companies.

ii. The Doha Declaration on the TRIPS Agreement and Public Health

The governments of most developing nations had their own concerns about the flexibilities provided in the TRIPS Agreement. They also faced difficulty in interpreting those flexibilities and in judging the scope of patent protection to be given during health emergencies. Because of these concerns there was felt a serious need for clarification.

[29] *Id.* art. 30.
[30] *Id.* art. 31.

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This led to the Fourth Ministerial Conference of the WTO, held at Doha in November 2001, which adopted the Declaration on the TRIPS Agreement and Public Health on 14 November 2001. The Conference provided the needed guidance on how the TRIPS Agreement is to be interpreted in relation to public health. The members recognised the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics, and at the same time recognised that intellectual property protection is important for the development of new medicines while acknowledging the concerns about its effect on prices.[31]

The Declaration also made it clear that national governments retained the freedom to legislate in order to protect the health of their populations, and in particular that of the poorest among them. It responded to the perception that the TRIPS Agreement posed a significant danger to developing countries by impeding measures to improve access to quality drugs in the public interest.[32]

It is important to be precise about what the Declaration decided, because it is often described in stronger terms than its text will bear. The Declaration is a WTO trade instrument; it does not use the language of human rights, and it establishes no hierarchy between patent rights and the right to health. What paragraph 4 does is to record the members' agreement that the TRIPS Agreement "does not and should not prevent Members from taking measures to protect public health" and to affirm, "while reiterating our commitment to the TRIPS Agreement", that the Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all".[33] That is an interpretive direction addressed to the reading of a trade agreement, and a reaffirmation of the right of members to use its flexibilities to the full. It is not a rule of precedence. The Declaration then spells out what those flexibilities include: each member has the right to grant compulsory licences and the freedom to determine the grounds upon which they are granted; each member has the right to determine what constitutes a national emergency or other circumstance of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent such circumstances; and each member is left free to establish its own regime for the exhaustion of intellectual property rights, which is what makes parallel importation available.[34] Paragraph

[31] Declaration on the TRIPS Agreement and Public Health, WTO Doc. WT/MIN(01)/DEC/2 (adopted Nov. 14, 2001) [hereinafter Doha Declaration].
[32] Doha Declaration, *supra* note 31, paras. 1-3.
[33] *Id.* para. 4.
[34] *Id.* paras. 5(b)-(d).

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6 recognised that members with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulty in making effective use of compulsory licensing and instructed the Council for TRIPS to find an expeditious solution, and paragraph 7 relieved least-developed country members of the obligation to grant or enforce pharmaceutical patents until 1 January 2016, a period since extended to 1 January 2033.[35] Read together, these paragraphs give a State that wishes to act on public health grounds a strong interpretive presumption and a defined set of tools. They do not tell it that the right to health automatically defeats a patent.

The TRIPS Agreement and the Doha Declaration are both efforts by the international community to strike a balance between the incentives which patents give to research and development on the one hand, and the protection of public health and the accessibility of medicines on the other.

Despite these efforts, the problems faced by developing nations are nowhere near over, because in practice they have limited room to follow a regime of their own. They depend on developed countries for support and cannot readily afford to jeopardise their trade relations, which would make their position worse still.

iii. From the Doha Mandate to the Amended TRIPS Agreement

The story of the Doha flexibilities does not end in 2001, and a paper which stops there leaves out the machinery that actually delivers medicines. The difficulty identified in paragraph 6 arose from Article 31(f), which requires that use under a compulsory licence be predominantly for the supply of the domestic market of the member granting it. A country with no manufacturing capacity of its own therefore gained little from a licence, because no other country could lawfully manufacture in quantity for export to it. The Council for TRIPS answered the mandate with the General Council Decision of 30 August 2003, which waived the obligations of an exporting member under Article 31(f) in defined circumstances.[36] That waiver was made permanent by the Protocol Amending the TRIPS Agreement, adopted on 6 December 2005, which inserted Article 31bis into the Agreement together with an Annex and an Appendix. The amendment entered into force on 23 January 2017, when it had been accepted by two thirds of the membership, and it is the first amendment ever made to a WTO agreement.[37]

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[35] *Id.* paras. 6-7; Decision of the Council for TRIPS on the Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, WTO Doc. IP/C/73 (Nov. 6, 2015) (extending the period to Jan. 1, 2033).

[36] Doha Declaration, *supra* note 31, para. 6; Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO General Council Decision of Aug. 30, 2003, WTO Doc. WT/L/540.

[37] Protocol Amending the TRIPS Agreement, WTO Doc. WT/L/641 (Dec. 6, 2005) (entered into force Jan. 23, 2017) (inserting art. 31bis of, and the Annex to, the TRIPS Agreement).

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Article 31bis provides that the obligations of an exporting member under Article 31(f) do not apply where a compulsory licence is granted to the extent necessary for the production of a pharmaceutical product and its export to an eligible importing member, and it makes corresponding provision for regional trade arrangements a substantial part of whose membership consists of least-developed countries. The detail is in the Annex, which defines the pharmaceutical products covered, identifies who may be an eligible importing member, and sets out the notifications to be made to the Council for TRIPS, together with the conditions attached to the licence: production is limited to the quantity notified, the product must be clearly identified by specific labelling or marking and by distinctive packaging or colouring, and the licensee must post the relevant information on a website before shipment. The Appendix governs the assessment of manufacturing capacity: least-developed country members are presumed to lack it, while other members must establish either that they have no capacity in the pharmaceutical sector or that their existing capacity, excluding any owned or controlled by the patent holder, is insufficient for their needs.[38] India gave effect to the same mechanism domestically through Section 92A of the Patents Act, 1970, which was inserted by the Patents (Amendment) Act, 2005.[39]

The COVID-19 pandemic tested that machinery and produced a further instrument which any current account of this subject must take into consideration. At its Twelfth Ministerial Conference the WTO adopted the Ministerial Decision on the TRIPS Agreement on 17 June 2022.[40] Its reach is narrower than the public debate around it suggested. It permits an eligible member, notwithstanding the patent rights conferred under its domestic law, to authorise the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right holder. It clarifies that such authorisation may be given through any instrument available in the law of the member, including executive orders, emergency decrees and administrative orders, whether or not a compulsory licence regime is in place; it removes the requirement of prior negotiation with the right holder under Article 31(b); it waives the domestic market limitation in Article 31(f) so that any proportion of the product may be exported to other eligible members; it allows the humanitarian and not-for-profit purpose of a vaccine programme to be taken into account in setting remuneration under Article 31(h); and it confirms that Article 39.3 does not prevent rapid regulatory approval of a vaccine produced

[38] TRIPS Agreement, *supra* note 10, art. 31bis and Annex, paras. 1-2, and Appendix.
[39] The Patents Act, 1970, No. 39 of 1970, sec. 92A (India).
[40] Ministerial Decision on the TRIPS Agreement, WTO Docs. WT/MIN(22)/30, WT/L/1141 (adopted June 17, 2022) [hereinafter MC12 Decision].

