Pakistan Perspectives
Vol. 19, No.1, January-June 2014

Rationale of Compulsory Licensing of Pharmaceutical Patents in the Light of Human Rights Perspective

Muhammad Zaheer Abbas* **& Shamreeza Riaz*****

Abstract

Patents render prices of patented products unaffordable for general masses because of the 20 years monopoly granted to owner of the patent to manufacture, sell, and import the patented product. Overpricing caused by monopoly rights has serious human rights implications in case of pharmaceutical patents especially in situations of public health crisis. Compulsory licensing of patents has been provided under TRIPS Agreement as a legitimate safeguard to check abuse of monopoly and to deal with special situations of public health crisis. First part of this paper discusses relationship of TRIPS and the human right to health as TRIPS Agreement for the first time made it mandatory to protect all innovations including pharmaceuticals. Second part of this paper discusses rationale of compulsory licensing of pharmaceutical patents in the light of Indian case Bayer Corporation v. Natco Pharma Limited. Last part of this paper concludes the discussion.

Introduction

The concept of Intellectual Property Rights (hereinafter IPRs) is based on the principle that a person who comes with an original creation carrying a utility has an exclusive right to exploit their creation. IPRs protection is, therefore, a tool that can be used to foster innovation by providing temporary monopoly to the IPRs holders as a reward of their effort. As a result, consumers get improved goods and services. Competition law, on the other hand, is meant to ensure fair prices by preventing monopoly. The relationship between intellectual property rights and competition law is complex, and it has always been a

* Muhammad Zaheer Abbas, PhD Scholar and Research Associate, Department of Law, Faculty of Shariah & Law, International Islamic University Islamabad.

** Shamreeza Riaz, PhD Scholar and Research Associate, Department of Law, Faculty of Shariah & Law, International Islamic University Islamabad.

challenge to strike a proper balance between competition and innovation protection.[1]

Though common purpose of both IPRs and competition law is to enhance consumer welfare and promote innovation, the goals of intellectual property laws and competition law often convergent. There is a conflict between the two because the former creates legal monopolies and the latter eliminates monopolies and anticompetitive practices.[2]

Patent[3] protection, despite being contradictory to competition law, has been accepted across the globe because it provides incentive to innovate. Sometimes monopoly right provided to patent holder may be required to be breached in certain special situations when public interest demands so. For instance, in case of an outbreak of an epidemic, a pharmaceutical patent may be diluted compulsorily to the detriment of the patent owner. The philosophy underlying compulsory licensing is, therefore, based on an often repeated saying 'Necessity is the mother of invention'.[4]

Pharmaceutical patent protection versus right to health

The right to health as a human right has been recognized by a number of international instruments. In 1948, the United Nations Universal Declaration of Human Rights (hereinafter UDHR) stipulated that 'Everyone has the right to a standard of living adequate for the health

---

1 *Compulsory Licensing And The Anti-Competitive Effects of Patents for Pharmaceutical Products: From A Developing Countries' Perspective,* p.2, (last accessed date 13 February 2012), doi:http://www.idra.it/garnetpapers/C14A_Kaushik_A_Jaktar.pdf.

2 Arutyun Arutyunyan 'Proceedings of the Institute for European Studies', *International University Audentes, Tallinn University of Technology*, Vol.4 (2008), p.168, (last accessed date 13 February 2012), doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=28&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

3 A grant of right to exclude others from making, using or selling one's invention and includes right to license others to make, use or sell it. *Black's Law Dictionary* 1125 (6th ed. 1990). A patent is a form of intellectual property. It consists of a set of exclusive rights granted by a sovereign state to an inventor or their assignee for a limited period of time in exchange for the public disclosure of an invention.

4 Tarun Jain, 'Compulsory Licenses Under Trips and Its Obligations for Member Countries', *ICFAI Journal of Intellectual Property Rights*, 8:1 (Feb. 2009), p.1, (last accessed date 13 February 2012), doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=34&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

and well-being of himself and of his family, including food, clothing, housing, and medical care'.[5] In 1966, the right to health as a human right was reaffirmed under Article 12 of the International Covenant on Economic, Social and Cultural Rights (hereinafter ICESCR).[6] The Convention on the Rights of Child,[7] the International Convention on the Elimination of All Forms of Racial Discrimination (hereinafter ICERD), and the Convention on Elimination of all forms of Discrimination Against Women (hereinafter CEDAW)[8] further elaborated right to health care.[9]

Similarly, at national level, national constitutions of at least 135 states have recognized right to health as a human right.[10] For instance, right to health care has been guaranteed[11] in constitution of Brazil,[12]

---

5 Article 25(1), *Universal Declaration of Human Rights*, For details visit, doi:http://www.un.org/en/documents/udhr/index.shtml#a25, (last accessed date 22 April 2012).

