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A Study on Incorporation of Right to Health into the Resolution of Patent Law Disputes: A Human Rights Critique

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ABSTRACT

In India, the huge amount of the population is living below the poverty line, and the costs towards health protection are excessive which simply shows that there is a serious wellbeing emergency with inadequacy as for human services and the convenience, sensibleness, and availability of the medicines in India. Section 3(d) is an exclusive provision under the Indian Patent Law. It attains unbelievable stability between The Agreement on Trade Related Aspects of Intellectual Rights (TRIPS) command and obtains access to medicine for poor people. This has made India a leader in the pharmaceutical industry. The condition has without a doubt encountered a change after the TRIPS. The pharmaceutical patenting in India is of exclusive importance to the present issues of public wellbeing since the Indian market and the pharmaceutical firms are significant providers of the low-priced pharmaceutical items as conventional medicines. The issue of access to drugs has acknowledged worldwide measurements for a thousand years on account of India being a part of the Doha Declaration on the TRIPS Agreement and Public Health, 2001. With it's established and increasingly export arranged pharmaceutical industry being acclaimed by common society awareness. India has been at the focal point of the worldwide access to medications campaign. The Indian business gave the campaign a financial spine by demonstrating that an elective pharmaceutical industry was attainable. The ongoing patent law decisions including that of the Supreme Court in the Novartis case, demonstrates that India keeps on placing a quality on public wellbeing in connection to pharmaceutical patent law judgments. Therefore we see that the pharmaceutical patents curb the conventional challenges and therefore increment costs, and are believed to be a noteworthy obstacle to access to medications in evolving nations.

I. INTRODUCTION

India has for since a long time ago been a developer in the evolving world in attempting to

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change pharmaceutical patent law to evaluate the local wellbeing needs, continuing more on the need of the normal man, in this manner to be in accordance with its development.

The right to health is a significant, basic human right. This right is enshrined widely, both at the international level, in the form of different treaties, that were extensively adopted by different states, and at the national level, as part of the Constitution and the laws of different states. The right to access medicines is an essential part of the right to health and aims to allow all human beings to obtain medical care when they need it, irrespective of their economic resources.

Notwithstanding the extensive recognition of the existence of the right to health, the question of protecting and executing this right is under a continuous controversy. One of the main problems that arise in this context deals with the unavoidable conflict between the right to health and intellectual property rights.

The foundation behind intellectual property rights is fairly clear. These rights, which provide exclusive rights to their holder (at least when it comes to patents holders), are designed to assist as an incentive for researchers to discover and develop science. When we are dealing with pharmaceuticals, the patent was usually perceived as a vital incentive, since it gives the inventor exclusive rights, designed to protect his huge financial investment involved in the development, production and, marketing of pharmaceuticals.

The Patent is one of the important kinds of Intellectual Property Rights (IPRs) used in the pharmaceutical industry. Trademark, Industrial Design, Geographical Indication and Copyright are different kinds of IPRs accessible in India. Grant of the patent in India is governed under The Patents Act, 1970. Noteworthy changes like provision of product patents and increase in the term of the patent to 20 years were introduced in the Indian Patent Law after India signed TRIPS (Trade Related Aspects of Intellectual Property Rights) agreement in 1995. This paper gives a brief outline of the development of patent law in India as a consequence of the TRIPS agreement. Conditions of patentability and numerous types of pharmaceutical patents as of now are being granted in India are illustrated to give vital information on pharmaceutical patenting to the researchers. Other important provisions related to patenting of pharmaceuticals like section 3(d), compulsory licensing and so on are explained.

