



Interface Between Human Rights and Intellectual Property Rights with Special Reference to Patent Regime and Right to Health in India

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Received: 31st January 2020; accepted: 15th November 2020

Human Rights are the pioneer of all rights and it has been neglected until the establishment of the United Nations (UN) in 1945. The United Nations have recognized the Right to Health in various international conventions, including the right to access essential medicines as a human right, but still many people living in developing countries are denied access to essential medicines due to the heavy cost of patented medicines. In the year 2000, the UN Committee on Economic, Social and Cultural Rights (CESCR) adopted General Comment No.14 to define Article 12 of the International Convention on Economic Social and Cultural Rights (ICESCR), it provides that four essential components are very important for access to medicine i.e. availability, accessibility, acceptability, and quality. On the other hand, the developed nations are using the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provisions as per their advantage which in turn affects human rights in developing countries like, India. There is a debate between the Right to Health and the patent regime in India. In the light of the above statements, the author tries to examine the existing issues and challenges with respect to the interface between human rights and intellectual property rights with special reference to protections of Right to Health and pharmaceutical patents.

Keywords: Human Rights, Right to Health, Intellectual Property Rights, Patents, Compulsory Licenses, Doha Declaration, WTO, Priority Watch List, Developing Countries, Pharmaceutical Patents

The Patents Act, 1970 begins with the object to consolidate the laws relating to patents in India. It is to protect the interest of inventors. The rights of patent holders are protected through the registration of a patent in the patent office. Presently, the Indian Patents Act, 1970 is known for both process and product patents. In India, pharmaceutical companies and individuals do their registration under the Patents Act to protect their pharmaceutical products. The Patents Act, 1970 has been amended many times, and the Patents (Amendment) Act, 2005 is considered a landmark amendment because it allows product patents in India. This amendment has started a debate in the field of the right to health and the patent regime in India.¹ India was the top exporters of generic medicine before 2005, also it has almost 60,000 generic brands and 60 therapeutic categories in the market but which has declined after 2005.² Mostly, the success of generic manufactures was possible due to the non-availability of the product patent in India. However, after the amendment of 2005, India has granted product patents in pharmaceutical products and which has reduced the production of generic

medicines due to lack of technology transfer and fear of trade sanctions on the generic manufacturer.³ It is one of the reasons for the decline in generic medicine in India. The new process of manufacturing drugs without an altruistic approach is creating a hurdle in productions of generic medicines. The generic products industry is having certain restrictions of non-infringing patents because the patent holder holds patents even after the product patent expires. Whereas, the interface between human rights and intellectual property rights is a peculiar area which has emerged for the protection of right to health of an individual. Therefore, there is a conflict of interest between human rights and intellectual property rights. The reason is that of the individual-oriented rights of IPR whereas human rights are known for collective rights and individual rights. Hence, it is required to study the relationship between these two rights. Although, the right to health has found a place in the United Nations Declaration of Human Rights 1948, it has not been the subject of academic debate concerning intellectual property rights a long time. In India, there are problems for primary necessities as most of the population is below the poverty line. Access to basic necessary medicines related to cancer,

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tuberculosis, HIV/AIDS, etc are not also affordable.⁴ According to Indian Medical Association Report 2016, 14 lakh people are suffering from cancer and it is increasing every year in numbers hence there is a need to look into with a sequitur.⁵

There is a struggle for basic medicines with mostly proliferating diseases year by year due to which their right to health is violated. The rights to health, the right to access basic medicine, etc., are considered as human rights involved in Intellectual Property Rights. The right to health is also considered as a fundamental right under the right to life in the Constitution of India.⁶ Because of this, human rights and patent laws concerning compulsory licenses (CL) are required to be studied for a better understanding of the concept of human rights in Intellectual Property Rights and also the issues and challenges involved in it. The development of the concept of human rights in IPR is linked with international conventions. For this purpose, it is necessary to understand the various legal frameworks available at the national and international levels for the right to health and intellectual property rights.