6 The International Covenant on Economic, Social and Cultural Rights (ICESCR) is a multilateral treaty adopted by the United Nations General Assembly on 16 December 1966, and in force from 3 January 1976. Available at doi:http://www2.ohchr.org/english/law/cescr.htm, (last accessed date 22 April 2012).

7 Article 24(1), *Convention on the Rights of Child 1989*, Available at (last accessed date 22 April 2012), doi:http://www.unicef.org/crc/.

8 Article 12(1) and Article 14(2)(b), *Convention on Elimination of all forms of Discrimination Against Women 1979*, online available at (last accessed date 22 April 2012), doi:http://www.un.org/womenwatch/daw/cedaw/text/econvention.htm.

9 Article 5(e)(iv), *International Convention on the Elimination of All Forms of Racial Discrimination 1965*, available at doi:http://en.wikipedia.org/wiki/Convention_on_the_Elimination_of_All_Forms_of_Racial_Discrimination, (last accessed date 22 April 2012).

10 Dilip K. DAS, 'Intellectual Property Rights and the Doha Round', *Journal Of World Intellectual Property* (2005), p.522, (last accessed date 13 February 2012), doi:http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2005.tb00236.x/pdf.

11 Pier DeRoo, 'Public Non-Commercial Use Compulsory Licensing For Pharmaceutical Drugs In Government Health Care Programs', *Michigan Journal of International Law* (2011), p.364, (last accessed date 13 February 2012), doi:http://students.law.umich.edu/mjil/uploads/articles/v32n2-deroo.pdf.

12 Article 196, *Constitution of Brazil*, available online, (last accessed date 22 April 2012), doi:http://karari.org/de/node/36870

Thailand,[13] and South Africa.[14] Access to essential medicines is a prerequisite to protect the fundamental human right to health.[15]

States, owing to these commitments made at national and international level, are obliged to make arrangements for the protection of life and health of their nationals.[16] States are, therefore, under an obligation not to interfere with the right to health care and to adopt all suitable and feasible administrative and legislative measures to make sure that this right is not violated. States should also prevent those trying to interfere with the right to health. Moreover, states, while entering into international agreements or treaties, should make sure that it would not have an adverse effect on the right to health.

Over 14 million patients of curable or preventable diseases die each year.[17] The situation is even grimmer in the most affected regions of Asia and Africa.[18] It may be astonishing to note that although developing countries comprise about 80 per cent of the total population but they buy

---

13 Section 51, *Constitution of the Kingdom of Thailand* (last accessed date 22 April 2012), doi:http://en.wikisource.org/wiki/Constitution_of_Thailand_%282007%29/Chapter_3. It provides the right to health care.

14 Section 27, *Constitution of South Africa*. Available at doi:www.info.gov.za/documents/constitution/1996/a108-96.pdf, (last accessed date 22 April 2012).

15 Jillian Clare Cohen-Kohler and Lisa Forman, 'Addressing legal and political barriers to global pharmaceutical access: Options for remedying the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the imposition of TRIPS-plus standards, Health Economics', *Policy and Law*, Vol.3 (2008), p.249, (last accessed date 13 February 2012), doi:http://journals.cambridge.org/action/displayFulltext?type=1&pdftype=1&fid=1914284&jid=HEP&volumeId=3&issueId=03&aid=1914276.

16 M. Rafiqul Islam, 'The Generic Drug Deal of the WTO from Doha to Cancun, A Peripheral Response to a Perennial Conundrum', *Journal of World Intellectual Property*, 7:5 (2005), p.689. (last accessed date 13 February 2012), doi:http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2004.tb00224.x/pdf.

17 Third World Network, 'TRIPS, Drugs and Public Health: Issues and Proposals', *Intellectual Property Rights Series*, Vol.2 (2001), p.4, (last accessed date 13 February 2012), doi:http://www.twnside.org.sg/title2/IPR/pdf/ipr02.pdf.

18 Philippe Cullet, 'Patents and medicines: the relationship between TRIPS and the human right to health', *International Affairs*, Vol.79 (2003), p.143, (last accessed date 13 February 2012), doi:http://onlinelibrary.wiley.com/doi/10.1111/1468-2346.00299/pdf.

hardly 20 per cent of pharmaceuticals manufactured across the globe.[19] Low purchasing power of the masses in these countries may be one of the major reasons behind this. Moreover, about 90 per cent people living in the third world pay for medicines from their own pocket.[20]

Trade Related Aspects of Intellectual Property Rights Agreement (hereinafter TRIPS) introduced a strict legal regime for the protection of IPRs. Under TRIPS Agreement, WTO member countries are obliged to provide patent protection, for a period of 20 years to innovations in all fields of technology including pharmaceuticals.[21] Prior to TRIPS, about fifty countries, including many of the present world's developed countries, had excluded drugs from patent protection in their municipal laws. For instance, 'Germany until 1968, Switzerland until 1977, Italy until 1978, Norway, Portugal and Spain until 1992, Finland until 1995',[22] had done so.

