



**IPR V. HUMAN RIGHTS:
PROTECTION OF
PHARMACEUTICALS AND DRUGS BY
MEANS OF PATENTS AT THE COST
OF RIGHT TO HEALTH OF PEOPLE**

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ABSTRACT

Initially, Intellectual Property Rights and Human Rights were two different fields of law. But recently, it has been very widely noticed that these two fields of study have been conflicting each other. This article attempts to explain this conflict in context of the collision between Intellectual Property Rights and Right to Health of the people and trace its detrimental impact on this basic human right of right to health. The article elaborates on how it is an irony that drugs which are being manufactured to improve the health conditions of people are not even accessible to them, due to its patent protection, let alone affording them. This article limits itself to the impact of patent protection on access to affordable medicines. It also tends to describe the impact of patent protection on biological resources which are used as a source of raw material for the development of new drugs. Further, this article discusses the patent protection of the pharmaceuticals and drugs under TRIPs agreement and its implementation in Indian pharmaceutical industry. It has also been the effort of the author to propose certain recommendations for the improvement of patent protection regime in furtherance of public interest. The article attempts to assert that sheer and compulsive attention is required to be paid to this conflict. There is a dire need to take

into consideration the human physical well-being while allocating IP rights.

1. Introduction to Conflict Between Intellectual Property Rights and Human Rights

Just as in the industrial revolution, the key resources were raw materials and labour, similarly, when it is about an information or knowledge-based economy, intellectual property plays the role of a central asset.¹ Intellectual property is the generic term used to designate the subjective rights that the various legal orders grant to the creators of immaterial assets of intellectual origin which acquire their value primarily from creative efforts.² Those immaterial assets may be of two kinds, namely either literary and artistic creations or distinctive signs and inventions. Intellectual property therefore establishes the protection of ideas and designs in art and technology, in industry and in trade.³

The domain of Intellectual Property Rights is universal in its nature. This is because of the assumption that such rights are not meant or need to be culture specific. The cultural and intellectual domination that is implied by intellectual property rights impinges and infringes a range of rights like

¹ Robert L. Ostergard, *Intellectual Property: A Universal Human Right?*, 21 Human Rights Quarterly 156, 158 (1999).

² K. Outtersson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5(1) Yale J Health Policy, L & Ethics 193, 195 (2005).

³ J. A. DiMasi, R. W. Hansen & H. G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22(2) J of Health Economics 151, 178(2003).



knowledge rights, livelihood rights, right to subsistence, health rights, right to life, etc.⁴ All of these latter rights have become an important part of the human rights discourse. Even though these are referred to be a part of domain of human rights but they lack legal protection that "rights" stipulate. So, instead of being enforced as the legal rights, these rights are still seeking protection as they stand diminished by Intellectual Property Rights.⁵

Human rights and intellectual property are two different bodies of law which are now increasingly coming together to become intimate bedfellows. Initially, the two subjects developed aloof from each other but lately tensions between intellectual property rights and human rights are budding continually leading to several discourses pertaining to the intersection of the fields.⁶ A human-rights approach acknowledges to recognize the normative primacy of artistic and scientific works, first and foremost, as an expression of human dignity and creativity and not economic commodities whose value is determined by their utility and economic price tag.⁷ A human-rights orientation is predicated on the supremacy of protecting and nurturing human dignity and the common good. It seeks to preserve a balance between the rights of inventors and

creators and the interests of the wider society.⁸

2. Detrimental Impact of IPRs on Realization of Right to Health

Article 25(1) of the Universal Declaration of Human Rights, 1948, states explicitly that "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and *medical care [emphasis added]* and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control." This principle of the right to health is underpinned by Article 12 of the United Nations International Covenant on Economic, Social and Cultural Rights, 1966, which states that "The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health". On the other hand, Article 27(2) of the Universal Declaration of Human Rights, 1948, states that "Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author."

United Nations Sub-Commission on the Promotion of Human Rights had affirmed, in Resolution 2000/7 that the right to protection of the moral and material interests resulting from any scientific, literary or artistic production of which one is the author

⁴ Edwin C Hettinger, *Justifying IP*, 18 *Philosophy and Public Affairs* 31, 35 (1989).

⁵ Rajshree Chandra, *Intellectual Property Rights: Excluding Other Rights of Other People*, 44 *Economic and Political Weekly* 86, 87 (2009).

⁶ Laurence R. Helfer, *Human Rights and Intellectual Property: Conflict or Coexistence?*, 5 *Minn. Intell. Prop. Rev.* 47, 52 (2003).