Intellectual Property Rights and Human Rights

Intellectual property rights came into existence to serve the basic goal to protect the interest of intellectuals. It simply envisages that the intellectuals who created the novelty should not only be recognized but also receives some monetary benefits out of their work. Sometimes, it is also labeled as a negative right that prevents others from stepping against the already created work. On the other hand, human rights are natural rights and to which every human being is entitled to enjoy right by birth. Human rights are also those fundamental rights which are inalienable and essential for every human being. In addition to this, Indian law defines human rights under Section 2(d) of the Protection of Human Rights Act, 1993, as right relating to life, liberty, equality, and dignity of an individual recognized by the constitution and international covenants and enforceable into the court of law.⁷ However, in the past several years the impacts of intellectual property rights on basic human rights have come under scrutiny. There are different kinds of links between human rights and intellectual property right like patent laws recognize the socio-economic dimensions to the patent rights and to that is the interest of patent holders and the interest of society.⁸ It has been discussed in the World Trade Organisation (WTO)

Ministerial Conference in 2001 that the link between the human right to health and pharmaceutical patents has wider importance at the international level.⁹ In India, the impact of pharmaceutical patents on the right to health can be understood from several examples. For instance, every year 69,000 people die due to HIV/AIDS and 2.1 Million people are suffering from HIV/AIDS until 2017.¹⁰ Although, the Government of India has released the 2013 drug price control order and it has worked through the National Pharmaceutical Pricing Authority (NPPA) to control the high prices of medicines in India.¹¹ In the last 20 years, prices of medicines have changed due to the want of patent holders to maximize profit in return for their investments.¹² Moreover, the cost of a patented drug for HIV is enormous. One month's dose of Atripla which is an anti-HIV drug costs US \$ 1,300 per month. Such a huge amount is not affordable to necessitous population living in developing countries claiming maximum lives.¹³ The lack of access to life-saving drugs takes away the lives of the poor people living in third world countries and they are the most affected ones.¹⁴ In 2018, the Indian economy was considered as the seventh-largest economy in the world by nominal Gross Domestic Product (GDP) with the third-largest in purchasing power parity (PPP) terms.¹⁵ According to the 2017 Report of the WHO and World Bank, it was noticed that more than half of the world's population and more than 7.3 billion people do not have access to essential medicines and health services.¹⁶ In India, most of the population is not able to spend money on health care including women, and other vulnerable groups are mostly affected due to poverty and social hierarchy.¹⁷ Interestingly, India has never spent more than 2 percent of its GDP on healthcare and healthcare facilities.¹⁸ Therefore, there is a need for a detailed discussion of these particular aspects of the right to health and intellectual property rights.

Evolution of Intellectual Property Rights and Right to Health: International Scenario

Although, the international right to health has been introduced in the United Nations in 1945, it was not noticed by the international community until 1978 and therefore not come up for academic discussions. It was the first Director-General of the World Health Organization who was a strong supporter of the right to health and due to his leadership, the right to health was firmly established in the International Bill of rights.¹⁹ Further, WHO started the programme 'Health

for All' in the 1970s according to the right to health standards (World Health Assembly 1977). Therefore, this perspective is reflected in the Alma-Ata Declaration of 1978 underlying the importance of primary healthcare.²⁰ In 1985, the University of Sherbrooke, Quebec hosted an event on right to health. Thereafter, American Health Organization published a voluminous study on the Right to Health in America.²¹ It was mainly focused on comparative examinations of constitutions and international law to give a response to the Alma-Ata conference of 1978 which affirms health as "a fundamental human right." During 1992-1993, the American Association for the advancement of Science held a conference on 'the right to health care' which contributed to Audrey Chapman's work on exploring a Human Rights Approach to Health Care Reforms.²² In 1993, there were two significant meetings held on the right to health. The first was held in September 1993 at Harvard Law School and the second in December 1993 by the United Nations Committee on Economic, Social, and Cultural Rights for general discussion on right to health and attributed to the meaning of Article 12 of International Covenant on Economic Social and Cultural Rights.²³

The role of the World Health Organization in propounding the right to health is remarkable and therefore in 1978 World Health Organisation (WHO) called the Alma Ata Conference in Kazhakisthan for declaration of the right to health. Further, Article 12 of the International Covenant on Economic Social and Cultural Rights, (ICESCR) 1966, provides 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*".²⁴ In 2000, the UN Committee on Economic, Social and Cultural Rights (CESCR) adopted General Comment No.14 in an attempt to define Article 12 of the ICESCR, which provides that four essential components are very important for access to medicine i.e. availability, accessibility, acceptability, and quality.²⁵ The International Covenant on Economic, Social and Cultural Rights, 1966, (the ICESCR, 1966) under Article 15 (1)(c) provides that States Parties who have ratified and acceded to this instrument, "*recognize the right of everyone to enjoy the benefits of scientific progress and its applications*".²⁶ Apart from this Article 25 of the Universal Declaration of Human Rights, 1948 also provides for the right to health as one of the components of human rights.