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under it. The Decision applies for five years from its adoption.[41] It is not a waiver of patent rights as such; it does not touch trade secrets, know-how or regulatory data; and it is confined to vaccines. Paragraph 8 committed members to decide within six months on extending it to COVID-19 diagnostics and therapeutics. No such extension was ever adopted: after more than eighteen months of discussion the Council for TRIPS reported to the General Council on 13 February 2024 that consensus could not be reached.[42] For a paper which argues that the flexibilities of the international regime can be made to serve public health, that outcome is a sobering piece of evidence: the flexibilities exist, but the political will to extend them does not follow automatically from the need.

III. Generic Medicine and its Relevance to Global Health

A. Introduction

The importance of generic medicine in terms of global health can be understood from the role that the pharmaceutical industry plays in maintaining the health of a community. One of the main challenges before governments in providing proper health care is the ever increasing budget it requires. The cost of drugs and their availability to the public are inversely related, so that when the price falls after the expiry of a patent, as other companies make generic versions of the original drug, availability and affordability automatically increase.

The concept of generic medicine has been defined by different organisations as follows:

The World Health Organization defines a generic product as a pharmaceutical product intended to be interchangeable with the innovator product, manufactured without a licence from the innovator company and marketed after the expiry of the patent or other exclusive rights.[43]

The Food and Drug Administration of the United States describes a generic drug as a medicine created to be the same as an already marketed brand name drug in dosage form, safety, strength, route of administration, quality and performance characteristics, and intended use.[44]

The European Medicines Agency defines a generic medicine as one developed to be the same as a medicine which has already been authorised, called the reference medicine. It contains the

[41] MC12 Decision, *supra* note 40, paras. 1, 3(a)-(b), 3(d), 4, 6.

[42] *Id.* para. 8; Council for Trade-Related Aspects of Intellectual Property Rights, Report to the General Council (Feb. 13, 2024) (recording that consensus could not be reached on extending the Decision to COVID-19 diagnostics and therapeutics).

[43] World Health Organization, Marketing Authorization of Pharmaceutical Products with Special Reference to Multisource (Generic) Products: A Manual for National Medicines Regulatory Authorities (2d ed. 2011), https://apps.who.int/iris/handle/10665/44576.

[44] U.S. Food and Drug Administration, *Generic Drugs: Questions and Answers*, https://www.fda.gov/drugs/generic-drugs/generic-drugs-questions-answers.

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same active substance and is used at the same dose to treat the same disease, although its inactive ingredients, name, appearance and packaging may differ.[45]

A generic medicine can appear on the market only after the expiry of the patent rights of the innovator company, so that the innovator has the opportunity to recover its research costs. The term varies between countries, but in most of them patent rights expire twenty years from the date of filing. The availability of generic versions reduces the cost of drugs considerably and so reduces the health care cost of the community at large.

B. Nomenclature of Innovator Medicines and Generic Medicines

Medicines may be sold under a brand name or under a globally accepted non-proprietary name. The bulk of innovator drugs are marketed as patented medicines. Pharmaceuticals which are under patent protection and marketed under a trade name granted by the manufacturer are referred to as patented medicines. Generic copies of a medicine may become available once the patent expires, and these are often marketed under generic, non-proprietary names. All member countries of the World Health Organization have accepted the system of the recommended International Nonproprietary Name. A variety of pharmaceutical companies produce generic drugs, which may be marketed as commodity generics or as branded generics. The expression branded generic refers to a generic medicine which has been branded by a particular pharmaceutical company. Branded generics are identical in substance to non-branded generics, but they are more costly, and they have a market thanks to the marketing efforts of the manufacturer and the larger margins available to retailers.[46]

C. Evolution of Generic Medicine

The concept of generic medicine is directly linked to the history of drug discovery. The most significant modern drug discoveries began in the eighteenth century, when medicine as we know it today started to develop.[47] The idea of drug patents came soon after, in the nineteenth century, although patenting was not then a prominent concern, since the emphasis lay on protecting communities from diseases such as cholera and influenza. One of the earliest and commercially most successful examples was Bayer's acetylsalicylic acid: the trade mark Aspirin was registered in 1899 and a United States patent for the compound was granted in 1900.[48]

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[45] EUROPEAN MEDICINES AGENCY, *Generic Medicine*, https://www.ema.europa.eu/en/glossary-terms/generic-medicine.

[46] P. Rana & V. Roy, *Generic Medicines: Issues and Relevance for Global Health*, 29(6) FUNDAMENTAL & CLINICAL PHARMACOLOGY 529, 529-42 (2015).

[47] U.S. FOOD AND DRUG ADMINISTRATION, *Generic Drug Facts*, https://www.fda.gov/drugs/generic-drugs/generic-drug-facts.

[48] Acetyl Salicylic Acid, U.S. Patent No. 644,077 (issued Feb. 27, 1900).

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The introduction of patents into the pharmaceutical industry started a debate about how long an innovator company should enjoy exclusive rights, and about how the cost effectiveness of expensive medicines could be secured once the patent expired. This resulted in the establishment of regulatory processes which ensure the safety of medicines, grant patents, and then, on expiry, approve generic medicines so as to bring prices down.

The regulatory structure of the United States differed from that of other nations. As the world's largest market for generic drugs, the United States has a long history of drug regulation. The Federal Food, Drug, and Cosmetic Act of 1938 and the Kefauver-Harris Drug Amendments of 1962 required manufacturers, generic manufacturers included, to submit clinical trial evidence supporting the efficacy as well as the safety of their products.[49] After the Kefauver-Harris Amendments, generic drug firms struggled to devote the time and money required to perform clinical trials in order to obtain approval for their versions, and as a result the number of generic drugs on the market fell.

In 1984 the United States Congress passed the Hatch-Waxman Act, properly the Drug Price Competition and Patent Term Restoration Act. This Act allowed generic drug companies to seek approval through Abbreviated New Drug Applications, which required them only to demonstrate that their product is equivalent to the original in terms of bioavailability and pharmacological effect.[50]

The Hatch-Waxman Act made generics more available and quicker to obtain, and it is generally credited with laying the groundwork for today's generic pharmaceutical industry. Since 1984 many thousands of generic medicines have been approved in the United States, and generics now account for the great majority of prescriptions dispensed there.[51]

In March 2010 the United States Congress enacted the Biologics Price Competition and Innovation Act of 2009, which allows a simplified approval pathway for biosimilar and interchangeable biological products, sometimes described loosely as generic copies of biotechnology medicines, although a biosimilar is by definition not an identical copy.[52] In the last twenty years several other countries, including emerging pharmaceutical producers such as India and China, have framed their own regulatory guarantees, and these provisions are broadly similar across jurisdictions apart from minor variations.

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[49] Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938); Drug Amendments of 1962 (Kefauver-Harris Amendments), Pub. L. No. 87-781, 76 Stat. 780.
[50] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.
[51] *Generic Drug Facts*, *supra* note 47.
[52] Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, tit. VII, subtit. A, 124 Stat. 804 (2010).