II. EFFECT OF TRIPS ON PHARMACEUTICAL PATENT AND HEALTHCARE PROTECTION

a. Effect of TRIPS on Pharmaceutical Creations

The TRIPS appears to give member states expresses some room regarding assuring that the safety of intellectual property rights (IPRs) doesn't block general wellbeing interests.³ Patent protection is the basis of a compact and vibrant research condition of any nation; product patents safeguard the recently created items from abuse without consent of the patent holder, though process patents ensure the strategy for generation of a product.⁴ India's extension to the World Trade Organization (WTO) and its commitment to implement the TRIPS Agreement has brought about the drastic change in the Indian pharmaceutical industry.⁵

b. Trips Initiatives, Threat and Burden of the Evolving Nations

The objective of the TRIPS Agreement is to execute the worldwide least models for the protection of the intellectual property, the agreement does not set down a solitary and widespread Intellectual Property Right framework that the individuals need to follow, they are permitted to adopt a system that is stringent than the one required by TRIPS Agreement (Article 1).⁶ The World Trade Organization identifies the necessity for the individuals to meet the goals in regards to development and general wellbeing, however, the individuals can direct in regard of standards, for example, the development of general wellbeing and public interest in sectors of indispensable significance to their financial and mechanical development.⁷ TRIPS Agreement means to execute enough insurance of IPR that fits with the general wellbeing needs of developing nations and spreading of development in the world.

It is seen that the developing nations can't use these flexibilities, even when they have included them in their national enactments because of the pressure from the industrialized nations. Consequently the current worldwide patent law system does not support the developing nations in achieving the opportunity to wellbeing to their residents as a rule and poor precisely.

The TRIPS Agreement has left some space for nations to take public interest measure including

³ Emmanuel KolawoleOke, "Incorporating a Right to Health Perspective into the Resolution of Patent Law Disputes" Health and Human Rights Journal <http://www.hhrjournal.org/2013/12/06/incorporating-a-right-to-health-perspective-into-the-resolution-of-patent-law-disputes/html>.

⁴ National working group on patent laws and public interest legal support and research centre, Report of the Fourth Peoples' Commission on Review of Legislations Amending Patents Act 1970, <http://www.who.int/intellectualproperty/documents/Report4thCommission.pdf>.

⁵ *Ibid.*

⁶ Samira Guennif and N Lalitha, "TRIPS Plus Agreements and issues in Access to medicines in Developing Countries" 12 Journal of Intellectual Property Rights 471 (Sep. 2007).

⁷ *Ibid.*

measures to protect the general wellbeing, the adaptability provides the government with chances to tune the protection approved to meet social goals, the concerns of the developing world as to pharmaceutical patent has been explained and amended by the 2001 DOHA declaration on the TRIPS and general wellbeing and the 2003 structure authorizing nations who cannot assemble medications themselves to import pharmaceutical made under the compulsory license.⁸ The essential DOHA ministerial declaration, WTO member governments concentrated on that it is crucial to actualize and interpret the TRIPS Agreement in a way that it supports the general wellbeing by uplifting both access to existing medications as well as the creation of new drugs. Thus adopted a separate declaration on TRIPS and general wellbeing. They concurred that the TRIPS agreement doesn't and ought not to keep individuals from taking measures to ensure public health.⁹

Apart from compulsory licenses, the TRIPS Agreement similarly offers certain flexibilities that nations can use to address public wellbeing challenges in their nations. Such flexibilities include the chance to evade new kinds of known medications from patent protection, opportunity to receive the guideline of global exhaustion of patent rights to inspire the parallel importation of medications (Article 6), administrative survey exclusion for makers of generic drugs, research exclusion, and delinking the allocation of promoting endorsement for generic drugs from the patent status of branded drugs.¹⁰ The use of flexibilities was moreover strengthened and reaffirmed by the Doha Declaration on the TRIPS Agreement and Public Health of 2001.

III. RIGHT TO HEALTH AND PHARMACEUTICAL PATENTS

a. The Contrast between Human Right to Health and Patent Right

Henry Sigerist¹¹ has rightly observed that wellbeing is one of the products of life to which man has a right; wherever this idea wins the logical consequence is to make every one of the measures for the protection and rebuilding of wellbeing to all, for nothing out of pocket; medication, similar to education is then no longer exchange it turns into a public function of the state.