The fact that patented drugs are unaffordable for general masses in the third world, because of monopoly provided to patent holders, raises serious concerns for developing countries considering stronger IPRs protection.[23] While framing TRIPS Agreement human rights implications were not given due consideration. In 1990s outbreak of

---

19 Faizel Ismail, 'The Doha Declaration on TRIPS and Public Health and the Negotiations in the WTO on Paragraph 6why P h w Needs to join the Consensus', *Journal of World Intellectual Property*, 6:3 (2003), p.395, (last accessed date 23 February 2012), doi:http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2003.tb00221.x /pdf.

20 Rudolf V. Van Puymbroeck, 'Basic Survival Needs and Access to Medicines – Coming to Grips with TRIPS: Conversion +Calculation', *Journal of Law, Medicine & Ethics*, 38:3 (2010), p.522, (last accessed date 13 February 2012), doi: http://onlinelibrary.wiley.com/doi/10.1111/j.1748-720X.2010.00510.x/pdf.

21 Sandra Bartelt, 'Compulsory Licences Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health', *Journal Of World Intellectual Property*, 6:2 (2003), p.283, (last accessed date 23 February 2012), doi:http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2003.tb00202.x /pdf.

22 F M Scherer: Jayashree Watal, 'Post-Trips Options for Access to Patented Medicines in Developing Countries', *Commission on Macroeconomics and Health*, 2001, p.4, (last accessed date 23 March 2012), doi:http://www.icrier.org/pdf/jayawatal%20.pdf.

23 Richard P. Rozek, 'The Effects of Compulsory Licensing on Innovation and Access to Health Care', *Journal of World Intellectual Property*, 3:6 (2000), p.892, (last accessed date 23 March 2012), doi:http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2000.tb00158.x/pdf.

pandemics like HIV/AIDS[24] drew attention of the world community towards consequences of stringent pharmaceutical patent, protection provided under TRIPS Agreement, for patients in the poor countries. For the first time, public health concern emerged as a political issue at international level[25] and it sparked serious debate at World Health Organization (WHO) and World Intellectual Property Organization (WIPO). [26]

The United Nations Sub-Commission on Human Rights, in 2001,[27] recognized that 'there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other'.[28] WTO Ministerial Conference was held in 2001 at Doha; in this conference representatives of third world countries raised their voices and Doha Declaration 2001 and WTO General Council's Waiver Decision of 2003 were the result of their efforts. Right of WTO member countries to invoke safeguards, like compulsory licensing, provided under TRIPS Agreement was reaffirmed in the Doha Declaration 2001. Theoretically, safeguards have been provided in the TRIPS to deal with public health crisis but practically to what extent third world countries have availed these flexibilities is a debatable issue.[29]

The private and philanthropic sectors have been actively working for increasing availability of essential medicines in the most

---

24 A pandemic is an epidemic of infectious disease that spreads through human populations across a large region: for instance multiple continents, or even worldwide. For details visit, (last accessed date 23 April 2012), doi:http://en.wikipedia.org/wiki/Pandemic.

25 Robert Bird: Daniel R. Cahoy, 'The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach', *American Business Law Journal*, 45:2 (2008), p.286, (last accessed date 23 March 2012), doi:http://onlinelibrary.wiley.com/doi/10.1111/j.1744-1714.2008.00056.x/pdf.

26 Jacques H.J. Bourgeois, 'Thaddeus J. Burns, Implementing Paragraph 6 of the Doha Declaration on TRIP Sand Public Health The waiver Solution', 5:6 (2005), p.836, (last accessed date 23 March 2012), doi:http://onlinelibrary.wiley.com/doi/10.1111/j.1747-1796.2002.tb00184.x/pdf.

27 See Resolution 2001/21, *Intellectual Property And Human Rights*, United Nations Sub-Commission on Human Rights, UN Doc. E/CN.4/Sub.2/RES/2001/21 (2001), (last accessed date 24 April 2012), doi:http://www.unhchr.ch/huridocda/huridoca.nsf/%28Symbol%29/E.CN.4.SUB.2.RES.2001.21.En?Opendocument.

28 Pier DeRoo, *op.cit.*, p.364.

29 *Ibid*, p.101.

affected regions of the third world. Bill and Melinda Gates Foundation's[30] AIDS program in Botswana is just one example. There are various instances where even the much criticized pharmaceutical companies have made non-profit investments on humanitarian grounds. The first AIDS hospital and the first AIDS laboratory constructed by Bristol Myer-Squibb Philanthropy[31] in Botswana (Africa), Pfizer's[32] initiative to build the first Infectious Disease Institute in Uganda, the Institute for Tropical Diseases (NITD) built by Novartis[33] in Singapore, and the AIDS Hospital built by Abbott Laboratories[34] in Tanzania are some of the examples.[35]

No doubt, these initiatives are providing access to health care to a limited number of people in some parts of the third world but only philanthropic work is no solution to the problem of access to essential medicines. Some substantial steps must be taken both at national and global level to overcome the barriers to access to necessary drugs.