⁷ K. M. Lybecker & E. Fowler, *Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules*, 37(2) *J of L, Medicine & Ethics* 222, 225 (2009).

⁸ Laurence R. Helfer, *Adjudicating Copyright Claims Under the TRIPs Agreement: The Case for a European Human Rights Analogy*, 39 *HARV. INT'L L J* 357, 397 (1998).



is, in accordance with Article 27(2) of the Universal Declaration of Human Rights, is subjected to limitations in the public interest.⁹ But even though human rights should enjoy primacy over patents, there is no evidence which suggests that the right to health is considered as a prioritised norm under international law.¹⁰

It is pertinent to note that just as the other rights of an individual are protected and safeguarded by the State, similarly, an individual's right to health must be guaranteed by the State. But it cannot be implemented in the same manner for right to health can be attained only after obtaining certain variables which actually lead to the improvement of one's health.¹¹ These variables include food, medical assistance, nutrition, hygiene, etc. Furthermore, these variables can be achieved through various combined actions such as access to drugs, therapeutic diagnosis' techniques and apparatuses, affordable treatments, quality of health facilities, goods and services including prevention and cure of diseases.¹² States are bound to promote the

right to health through the ensuring of access to affordable treatments.¹³

The detrimental impacts of IPRs on the right to health can be encapsulated in the following points

2.1 Skimp Access to Affordable Medicines/ Drugs

The right to health includes access to appropriate health care. Lack of access to affordable medicines is a global issue now. In this regard IPRs has a major role to play. When a medicine is protected through patent it causes an increase in its price which in return has a negative impact on patients' access to medicine.¹⁴ Mostly, patent protection leads to a monopoly situation as patent holders, which are almost always corporations, have the freedom to price their products arbitrarily, often high, and thus, again making patented drugs far more expensive than their generic counterparts.¹⁵ Furthermore, over the years total costs of discovering or manufacturing a new drug, through usage of biotechnology, has escalated and thus the cost of bringing a drug to market is approaching US\$ 3 billion, which is a 145% over the estimate made in 2003.¹⁶ As a result, pharmaceutical

⁹ R. Shretta, G. Walt, R. Brugha & R.W. Snow, *A Political Analysis of Corporate Drug Donations: The Example of Malarone in Kenya*, 16 Health Policy Plan 161, 163 (2001).

¹⁰ D. Weissbrodt & M. Kruger, *Norms on The Responsibilities of Transnational Corporations And Other Business Enterprises With Regard to Human Rights*, 97 Am J Int Law 901, 902 (2003).

¹¹ B.A. Liang, *Fade to Black: Importation And Counterfeit Drugs*, 32 Am J Law Med 279, 283 (2006).

¹² HENRY SHUE, *BASIC RIGHTS: SUBSISTENCE, AFFLUENCE AND US FOREIGN POLICY* 394 (2nd edn. 1996).

¹³ Audrey Chapman, *Conceptualizing the Right to Health: A Violations Approach*, 65 TENN. L REV. 389, 395 (1998).

¹⁴ J. Cornides, *Human Rights and Intellectual Property: Conflict or Consensus*, 7(2) J of Intellectual Property 135, 162 (2004).

¹⁵ Joseph A. Dimasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Cost*, 22 Journal of Health Economics 151, 175 (2003).

¹⁶ Rick Mullin, *Tufts Study Finds Big Rise in Cost of Drug Development*, Chemical and Engineering News, (Nov 20,



corporations are always disinclined towards making these drugs available at reduced rates for low prices of drugs fetch them less profit.¹⁷ But since patents are the first and foremost reward that provides an incentive to these pharmaceutical corporations, it stimulates them to further research and innovate in the development and production of new medicines. This results in higher prices for medicines in rich and poor countries alike.¹⁸ The final conclusion, thus, remains the same that expensive drugs are a fundamental outcome of patent regime leading to unavailability of drugs to penurious people.