According to the Black's Law Dictionary, health means, "freedom from pain and sickness, the most perfect state of animal life and the natural agreement and concordant disposition of the

⁸ Elizabeth Verkey, Law of patents 565 (Eastern Book Company, Lucknow, 2nd edn., 2012).

⁹ *Ibid.*

¹⁰ "India's Pharmaceutical Industry on Course of Globalisation", https://www.dbresearch.com/PROD/CIB_INTERNET_EN-PROD/PROD000000000224095.pdf.

¹¹ Ravi Duggal, "Operationalising Right to Health care in India" available at: who.int/intellectualproperty/documents/Report4thCommission.pdf.

parts of the living body”.¹² Wellbeing is characterized as a perfect condition and a significant social and political good and is the condition of complete physical, mental and social prosperity and not simply the absence of disease or infirmity.¹³ According to World Health Organization Report (2000) Health Care is characterized as the aversion, treatment and the administrators of disease and the safeguarding of wellbeing through the services provided by the therapeutic, nursing and associated healthcare professions, so medicinal services hold every one of the products and ventures planned to improve wellbeing, including precautionary, corrective and palliative interventions, irrespective of whether synchronized to people or populations.

Human rights are claims held by the people against the state in the goodness of their mankind. At root on the off chance that we see that human rights are those rights that people deserve to have realized independent of the legal system, they reside under.

Access to medicinal services focuses mainly around the accessibility of medical care as a chief aspect of an individual right, the different international conventions like Universal Declaration Of Human Rights, 1948,¹⁴ International Covenant on Civil and Political Rights, 1966,¹⁵ International Covenant¹⁶ on Economic, Social and Cultural Rights, 1966,¹⁷ Convention on the Elimination of all types of Discrimination Against Women, 1979,¹⁸ and Convention on the Right of the Child, 1989,¹⁹ perceive access to health care at the global level. Article 27(2)²⁰ of the Universal Declaration of Human Rights (UDHR) and Article 15(1) (c)²¹ of the International Covenant on Economic Social Cultural Rights (ICESCR) attempt to relate IPRs with various kinds of human rights, this has driven few authors to conclude that they give a human rights

¹² Mallika Ramachandran, “The Right to Health and the Indian Constitution” 1 Delhi Law Review 1 (2004).

¹³ G.R.Lekshmi, “Access to Health Care: Problems and Prospects”, Cochin University Law Review 271 (2007).

¹⁴ Article 25 - Everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing and medical care 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, United Declaration of Human Rights, 1948.

¹⁵ International Covenant on Civil Political Rights, 1966.

¹⁶ 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. The steps to be taken by the States parties ... to achieve the full realization of this right shall include those necessary for: (a) The provision for the reduction of the still birth rate and of infant mortality and for the healthy development of the child; (b) The improvement of all aspects of environmental and industrial hygiene; (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases; (d) The creation of conditions which would assure to all medical services and medical attention in the event of sickness.

¹⁷ Art. 7, 11 and 12, International Covenant on Economic Social and Cultural Rights, 1966.

¹⁸ Art. 10, 12 and 14, Convention on elimination of discrimination Against Women.

¹⁹ Art. 24, Convention on the Right of the Child.

²⁰ 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.

²¹ Right of everyone to “benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author”.

premise to patent rights and different types of IPRs.²²

The right to wellbeing is a human right inherent for the complete improvement of human character. Wellbeing is essential to improvement, the part of wellbeing in the post-2015 has taken up a lot of discussion regarding how the medical problems can be addressed more effectively. The new agenda as taken up by the UN System Task Team on the Post-2015 UN development agenda²³ is to aggravate how to make wellbeing as a comprehensive right all-inclusive hence surrounding a complete wellbeing objective that interests people in general and is quantifiable.