---

30 The Bill & Melinda Gates Foundation is the largest transparently operated private foundation in the world, founded by Bill and Melinda Gates. The primary aim of the foundation is to enhance healthcare and reduce extreme poverty. For further details visit doi:http://www.gatesfoundation.org/press-releases/Pages/comprehensive-hiv-aids-partnership-000710.aspx, (last accessed date 25 April 2012).

31 Bristol-Myers Squibb Philanthropy, 'An Introduction to Secure the Future', (last accessed date 25 April 2012), doi:http://www.securethefuture.com/our_experience/commitment.shtml.

32 Pfizer, 'Global Health Infectious disease', *The world's largest research based Pharmaceutical company*, (last accessed date 25 April 2012), doi:http://www.pfizer.com/responsibility/global_health/%20infectious_diseases_institute.jsp.

33 Novartis Global, 'Access to Health Care', (last accessed date 25 April 2012), doi:http://www.novartis.com/corporate-responsibility/access-to-healthcare/index.shtml.

34 Abbot Laboratories, 'Global Health Care & Medical Research', (last accessed date 25 April 2012), doi:http://www.abbott.com/index.htm.

35 Alec Van Gelder: Philip Stevens, 'The Compulsory License Red Herring', *International Policy Network* (2010), p.9, (last accessed date 23 March 2012), doi:http://scholar.googleusercontent.com/scholar?q=cache:7yHHlJFIXuwJ:scholar.google.com/+Roche+v.+Natco&hl=en&as_sdt=0,5.

Rationale of compulsory licensing

'Compulsory licensing[36] is a license issued by a state authority to a government agency, a company or other party to use a patent without the patent holder's consent'.[37] The patent holder is, however, entitled to receive royalty for the use of their patent without their consent.[38]

Patents, no doubt, play a vital role in promoting innovation and creativity. Without patent protection innovators will not have an incentive to make new innovations. Absence of patents, on the other hand, means absence of monopoly rights and low prices of products is an obvious result. But low prices at the cost of innovation are detrimental for the society in the long run because the society will be deprived of innovations and improved products.[39] Despite their conflict with competition laws, patents have been accepted globally as a compromise to encourage innovation. Patents come into conflict with human rights law when monopolistic patent rights are conferred on the products which are essential for human life.[40]

Multi-national pharmaceutical companies own patents on drugs and set exorbitantly high prices for patented drugs to maximize their profits; this renders prices of life-saving medicines unaffordable for common masses in the third world where per capita income is very low

---

36 The birth of the concept of compulsory licenses is linked to the obligation, introduced by the United Kingdom (UK) Statute of Monopolies in 1623. Compulsory licensing has been reported to be popular in Britain as early as 1850s. Later it was recognized by the international community through Paris Convention of 1883. For details visit doi:http://www.legislation.gov.uk/aep/Ja1/21/3/contents, (last accessed date 13 February 2012).

37 Ebenezer Durojaye, 'Compulsory Licensing And Access To Medicines In Post Doha Era: What Hope For Africa?', *Journal of Intellectual Property Law*, 18:2, p.35 (Spring2011), (last accessed date 13 February 2012), doi:http://web.ebscohost.com/ehost/results?sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13&vid=19&hid=122&bquery=(compulsory+licensing)&bdata=JmRiPWE5aCZ0eXBlPTAmc2l0ZT1laG9zdC1saXZl.

38 *Ibid*, p.35.

39 Aidan Hollis, 'The Link Between Publicly Funded Health Care And Compulsory Licensing', *CMAJ: Canadian Medical Association Journal*, 167:7 (2002), p.756, (last accessed date 13 February 2012), doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=28&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

40 Jakkrit Kuanpoth, 'Give The Poor Patients A Chance: Enhancing Access To Essential Medicines Through Compulsory Licensing', *Journal of Generic Medicines*, 6:1 (Nov 2008), p.1, (last accessed date 13 February 2012), doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=27&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13.

as compared to advanced countries. In case of national emergency, the availability of needed drugs becomes even more uncertain. To deal with such situations, TRIPS provides flexibility to national governments to invoke compulsory licensing provisions. It is pertinent to note here that for issuance of compulsory license national emergency is not the only ground. Under Doha Declaration on Public Health 2001 WTO member states have been provided the freedom to determine grounds of compulsory licensing.[41] The grounds for granting compulsory licensing vary from country to country because international norms and standards for this practice have not developed so far.

Following Indian case is an example where compulsory licensing provisions have been invoked to deal with the issue of affordability of the patented drug.