Further that, Article 27 of the UDHR, 1948 is a key player in the relationship between human rights and IPR. It provides that "*everyone has the right to freely participated in the cultural right of the community and it gives the right to enjoy the share of scientific development*".²⁷ Further interprets that it is for the protection of moral and material interest coming from scientific, literary, and artistic work created by the author. Therefore, it indicates that the monopoly rights of the author in case of intellectual property rights are subject to the enjoyment of others. Thereafter, in 2005 the General Comment No. 17(2005), of the ICESCR, 1966, clearly mentioned that it is the right of everyone to enjoy and share the benefits of scientific developments. It also fixed the responsibility of participant countries to ensure that everyone should enjoy the benefit of scientific development and its applications. Because of this, all the benefits coming from Intellectual Property Rights must be available to all and everyone has an equal share in the scientific progress and its applications.

It is said that human rights and intellectual property rights being treated separately and isolated but today, they are becoming intimate bedfellows.²⁸ After World War II, Human Rights Communities were busy in codifying Human Rights laws and norms. Whereas, IPR organizations, since the incorporation of the Paris Convention, 1883, and Berne convention, 1886, and TRIPS, were busy in trade and commerce and has no direct connection with human rights. However, it was the human rights community that first took notice of the human rights approach in IPR. The First Event was related to the neglected rights of indigenous peoples because it has been found that multinational companies through patents, copyrights, and plant breeder's rights lead to exploit indigenous people's rights. The Second Event was related to the consequence of linking intellectual property and trade through the TRIPS Agreement. It was related to a conflicting interest of TRIPS and Human Rights because noncompliance of TRIPS for least developed and developing countries can be the WTO threat of trade sanctions. The UN Human Rights system turned its attention to TRIPS in 2000.²⁹ The United Nations took initiative by Special Rapporteur and Draft Declaration on the Rights of Indigenous Peoples in 1994 that started the protection of traditional knowledge and indigenous people. Another report of WIPO and High Commissioner for Human rights in 1998 has been one of the most important events which

discussed IPR and human rights in detail and it has provided a right to health, right to medicine as an integral part of human rights in IPR.³⁰ The United Nations Sub-commission on Protection and Promotion of Human Rights, 2000/7 has been set up to see all these issues and stated that human rights must be given primacy over economic policies and agreement and also discussed public health and TRIPS.³¹

The interface between intellectual property rights and human rights received the attention of the world due to criticism by several human rights groups. With the increasing demand for access to medicines, the right to health has emerged as the major ground for social interest instead of individual interest in the developing countries. The debate is on the conflict between intellectual property rights which empower the individual with the fruits of growth and development. On the other hand, human rights confer equal status and rights on the part of everyone without any discrimination. Although, the Doha Ministerial Conference Declaration on TRIPS Agreement and Public health, 2001, recognized the importance of public health and intellectual property rights protection but still there is scope for its implementation in various countries.³² Because of the individual greed for patents, it has given the scope for experimentation at various levels and created a fight between human rights and intellectual property laws. However, there are instances in which the Supreme Court of India in *Novartis v Union of India* AIR 2013 SC 1311 has given importance to the lifesaving drugs instead of Patent rights.³³ In this case, the Novartis Pharmaceutical Company challenged the constitutional validity of Section 3 (d) of the Patent Act, 1970 for a patent over a cancer drug. It was related to the substance *imatinibmesylate* used for a cancer drug. The Supreme Court of India held that *imatinibmesylate* is not patentable as it fails the test of Section 3(d) of the Patent Act, since it provides that mere discovery of a new form of a known substance does not result in innovation. Section 3(d) has been interpreted in detail and held that it was constitutionally valid. This interpretation has given a new approach to patent and lifesaving drugs. In this case, it was observed that it is no longer acceptable to the global public that hundreds of millions of people have been denied access to lifesaving medicines only because of the monopoly of pharmaceutical companies. In another case of *Roche v Cipla* MIPR 2008 (2) 35, the patent holder Roche was denied an injunction before the Kerala High Court because of public interest and

lifesaving drug in question.³⁴ The High Court held that access to lifesaving drugs is more important than granting an injunction to pharmaceutical companies. The present discourse of the right to health and patents shows that developing countries are facing problems in access to medicines and the judiciary has the least role to protect the interest of society. The giant pharmaceutical companies from the developed world are major stakeholders. Therefore, the social, economic, and political backwardness of developing and least developing countries are responsible for the conflict between intellectual property rights and human rights.