Earlier mentioned covenants impose obligations on the state/nations to respect, protect and satisfy the privilege just as the approach to wellbeing consequently making it necessary concerning the state along with the state on-screen characters to refrain from direct infringement of the right to wellbeing in this manner protecting this human rights.²⁴ The expense brought about towards development in medicinal services is a genuine test because of the limited stock of assets and the huge demand for health care.

In this way, it isn't just about advancement in average healthcare yet moreover about the wellbeing and financial wellbeing of the socially and economically marginal groups in the society and an attempt must be made to achieve an unbiased flow of the monetary burden of ill health and disease. The acknowledgment of the right to health perceives that "health is the most significant overall social objective the acknowledgment of which requires the activity of numerous other social and financial areas notwithstanding the healthcare segment". Thus, the states should give both material assets and the cultural and financial conditions crucial to assure that the right to health is affective as a lawful right.²⁵

The right to health includes a variety of rights. The continuous development of present-day science and invention encourages in taking into account the health needs of people, in this manner, we can say that the development of new technology is an essential part of the right to health both at the national and worldwide level.²⁶

The right to health is perceived as a fundamental right in India as well as in numerous other underdeveloped nations. Certainly, even the TRIPS Agreement observes that the member

²² Joseph Millum, "Are Pharmaceutical Patents Protected By Human Rights?" 25 Journal of Medical Ethics 34 (2008).

²³ Health in the post-2015 UN development agenda, http://www.un.org/millenniumgoals/pdf/Think%20Pieces/8_health.pdf.

²⁴ G.R.Lekshmi, "Access to Health Care: Problems and Prospects", Cochin University Law Review 271 (2007).

²⁵ *Ibid.*

²⁶ G.B. Reddy, "Impact of TRIPS Agreement on Patent Regime in India with Special Reference to Health Carestrategies for the New Millennium 5 Apex code expressions Journal 11 (2003).

countries may eradicate from patentability certain inventions, exploitation of which is vital to guarantee order and morality including human, animal or vegetation or health and to maintain a strategic distance from genuine preference to the condition²⁷ accordingly the right to health care and also access to health care at reasonable costs have become generally known human rights. In a nation like India which has a variety of socio-economic sceneries, national health programs must be organized with sufficient flexibility to permit the state public health organization to create their programs as indicated by their needs.

b. Right to Health According to the Indian Constitution

The right to health is a fundamental part of the right to life provided under the Indian Constitution.²⁸ The Constitution of India under Article 14 and 21 have an indirect bearing on health care, therefore, directing the state to take steps to improve the conditions of health care services of the individuals of India. Apart from the fundamental rights, the Constitution accommodates certain Directive Principles or be followed by the state which has an indirect bearing on the approach to healthcare services that includes Articles 39, 41, 42, 43 and 51A. Also, Article 51 of the Constitution of India provides India's commitment to submit to execute the treaty obligations that directly affect the health condition.

To understand the above objectives the Government of India has introduced various policies for poor in the urban just as the rustic areas, for example, National Rural Health Mission,²⁹ National Urban Health Mission³⁰ which is a reproductive and child health care program to implement institutional deliveries with the aim that skilled deliveries are available so ladies and new conceived can be saved from pregnancy-related deaths, and the most important activity taken by the Government under this plan is free medications to the pregnant mothers and newborn children, Universal health coverage model,³¹ Polio Drop Scheme, Mission Indradhanush is focused on the vaccination drive through the 'catch-up' campaign where the goal will be to cover each of the kids who have been forgotten about or passed up a great chance for immunization.³²

The developed nations just as the progressing nations have their issues for healthcare services. The awareness recognizing with health is high among the individuals and the interest like

²⁷ Art. 27(2) TRIPS Agreement, 1995.

²⁸ State of Punjab v. Mohinder Singh Chawla, (1997), 2 SCC 83.

²⁹ <https://nhm.gov.in/>.

³⁰ http://www.health.mp.gov.in/nuhm/Implementation_Framework_NUHM.pdf.