Bayer Corporation[42] v. Natco Pharma Limited

Sorafenib Tosylate: Sorafenib, originally patented in the United States in 1999,[43] is a kidney and liver cancer patented drug of Bayer Corporation which is sold under the brand name 'Nexavar'. Sorafenib is not a life-saving drug, but a life extending or life prolonging drug.[44] The life of a patient can be extended by 4-5 years and 6-8 months in the case of kidney cancer and liver cancer respectively. It is pertinent to mention

---

41 Manthan Janodia, Rao J. Venkata & Udupa, N., 'Correspondence', *Current Science*, 91:8 (2006), p.998, (last accessed date 13 February 2012), doi:http://web.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=28&hid=122&sid=b06a26af-6028-4687-93e0-06fa097c0197%40sessionmgr13

42 Bayer AG is chemical and pharmaceutical company founded in Germany in 1863. It is well known for its original brand of Aspirin. For over a quarter of a century, Aspirin became synonymous with Bayer but the company lost its naming right during World War 1, due to its German origin. Bayer started its marketing in America soon after its inception in Germany. Bayer Corporation, a party in the case Bayer v. Natco, is American arm of Bayer. Bayer Corporation is an internationally renowned manufacturer of innovative drugs. In the 1990s, it invented 'sorafenib', a liver and kidney cancer drug which is subject of controversy in the Bayer v. Natco case. For details visit doi:http://en.wikipedia.org/wiki/Bayer_USA, (last accessed date 8 June 2012).

43 Raja Murthy, 'India patent bypass delivers life-saving blow against cancer', (last accessed date 20 April 2012), doi:http://www.atimes.com/atimes/South_Asia/NC21Df01.html.

44 Betsy Vinolia Rajasingh, *India's first compulsory license over Bayer's patent (2012)*, (last accessed date 20 April 2012), doi:http://jiplp.blogspot.com/2012/05/indias-first-compulsory-licence-over.html.

that the patient needs to use the pharmaceutical throughout their lifetime.[45] It is also worthy noting that in India, one month dose of Sorafenib costs Rs.2,80,428/- (Rs.33,65,136/- per annum).[46]

On 12 January 2001, Bayer applied for Sorafenib product patent in India. The patent was granted on 3 March 2008 under patent number 215758.[47] The drug was, however, launched in India in 2009 after receiving regulatory approval for importation.[48]

The compulsory licensing application by Natco

Natco Pharma Ltd. developed the process for manufacturing of Sorafenib and in April 2011, received a license from the Drug Controller General of India for bulk manufacturing and marketing of Sorafenib in India. Natco Pharma approached Bayer Corporation for a voluntary license to manufacture and sell a generic version of their patented pharmaceutical product in India. The voluntary license was, however, denied by the Bayer Corporation.

Under Indian patent law, an application for compulsory licensing is allowed only after a lapse of three years after the grant of patent. Since the patent was granted in 2008, on 29 July 2011, Natco filed an application before the Controller General of Patents, Designs and Trademarks (CGPDTM) for the compulsory license in respect of Sorafenib under Section 84(1)(a)(b)(c) of the Indian Patent Act 1970.[49] Natco alleged that the patented invention does not satisfy the reasonable

---

45 Frederick Noble, 'Indian Patent Office Grants License For Anti-Cancer Drug', (last accessed date 20 April 2012), doi:http://www.albrightpatents.co.uk/articles/indian-patent-office-grants-licence-for-anti-cancer-drug/.

46 NATCO Pharma Limited v. Bayer corporation, CLA, no 1, 2011. Available online at doi:http://ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf, (last accessed date 8 June 2012).

47 Joseph Alexander, 'Planning Commission Calls For Grant Of More Compulsory Licenses To Ensure Drug Security', *Pharmabiz,* (last accessed date 20 April 2012), doi:http://pharmabiz.com/NewsDetails.aspx?aid=68849&sid=1.

48 Patricia Van Arnum, 'Pharmaceutical Industry Faces Compulsory Licensing in India', *Pharamatech,* 2012, (last accessed date 20 April 2012). doi:http://www.pharmtech.com/pharmtech/Pharmaceutical-Industry-Faces-Compulsory-Licensing/ArticleStandard/Article/detail/766949?ref=25.