Right to Health and Patent Regime in India

In India, the right to health and the patent regime has developed drastically and both have significance under the constitution of India and other legislations. The constitution of India guarantees everyone's right to the highest attainable standard of physical and mental health. In the case of the *State of Punjab v Mohinder Singh Chawla* (1997) 2 SCC 83, it was held by the Supreme Court that the right to health is an integral part of the right to life, and the government should provide the basic healthcare facilities.³⁵ In *Hoffmann-La Roche Ltd. v Cipla Ltd.*, MIPR 2008 (2) 35, the Delhi High Court refused to grant an injunction to Roche against Cipla for the production of patented drugs.³⁶ In the present case, a right to health perspective can be seen by referring Article 21 of the Constitution of India where the court considering the balance of convenience in a case where a pharmaceutical company was trying to obtain an injunction to prohibit the production of cheaper generic drugs. Article 21 of the Indian Constitution, which provides for the right to life and which forms the bedrock of the right to health in India. The Supreme Court of India in the case of *C.E.S.C. Ltd. Etc v Subhash Chandra Bose and Ors* AIR 1992 SC 573, held that right to health is a fundamental right under Article 21 of the constitution of India.³⁷

Further, even if the right to health is considered as a fundamental right in every democratic country, it has not been implemented properly therefore there are various reports of WHO and WTO where it has shown that how developing and least developing countries are poor in the implementation of the right to health policies. According to the WHO estimates that one-third of the world's population including the poorest South African and Asian countries are not having access to essential medicines.³⁸ There are

many reasons for not having access to medicines like poverty, poor health infrastructure, high prices of medicines, etc. One of the reasons is that patent protection is given to the pharmaceutical company and therefore the generic medicines could be a solution through compulsory licenses and voluntary license provisions under the patent laws. Otherwise, pharmaceutical firms can only produce the patented drugs which lead to the renunciation of affording newly invented drugs due to high prices. The primary object of pharmaceutical companies is to gain profit and therefore they opposed the compulsory licenses. The important contention of the pharmaceutical companies is that compulsory licenses will kill innovation and discourage Research and Development (R&D). However, the fact remains that compulsory licensing is the remedy to curb the abuse of exclusive protection of patents.³⁹ The provision relating to the compulsory licenses is provided under Sections 84 to 92 of the Patents Act 1970. The object of the compulsory license is to give authority to a third party by the government to work on the already patented subject matter. Therefore, the compulsory license could be a tool to protect public health at large in case of certain conditions and it could be helpful to reduce the cost of patented medicines.⁴⁰ The TRIPS Agreement is under Article 31 provides compulsory licensing and certain flexibilities are given to grant a compulsory license in an emergency. The role of the Doha Declaration in 2001 is a turning point in public health and TRIPS. Paragraph 5(b) and 6 of the Doha Declaration also provides for compulsory lessening which was the basis for the protection of public health in case of emergency and against the monopoly of pharmaceutical companies in case of patented medicines. Therefore, the compulsory license has been considered as a tool of government to fight against the monopoly of pharmaceutical companies. However, the developing countries lacking in granting the compulsory license and using the TRIPS flexibilities due to the fear of trade sanctions imposed by developed nations.⁴¹ The Patents Act, 1970 grants patent for 20 years and it gives protection to pharmaceutical companies for their patented drugs. Whereas, the provision of compulsory license given under Section 84 grants compulsory license after three years of patent grant that the government can allow anyone to research a particular patent on certain grounds without the consent of patentee in an already patented subject matter. The three grounds must be

fulfilled to get compulsory license i.e. a) reasonable requirement of the public concerning the patented invention have not satisfied b) the patented invention is not available to the public at a reasonably affordable price c) the patented invention is not worked in the territory of India. In the history of the Indian Patent laws, only one compulsory license has been granted and two were rejected.⁴² The reason for granting the first compulsory license was very interesting and has legal standing in India. In the first case of *Bayer Corporation v Union of India and others*, AIR 2014 Bom 178 the compulsory license has been granted to NATCO Pharma Ltd., a generic drug manufacturer to produce and sell Nexavar. In the present case, the judiciary made it clear that the public interest is of prime importance and India will not tolerate the exploitation of its masses by drug giants.⁴³ The other two applications for a compulsory license were filed by the BDR pharmaceutical in March 2013 and LEE Pharmaceutical Ltd., 29 June 2015 to the controller of patents. However, both these applications were rejected on the ground that they do not fulfill the conditions given under Section 84 of the Patents Act, 1970.⁴⁴