³¹ Rakesh Sarwal, "Reforming Central Government Health Scheme into a 'Universal Health Coverage' model", 28 (1) National Medical Journal of India, (2015).

³² <http://indiatoday.intoday.in/education/story/union-government-launched-health-mission--mission-indradhanush/1/408944.html>.

healthcare along these lines in a manner the consumption of the medicinal services is additionally high. So the Government has not been productive in giving universal access. Despite what might be anticipated the developing nations have less approach to wellbeing both regarding health determinants and variables giving access to healthcare services. Most of the population in these nations are below the poverty line or is uneducated or not alert of the advantages and disadvantages of sanitation and neatness.

In India, the approach to healthcare faces various difficulties and hence there are constitutional provisions and abundant judicial decisions assisting access to healthcare services. Although the judiciary has pronounced various judgments of various aspects of access, legislative executions are what is missing. A lot should be done in the administrative field and the constitutional framework alongside the statutory, administrative and judicial role in such manner should be analyzed.³³

c. Scope for Enforcing Right to Health under the Patents Act, 1970

The most important influence of the TRIPS Agreement on Indian patent law was the re-initiation of the product patent regime.³⁴ Article 7 of the TRIPs Agreement sets out the "objectives" that is: "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to the balance of the rights and obligations."

Therefore this article in simple words gives two expressions "to the mutual advantage" and "the balance of rights and commitments" which portrays the way wherein the objectives would be figured out. The substantive objectives of encouraging inventions; move and dissemination of innovation, and encouraging the social and financial welfare have been exceptionally recognized.³⁵ Article 8 expresses the "principles" "Members may in formulating or amending their national laws and regulations adopt measures necessary to protect public health and nutrition and to promote the public interest (health) in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this agreement".³⁶

³³ *Ibid.*

³⁴ Gopakumar G. Nair, "Impact of TRIPS on Indian Pharmaceutical Industry" 13 *Journal of Intellectual Property Rights* 432 (2008).

³⁵ "Report of the Fourth Peoples' Commission on Review of Legislations Amending Patents Act 1970", <http://www.who.int/intellectualproperty/documents/Report4thCommission.pdf>.

³⁶ *Ibid.*

The suitable measure might be expected to avoid the abuse of intellectual rights by the right holders or resort to rehearses which unreasonably control or unfavorably influence the worldwide exchange of technology.³⁷ Article 30 of the TRIPS Agreement allows the member nations to "provide limited exceptions to the exclusive rights that have been conferred by patents " subject to the condition that it doesn't "unreasonable clash with the typical abuse of the patent and do not unreasonably combat the rights of the patent holder (proprietor), remembering the authentic interests of the third parties. But the TRIPS in no way defines these terms of 'genuine interests', unreasonable conflict, and 'limited exceptions'.³⁸ Article 31 of the TRIPS Agreement dealing with compulsory license, this article does not put any limitation on the grounds for allowing compulsory license.³⁹

IV. COMPULSORY LICENSING UNDER TRIPS

The WTO nations can give several types of compulsory licenses as in respect of patents which are specifically accepted by the TRIPS Agreement.⁴⁰ Compulsory licenses as traditional out in the TRIPS Agreement are proposed to find some kind of harmony between public interests and the authentic interests of the owners of the patents. The TRIPS Agreement also gives a few restrictions to the utilization of the compulsory licenses and can be permitted on a case-by-case basis, the different justification for compulsory licenses: crisis and outrageous urgency; anti-competitive practices; public non-business use and ward patients.

Compulsory licensing will upgrade people in the public interest while keeping up the incentive to grow innovations, it is important to remember that compulsory licensing be permitted just where it is important to promote open interest, not essentially diminishing the incentive to build up another drug.⁴¹

One should not forget that patents serve as an interventionist instrument, at last for community welfare. Accordingly, intervention to confine a portion of the impacts of the patent might be required, when the community welfare is never again served. Compulsory licensing implies that the government permits another person to deliver the patented item or procedure without the assent of the patent owner. This is one of the basic pillars of the patent system. A compulsory license for the patented invention is a part of the Paris Convention and the TRIPS Agreement.