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D. Relevance of Generic Medicine to the Human Right to Health

It is well known that generic medicines are available at a much lower price than the originator product. This is largely because their manufacturers do not have to spend on advertising and marketing, and above all because they do not invest the very large sums spent by the innovator on research and development. That is also why they may compete with the original drug only after the patent has expired, which gives the developer the opportunity to recover its costs. The introduction of generic medicines ensures that patients of all economic and social backgrounds receive medicine at an affordable price once the patent has expired.[53] Competition between generic and originator medicines lowers price, which in turn improves accessibility and helps secure continuity of supply. Generic medicines also matter when demand rises suddenly because of an outbreak of disease, since a single company would be unable to meet the needs of so large a population. The recent experience of COVID-19 vaccines illustrates the point: had only one manufacturer been permitted to produce a vaccine, it would not have been possible to inoculate the world. Because their margins are small and their revenues modest, generic manufacturers also tend to maintain supply for years after the innovator product has been withdrawn from the market.

Beyond continuity of supply, it has been observed that patients suffering from chronic disease adhere better to treatment when prescribed generic drugs over the long term, despite, or perhaps because of, their lower cost. It can therefore be said that generic medicines are not only cost effective but may also improve patient compliance.[54]

Generic medicines are without doubt among the most important tools for securing savings in a country's health care budget. However, because of strict regulatory requirements and government policies the cost of producing generic medicine has been increasing, which is not a welcome development given the part generic medicines play in bringing health care to all sections of society. It is important that governments frame policies which keep the cost of production down so that generic medicines remain within the reach of the disadvantaged.

E. The Legal Dilemma of the Pharmaceutical Sector

As we have seen, when a new medicine is developed it becomes the intellectual property of its developer. This means that the manufacturer has exclusive rights over production and may determine the price for the limited period during which those rights subsist. As a direct result, patented medicines are generally expensive and beyond the reach of most people; the

[53] WORLD HEALTH ORGANIZATION, THE WORLD DRUG SITUATION (1988).

[54] William H. Shrank et al., *The Implications of Choice: Prescribing Generic or Preferred Pharmaceuticals Improves Medication Adherence for Chronic Conditions*, 166(3) ARCHIVES INTERNAL MED. 332, 332-37 (2006).

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populations of developing countries such as India are directly affected, because they are unable to afford high cost medicines, which impairs the health care available to them. The high cost is intended to allow the inventor to recover the cost of development, including expenditure on research. That is why a balance has to be struck between the affordability of medicine, which serves the welfare of society, and the profit of the inventor, which rewards his contribution. The World Trade Organization agreements, and the TRIPS Agreement in particular, are landmark documents in this respect.

i. The TRIPS Agreement and the Doha Response

The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights was the first instrument to establish internationally accepted minimum rules for intellectual property. It was concluded during the Uruguay Round of the General Agreement on Tariffs and Trade. It made it compulsory for member countries to provide intellectual property protection for new inventions, including medicines and other pharmaceutical products, by protecting the exclusive rights of the inventor throughout the membership.[55]

The Agreement raised serious concerns about the effect of patent protection for pharmaceuticals on the health infrastructure of member nations. That concern led to the Doha Declaration on the TRIPS Agreement and Public Health at the Fourth Ministerial Conference of the WTO in November 2001. The Declaration on the one hand reaffirmed the members' commitment to the TRIPS Agreement, and on the other affirmed that the Agreement should be interpreted and implemented in a manner supportive of the right of members to protect public health, especially as regards access to medicines. It also confirmed the flexibilities available to developing and least-developed countries, including compulsory licensing and freedom in matters of exhaustion, and it instructed the Council for TRIPS to find a solution for countries with insufficient or no manufacturing capacity in the pharmaceutical sector, so that a compulsory licence granted elsewhere could supply them by way of export. The aim of the Declaration was to strike a balance between honouring TRIPS obligations and prioritising public health.[56]

ii. Free Trade Agreements

While most developing countries were struggling with the implementation of the TRIPS Agreement, and trying to keep the cost of health care affordable, developed countries such as the United States turned to bilateral free trade agreements. These agreements often require the partner country to implement intellectual property protection going beyond the TRIPS

[55] TRIPS Agreement, *supra* note 10.
[56] Doha Declaration, *supra* note 31, paras. 4-6.

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minimum, particularly in the pharmaceutical sector, a phenomenon commonly described as TRIPS-plus. The arrangement causes little difficulty for the developed country, which is generally the party setting the terms, but it can compel a developing country to accept stronger patent protection at the cost of its health infrastructure. To that extent such agreements sit uneasily with the spirit of the Doha Declaration.[57]

iii. Delaying Tactics of the Innovator Company

Pharmaceutical companies also leave no stone unturned to ensure that their revenue is not disturbed for as long as possible, and for this purpose they use various strategies whose object is to delay the entry of affordable generic medicines into the market and to prolong the period of exclusivity. The most common method is strategic patenting, and in particular the building of patent clusters, which involves protecting a single drug with a large number of granted patents and pending applications. This delays the approval of generic medicines because it creates uncertainty for the generic manufacturer about what it is free to do. It has often been observed that as a patent approaches expiry the company applies for new patents on the same drug with slight modifications, which creates an ambiguous environment for competitors. In its pharmaceutical sector inquiry the European Commission found that a single blockbuster medicine could be covered by as many as 1,300 patents and pending applications across the Member States of the European Union.[58]

iv. Substitution Laws

The concept of generic medicine rests on the proposition that a generic product is therapeutically equivalent to the original and can therefore be used as its substitute. The basic convention of generic substitution is that a prescribed proprietary drug may be replaced by a generic version containing the same active principle. Generic substitution can be an effective mechanism for reducing the cost of health care without reducing quality, and it also promotes the use of generic medicines. Substitution rules of one kind or another are in place in a number of countries, although they differ considerably in whether substitution is mandatory or merely permitted, and in some federal systems the question is governed by state rather than national law.[59]

[57] Cullet, *supra* note 12.
[58] EUROPEAN COMMISSION, *Pharmaceutical Sector Inquiry: Final Report* (July 8, 2009).
[59] Rana & Roy, *supra* note 46.

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F. Concluding Observations on Generic Medicines

Generic medicines can prove to be the most appropriate and affordable alternative to branded medicines. The quest of pharmaceutical companies to increase their economic gains has led to complex legal problems concerning the patent protection of pharmaceutical products, which delay the entry of generic medicines into the market. In order to make the best use of generic medicine it is important to address the questions of quality and the legal issues which accompany patent protection. Policy makers framing health and welfare policy should keep the potential of generic medicine in view and make provision for its ready availability, so that poorer patients also have access to medicine. Education about the benefits of generic medicines can play an important part in creating awareness of their quality, and healthcare workers should be encouraged to prescribe them. Generic medicines can play a very important role in bridging the gap between the cost of medicine and the income of the patient, since accessibility to medicine is a basic human right of all irrespective of income.[60]

IV. The Indian Regime on Medical Patents

The direct relationship between medical patents and the price of medicine, which in turn governs accessibility, is always taken into consideration in framing healthcare policy in developing countries, and especially in India. As discussed earlier, India was one of the countries which prohibited product patents for medicines, and that is one of the major reasons for the development of so strong a domestic pharmaceutical industry.