2.2 Health Crisis in Developing Countries

Another negative impact of patent regime of pharmaceuticals in on the developing countries where population not only have lower economic status, but also lower health status and higher needs to medicine. It has already been discussed that how pharmaceutical corporations arbitrarily price their drugs very high. As a result, most of the essential drugs that are being manufactured by these corporations are beyond the means of poor persons lacking health insurance, which includes the majority of residents in less developed

countries.¹⁹ It is ironic to note that mostly it is the developing countries which has the highest rates of medicines and other drugs.²⁰ It was seen in Kenya that Nevirapine, which prevents mother-to-child transmission of H.I.V., costs \$874 despite the desperate need of the drug but only \$430 per 100 units in Norway, where there is hardly any market for it.²¹

Increasing access to essential medicines in poorer countries, including a loosening of patent protections on medicines has become a significant matter of discourse now. But it has always been opposed by pharmaceutical giants claiming that their profits will dry up if patent protection is removed from the drugs and medicines.²² Pharmaceutical corporations consider patents as the only reward to encourage research and innovation for the development and production of new medicines. As a result, it is followed by the production of only those drugs which have an alluring market and increasing sales because it procures them high profits apart from having patents as the only incentives.²³

2014), <https://cen.acs.org/articles/92/web/2014/11/Tufts-Study-Finds-Big-Rise.html>.

¹⁷ Frederick M Abbott, *Seizure of Generic Pharmaceuticals in Transit Based On Allegations Of Patent Infringement: A Threat To International Trade, Development And Public Welfare*, 1 WIPO J 47, 56 (2009).

¹⁸ R. C. Bird, *Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines while Minimizing Investment Side Effects*, 37(2) J of L, Medicine & Ethics 209, 216 (2009).

¹⁹ Cecilia Oh, *IPRs and Biological Resources: Implications for Developing Countries*, 8 J of Intellectual Property Rights 400, 404 (2003).

²⁰ Jennifer Anna Sellin, *Does One Size Fit All? Patents, the Right to Health and Access to Medicines*, 62 Neth Int L Rev 445, 457 (2015).

²¹ Donald G. McNeil Jr, *Prices for Medicine are Exorbitant in Africa, Study Says*, New York Times, June 17, 2000, <https://www.nytimes.com/2000/06/17/world/pri ces-for-medicine-are-exorbitant-in-africa-study-says.html>.

²² Michael Schull, *Effect of Drug Patents in Developing Countries*, National Centre for Biotechnology Information, Sep 30, 2000, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1118638/>.

²³ M. Koning, *Biodiversity prospecting and the equitable remuneration of ethnobiological*



Thus, there is no significant growth in research and development of drugs pertinent to diseases of developing countries, as it is non-profitable, leading to a substantial neglect of these disease which are termed as neglected diseases.²⁴

Furthermore, these corporations are supported by the governments of their own country. These governments impede the governments in poor countries to obtain drugs from other cheaper sources through parallel importing so that their people can have access to modern essential treatments.²⁵ For example- in late 90s when there were millions of people suffering from HIV/AIDS who could not afford the original brand medicine, South African government imported generic anti-retroviral medicine for treating HIV/AIDS endemic situation. As a result, giant pharmaceutical companies such as GlaxoSmithKline filed a lawsuit against the government.²⁶ Wherefore, the only option the governments of developing countries are left with, to guarantee the citizens their health, is to import the branded medicine despite them being unaffordable for a part of the population.²⁷

2.3 Biopiracy

Biopiracy can be defined as the appropriation of another's knowledge of use of biological resources.²⁸ It is the commercial exploitation of those biological resources or genetic material, which occur naturally, by obtaining patents in order to restrict its future use. The most ruinous consequence of this is that this happens without providing any incentive to the community from which these biological resources originates²⁹ It was in 1980 when the patent on a living organism per se was accepted for the first time after the decision of the US Supreme Court in *Diamond v. Chakrabarty*.³⁰ Ever since then the question arose that whether biological resources which can be used as a raw material for the development of new drugs, such as, cells and sub-cellular parts, including genes, as well as multicellular organisms as well as micro-organisms, that exist in nature should also be patented under this provision.³¹ Even though, generally accepted norm is that a naturally existing biological resources are not patentable, in some jurisdictions once a micro-organism is isolated and its use is

knowledge: reconciling industry and indigenous interests, 12 Intellectual Property J 68, 75 (1998).

²⁴ Joseph Wambugu Githaiga, *Intellectual Property Law and the Protection of Indigenous Folklore and Knowledge*, 5 Murdoch U Electronic J of L 206, 234 (1998).

²⁵ A. O. Sykes, *TRIPs, Pharmaceuticals, Developing Countries and the Doha Solution*, 3(1) Chicago J of Intl. L 47, 52 (2002).

²⁶ Virginia Barbour, *Drug Companies Should Be Held More Accountable for Their Human Rights Responsibilities*, PLoS Medicine (Sep 28, 2010) [10.1371/journal.pmed.1000344](https://doi.org/10.1371/journal.pmed.1000344).