The right to health is considered a fundamental right under Article 21 of the Constitution of India. Apart from this Directive Principles of State Policy under Article 39 of the Constitution of India provides that the state shall provide adequate means of livelihood and ownership and control of material resources for common good. Article 47 provides the responsibility of the State to raise the level of nutrition and standard of living and to improve public health. The State has to provide basic health facilities and medicines to poor people. Therefore, to fulfill the above obligation Government of India through the Ministry of Health and Family Welfare through its various schemes like National Health Mission (NHM), Mission Indradhanushya, Affordable Medicines, and Reliable Implant for Treatment, Pradhan Mantri Swasthya Suraksha Yojana (PMSSY), Ayushman Bharat, and Pradhan Mantri Jan Arogya Yojana (AB-PMJAY), etc., tries to provide medicines to people who are suffering from tuberculosis, HIV/AIDS, cancer, and various other diseases.⁴⁵ However, it can be possible only when medicines are available at low cost and grants of compulsory license by the government to patented medicines for producing more generic medicines in public health. In India the situation is different, only one compulsory license has

been granted and costly medicines relating to cancer, HIV/AIDS, and tuberculosis are beyond the reach of poor people. In addition to that, India is the signatory country to the Universal Declaration of Human Rights, 1948, and International Covenant on Economic Social and Cultural Rights, 1966, and other international instruments. The above international instruments have recognized the human rights approach in IPR for public health, right to life, right to access medicine, right to health, etc. Therefore, the Government of India must implement the agreements of these conventions with requisite seriousness and stringent actions.

From TRIPS, 1994 to Doha Declaration, 2001 and TRIPS-plus

The Agreement on the Trade-Related Aspects of the Intellectual Property rights 1994 has changed the world of intellectual property rights protection in India. It has come into force on 1 January 1995. The significance of this agreement is that it has given targets and transition periods to the member countries to implement its provisions as per their convenience. In the field of patents and human rights Articles 27 to 34 are directly related to its implementation.⁴⁶ Article 31 provides for the compulsory licensing in the patents and gives the flexibility to implement it. According to Article 31 of the TRIPS Agreement, a patent can be used by the government or third parties authorized by the government to use a patent without the authorization of the patentee. It is granted on certain grounds and the first effort to obtain a license from patentee and other conditions is like an extreme emergency. Article 8 of TRIPS provides for public health and it imposes an obligation on member states in formulating laws relating to patents they must give importance to public health.⁴⁷ Therefore, considering the need for the right to health the World Trade Organization in its Ministerial Conference held at Doha discussed the TRIPS and public health in 2001. The Doha Declaration, 2001 in Paragraph 4, 5(b) and 6 have great importance since it provides compulsory license provisions. Paragraph 5(b) of the Doha Declaration provides that the right to issue the compulsory license depends on the country that wants to grant it. Paragraph 6 of the Doha Declaration, 2001 was very much debatable in the field of right to health and patents.⁴⁸ The role of the United States and other developed countries opposed compulsory license and they argued that granting compulsory licensing should be limited to the most severe public health problems and the

needy nations.⁴⁹ However, the developing countries (especially, India and Brazil) opposed the US and other developed countries to provide basic medicines to the needy and poor people of the developing Country. After all deliberations Paragraph 6 provides that WTO member countries lacking in manufacturing capacities in pharmaceuticals can make effective use of the compulsory license for public health.⁵⁰ Further, the Doha Declaration recognizes various flexibilities in Paragraph 4 which provides that public health rights prevail over individual intellectual property rights.⁵¹ After this, Doha Declaration and TRIPS provisions right to health and public health come to light but to bypass these provisions new agendas were set by the developed countries through bilateral and multilateral agreements between countries. The TRIPS-plus is one of the forms of it and it provides that minimum standard protection commitment by WTO members has to follow in implementing TRIPS provisions. Therefore, in brief, it can be said that pharmaceutical companies have a big budget for research and development. They spend huge money on patented drugs and after getting product patent they will have exclusive licenses for production and marketing and hence they increase the price of the patented drugs.⁵² It includes the cost of research and development and the profits are shared among shareholders, in this way the pharmaceutical companies do the business.⁵³ Pharmaceutical companies base their claim largely on two grounds. Firstly, that they have spent money on research and development of the invention and one can make a profit from these patents for a limited period of 20 years, therefore, many multinational companies work for a profit. And if compulsory licenses are granted to patented medicines then it would discourage them to work without profit in return.