During the initial years after Independence the domestic pharmaceutical industry was comparatively small, and by the time the Patents Act was passed in 1970 Indian firms accounted for only about a quarter of the domestic market. There followed a series of changes in the regulatory framework, including the exclusion of product patents for medicines and controls on foreign investment and prices. These factors contributed to the rapid development of an industry which by the end of the century supplied the great bulk of the country's requirement of drugs.[61]

One of the landmark features of the Indian Patents Act before its TRIPS-related amendments was that the price of drugs in India was significantly lower than in other countries, and that a generic pharmaceutical industry developed. Although in the early stages of development drug prices in India were among the highest in the world, they are now among the cheapest.

[60] Rana & Roy, *supra* note 46.

[61] Government of India, Department of Chemicals and Petrochemicals, Annual Report 1999-2000.

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Accessibility of medicine to all is still a distant goal, and millions still do not have access to basic medicine, but the steps taken since 1970 have been in the right direction.[62]

Besides excluding product patents, the Patents Act contained other provisions designed to improve access to drugs. It placed a special restriction on the duration of patent protection in the health sector: while other patents ran for fourteen years, a patent for a process for producing a substance intended for use as food, medicine or drug ran for five years from sealing or seven years from the date of the patent, whichever was shorter.[63] The Act also made provision not only for compulsory licences but for the endorsement of a patent with the words "licence of right", and in the case of substances used as food, medicine or drug that endorsement was deemed to have been made three years after sealing. Those provisions no longer exist; they were omitted in 2002 as incompatible with the TRIPS Agreement.[64]

A. TRIPS and the Indian Patents Act

India signed the TRIPS Agreement when it became a member of the World Trade Organization in 1995. As we have seen, TRIPS prescribes a minimum standard of patent protection to be observed by member countries, and since India was a signatory it had to amend its Patents Act to bring it into conformity with those obligations. One of the main requirements was to provide for product patents in pharmaceuticals, which India did not then allow. To make a start on compliance, the Patents (Amendment) Act, 1999 was enacted with retrospective effect from 1 January 1995; it introduced the mailbox procedure for pharmaceutical and agricultural chemical product applications and provided for the grant of exclusive marketing rights.[65]

In order to comply with the second set of TRIPS obligations India further amended the Act by the Patents (Amendment) Act, 2002. That amendment fixed a uniform term of patent protection of twenty years, changed the definitions of invention and inventive step so as to make them compatible with the TRIPS Agreement, and introduced a provision reversing the burden of proof in cases of process patent infringement. The same Act omitted the licence of right provisions.

Product patents arrived with the third set of amendments, the Patents (Amendment) Act, 2005. That Act did not, however, open the door to every pharmaceutical claim. Alongside the introduction of product patents it substituted Section 3(d), which excludes from patentability

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[62] Cullet, *supra* note 12.

[63] The Patents Act, 1970, No. 39 of 1970, sec. 53 (India) (as originally enacted; a uniform term of twenty years was substituted by the Patents (Amendment) Act, 2002).

[64] *Id.* secs. 86-88 (omitted by the Patents (Amendment) Act, 2002).

[65] WORLD TRADE ORGANIZATION, *Overview: The TRIPS Agreement*, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm.

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the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance, and the mere discovery of any new property or new use for a known substance. The Explanation to the section treats salts, esters, ethers, polymorphs, metabolites, isomers and other derivatives of a known substance as the same substance unless they differ significantly in properties with regard to efficacy.[66] In the case of a medicine, as the Supreme Court later held, the efficacy which must be shown is therapeutic efficacy.[67] The 2005 Act also introduced a provision for a compulsory licence for the export of pharmaceutical products.

B. The Indian Patents Act

The pharmaceutical industry is driven by knowledge, research and creativity, and its final product is a benefit to the community; any development in the medical sector makes human life easier. Although patents are a means of providing an incentive for that work, it is also important to ensure that the patent regime does not make the goal of public health harder to reach. In a developing country such as India this matters all the more, because a large part of the population is poor and lives in conditions which breed disease. The point was made in the report which laid the foundation of the present Act, which recommended a patent law shaped to the economic conditions of the country.[68] An efficient healthcare regime is essential if the human right to health of the population is to be protected. This section discusses two of the most important provisions of the Indian Patents Act which assist the government in protecting the human right to health against the effect of pharmaceutical patents on access to medicine.

i. Compulsory Licensing

Chapter XVI of the Patents Act, 1970, comprising Sections 82 to 94, deals with compulsory licensing, along with Chapter XIII of the Patents Rules, 2003, comprising rules 96 to 102. A compulsory licence is an authorisation by the government to a third person, or to itself, to work a patented invention without the permission of the patent holder in the public interest.[69]

Section 84 provides for the situations in which a compulsory licence may be granted. At any time after the expiration of three years from the grant of a patent, any person interested may apply to the Controller on any of three grounds: that the reasonable requirements of the public with respect to the patented invention have not been satisfied; that the patented invention is not

[66] The Patents Act, 1970, No. 39 of 1970, sec. 3(d) (India) (as substituted by the Patents (Amendment) Act, 2005).
[67] *Novartis AG v. Union of India*, (2013) 6 SCC 1.
[68] N. Rajagopala Ayyangar, REPORT ON THE REVISION OF THE PATENTS LAW (Government of India, Ministry of Commerce and Industry, Sept. 1959).
[69] Ahuja, *supra* note 2.

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available to the public at a reasonably affordable price; or that the patented invention is not worked in the territory of India.[70] Section 92A deals with the grant of a compulsory licence for the manufacture and export of patented pharmaceutical products to a country having insufficient or no manufacturing capacity in the pharmaceutical sector, provided that the importing country has itself granted a compulsory licence or has otherwise allowed importation from India. It is the domestic counterpart of the international export mechanism discussed above.[71]

Bayer Corporation v. Union of India, commonly known as the Natco case, is one of the landmark decisions for understanding the relationship between the Indian pharmaceutical industry and pharmaceutical patents, and it established a working balance between the TRIPS Agreement and Indian patent law.[72] The judgment offers guidance to developing countries on how the flexibilities of the TRIPS Agreement may be used to provide better healthcare facilities to a population, consistently with the obligations of the State under INDIA CONST. art. 21. Natco Pharma had applied for a compulsory licence over Bayer's patented anti-cancer drug sorafenib tosylate, marketed as Nexavar, which was available only at a very high price. The Controller granted the licence, and Bayer challenged the grant. The Bombay High Court upheld it, holding that the patentee had failed to make the drug available in adequate quantity at a reasonably affordable price and had failed to work the patent in India. This remains the only compulsory licence granted in India; no other application has succeeded before the Controller General of Patents.