49 Patralekha Chatterjee, 'India's Generics-Big Pharma Battle Drops Drug Prices, Raises Legal Debate'. (last accessed date 20 April 2012), doi:http://www.ip-watch.org/2012/05/20/india%E2%80%99s-generics-big-pharma-battle-drops-drug-prices-raises-legal-debate/.

requirements of the public; the patented invention is not available to the public at a reasonably affordable price; and the patented invention is not worked in the territory of India. Moreover, Natco Pharma proposed to sell the drug at a price of Rs.8800 for a month's therapy.[50]

Preliminary issues raised by the patentee

On 7 October 2011, Bayer Corporation filed an interlocutory petition seeking a stay on the ground that Natco Pharma had infringed their patent on Sorafenib and an infringement suit against Natco was pending in the Delhi High Court. On 27 October 2011, the Patent Office refused the patentee's request for a stay in the matter. The parties were heard on 13 January 2012 and the patentee raised several preliminary issues during the course of the hearing. For instance, the patentee raised an issue that the application should be rejected on the ground that the applicant had suppressed a material fact that Cipla, another generic manufacturer in India, had been selling Sorafenib at the cost of Rs.30,000/- for a month's therapy since April 2010.

Natco Pharma in reply submitted that they were aware of the pending infringement suit filed by the patentee against Cipla but it was not suppression of a material fact because the pending suit had no relevance to the compulsory licensing application. It was the duty of the patentee and not of any third party to meet the demand of the patented drug in the Indian market. Moreover, an infringement suit was pending against Cipla. Cipla could be injuncted by the High Court at anytime and supply of Sorafenib by Cipla could stop totally. The objection raised by the patentee was therefore overruled.

The main controversy

As the application for the grant of compulsory license was made under Section 84(1)(a)(b)(c) of the Indian Patent Act 1970, the main issues to be decided in the case were as under:

- Whether the reasonable requirements of the public with respect to the patented invention had not been satisfied.
- Whether the patented invention was not avail able to the public at a reasonably affordable price.
- Whether the patented invention was not worked in the territory of India.[51]

---

50 Patricia Van Arnum, *op.cit.*

51 'Compulsory licensing: Road ahead', (last accessed date 4 June 2012), doi;http://viamediagroup.in/paradox.html.

Under Indian patent laws, compulsory license could be granted if anyone of these three grounds was established.[52] The submissions of the applicant and the patentee on these issues are as under:

Reasonable requirements of the public: The applicant relied on statistics published in GLOBOCAN 2008[53] to support their contention that Bayer's patented invention had failed to fulfill the reasonable requirements of the public. According to the publication, there were approximately 20000 liver cancer patients in India while the number of kidney cancer patients was about 8900. Whereas no bottles of Sorafenib were imported in 2008 and only 200 bottles of the patented drug were imported in 2009. There was a huge difference between supply and demand of the drug. Consequently, the product in question was out of stock or not available in common pharmacies even in metro cities of India. The patentee thus failed to meet the demand of even 1% patients in India, the applicant contended.

In reply, the patentee also relied on GLOBOCAN 2008 contending that Sorafenib was needed by the liver and kidney cancer patients who were in advanced stage.[54] Thus approximately 4838 (out of 20000) liver cancer patients and about 4004 (out of 8900) kidney cancer patients were entitled for treatment with Sorafenib. Moreover, the patentee argued that supply of the drug was not necessary in villages as the treatment with the drug should be supervised by doctors.[55] Furthermore, the patentee argued that supply of the drug was considerably enhanced due to sale of Sorafenib by Cipla.[56]

---

52 Khomba Singh, 'Bayer demands withdrawal of Natco Pharma's compulsory license', (last accessed date June 4, 2012), doi:http://articles.economictimes.indiatimes.com/2012-05-19/news/31778153_1_compulsory-licence-natco-pharma-compulsory-licensing.

53 GLOBOCAN 2008 is a publication by GLOBOCAN project of the World Health Organization. The aim of the project is to provide contemporary estimates of the incidence of, mortality and prevalence from major type of cancers, at national level, for 184 countries of the world. For details visit doi:http://globocan.iarc.fr/, (last accessed date 8 June 2012).

54 Rahul Dhote & Mita Sheikh, Krishna & Saurastri Associates, 'Natco win: Deterrent for FDI?', (last accessed date 4 June 2012), doi:http://www.moneycontrol.com/news/the-firm/natco-win-deterrent-for-fdi_682903.html.

55 NATCO Pharma Limited v. Bayer corporation, CLA, no 1, 2011. Available online at doi:http://ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf, (last accessed date 8 June 2012).

56 Rahul Dhote**,** *op.cit.*

Reasonably affordable price: The Applicant contended that price of the drug was too high for a common man in India and the patentee had failed to meet the demand for the drug on reasonable terms. Rs. 2,80,428 – price fixed by Bayer Corporation for a month's therapy- was more than total income of three and half years of a government worker in India.[57] About 30 per cent Indians were already below the poverty line;[58] the exorbitant price of the drug would push more Indian population below the poverty line.[59] Setting of such a high cost of the drug was unfair, anti-competitive and misuse of the monopolistic rights, contended the applicant.