Secondly, those competitors can produce the same drug through reverse engineering and it would discourage innovation and research in the field of science and technology.⁵⁴ Therefore, both the arguments of the right to health and patents are important. However, the fact is that due to the high prices of patented drugs many people could not afford medicines and it restricts them to enjoy their fundamental right to health.

Role of Developed Nations in Patents and its Impact on Right to Health in India

There is no clear definition for developed and developing countries. However, the World Trade Organisation provides some criteria for developed

and developing countries. In the field of patents and the right to health, the role of developed nations is decisive. The United Nations has accepted the accessibility of essential medicine is basic human rights to health in various international instruments.⁵⁵ The lack of access to essential medicine in a country is the result of many factors, but the primary reason is the prevalence of high prices of medicines and strong intellectual property protection. Although, the TRIPS Agreement lays down minimum standards for the protection of intellectual property and offers safeguards and flexibilities to prevent patent abuse but the developed countries like United States (US) and European Union (EU) by signing bilateral trade agreements usurp the flexibilities of TRIPS Agreement. The use of Free Trade Agreements, Anti-Counterfeiting Trade Agreement, Trade Pacific Partnership Agreement and Transatlantic Trade and Investment Partnership Agreements by the United States affected the accessibility of essential medicines to the population in developing countries.⁵⁶ It also coerces the developing countries to accept the stringent provisions of TRIPS-plus.⁵⁷ The developed nations supported the pharmaceutical giants and demanded increased patent protection under strict intellectual property laws. They contended that an increase in the compulsory license will discourage their R&D.⁵⁸ However, there is no link between compulsory license and decline in R&D of the pharmaceutical product. In various instances, the US has established that developed countries can be hypocritical about their stand by using the threat of compulsory license in times of need.⁵⁹

The experiences of developing countries like South Africa, Thailand, and India are indicative of the difficulties faced by the other developing and least developed countries in implementing TRIPS flexibilities for making essential medicines available to their population at affordable prices.⁶⁰ The Thailand government issued three compulsory licenses in Plavix for heart disease and Kaletra (Abbott) and Efavirenz (Merck) for a drug against AIDS on the ground that such licenses could benefit many people and their use would establish the example for other countries to use compulsory license for social welfare.⁶¹ The action of Thailand started a debate between developing and developed countries. The US issued a Special Report 301 Watch List against Thailand due to weakening respect for the patent. The US demanded the Thailand Government to cancel the

compulsory license unless they confirm their scope in using them. This type of action of the US shows bypassing TRIPS flexibilities and accepting TRIPS-plus provisions to institute more stringent pharmaceutical IP protection and thereby preventing access to essential medicines to the population of developing countries.⁶² Therefore, there is a debate between compulsory license in patents and public health.

The first issue to discuss is why there are fewer applications for compulsory licenses in India and which in turn affects the production of generic medicines and public health. The second issue is that how big pharmaceutical companies and developed nations have involvement in dealing with the compulsory license. Therefore, it is a matter of human rights because the inaccessibility of patented medicines is one of the aspects of the right to health. In the case of the first issue, the debate starts with the fewer number of compulsory license applications and which in turn affects the production of generic medicines and public health. In India, the right to health is considered a fundamental right under Article 21 of the Constitution of India. However, people are struggling for basic medicines and their fundamental rights are being violated due to patented medicines. It is accepted that the provisions in TRIPS under Article 31 and Section 84 of the Patents Act, 1970 are dealing with the compulsory license. The lacuna under Article 31 is that it has given a wider scope to the concerned state parties to implement the compulsory license policies. However, after the WTO conference on Public health and TRIPS in 2001 warned about issuing a compulsory license in an emergency like public health. On the other hand, provision of Section 84 is very clear about compulsory license and only one compulsory license is granted in India. There are many advantages of the compulsory license and one advantage is that it allows firms in developing countries to have foreign-owned inventions without the consent of the patent owner.⁶³ It gives the right to the third party to research in an already patented subject matter. However, pharmaceutical companies make their promises and threats to coax developing nations into strengthening patent protection and use developed country government for their self-interest.⁶⁴ There are also serious problems with the capacity of government at the local level. Even most of the developing countries don't have domestic manufacturing capacities and many governments lack the administrative

resources to navigate even the relatively simple requirements of compulsory licensing.⁶⁵ All these factors were responsible for the widespread prioritization of intellectual property protection over health-related rights. Therefore, as discussed above regarding compulsory license in India that only three cases of compulsory licensing have been filed and out of which only one is granted and the rest two were rejected.