On this analysis it is fair to say that the compulsory licensing provisions of Indian law are compatible with the TRIPS Agreement.

ii. Evergreening of Patents and the Statutory Safeguards

There is no doubt that patents play an important role in the development of medicines and act as a necessary motivation for the innovator who makes life saving drugs. There are, however, limits to the concept of the pharmaceutical patent. India's position on those limits is best explained by *Novartis AG v. Union of India*.[73] Section 3 of the Patents Act was framed with the object of limiting the subject matter which may be patented, and it operates by declaring that certain things are not inventions at all. Two of its clauses matter here, and they work as statutory safeguards for public health. Section 3(d) restricts the practice of evergreening by providing that a new form, derivative or new use of a known substance is not patentable unless it shows a

[70] The Patents Act, 1970, No. 39 of 1970, sec. 84(1) (India).
[71] *Id.* sec. 92A; WORLD TRADE ORGANIZATION, *Compulsory Licensing of Pharmaceuticals and TRIPS*, https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm.
[72] *Bayer Corp. v. Union of India*, 2014 SCC OnLine Bom 963 : 2014 (60) PTC 277 (Bom).
[73] *Novartis*, *supra* note 67.

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significant enhancement of efficacy, which in the case of a medicine means therapeutic efficacy. Section 3(i) excludes from patentability any process for the medicinal, surgical, curative, prophylactic, diagnostic or therapeutic treatment of human beings, and any similar process applied to animals. Together these provisions hold the balance between intellectual property rights and the public interest, by keeping essential medical procedures and incrementally modified drugs outside the reach of monopoly.[74]

Although the term evergreening is not defined anywhere in the Act, it is understood as a strategy by which pharmaceutical companies seek to enjoy patent protection for as long as they can, by obtaining fresh patents for trivial modifications of an existing compound. It is usually done to extend the effective life of a patent beyond twenty years without any real improvement in the product. This was the question argued in detail in the *Novartis* case, which is a landmark in Indian medical patent law and which shows how seriously India takes social, economic and cultural rights when they come into contact with the patent rights of pharmaceutical companies.

C. A Case Study on *Novartis AG v. Union of India*

The decision was given by a two judge Bench of the Supreme Court of India on 1 April 2013. The patent application filed by Novartis had been rejected by the Assistant Controller of Patents and Designs at Chennai and, on transfer, by the Intellectual Property Appellate Board. The application related to the beta crystalline form of imatinib mesylate. The Supreme Court dismissed the appeals, holding that the product failed both the test of invention and the bar in Section 3(d), because it did not establish any enhancement of therapeutic efficacy over the known substance, imatinib mesylate. The decision was an important step in preventing the evergreening of patents.[75]

i. Facts of the Case

In 1998 Novartis AG, one of the largest pharmaceutical companies in the world, filed an application before the Chennai Patent Office under the mailbox procedure introduced with retrospective effect from 1 January 1995. The application was for the anti-cancer drug marketed as Glivec, a drug which was patented in more than thirty-five countries and which is used to treat gastrointestinal stromal tumour and chronic myeloid leukaemia. The claim was to the beta crystalline form of imatinib mesylate.

[74] The Patents Act, 1970, No. 39 of 1970, secs. 3(d), 3(i) (India).
[75] *Novartis*, *supra* note 67, para. 191.

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At that time there was no provision for product patents in India, patents being granted only for processes and methods, by virtue of Section 5 of the Patents Act, 1970. Section 5 was repealed by the Patents (Amendment) Act, 2005, which introduced product patents.

In 2005 the application for Glivec was taken up for consideration, and the Madras Patent Office found in January 2006 that there was no ground for granting the patent, since the invention lacked novelty and was obvious. Applying Section 3(d), the office further found the claim unpatentable because there was no enhancement of the therapeutic efficacy of the substance over the compound already disclosed in the Zimmermann patent, and the application was rejected.

In 2006 Novartis filed writ petitions in the Madras High Court under Article 226 of the Constitution of India, claiming that Section 3(d) was unconstitutional because it was contrary to the TRIPS Agreement and violated Article 14. A further petition challenged the order of the Madras Patent Office. The High Court dismissed the constitutional challenge in August 2007, holding that the question of compatibility with the TRIPS Agreement was for the WTO and not for an Indian court, and transferred the remaining matters to the Intellectual Property Appellate Board. The Board held that although the invention satisfied the test of novelty it could not be granted a patent, because that would be contrary to Section 3(d), the object of which is to prevent evergreening and to improve the accessibility of life saving drugs.

Having failed at every level, Novartis made a final attempt by filing a special leave petition in the Supreme Court under Article 136 of the Constitution.

ii. Issues Raised in the Supreme Court

What is meant by the term substance in Section 3(d) of the Patents Act, 1970?

What is meant by the term efficacy in Section 3(d)?

Does an increase in bioavailability qualify as an increase in therapeutic efficacy under Section 3(d)?

Is the invention claimed by Novartis, the beta crystalline form of imatinib mesylate, more efficacious than the substance from which it was derived, namely imatinib mesylate?

iii. The Decision

In April 2013 the two judge Bench made the following findings.[76]

[76] *Novartis*, *supra* note 67, paras. 180, 189.

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The Supreme Court rejected the appeal filed by Novartis and held that the beta crystalline form of imatinib mesylate is a new form of a known substance, namely imatinib mesylate, whose efficacy was already known.

The Court made it clear that in the case of a medicine, efficacy in Section 3(d) means therapeutic efficacy alone. Not all properties of a drug are relevant; the property which counts is the one which relates directly to the healing effect of the medicine.

On the third issue the Court held that an increase in bioavailability does not by itself amount to an enhancement of therapeutic efficacy. Whether it does so in a given case must be specifically claimed and established by research data. Novartis relied on an increase of about thirty per cent in bioavailability, together with better flow properties, greater thermodynamic stability and lower hygroscopicity, but the Court held that none of these established any increase in therapeutic efficacy over imatinib mesylate, and that no material had been produced linking the increased bioavailability to a therapeutic effect.

The judgment sheds light on the approach of the Supreme Court to the importance of public health. The Court emphasised that the patent system must not be allowed to operate so as to keep essential medicines out of reach through trivial modifications of known substances. This makes the Indian position clear in the continuing debate about the patent protection of medicines and the human right to health. In the present case the patent authority had rightly rejected the application, since there was no real development over the original product, and the claim was in substance a strategy to prolong the benefits of patent protection, which would have meant that the medicine remained inaccessible to the public for a longer period. In upholding the rejection the Supreme Court protected the public interest and kept the medicine within reach of a larger section of the population.

Developing countries would do well to frame their health policies on similar ground, since public health is a pressing problem in all of them and cannot be addressed unless the patent system is read with the needs of the population in view.