²⁷ D. Matthews, *WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the*

Access to Essential Medicines Problem?, 7(1) J of Intl. Economic L 73, 77 (2004).

²⁸ Gollin, *Biopiracy: The Legal Perspective*, American Institute of Medical Sciences, Action Bioscience, Feb 2001, <http://www.actionbioscience.org/biodiversity/gollin.html>.

²⁹ M. Lee & J. Kohler, *Benchmarking And Transparency: Incentives For The Pharmaceutical Industry's Corporate Social Responsibility*, 95 J Bus Ethics 641, 648 (2010).

³⁰ *Diamond v. Chakrabarty*, 447 U.S. 303, 334 (1980).

³¹ M.E. DeGeer, *Biopiracy: The Appropriation of Indigenous Peoples Cultural Knowledge*, 9 New England Journal of International and Comparative Law 18, 21 (2002).



discovered, it is sufficient to obtain a patent for it.³²

One of the major incidents of biopiracy is of patenting of Neem (*Azadirachta Indica*). Neem tree is a native to India and Burma. The tree is well known for its medicinal qualities because it is unique in its nature as it does not kill but rather repel micro-organisms and has been used widely for a whole range of purposes, from a teeth cleaner to a fungicide.³³ These findings were pirated by a multinational chemical company, W. R. Grace and Co., which sought a patent for the fungicidal properties of Neem.³⁴ Later, European Patent Office revoked the patent on the ground that neem had already been in prior use. But this neem patent case was only one of the patents that was granted on the inventions derived from the neem tree otherwise there are several neem patents granted by United States Patent and Trademark Office which are not revoked.³⁵ Similarly, US has a patent for the use of a combination of certain herbal compositions as anti-diabetic agents that have been in use and are also well-

documented in Indian Scientific literature and ancient texts for the same anti-diabetic properties.³⁶ British company Phytopharm acquired a patent over the active ingredient of Hoodia cactus, used as a slimming drug and an appetite suppressant, after the findings of its medicinal qualities was passed on to the company by San community of Southern Africa which was already traditionally using it. Later, to commercialise the drug, Phytopharm sold the exclusive global license of the drug to Pfizer for US\$ 21 million.³⁷ This patent is criticized as San community receives less than 0.003 per cent of net sales of the product and is not only exempt from sharing their benefits but also prevented from using their knowledge of Hoodia in any other commercial application.³⁸

Therefore, the peroration invokes that biodiversity is the reserve and resource of mankind. It belongs to everyone yet no one. Therefore, everyone has a right to make its utilization but no one has a right to secure exclusive rights over its use.

3. Patent Protection of Pharmaceuticals Under TRIPS

Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement was introduced with an intent to produce certain universal standards for implementation of Intellectual Property Rights and frame the

³² A. Kothari & R.V. Anuradha, *Biodiversity and Intellectual Property Rights: Can the Two Co-exist?*, 2(2) *Journal of International Wildlife Law & Policy* 204, 208 (1999).

³³ Shayana Kadidal, *Subject-Matter Imperialism? Biodiversity, Foreign Prior Art and the Neem Patent Controversy*, 37 *IDEA: The Journal of Law and Technology* 371, 379 (1996).

³⁴ C. Hamilton, *Biodiversity, Biopiracy and Benefits: What Allegations of Biopiracy Tell us About Intellectual Property*, 6(3) *Developing World Bioethics* 159, 169 (2006).

³⁵ L. Bullard, *Freeing the Free Tree: A Briefing Paper on the First Legal Defeat of a Biopiracy Patent: The Neem Case*, *International Federation of Organic Agriculture Movements*, Mar 8, 2005, <http://nwrage.org/content/freeing-free-tree-briefing-paper-neem-biopiracy-case>.

³⁶ *Id.* at 209.

³⁷ N. Roht Arriaza, *Of Seeds and Shamans: The Appropriation of The Scientific and Technical Knowledge of Indigenous and Local Communities*, 17 *Michigan Journal of International Law* 919, 1004 (1996).