The patentee, in reply, justified the high price on the ground that innovation was not possible without huge costs spent on research and development. Manufacturing of innovative products was different from that of generics which are mere copies of the patented products. Almost 75 per cent of the total research and development cost was incurred on failed projects. That cost too was recouped by setting a high price of successful formulas. Moreover, the patentee submitted that the term 'reasonable' means reasonable not only to public but also to patentee. Therefore there must be a balance between public interest and interest of the innovator taking into account the cost incurred on research and development.[60]

Patented invention not worked in the territory of India: The applicant contended that the patented invention was not worked in the territory of India because it was being imported into India and not being manufactured in India. The patentee had failed to exploit the patent in India without ascribing any reason for such neglect. The patentee already having manufacturing facilities in India had no excuse for not working the patent in India.[61]

---

57 Murthy, 'India patent bypass delivers life-saving blow against cancer' 2012.

58 The poverty line set in India is already below international standards. In March 2012, Planning Commission further reduced poverty line to Rs 28.65 per capita daily consumption in cities and Rs 22.42 in rural areas. For details visit doi:http://ibnlive.in.com/news/indias-poverty-line-now-lowered-to-rs-28-per-day/240737-3.html, (last accessed date 8 June 2012).

59 Raja Murthy, *op.cit.*, 2012.

60 NATCO Pharma Limited v. Bayer corporation, CLA, no 1, 2011. Available online at doi:http://ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf, (last accessed date 8 June 2012).

61 Jose Madan, Adheesh Nargolkar and Fiona Desouza of Khaitan & Co, *A Rare Win for Natco!*. (last accessed date 4 June 2012)

In reply, the patentee argued that 'worked in India' did not mean 'manufactured in India'. Domestically worked meant 'commercial working' or 'supplied to the Indian markets'.[62] Bayer argued that the words 'manufacture in India' were deleted from Section 84(7)(a)(ii) while amending the patent law in 2002.[63] Moreover, the patentee contended that manufacturing of the product required huge investments on infrastructure and logistics which could further increase the manufacturing cost of Sorafenib — a product of small global demand. The quantity of the product required in India, therefore, did not justify spending of huge amounts on infrastructure and logistics.[64] Furthermore, under Article 27 of the TRIPS Agreement, the patentee's right should not be affected only because of importation of the patented product.[65]

The order of grant of compulsory license

After 18 hours of hearings in three days, on 9 March 2012, minutes before leaving his office on the last day of his stint at the Indian Patent Office, P.H Kurian, Controller General of Patents, issued the order of grant of first Indian compulsory license[66] to Natco Pharma allowing it to manufacture and sell Bayer's patented product Sorafenib.[67]

As regards the question of meeting reasonable requirements of the public, the Controller concluded that even if Bayer's estimate of cancer patients in India is accepted, the negligible quantity of the drug imported into India by Bayer could hardly suffice for 2 per cent cancer patients.[68] This nominal quantity of the drug was available only at certain

---

doi:http://www.moneycontrol.com/news/features/a-rare-win-for-natco_682506.html.

62 Rahul Dhote, *op.cit.*

63 Betsy Vinolia Rajasingh, *op.cit.*

64 NATCO Pharma Limited v. Bayer corporation, CLA, no 1, 2011. Available online at doi:http://ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf, (last accessed date 8 June 2012).

65 Rahul Dhote, *op.cit.*

66 The compulsory licence is valid till the patent for Nexavar expires in 2021. (last accessed date 9 June 2012), doi:http://www.business-standard.com/india/news/us-to-keep-an-eyeindias-compulsory-drug-licensing-move/473520/.

67 Breaking News: 'India's First Compulsory License Granted' (2012), (last accessed date 4 June 2012), doi:http://ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf.

68 Nandan S. Nelivigi, James R.M. Killick, Carolyn B. Lamm, Gregory J. Spak, Dimitrios T. Drivas, Bijal V. Vakil, 'Indian Patent Office Grants Compulsory License for Bayer's Nexavar: Implications for Multinational

premier hospitals and that too was excessively high-priced rendering it unaffordable for potential users. The Controller, therefore, concluded that the patentee had not adequately met the demand of the patented invention on reasonable terms.[69]

As regards the question of reasonably affordable price, the Controller rejected Bayer's interpretation of the term and concluded that the term 'reasonable' used in the provision referred predominantly to the purchasing power of the public.[70]

With regards to question of 'working of the patented invention in the territory of India', the Controller referred to Article 5(A)(2) of the Paris Convention according to which patentee's failure to work the invention may be used as a ground for grant of compulsory license. Moreover, the Controller referred to Article 2(1) of the TRIPS Agreement under which member countries are required to comply with provisions of the Paris Convention. Furthermore, the Controller referred to Section 83(b) of the Patents Act 1970 (India) which stipulates that: 'they (patents) are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article'.[71] Applying the rationale of Section 83(b), the Controller concluded that working of the invention in India meant manufacturing of the patented product in India and not mere its importation in India. Bayer had, therefore, failed to comply with Section 84(1)(c) of the Indian Patent Act 1970.[72]

The grant of compulsory license was, however, subject to certain conditions. Firstly, Natco was required to pay a 6% royalty to Bayer on net sales of Sorafenib manufactured under the compulsory license. Secondly, Natco was not allowed to charge more than Rs.8800 for a month's therapy.[73] Thirdly, Natco was required to manufacture the drug

---

Drug Companies', (last accessed date 4 June 2012), doi:http://www.whitecase.com/alerts-04022012/.