³⁷ *Ibid.*

³⁸ Sudip Chaudhary, "TRIPS Agreement and Amendment of the Patents Act in India" 10 *Economic and Political Weekly* 3356 (2002).

³⁹ *Ibid.*

⁴⁰ Art. 31 TRIPS Agreement.

⁴¹ Surabhi Shekhawat, "Compulsory Licensing of Pharmaceutical Patents, 5 *Madras Law Journal* 36 (2014).

a. Compulsory Licensing in India

The Indian patent Act does provide that a solicitation to the document of the compulsory license may be made essentially subsequent three years after the date of the funding of patent excluding if an outstanding condition like that of the national crisis or unusual crisis may be recycled to legitimize the allowance of a license on a previous date. Three wide explanation for the endowment of compulsory licenses have been spelled out -

- i) evenhanded necessities of the overall population regarding the untested development have not been rewarded
- ii) the patented invention isn't available to people in common at a judiciously affordable rate;
- iii) The patented development isn't operated inside the territory of India. The Patent Act circles out the situations underneath which "reasonable requirement of the public" will not have been met.⁴² Such circumstances will develop if the patent holder trash to a document on serviceable standings, and which, thusly, affect:⁴³
 - i. Expansion of new business or industry in the nation;
 - ii. Formation or the development of profitable movement privileged India; and (to start from here)
 - iii. The substantial consequence of this particular provision may be felt in the pharmaceutical division where India can well progress by way of a significant bill payer of the generic pharmaceutical to those developing nations that don't have satisfactory domestic industrialized offices (development of the practiced market for the patented article) one of the reasons for permitting compulsory licenses in India is to see that the patented innovations have been taken a shot at a business balance inside the territory of India and that the curiosity of any of the individual occupied or building up a conception isn't partial.

The attendance of a solid and controlling patent agenda can bring several recompenses, for example, distribution of data and open-handed an ingenious to advance into the development

⁴² Ricardo Melendez-ortiz and Pedro Roffe (eds.) Intellectual Property and Sustainable Development Agendas in A Changing World 106 Edward Elgar Publishing Ltd., Massachusetts, (2009).

⁴³ Indian Patents Act 1970, s. 89 reads: The powers of the controller upon an application made under s. 84 shall be exercised with a view to securing the following general purpose, that is to say:
a. That patented inventions are worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable;
b. That the interest of any person for the time being working or developing an invention in the territory of in India under the protection of a patent is not unfairly prejudiced.

of new kinds of stuff and procedure that will in the long run fall in the public domain.⁴⁴

b. Judicial Pronouncements on Compulsory Licensing in India

In the current judgment of *Novartis v. Association of India*⁴⁵ the Supreme Court of India concluded its judgment has had a noteworthy insinuation on the pharmaceutical patents. In this particular case, the Novartis, a Switzerland grounded pharmaceutical organization affianced in developed anti-cancer drug baptized 'Glove' and became it untested in frequent nations from 1994. Resultant to this, the medication Glivec was hawked in India in the year 2002 after getting the market endorsement notwithstanding the circumstance that the patent request was marched in the year 1998. In the year 2006, countless, domestic pharmaceutical businesses like Ranbaxy, Cipla, etc., challenged this patent submission and henceforth the patent was rebuffed. Distraught by this order, the Novartis challenges Section 3(d) in light of the fact which this section was not likeminded to TRIPS and is optional, illogical, and ambiguous and offense Article 14 of the constitution of India. This order has sanctioned the Indian organizations to production less exclusive generic medications which would be rational to the third world countries for the handling of blood cancer. On support, the appellate board was of the sensitivity that under the TRIPS India can shield public health and to upraise admittance to medicines for all. The Novartis charged Rs1, 20,000 every month for the dosage; notwithstanding what might be predictable, the generic description of this specific medication was available in India at an evenhanded cost at Rs.10, 000 in precise. Article 27(2) that authorization personalities to discard convinced inventions that are significant to shelter public interest or ethical quality and too sheltered human life. Many emphasized factors were measured by the judges in the Novartis decision. The main influence was to preserve the anticipation of the lawmaking body in introducing section 3(d) to dodge frequently greening of patents that is a patenting system including of getting patents on minor, frequently trifling, changes of existing pharmaceutical items or actions to through inference increase the time of patent protection over the beforehand patented compounds.⁴⁶ Novartis was endeavoring to evergreen the patent by filing a patent application for the PETA crystalline type of Imatinib Mesylate. Henceforth implying that the new form of the medication will have a later patent expiration date and Novartis can keep on selling the medication knowingly after the first form was never again endangered. The Madras High Court⁴⁷ in its understanding mentioned that sec