³⁸ LAURA A. FOSTER, *REINVENTING HOODIA: PEOPLES, PLANTS, AND PATENTS IN SOUTH AFRICA*, (2nd edn. 2017).



rules of the game of the developing countries on par with the developed countries.³⁹ This agreement forced the World Trade Organization (WTO) members to take action for protecting intellectual property rights. The WTO has extensive membership and all the members are required to fully implement TRIPS except for the least developed members. This has greatly influenced domestic developments in the field of patent protection for medicines.⁴⁰ The agreement entails that any patented product should be produced, imported, sold or used under permission of the patent owner.⁴¹

Article 27 of TRIPS that patent protection is extended to all the fields of technology. This includes the necessity for protecting intellectual property rights of the owners and manufacturers of medicines as well. Article 28 and 33 of TRIPS makes it necessary for the members of WTO to grant exclusive rights for a minimum period of 20 years. These exclusive rights are to prevent any other party from making, using, offering for sale, selling or importing for these purposes the patent product without consent.⁴² Thus,

with the implementation of TRIPS, a monopoly in the market was created every time a medicine was created. Furthermore, these medicines were sold at the highest possible price with the absence of any other low price generic drug of the same nature. As a result, these patented drugs costs patients an arm and a leg.⁴³

It was the non-availability of drugs used in the treatment of HIV/AIDS in Latin American and African countries which started off the discourse of the conflict between the provisions of TRIPS and right to health. Consequently, European Union and WHO insisted that detrimental impact of TRIPS on the availability and affordability of drugs should be taken into consideration and calls for appropriate action.⁴⁴ It was in 2001, at Inter-Ministerial Conference in Doha, that this problem was realized in its totality for the first time. As a result, Doha Declaration made it an obligation for the members of WTO to implement and interpret the provisions of TRIPS with a view to safeguard public health and promote public interests.⁴⁵ It also recommended that patented medicines must be supplied, by issuing compulsory licenses under Article 31 of TRIPS, to those needy countries which

³⁹ K. Outtersson, *Should Access to Medicines and TRIPS Flexibilities Be Limited to Specific Diseases?*, 34(3) American Journal of Law & Medicine 279, 286 (2008).

⁴⁰ F. M. Abbott & J. H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 4 Journal of International Economic Law 921, 943 (2007).

⁴¹ Hulme E., *History of The Patent System Under the Prerogative and at Common Law*, 46 L Q Rev. 141, 150 (1996).

⁴² Reddy Prasada & Sigurdson, *Strategic Location of R&D and Emerging Patterns of Globalization: The Case of Astra Research Centre India*, 14

International Journal of Technology Management 344, 356 (1997).

⁴³ Danzon M Patricia & Chao Wei-Li, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, 43(2) The Journal of Law and Economics, 243, 256 (2000).

⁴⁴ Amanpreet Kaur & Rekha Chaturvedi, *Compulsory Licensing of Drugs and Pharmaceuticals: Issues and Dilemma*, 20 Journal of Intellectual Property Rights 279, 280 (2015).

⁴⁵ M.D. Nair, *TRIPS and Access to Affordable Drugs*, 17 Journal of Intellectual Property Rights 305, 310 (2012).



cannot manufacture them by due to technical incapability. Rwanda was the first country which managed to attain a compulsory license for an antiretroviral drug, TriAvir, from a Canadian generic company Apotex.⁴⁶ Even though Doha Declaration stated that public interests are above private interests but still, very few compulsory licenses have been granted till today. The major reason behind this is that in order to get a compulsory license, certain conditions are imposed on the importing country which become really challenging to implement.⁴⁷ For example, the exporting country should obtain a license to export the product, produce batches only for the required quantity which has to be specially labeled and colour coded for the purpose and stop production once that demand is met.⁴⁸ Furthermore, granting of compulsory licenses also leads to the creation of “gray market.” It happens when patented drugs are sold in the local market a price less than the price it is listed at to sell in the targeted market.⁴⁹ This might not be supply of illegal products such as black marketing but this causes a revenue loss to the governments and economically burden the country due to

the shrinkage of Foreign Direct Investment in the country.⁵⁰

4. Pharmaceutical Industry in India- Implementation of TRIPS

In 1950s, Indian Pharmaceutical Industry was not technologically capable enough to manufacture drugs and medicines indigenously.⁵¹ But by the late 1980s, India emerged as one of the largest drug exporters in the world by attaining self-sufficiency in its pharmaceutical production. This progress was the result of implementation of Patent Act of 1970 and the Drug Policy of 1978.⁵² Under this patent regime, Indian drug manufacturers could copy pharmaceutical products that were otherwise patented in foreign nations, leading to a boom in the production of generic drugs.⁵³ The Drug Policy of 1978 paved way for the enhancement of R&D and technology and production of bulk drugs and intermediates by promoting several measures to guide and control foreign companies with a 75 percent share of the domestic market. This turned out to be a disincentive to foreign companies

⁴⁶ D. Yang, *Compulsory Licensing: For better or For Worse, The Done Deal Lies in The Balance*, 17 *Journal of Intellectual Property Rights* 76, 78 (2012).