69 Betsy Vinolia Rajasingh, *op.cit.*, (last accessed date 20 April 2012), doi:http://jiplp.blogspot.com/2012/05/indias-first-compulsory-licence-over.html.

70 Bijal V. Vakil, 'Indian Patent Office Grants Compulsory License for Bayer's Nexavar: Implications for Multinational Drug Companies', 2012.

71 Full text of Section 83(b) of the Patents Act 1970 (India) is available online at doi:http://indiankanoon.org/doc/471445/, (last accessed date 9 June 2012).

72 Bijal V. Vakil, *op.cit.*

73 Patralekha Chatterjee, 'India's Generics-Big Pharma Battle Drops Drug Prices, Raises Legal Debate', (last accessed date 4 June 2012), doi:http://www.ip-watch.org/2012/05/20/india%E2%80%99s-generics-big-pharma-battle-drops-drug-prices-raises-legal-debate/.

at its own manufacturing facility. Fourthly, the generic version of the drug could only be sold within territory of India and Natco was not allowed to export the drug.[74] Fifthly, the generic version must have a distinct physical appearance, trade name, and packaging.[75] Moreover, Natco Pharma committed to donate the drug free of cost to six hundred needy patients every year. The Controller also recorded this commitment in the order for the grant of compulsory license.[76]

The Controller's decision, which brought down the costs Sorafenib by 97 percent, was appreciated by many, especially cancer patients, human rights activists and advocates of cheaper drugs, who believe that it would bring relief, hope and cheer for helpless cancer patients[77] in India who – in the absence of any form of health insurance- were unable to afford the excessively expensive therapy otherwise.[78] The price set by the patentee could be afforded only by richest patients in India and importation of a very negligible quantity of the drug was testimony to this fact.[79]

Supporters of the ruling believed that this bold decision would check abuse of patent rights and put pressure on other brand name pharmaceutical companies to rethink and revise prices of their products. Soon after this judgment, Roche Holding, a Swiss drug maker, announced that it will cut price on two of its cancer drugs, Herceptin and Mabthera,[80] and partnered with an Indian pharmaceutical company

---

74 Particia Van Arnum, *op.cit.*

75 Jose Madan, *op.cit*.

76 Breaking News: 'India's First Compulsory License Granted*', op.cit*.

77 Government surveys have shown that 65 per cent of the 1.1 billion population of India falls into debt as result of 'out-of-pocket' healthcare spending, (last accessed date 4 June 2012), doi:http://ipsnews.net/news.asp?idnews=107126.

78 Rajasingh, 'India's first compulsory license over Bayer's patent', (2012), (last accessed date 20 April 2012), doi:http://jiplp.blogspot.com/2012/05/indias-first-compulsory-licence-over.html.

79 Brook Baker, 'Bayer Appeals Indian Compulsory License for Nexar', 2012, (last accessed date 4 June 2012), doi: http://infojustice.org/archives/20207.

80 Marie Daghlian, 'US Protests India's Compulsory License for Nexavar', (last accessed date 4 June 2012), doi:http://www.burrillreport.com/articleus_protests_india%E2%80%99s_compulsory_license_for_nexavar.html.

Emcure Pharmaceuticals to repackage and sell the same under different brand names only in the Indian markets.[81]

Conclusion

Patents cause overpricing of patented products as a result of monopoly rights provided to patent owner for a period of twenty years. Despite this fact patents have been accepted globally as a necessary evil because patents provide incentive to innovators to further innovate. In case of pharmaceutical patents, monopoly rights enjoyed by patent owners have serious human rights implications because the price set by the patent owner to maximize their profits may be unaffordable for patients especially in the third world countries where purchasing power of general masses is low.

Compulsory licensing has been provided under TRIPS Agreement as a safeguard to make sure that monopoly rights are not abused by patent owners especially in cases of public health crisis. Compulsory licensing is condemned by advanced countries and multinational companies because use of compulsory licensing reduces their profits. Compulsory licensing is a violation of the rights of the patent holder. But in certain cases where human lives are at risk owing to unaffordability of needed drugs, it may not be possible to fully protect corporate interests of multinational companies.

[81] Bayer challenges 'compulsory license' ruling, for detail see, (last accessed date 20 April 2012), doi:http://health.india.com/news/bayer-challenges-compulsory-license-ruling/.