V. Propositions to Aid the Accessibility of Medicines

In order to protect the human right to health and to achieve the highest attainable standard of health for individuals, a collective effort is needed from all stakeholders, in both the private and the public sector. Everyone has to discharge their duties and obligations towards society if the common goal is to be reached. Since States and pharmaceutical companies are the major stakeholders in this process, this chapter discusses propositions which each of them should follow in order to advance public health.

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A. Certain Responsibilities of States

i. Ensuring that Medicines of Good Quality are Accessible and Available

National governments should do everything in their power to ensure that essential medicines and vaccines are available in adequate quantity to all people within their jurisdiction.[77] For this purpose governments may take advantage of the flexibilities of the TRIPS Agreement, including the provisions on compulsory licensing. The needs of low income countries have been neglected in the past, and that must change; within the framework of international assistance and cooperation, States should promote health care in developing countries by helping to secure the availability of medicines, vaccines and other health tools. India's cooperation with Bangladesh, Nepal, Afghanistan, Sri Lanka and other developing countries in supplying COVID-19 vaccines is a commendable example.

In other words, national governments have a responsibility not only to ensure that existing medicines reach everyone, but also to provide incentives for the development of new medicines and to see that, once developed, they are widely distributed.

Most of the time availability is not the difficulty; the problem arises in accessibility, which has four overlapping dimensions. The first is physical accessibility. Medicines, once developed, should be within reach of people living in any part of the country. In smaller countries this is not a great obstacle, but in a country such as India it is a serious one, and it calls for better supply systems and outreach programmes. The second is economic accessibility, or affordability: medicines must be priced so that they are within reach of the poorest, which means that States should improve their pricing arrangements and reconsider taxes and import duties, as well as the pricing of patented medicines. The third is non-discrimination: there should be no discrimination in access to medicines on grounds of age, sex, caste or ethnicity. The fourth is information accessibility: access to medicine also means access to relevant information, so that patients and doctors know what is available.[78]

Besides being available, medicines should be consistent with medical ethics and culturally acceptable. They must also be of appropriate quality and must not have been tampered with.

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[77] WORLD HEALTH ORGANIZATION, WHO MEDICINES STRATEGY: COUNTRIES AT THE CORE, 2004-2007, WHO/EDM/2004.5 (2004).

[78] General Comment No. 14, *supra* note 11, para. 12(b).

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ii. Measures to Combat Inequality

Health policies framed by government should be of such a nature that they do not leave behind the interests of disadvantaged sections of society, for example women, ethnic minorities and indigenous people, or populations affected by communicable disease.

Equality and non-discrimination are among the most fundamental principles of international human rights law, which is why they occupy so important a place in determining policy on the right to health. These principles do not necessarily mean identical treatment; on the contrary they sometimes require the State to make policy in favour of disadvantaged communities. Equality and non-discrimination are backed by law and can be enforced through legal mechanisms.

With respect to access to medicines, equality and non-discrimination can take many forms. For instance, it is the duty of every State to make special national medical supply programmes for vulnerable sections of society. It is also necessary to address the social, political and cultural factors which inhibit the access of vulnerable groups to medicines in particular and to health care generally. In order to identify vulnerable populations and track progress towards fair access, data should be disaggregated so far as possible.

iii. Monitoring Progressive Realisation

Under Article 2(1) of the International Covenant on Economic, Social and Cultural Rights, the right to the highest attainable standard of health, and therefore access to medicines, is subject to progressive realisation and to the availability of resources. Each State party undertakes to take steps, to the maximum of its available resources, with a view to achieving progressively the full realisation of the rights recognised in the Covenant. The obligation is one of continuous movement towards the goal, and a State may not use the language of progressive realisation as an excuse for inaction.[79]

What this implies is that States must set appropriate benchmarks which indicate progress in realising the right to health. Alongside progressive realisation there are obligations of immediate effect, and among the core obligations is the provision of essential medicines throughout the country without discrimination of any kind. These are the obligations which a State must discharge towards its citizens if the healthcare infrastructure is to develop at all.[80]

The World Health Organization prepares a Model List of Essential Medicines, and States are expected to adopt or adapt their own national lists in the light of it and of local priorities and

[79] ICESCR, *supra* note 11, art. 2(1); General Comment No. 14, *supra* note 11, paras. 30-31.
[80] General Comment No. 14, *supra* note 11, paras. 43-47.

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treatment guidelines. The Model List is not directly applicable to any State as a matter of law; what makes it matter is that the provision of essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs, has been identified as a core obligation flowing from the right to health.[81]

In short, the right to health covers access to both essential and non-essential medicines. While a State must steadily enhance access to non-essential drugs, it has an immediate obligation to make essential medicines available and affordable to all its citizens.

iv. The Duty to Protect the Right to Health

States must do everything in their power to ensure that the right of citizens to the highest attainable standard of health is not violated, and must also make provision to advance it through medical and healthcare policy. It is the duty of the State to see that the right to health is not violated by third parties and that healthcare policies are properly implemented; it is equally the duty of the State to see that the private interests of pharmaceutical companies do not interfere with the enjoyment of the human right to health. The State must also provide for marginalised groups who do not have the means to protect their rights on their own.

The delivery of healthcare services may be delegated to private companies, but the government cannot delegate away its obligation under the right to health. The State will always remain responsible for ensuring that policies are duly followed and that the interests of the disadvantaged are protected.

v. Public Participation in Policy Making

Public participation in the making of health policy can play a very important part in attaining the right to health, because involving local communities gives insight into their needs and produces a more inclusive framework with better prospects of implementation. A policy shaped by public participation is more likely to be understood and used by those it is meant to serve. In framing national medicines policy, therefore, the State should ensure active public participation alongside the recommendations of medical practitioners and professional associations.[82]

vi. International Cooperation in the Health Sector

The discussion in this section of international cooperation, medicines regulation, affordability and corporate responsibility follows the analysis of Paul Hunt, formerly United Nations Special

[81] *Id.* para. 43(d).

[82] Paul Hunt (Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health), *Report on a Human Rights-Based Approach to Health Indicators*, U.N. Doc. E/CN.4/2006/48, paras. 62 et seq. (Mar. 3, 2006).

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Rapporteur on the right to health, and Rajat Khosla, and the figures cited in it are drawn from their account unless otherwise indicated.[83] The international community plays a very important role in securing rights such as health, because it can influence national policy through treaties and other arrangements. It can also bring about a change of attitude among developed countries towards the healthcare needs of developing countries. The scale of the imbalance is well documented: about ninety per cent of the world's pharmaceutical output by value has been consumed by the fifteen per cent of the world's population living in high income countries. International cooperation can lead to more equitable development in the health sector rather than to development on one side alone.

Developed countries should encourage developing countries to improve their healthcare facilities and should assist them in doing so. The flexibilities of the TRIPS Agreement can be used as one mechanism of such cooperation.

vii. Accountability and Monitoring

The right to health requires open, transparent and efficient systems of monitoring and accountability. Those who bear obligations under the right to health must be held responsible for the discharge of their tasks, with the object of identifying both achievements and problems so that legislative and other changes can be made as required. Monitoring and accountability mechanisms come in many shapes, and although each State may decide which are most suitable in its circumstances, they must be reliable, accessible and transparent.