⁴⁷ G. Nair Fernandes, *Patent Policies and Provisions Relating to Pharmaceuticals in India*, 19 *Journal of Intellectual Property Rights* 7, 12 (2014).

⁴⁸ S. Flynn, A. Hollis & M. Palmedo, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, 2 *Journal of Law* 184, 195 (2009).

⁴⁹ R. Gupta, *Compulsory Licensing Under TRIPS: How Far it Addresses Public Health Concerns in Developing Nations*, 15 *Journal of Intellectual Property Rights* 357, 360 (2010).

⁵⁰ A. Taubman, *Rethinking TRIPS: Adequate Remuneration for Non-Voluntary Patent Licensing*, 11(4) *Journal of International Economic Law* 927, 948 (2008).

⁵¹ Anitha Ramannna, *Policy Implications of India's Patent Reforms*, 37(21) *Economic and Political Weekly* 2065, 2068 (2002).

⁵² Janice Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 *U. PITT. L. REV.* 491, 514–15 (2007).

⁵³ Carsten Fink, *Patent Protection, Transnational Corporations, and Market Structure: A Simulation Study of the Indian Pharmaceutical Industry*, 1 *Journal of Industry, Competition and Trade* 101, 111 (2001).



and thus, developing the ability to produce generic drugs.⁵⁴

With the enforcement of TRIPS Agreement in 1995, like many other developing nations, India was also not in favour of the TRIPS Agreement. But being a member of WTO, India, necessarily, had to modify its domestic intellectual property laws in order to comply with the agreement.⁵⁵ It was until 2005 that India fully implemented TRIPS. All this while Indian pharmaceutical industry had maintained a comparative advantage of cheap and skilled workers among developing economies.⁵⁶ India amended its domestic intellectual property law, namely Patents Act, 1970, in three stages. Firstly, in 1999, India adopted the provision which enabled the entities to submit product patent applications for pharmaceuticals and agricultural chemicals to the patent office that would be held until examination in 2005.⁵⁷ Second, in 2002, when India extended the patent terms to 20 years as mentioned in TRIPS. It is pertinent to note that initially the patent term was of 7 years from the time of filing of the patent or 5 years from the date sealing of the patent, whichever was shorter. Third, in 2005, India brought into compliance Patents (Amendment) Act, 2005, which made patent

protection available for all kinds of innovation. It also deals with the issuance of compulsory licenses of Pharmaceuticals for the export purposes.⁵⁸ Thus, with the incorporation of the provisions of TRIPS Agreement two major changes were introduced in the Indian Patent Law, first, it introduced product patents for pharmaceuticals as well and second, patent holders were ensured patent protection for a period of 20 years.⁵⁹

Post TRIPS, Indian Pharmaceutical Industry emerged as a major global exporter of drugs and medicines. On the list of countries that exported the highest dollar value worth of drugs and medicines during 2017, India was at 11th position with a total of \$8.7 billion worth of drugs which is equal to 2.6% of total drugs/medicines exports.⁶⁰ Another feather in the cap of India is the establishment of several research facilities, in the country, of major leading global generic pharmaceutical corporations. This due to the necessary adjustments and amendments made by India in its laws. One of them being limiting the reach of product patent protection in the country through Section 3(d) of the Patents (Amendment) Act of 2005.⁶¹ The section essentially

⁵⁴ Antara Dutta, *From Free Entry to Patent Protection: Welfare Implications for the Indian Pharmaceutical Industry*, 93 REV. ECON. & STAT. 160, 162 (2011).

⁵⁵ M. Lawless, *Deconstructing Gravity: Trade Costs and Extensive and Intensive Margins*, 43 Canadian Journal of Economics 1149, 1167 (2010).

⁵⁶ William J. Bennett, *Indian Pharmaceutical Patent Law and the Effects of Novartis Ag v. Union of India*, 13 Wash. U. Global Stud. L. Rev. 535, 540 (2014).

⁵⁷ N. Bedi, P.M.S. Bedi & B.S. Sooch, *Patenting and R&D in Indian Pharmaceutical Industry: Post TRIPS Scenario*, 18 Journal of Intellectual Property Rights 105, 108 (2013).