⁴⁴ P. Narayanan, *Intellectual Property Law*, 21 (Eastern Book Agency, Kolkata 3rd edn., 2001).

⁴⁵ (2013) 6 SCC 1.

⁴⁶ Priyamvada Gupta, "Pharmaceutical Innovations in India: Balancing the Value of Incremental Innovations" 5 *Supreme Court Cases Journal* 23 (2014).

⁴⁷ *Novartis AG v. Union of India* (2007) 4 MLJ 1153.

3(d) was familiarized to avert consistently greening to give modest admittance to the residents of this nation for the life-saving drug and to issue the constitutional obligation of philanthropic great human amenities to its residents. Section 3(d) was openly presented to grant rights for the genuinely creditable developments and not for those which are minor developments of the existing medications.

The judges throughout the records of this case felt that Novartis had just recovered its groundbreaking work cost for the Glivec drug inside an extremely short period. Consequently, the judges were of the interpretation that since Novartis had very much received the cost for its research in the exact medication, an added steady progression would seriously move the Indian culture. Consequently the judges of the Supreme Court memorizing the understanding of section 3(d) additionally predictable to diminution the medication costs and make health care services more affordable for the Indian patients. Consequently, we can see over this judgment that the Madras High Court was directly in protecting the constitutionality of section 3(d) which were steady with the previous Supreme Court precedents.

In *Bayer Corporation v. Cipla Union of India*⁴⁸ this given case being a significant reported case which tried to patent linkage practice of involving drug marketing approval to the patent status of the originator's item and not allowing the funding of marketing sanction to any third party previous the conclusion of the patent term excluding if settled by the patent owner. In this case, the petitioner Bayer was a corporations that got patent on its renal cancer drug 'SorefenibTosylate which was being sold for Rs.2, 85,000 for one-month dosage and file a petition to limit the grant of license to Cipla to make, sell and distribute its drug "Soranib" the Delhi High Court for this case held that the arrangement of patent linkage couldn't be read into the provisions of the Drugs Act and Patents Act system.

V. JUDICIAL APPROACH TO RIGHT TO HEALTH: INDIA

In the case of *Peoples Union for Democratic Rights v. Association of India*⁴⁹ it was held that the state is under a constitutional obligation to see that there is no infringement of the fundamental right of any individual. The government is, bound to guarantee acknowledgment of various social welfare measured in consistency with the Directive Principles of State Policy.

In *Consumer Education and Research Center v. Association of India*⁵⁰ the Supreme Court ruled that the right to wellbeing and medical care to protect health and strength while in

⁴⁸ 2009 (41) PTC 642 (Del); 2010 SCC Del 541.

⁴⁹ AIR 1982 SC 1473.