A national medicines policy should therefore be subject to appropriate monitoring and accountability. Such a policy should set out the government's obligations in relation to medicines and a plan of implementation identifying duty holders, responsibilities, timelines, objectives and reporting procedures. From time to time an independent body, such as a health ombudsman, should consider how well the national medicines administration has performed, not in order to apportion blame but in order to identify which strategies and institutions are working and which are not, and so to improve performance.[84]

viii. A Reliable System for the Supply of Medicines

It is the duty of the State to ensure a transparent, effective and affordable system for the distribution of medicines. It is immaterial whether supply is undertaken by a private company or by a public sector body. A transparent supply system secures affordable supply throughout

[83] Paul Hunt & Rajat Khosla, *The Human Right to Medicines*, 5(8) SUR - INT'L J. ON HUM. RTS. 99, 99-115 (June 2008).
[84] Hunt & Khosla, *supra* note 83.

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the jurisdiction. The system must be designed to meet the needs of people living in poverty and in backward communities as well as those of urban areas. Countries with different levels of resources will inevitably perform differently, but what every State must ensure is progressive improvement.

ix. Provision of Quality Medication

Under international human rights standards it is a legal obligation of the State to ensure the availability of medicines of good quality throughout the nation. It is therefore the duty of the State to make appropriate rules and regulations to ensure that quality is maintained throughout the supply chain in both the private and the public sector, and to see that relevant information about quality is provided to medical practitioners and to the public.

All countries, developed as well as developing, face problems arising from the supply of poor quality medicines, but the problem is far more prevalent in developing countries, partly because poor quality medicines are cheaper and therefore more readily reach those living in poverty. It has been reported that between fifty and ninety per cent of samples of antimalarial drugs failed quality control tests, and that more than half of the samples of antiretroviral medicines tested did not meet international standards.[85] The sale of counterfeit and substandard medicine is a serious international problem.

Roughly one in three States either has no medicines regulatory authority or has one without adequate capacity, and even where an authority exists it may fail to regulate the market effectively.[86] The presence of an effective medicines regulator is essential to attaining the human right to health, and States with well organised regulatory authorities should assist those which are seeking to build them.

x. Financing the Development of Medicines

The way in which a medicine is financed plays an important part in making it affordable, because financing is a determinant of price. There are various financial arrangements, including funding by government or by private companies, fees recovered from patients, and donations. Whatever the arrangement, it is the duty of the State to keep medicine affordable.

In most high income countries the development of medicines is funded substantially from the public purse, whereas in developing countries the government can often meet only the most basic needs of the population. That is why in developing countries a large part of the cost of

[85] Hunt & Khosla, *supra* note 83, at 105-06.
[86] Hunt & Khosla, *supra* note 83.

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medicine is recovered from patients themselves, which makes medicines expensive and puts them beyond the reach of the poor.

The comparisons are stark. A course of antibiotics for pneumonia may be bought in a developed country for the equivalent of two or three hours' wages, while in a developing country the same course may cost a month's wages. A year of paediatric HIV treatment may cost the equivalent of an adult's income for ten years in many developing countries, and in most cases it is paid for out of pocket rather than by insurance. Average per capita spending on medicines in high income countries has been estimated at about a hundred times that in low income countries.[87] Such disparities emphasise the urgency of the responsibility of developed countries for international assistance and cooperation.

The essential point is that in developed countries the cost of medicines is largely met from public funds, whereas in developing countries people must pay for their medicines from their own resources. Medicines are therefore less affordable in developing countries because of inadequate public funding of the health sector, and the burden falls hardest on the poor.

xi. Tackling Corruption

Abuse is widespread in some medicine delivery networks. Consignments are diverted, unofficial fees for customs clearance are demanded, counterfeit drugs are allowed to circulate. Corruption in the pharmaceutical supply chain can be fatal.

People living in poverty are especially affected by corruption in health care, because they are less able to pay small bribes for services which are supposed to be free, or to buy commercial alternatives where public health services have been depleted by corruption.

Participation, access to records, openness, oversight and accountability are all part of the right to health, and each of these contributes to a climate in which corruption cannot prosper. In other words, a right to health approach is also an anti-corruption strategy, and enforcing the right to health will assist in reducing corruption in health care generally and in medicine supply systems in particular.

B. The Role of Pharmaceutical Companies in Ensuring the Right to Health

States cannot be held solely responsible for securing the right to health. Pharmaceutical companies also have their share of responsibility, and must ensure that they do not violate the human right to health while pursuing their corporate goals. If the goal of ready access to medicine is to be achieved, all stakeholders, public and private, national and international, have

[87] Hunt & Khosla, *supra* note 83, at 99-100.

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important parts to perform. Since pharmaceutical companies are among the most important of those stakeholders, their responsibility is correspondingly great. One of the major contributions they can make is to develop essential drugs at an affordable price.[88]

The point has often been made in the policy literature on access to medicines that responsibility for improving access rests with the international community as a whole and not with any single member of it. Progress depends on working together in partnership to build strong health infrastructure in developing countries, on making medicines more affordable, and on increasing the volume of medicines produced for the diseases which cause the greatest burden in developing countries.

The pharmaceutical sector has often been criticised for its part in obstructing the human right to health. Practices adopted to promote commercial interest, such as high prices, ill-considered drug donations, questionable spending in the name of research and development and lobbying for TRIPS-plus standards, all create difficulties for States in implementing the right to health. Although pharmaceutical companies play a very important role in improving health and in making medicines for neglected diseases, they need to work on their social responsibility.

The relationship between the corporate social responsibility of pharmaceutical companies and the human right to health cannot be denied. The policy framework of pharmaceutical companies should incorporate the right to health so as to make provision for improving access to medicines. If companies formed their policies with their social responsibility in view, there would be less need for other measures, and States would be assisted in performing their duties. Implementation matters as much as policy, and the appointment of a health ombudsman within a company is one way of ensuring that such policies are actually applied.

While many pharmaceutical firms report on their corporate citizenship or corporate responsibility practices, few make clear reference to human rights in general, or to the right to health in particular, in their corporate mission statements. Fewer still appear to have considered their proposals through the lens of the right to the highest attainable standard of health. This is a wasted opportunity, because all pharmaceutical firms, large and small, research-based or generic, multinational or not, stand to benefit from adopting a rights-sensitive approach to their operations.

In the past few years general knowledge and understanding of socio-economic and cultural rights has increased considerably. If that trend continues, attention needs to shift from general discussion of these subjects to specific rights in specific sectors, such as access to medicine.

[88] Hunt & Khosla, *supra* note 83.

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The need of the hour in the pharmaceutical industry is to move from general discussion of social, economic and cultural rights to a close analysis of the questions specific to the right to health which arise in this sector, such as patent pricing.