⁵⁸ R. Kiran & S. Mishra, *Changing Pragmatics of the Indian Pharmaceutical Industry in the Pre and Post TRIPS Period*, 4 International Journal of Business and Management 206, 213 (2009).

⁵⁹ M.D. Nair, *Recent Happening in WTO*, 16 Journal of Intellectual Rights 267, 278 (2011).

⁶⁰ Daniel Workman, *Drugs and Medicine Exports by Country*, World's Top Exports, June 8, 2018, <http://www.worldstopexports.com/drugs-medicine-exports-country/>.

⁶¹ V.K. Himanghsu, *Patent Monopoly and Doctrine of Exhaustion: Limits on Exclusive Rights*, 16(6) Journal of Intellectual Property Rights 453, 462 (2011).



provides for a tougher standard for securing patents by postulating that in order to attain patent for a new version of any product it must be proved that new versions are therapeutically more beneficial than earlier versions on which patents had expired.⁶² This limiting of patent protection initiated in 1993 when Novartis filed patents around the world for its synthesis of the molecule *imatinib* but claimed that the molecule can only be administered to cancer patients as *imatinib mesylate*.⁶³ Thus, the resulting drug came to be known as Glivec. When Glivec approached Madras Patent Office for patent protection, it was rejected on the grounds that it was “an unpatentable modification of an existing substance, *imatinib*.” The Indian Supreme Court, following the same opinion, rejected the claim.⁶⁴

India has managed to prevent common abusive patenting practice by limiting the patent protection with a view that unless enhanced or superior efficacy of a drug is not demonstrated in accordance with section 3(d) of the Patents (Amendment) Act of 2005, it cannot be granted a patent. But this was possible only because of the interpretation of Article 27 of TRIPS which allows member states a fair amount of flexibility when enacting patent laws that conform to and protect their national interests.⁶⁵ Therefore, the resulting patent

laws of the member states cannot be entirely arbitrary. It is suggestive of the fact that TRIPS in itself is not catastrophic to the public health and their interests. Right to health of a country’s citizens depends on the manner in which TRIPS’s provisions are incorporated in the intellectual property laws of the country. Thus, when efforts are being made to reduce the impact of patents on prices and affordability of drugs, these efforts must be supported by governmental national programmes providing for insurance schemes for the betterment of healthcare of the people.

5. Recommendations for Better Patent Protection of Pharmaceuticals for Improvement of Public Healthcare

Evidently enough, the concern for securing access to affordable drugs is a real one, and there have been various arguments preaching that how increasing patent protection for the products of powerful MNCs works only to hurt the common man.⁶⁶ But at the same time, one cannot ignore the reality that protection of intellectual property rights provides these corporations with the needed incentive to invent and manufacture the drugs on which patients around the world rely, whether branded or generic. Therefore, a balance needs to be struck.⁶⁷

⁶² R. Sarma & K.K. Saxena, *Strengthening the Patent Regime: Benefits for Developing Countries*, 17 *Journal of Intellectual Property Rights* 122, 129 (2012).

⁶³ P. Mc Calman, *Reaping What You Sow: An Empirical Analysis of International Patent Harmonization*, 55 *Journal of International Economics* 161, 180 (2001).

⁶⁴ *Id.* at 549.

⁶⁵ Raju KD, *Interpretation of Section 3(d) in the Indian Patent Act 2005: A Case Study of Novartis*,

2(1) *Indian Journal of Intellectual Property Law* 7, 20 (2008).

⁶⁶ Aditi Bagchi, *Compulsory Licensing and Duty of Good Faith in TRIPS*, 55(5) *Stanford Law Review* 1529, 1545 (2003).

⁶⁷ K. Ravi Srinivas, *Interpreting Para 6: Deal on Patents and Access to Drugs*, 38 *Economic and Political Weekly* 3975, 3977 (2003).



5.1 Interventions by Governments

First and foremost, it is the responsibility of a government to prevent the rights of its citizens. Even though, governments cannot prevent the pricing of the medicines by the patent holders and restrict their trading activities. But there are several other ways through which governments in developing countries can actually prevent the violation of the human rights. The most appropriate method through which it can be achieved is the use of competition law.⁶⁸ By the means of competition law competition in the market can be controlled. Generally, patent holding pharmaceutical companies tend to enjoy a monopoly in the market and in order to perpetuate it they even make agreements with generic drug manufacturers.⁶⁹ Through these agreements, generic drug producers are paid by patent holding pharmaceutical companies for postponing the entrance of generic medicines in the market, which are cheaper than the patented drugs, and thus, these pharmaceutical companies enjoy monopoly in the market even after the expiration of their patents. Thus, appropriate implementation of the competition law will deter such pharmaceutical companies from illegally curtailing the competition in the market and thus, results in the decline in the price of the drugs making them accessible and affordable for the people.