⁵⁰ AIR 1995 SC 922.

administration or post-retirement is a basic right of the worker under Article 21 of The Constitution of India. In this case the Court, additionally held that the medical coverage while in service or after retirement, is a fundamental right and even private industries are advised to give health care coverage to the workman.⁵¹

In *Bandua Mukti Morcha v. Union of India*⁵² Bhagwati J in this case, held that:

It may not be possible to compel the state through the judicial process to make a provision by statutory enactment or executive fiat for ensuring these essentials which go to make up a life of human dignity but where legislation is enacted by the state providing these basic requirements to the workmen and thus investing their right to live with basic human dignity, the state can certainly be obligated to ensure observance of such legislation; for inaction on the part of the state would amount to denial to the amount to live with human dignity enshrined in Article 21, more so in the context of article 256⁵³ - which provides that the executive cannot remain inert when the administration does not provide an suitable measure to provide access to health

VI. CONCLUSION

The TRIPS Agreement by its adjustable constituents, for example, compulsory licensing, parallel importation, and opposition of patent have tried to adjust the access to medicines or treatment along with safeguarding the intellectual protection rights. These instruments have inspired and further gone about as an interruption to postpone and deny access to affordable drugs. Further, we see that the pharmaceutical organizations can increase their research in creating drugs for such infections if they realize that the incentive for this research they will get patent protection and can demand high monopoly prices from the well-to-do patients, government offices and NGOS's at first and after the term of patent protection is over the long haul huge number of individuals will have the option to profit so considering the two sides. The extension of strong intellectual property rights through TRIPS into less-developed nations loads the poor disproportionately as they lose access to generic duplicates of medications that are still under patent protection.

Then again, this extension of intellectual property rights may profit the poor in the future, given

⁵¹ Art. 21, read with art. 39(e), 41, 43, 48-A.

⁵² (1984) 3 SCC 161; AIR 1984 SC 802. Decided on Dec. 16, 1983 by three judge bench P.N. Bhagwati, R.S.Pathak and Amarendra Nath Sen JJ.

⁵³ Constitution of India art. 256 reads: obligation of states and the Union- the executive power of every state shall be so exercised as to ensure compliance with the laws made by the parliament and any existing laws which apply in that state, and the executive power of the Union shall extend to the giving of such directions to a state as may appear to the government of India to be necessary for that purpose.

that extra additional incentives are being given to address wellbeing needs in developing nations. From a utilitarian point of view, one may in this way contend the general advantages exceeded the general misfortunes. Above all, however, the three situations we have talked about up until now (no IPRs, pre-TRIPS, TRIPS) are not the only other options. Pharmaceutical industry and trade negotiators the same ought not to overlook the genuine objective of medication development: saving lives. Profit should always be a way to this end, not the other way around. Just by remembering this rule and accomplishing a superior comprehension of the advanced world health situation would we be able to plan to adequately guarantee the safety and well-being of the total population in the twenty-first century and beyond.

Thus, it can be said that in a period where the health is accepting a transnational character, the significance of worldwide human rights can't be understated. And every one of the nations should guarantee a powerful commitment at the universal level. It should be comprehended that the right to health cannot by itself be comprehended as a conventional right which is enforceable against the state however a conscious effort ought to be made to formulate and recognize the right to health as a positive right at the global level.

VII. SUGGESTIONS

After evaluating the status of India's pharmaceutical industry and the extent of the generic drugs in India just as outside India and the different legitimate instruments and enactments concerning health, compulsory licensing has a significant place in the patent system as the compulsory license acts as a significant device to adjust the enthusiasm of different IP and public health stakeholders. The government should step in to take genius dynamic measures to guarantee accessible human services for all, protection plans where health coverage stretches out to the poorest of poor people, it's at exactly that point would we be able to interpret negligible good health on papers to rehearse. Further, the government should invest in the type of innovative work at the college level and think of all the more economically priced medications and that the government ought to support the public sector undertakings (PSU's) to undertake the essential research. Open-source drug discovery (OSDD) network is a rising stage to have the option to accumulate assets for developing drugs that pharmaceutical organizations would not discover attractive to invest in. Whatever medications OSDD comes up with wouldn't be patented because it is the government cash that has been put into the research.

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