It has emerged that businesses, like all organs of society, have moral and ethical obligations with respect to human rights. According to the Preamble to the Universal Declaration of Human Rights, every organ of society, which must include commercial organisations, has a part to play in securing observance of the rights it proclaims. The United Nations Global Compact, whose participants now number in the tens of thousands, asks companies to support and respect the protection of internationally proclaimed human rights and to ensure that they are not complicit in human rights abuse. The OECD Guidelines for Multinational Enterprises, as revised in 2011, contain a dedicated chapter on human rights which states that enterprises should respect human rights, which means that they should avoid infringing on the human rights of others and should address adverse human rights impacts with which they are involved.[89] The draft Norms on the responsibilities of transnational corporations, prepared by the Sub-Commission on the Promotion and Protection of Human Rights, went further, but the Commission on Human Rights recorded in 2004 that although the draft contained useful elements and ideas for consideration, it had not been requested by the Commission and, as a draft proposal, had no legal standing.[90] Few national courts have considered the effect of prescription pricing policies on the rights of patients, and few companies have drawn up rules of their own expressly acknowledging obligations in respect of human rights.

The key questions today are, first, clarifying the scope and content of these responsibilities and, second, identifying which of them are legal and which ethical. The guidelines prepared by the Special Rapporteur on the right to health for pharmaceutical companies in relation to access to medicines, finalised in 2008, address the first of these questions in the specific context of the pharmaceutical industry, dealing among other things with differential pricing, donations, research and development, clinical trials and corruption. As for the second, it is difficult to maintain that no human right places any legal responsibility on a business enterprise. Businesses are bound not only by legal requirements but also by social values and moral considerations.[91]

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[89] ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, OECD GUIDELINES FOR MULTINATIONAL ENTERPRISES ch. IV (2011 ed.); UNITED NATIONS GLOBAL COMPACT, Principles 1-2.

[90] COMMISSION ON HUMAN RIGHTS, Decision 2004/116 (Apr. 20, 2004); Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights, U.N. Doc. E/CN.4/Sub.2/2003/12/Rev.2 (Aug. 26, 2003).

[91] Paul Hunt, *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines*, annexed to the Report of the Special Rapporteur, U.N. Doc. A/63/263 (Aug. 11, 2008).

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VI. Conclusion

Billions of people do not have access to basic medicines in their daily lives. This leads to avoidable illness, poor quality of life and premature death, much of which could be prevented with proper care. If that deprivation could be reduced, many lives would be saved every year, especially in the developing countries of Africa and South-East Asia. Alongside the lack of access there is gross inequality in availability: the rich have abundance while the poor go without.

Average per capita spending on medicines in high income countries has been put at about a hundred times that in low income countries.[92] On the estimate of the World Health Organization, about ninety per cent of the world's pharmaceutical production by value is consumed by some fifteen per cent of its population.[93]

These inequalities and this lack of access are in large part the product of existing national and international policy. Poor people rarely benefit from the policies made for them; national policy often does not reach those who need it most, at least not at an affordable cost. Even the distribution of COVID-19 vaccines showed that the most developed countries have not solved the problem of reaching the poor. Pharmaceutical companies seldom take the needs of underprivileged sections of society into account in their development work. What is needed are urgent reforms and alternative measures which focus on those sections.

Development goals such as combating HIV/AIDS, malaria and other diseases, reducing child mortality and improving maternal health all depend upon improving access to medicines. One of the Millennium Development Goal targets was, in cooperation with pharmaceutical companies, to provide access to affordable essential drugs in developing countries; the same commitment now appears in the Sustainable Development Goals, which call for access to safe, effective, quality and affordable essential medicines and vaccines for all.[94] Taking the right to the highest attainable standard of health seriously will help to meet those goals.

The right to the highest attainable standard of health includes the availability of medical care when a person is sick, as well as the prevention, control and treatment of disease, and each of these depends directly on access to medicine. The human rights instruments discussed in this paper, and the Indian decisions in *Novartis* and *Bayer*, support the proposition that access to

[92] Hunt & Khosla, *supra* note 83, at 99.
[93] World Health Organization, The World Medicines Situation (2004).
[94] United Nations, *Road Map Towards the Implementation of the United Nations Millennium Declaration*, U.N. Doc. A/56/326, annex, Target 17 (Sept. 6, 2001); G.A. Res. 70/1, Transforming Our World: The 2030 Agenda for Sustainable Development, Goal 3.8 (Sept. 25, 2015).

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essential drugs is a fundamental component of the human right to health.[95] The right to life is closely linked to access to medicine, because in a world where disease is common and new pathogens cross the species barrier so frequently, it is not possible to live an ordinary life without essential drugs.

The content of the right to the highest attainable standard of health has become clearer over time. In 2000 the Committee on Economic, Social and Cultural Rights produced a general framework which unpacked the right in terms of entitlements and freedoms, non-discrimination, the underlying determinants of health, participation, and accountability and monitoring.[96] This paper has sought to apply that framework to the system by which medicines are developed, priced and distributed.

The right to health plays an important part in improving access to medicines. It sharpens the analysis and clarifies the roles of the various stakeholders, and health policies framed with it in view are likely to be fairer, more equitable and more effective. That commitment is already acknowledged in some health policies and programmes, and the constructive impact of taking the right to health into account in decisions about medicines is increasingly appreciated. Experience also shows that conventional human rights techniques, such as public advocacy and litigation, have an essential part to play in securing different aspects of the right to health, including access to medicinal products.

From this research it emerges that the patent rights of pharmaceutical companies and the human right to health, although often in tension, can be reconciled through the flexibilities provided in the TRIPS Agreement and through a determination to give public health its proper weight. India has interpreted several provisions of the TRIPS Agreement and accommodated them in domestic legislation so as to create a workable balance between the two.

It is important to state that conclusion accurately. The international instruments do not establish that the human right to health will always prevail over patent rights in the event of a conflict. What the Doha Declaration does is to direct that the TRIPS Agreement be interpreted and implemented in a manner supportive of the right of members to protect public health, and to confirm the flexibilities, above all compulsory licensing and the freedom to determine the grounds for it and to decide what constitutes a national emergency, through which that protection may be given effect. The Ministerial Decision of 17 June 2022 worked in the same way, and the failure to extend it to therapeutics and diagnostics shows how much depends on

[95] *Novartis*, *supra* note 67; *Bayer Corp.*, *supra* note 72.
[96] General Comment No. 14, *supra* note 11.

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political will rather than on any legal hierarchy.[97] The Supreme Court in *Novartis* reached a similar result under domestic law, not by ranking rights against one another, but by construing a statutory condition of patentability strictly in the light of the public interest. The lesson is that the tools exist and must be used; they do not operate by themselves.

Beyond patented medication, other alternatives such as generic medicines must be part of any answer to the problem of access. A change in the patent regime alone is not enough to solve the global health crisis, particularly in the developing world.

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[97] Doha Declaration, *supra* note 31, paras. 4, 5(b)-(c); MC12 Decision, *supra* note 40, paras. 1, 8.

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