⁶⁸ Dr. ShuchiMidha& Aditi Midha, *Compulsory License: It's Impact on Innovation in Pharmaceutical Sector*, 2 International Journal of Application or Innovation in Engineering & Management 2319, 2327 (2013).

⁶⁹ Saeed Ahmadiani&ShekoufehNikfar, *Challenges of Access to Medicine And The Responsibility of Pharmaceutical Companies: A Legal Perspective*, 24 DARU Journal of Pharmaceutical Sciences 13, 19 (2016).

Furthermore, governments can also guarantee affordable healthcare through its schemes. It can various steps such as funding the research centers and labs which contribute in achievement of affordable medicines. This way these labs will be ore self-sufficient and procure better results. Governments can also itself purchase the patents of those life-saving drugs which are expensive and then provide licenses for them to local drug manufacturers at lower prices.

5.2 Voluntary Licensing of Patented Drugs

Governments in developing countries are doing firm efforts to improve the accessibility of affordable medicines for their citizens. This is being done by imposing price controls on all those medicines which are being sold by foreign pharmaceutical companies at a very high and unaffordable price. However, this effort is not very successful as these pharmaceutical companies explicitly refuse to provide their medicines to sell in the market of those developing countries which have very strict (consumer-friendly) price control regulations.⁷⁰ Therefore, developing nations choose the option of compulsory licensing. Compulsory licensing is the grant of an authority by the government to produce and manufacture the patented medicines without the consent of patent-holder.⁷¹ But again, compulsory licensing also comes with its upshots. Most of the times compulsory licensing leads to threats

⁷⁰ Justin Hughes, *The Philosophy of Intellectual Property*, 77 Georgetown Law Journal 287, 296 (1998).

⁷¹ E. EdemUdoaka, *Critical Appraisal of the Problems in Licensing of Patents in Nigeria*, 6 Indian Journal of Intellectual Property Rights 48, 67 (2013).



of trade retaliation and investment red flags.⁷² In such a condition, voluntary licensing is the most feasible option for the governments. Voluntary Licensing is obtained for patented drugs by international organization like WHO by paying a negotiable price to the patent-holder and then these organisations give the right to produce these patented drugs to the developing nations.⁷³ In return of this, developing nations pay these organisations and conduct massive production of the drugs which can later be imported to needful countries.⁷⁴ The fundamental reason for preferring voluntary licensing to compulsory licensing is that there is no threat to the rights of those pharmaceutical companies who are the real patent holders of the medicines as the production of the medicines is limited to the local market and there is no involvement of parallel importation.

6. Conclusion

Health is a basic human right and access to medicine is a basic tool to ensure health. It cannot be denied that outright unavailability of patented drugs is causing an impediment to this right. Furthermore, patents are being acquired for the usefulness of biological resources as well. Traditionally biodiversity

was considered a resource of mankind and that is why was known as heritage of the entire human race. It is clear that visible conflict between Intellectual Property Rights and Human Rights is embodied in TRIPs agreement as well. Patent protection is actually snatching away the right of everyone to enjoy the benefits of scientific progress and its applications. Thus, it is necessary that more human-rights advocates get involved with intellectual property issues then only it is likely that many of the problems will also be considered to be violations. Developed countries are required to come forward and help developing countries in the protection of right to health of people. More opportunities have to be allowed and welcomed for propounding the issues of intellectual property from a human rights' perspective.

⁷² Muhammad Zaheer Abbas, *Pros and Cons of Compulsory Licensing: An Analysis of Arguments*, 3(3) International Journal of Social Science and Humanity 254, 257 (2013).

⁷³ S. Gruskin, Z. Raad, *Are Drug Companies Living Up to Their Human Rights Responsibilities? Moving Toward Assessment*, 7(9) PLoS Med 310, 322 (2010).

⁷⁴ K.D. Raju, *Compulsory v. Voluntary Licensing: A Legitimate way to Enhance Access to Essential Medicines in Developing Countries*, 22 Journal of Intellectual Property Rights 23, 26 (2017).