The first compulsory license was granted to Bayer Corporation and in the case of *Bayer Corporation v Union of India*, AIR 2014 Bom 178, the court held that Bayer failed to prove under Section 84 of the Patent Act, 1970 and therefore NATCO was allowed to produce generic medicines. This case was related to the Cancer medicine Naxavar produced by the Bayer Corporation which cost around Rs.2,80,000 per month whereas NATCO a generic drug manufactures in India claimed it give for a cheaper price. Initially, Natco applied for the Voluntary license in December 2010 but Bayer did not respond, and therefore in 2011, NATCO applied for a compulsory license to the Controller of Patents. Then Controller of Patents granted a compulsory license to NATCO to produce generic medicines.

The second case is of *BDR Pharmaceutical Private Ltd. v Bristol-Myers Squibb* 2015(64) PTC 135 (Del) filed in March 2013. The BDR Pharmaceutical applied for a compulsory license to make generic medicine for anti-cancer drugs patented by Bristol-Myers Squibb in India. The Controller General of Patents has rejected the BDR pharmaceutical application of compulsory license for Bristol-Myers Squibb's (BMS) cancer drug *SPRYCEL*. *SPRYCEL* is a brand name of the medicine with the active pharmaceutical ingredient of *DASATINIB*. This medicine was used by patients with Chronic Myeloid Leukemia. In the present case, BDR first requested a voluntary license on 2 February 2012, for manufacturing *DASATINIB* in India. The Bristol-Myers Squibb's (BMS) reply to voluntary license is negative and therefore BDR treated it as a rejection of voluntary license. Further, BDR requested compulsory license of *DASATINIB* on 4 March 2013, and it claimed that *DASATINIB* is a suitable chemotherapeutic option for the treatment of cancer and Chronic Myeloid Leukemia. BDR also submitted that the price of each tablet sold by the BMS is Rs. 2761/- which will cost Rs.1,65,680/- tablets per month. Therefore, BDR claimed that they will provide this drug to the public at a proposed price of Rs.135/- per tablet which will cost around Rs.8100/- per month for the treatment of Chronic

Myeloid Leukemia patients. It will be available to cancer patients at a low cost and therefore compulsory license has to be granted. The Controller of Patent rejected the application on the ground that BDR has failed to make out the prima facie case for making of an order under Section 87 of the Patents Act, 1970. It also pointed out that BDR before applying for a compulsory license the applicant didn't try to convince the patentee for voluntary license and out-rightly rejected an application for the grant of compulsory license.

The third case is of *LEE Pharmaceutical Private Ltd., v AstraZeneca*, CLA No. 1 of 2015, filed for compulsory license against one of the patented drugs of BMS in the name of drug *Saxagliptin* for treating Diabetes Mellitus. This drug was assigned to Astra Zeneca by way of Deed of Assignment and therefore it was sold and marketed by Astra Zeneca. Lee Pharmaceutical contended that this drug was not manufactured in India even after 8 years of the grant of a patent to BMS. Further, it was argued that the cost of the imported drug was around Rs.0.80/- per tablet but it was sold at Rs.41-45/- per tablet. Therefore, LEE Pharmaceutical submitted that they will make it available for the public at Rs.27/- per tablet. The Controller of Patent discussed in detail the grounds given under Section 84 of the Indian Patent Act, 1970, and finally rejected the application on the ground that the application does not fulfill any one of the grounds of Section 84 of the Patents Act, 1970.

The second issue is that how big pharmaceutical companies and developed countries play a key role in patent and right to health. Therefore, to understand the nitty-gritty of compulsory license in the Patents Act and access to medicines the consequence of granting the first compulsory license in India is the eye-opener for the world. And India is not the only country that faced the difficulty of granting compulsory license but there are other countries like Brazil and Thailand which has the same history of Report 301 of the US Trade Act, 1974.⁶⁶ In India, after the grant of a compulsory license to NATCO, the USA issued Report 301 against India for granting the compulsory license on the ground that the Indian government is not complying with the provisions of TRIPS and WTO.⁶⁷ Report 301 is a US provision of the Trade Act, 1974 which has many amendments. It is a weapon of the US government to ban and threaten the other countries for not cooperating in IPR matters of US Companies.

According to Section 301 of Trade Act, 1974, United States Trade Representative issues an Annual

Report in which those countries which could not protect the IPR of US companies are identified and threatened.⁶⁸ Therefore, it was not a criticism of the US policies for trade sanctions because every country has its agenda for business and commerce. However, interestingly after the 10 years of Doha Declaration a policy brief prepared by South Centre to celebrate 10 anniversary of WTO Doha Ministerial Conference it was pointed out that Multinational Pharmaceutical Companies and developed countries put pressure on the developing countries from using TRIPS flexibilities of public health on compulsory licenses.⁶⁹ Because of the above, intellectual property rights and the right to health has a different object. Intellectual Property Law has a provision of compulsory license to balance the need of the society therefore it cannot be said that intellectual property laws creating a hurdle for human rights. But the fact is that despite having provision of compulsory license with specific grounds and power is given to the government to implement it. The TRIPS provisions also provide flexibilities for a compulsory license like under Section 84 it grants compulsory license only after three years of patent. Although the TRIPS provisions under Article 31 provides for public emergency and the locking period given under Section 84 of the Patents Act 1970 provides enough scope to the pharmaceutical companies to use patent. Therefore, the argument of not giving credit to the patent holder for his work is untenable and it will not reduce innovation in the field of pharmaceutical products. It is pertinent to understand both the aspects of patents and human rights. Further, the experience of India and other developing countries can be easily understood by the following example. The history of non-cooperation of the United States to India in case of patented medicines and human rights to access to lifesaving medicines can be traced from the National Human Right Commission (NHRC) notice to the government of India on 1 April 2016. The National Human Rights Commission (NHRC) issued a notice on first April 2016 to the Government of India to submit a report that the government had given private confirmations to the United States that India would embrace a rigorous methodology when granting compulsory licenses over protected medications.⁷⁰ While the Government of India, Ministry of Commerce and Industry in a Press Report in March 2016, had denied such claims in response to the NHRC notice. Further, immediately after the Ministry of Commerce and Industry Press Release in 2016, Lee

Pharma and BDR Pharma (the main two organizations to petition for compulsory licenses after NATCO) reported that they would not go in an appeal after rejection of application for a compulsory license by the Indian Patent Office.⁷¹ This is how developed nations put pressure on developing nations and these are the issues involved in compulsory license and human rights. The above study shows that how the government is rejecting compulsory licenses which in turn affect the production of generic medicines and public health.⁷² It creates serious questions about the role of State as facilitator and mediator between the monopoly of the patent holder and public good. Therefore, such trends of policy shift of government from human rights perspectives to economic point of view are menacing to the welfare states.

Conclusion

The concept of the human rights approach in Patents and Public Health has been discussed at the Doha Declaration on TRIPS and Public health in 2001. The compliance of Article 31 of the TRIPS Agreement and Section 84 of the Patent Act is purely based on the policy decisions of the countries who decide the grounds of compulsory license. Whereas the right to access basic medicines is considered as human rights, and international conventions recognized these rights in IPR. However, there is a contradiction in the action of the international community and the political will of a developed country to issue a compulsory license in pharmaceutical products as it is evident from the Indian grant of compulsory license in Bayer's Case and the reaction of the US after a compulsory license. The one incident of *suo-motu* action by the NHRC in 2016 against the Government of India and reply to the NHRC by the Ministry of Commerce and Industry has indicated the involvement of the political will of big pharmaceutical companies and their link with developed countries. Therefore, it may be one of the reasons for less number of compulsory license applications in India and across the world.

The above study shows that big pharmaceutical companies and developed countries (especially, the US and EU) have involvement in dealing with compulsory licenses and this creating obstacle in the dissemination of medicines to an individual which resultantly affect human rights. The economic expectation of pharmaceutical companies is higher in the patented products and therefore the prices of patented drugs are costly and beyond the reach of common people. Therefore, patent laws are responsible

for the lack of accessibility of medicines. It can be concluded that the laws at the international and national levels dealing with compulsory license and human health rights are not adequate to enforce it strictly. However, the role of developed nations and particularly the United States is one of the dominant factors in deciding the compulsory licenses in developing countries and particularly in India.

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