REKINDLING THE ACCESS DEBATE: THE SEARCH FOR THE PERFECT ANSWER CONTINUES

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INTRODUCTION

The debate between access and patent protection is nothing new to academia. For a couple of decades now, there has been a raging quest to find an answer that ends the debate once and for all. A mere search on any academic repository will reveal that hundreds of scholarly articles and have been written on this topic, beginning from as early as 1869.[1] And the irony is that the debate still continues. If analogy were to be used, an unending quest continues to find the equivalent of Hansmann and Kraakmann's "end of history for corporate law". This paper is yet another attempt towards resolving this debate. To do justice to the question involved, the authors believe that there is a need to understand the ambit of patent rights from scratch, explore its philosophical considerations, and then move on to the possible answers. This paper is an effort in this direction.

Patents are a governmental grant of a right, authority or privilege.[2] It is a right that denies to every other person, the use of the know-how protected by patent without the consent of the inventor, irrespective of the purpose of such usage. It is a negative right that denies access and maximizes the patent holder's gains, in addition aiding in recovery of costs associated with invention, specifically, research and development ("R&D") costs which often run into millions of dollars. Over centuries, the system of patents has yielded enormous benefits for humanity by incentivizing invention and promoting technological enhancement, effectively resulting in vast improvements in the quality of life. However, not every aspect of this right is beneficial for all.

The difficulty arises predominantly in respect of pharmaceutical products, particularly, life-saving drugs. These drugs, often very expensive due to the high costs of development, are beyond the reach of most patients. As such, despite the relevant drugs being available, patients languish and die for want of proper medication. The problem, thus, is one of access. For instance, with the advent of Sorafenib (marketed as Nexavar), it is possible to extend the life of patients suffering

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[1]Robert Andrew Macfie, *Recent Discussions on the Abolition of Patents for Invention in the United Kingdom, France, Germany, and the Netherlands* (Sir William Armstrong ed., Longmans, Green, Reader and Dyer, 1969)v-vi.

[2]Bryan A. Garner, *Black's Law Dictionary* (8th ed. 2008)1234.

from Hepatocellular Carcinoma and Renal Cell Caricoma (a type of liver and kidney cancer respectively) by a couple of years. Yet, less than 2 percent of the eligible patients in India can access this drug. This is a direct consequence of the high cost of monthly therapy, which exceeds the gross per capita income of Indians for 2010 by almost five times.[3]The law, however, is not without remedy. Using the provision for compulsory license under Article 31(f) of the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS"), India has brought down the cost of monthly dosage of Sorafenib to Rs. 8880.[4]

PATENT PROTECTION AND ACCESS: CAN THE TWO RECONCILE?

The contemporary patent regime does not recognize access as a 'right'. At most, it recognizes access as a 'privilege' to the public, which, as per Hohfeld's matrices, does not confer any 'right' on them.[5] However, as is evident from the works of Locke, Kant and Rawls, whose theories form the very basis of law relating to intellectual property, access to life saving drugs is in-fact a 'right' to the public at large entailing a corresponding 'duty' on patent holders as per Hohfeld's matrices.[6] The philosophical basis for the same is discussed below:

LOCKE'S THEORY OF APPROPRIATION AND THE CHARITY PROVISO

The Earth, as per Locke, is a gift given to mankind by god.[7] This gift is to human beings collectively rather than to individuals specifically.[8] The only way one can appropriate resources from the commons is to work or labour on it: no one has a superior claim on it, and anyone can labour on it, for the public domain is an egalitarian resource.[9] In other words, common ownership is the default state; individual appropriation comes through effort, which is required to alter the default condition. In the case of intellectual property also, this theory holds good. All intellectual creations draw from the public domain, which is analogous to the

[3]"The monthly dosage of Sorafenib costs Rs. 280,000, and the Indian Gross National Income per capita is Rs. 60,455." *NatcoPharma Ltd. v. Bayer Corporation* 25-26 (March 12, 2012) (India), available at <http://www.ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf.> (hereinafter Natco).

[4]*ibid*60.

[5]Wesley Newcomb Hohfeld, 'Some Fundamental Legal Conceptions as Applied in Judicial Reasoning.'(1913)23(1) YALE L.J 16, 30.

[6]ibid.

[7]John Locke, *Two Treatises of Government- Second Treatise* (first published 1690,Cambridge Univ. Press, 1988)286 (hereinafter *Second Treatise*).

[8]*ibid.see also* Peter C. Myers, 'Between Divine and Human Sovereignty: The State of Nature and the Basis of Locke's Political Thought', (1995)27(4) POLITY 629.

[9]*Second Treatise*(n 7)288.

state of nature the Appropriation theory.[10] No single person has a superior claim over it. With the addition of labour, materials sourced from the public domain gets transformed into Intellectual Property (*hereinafter* "IP").[11]

This theory is not absolute, and is constrained by three provisos given by Locke himself. The relevant limitation for the present study comes through the charity proviso. Locke's main passage on charity can be found in his First Treatise:

> *God the Lord and Father of all, has given no one of his Children such a property, in his peculiar Portion of the things of this world, but that he has given his needy brother a right to the Surplus of his Goods; so that it cannot be justly denied him, when his pressing Wants call for it. And therefore no Man could ever have a just Power over the life of another, by right of property in Land or Possessionis; since it would always be a Sin in any Man of Estate, to let his brother perish for want of affording him relief out of his plenty.*[12]

In this passage, Locke makes two indispensable observations: 1) property does not confer the right to deny relief to those in pressing want; and 2) people in desperate need have an actual, binding right to the assets held by lawful owners. In essence, he argues that charity gives every man a legitimate title to so much out of another's plenty, as will keep him from extreme want. Even in the state of nature, before civil society was established, this proviso embodied the foundational idea that all property was given by god for the maintenance, development and preservation of the human race.[13]

This proviso is of particular relevance in the debate between access and patent protection. It tilts the balance in favour of access by granting a legitimate title over life-saving drug(s) to patients suffering from the corresponding curable life threatening diseases, insofar as the same is necessary for curing or mitigating the effects of their disease. The justification is simple: no property owner has the harsh power over life and death.[14]

KANT'S UNIVERSAL PRINCIPLE OF RIGHT

Like other contemporary philosophers of his era, Kant also recognized the concept of property. This concept, he said, originated in a deep and abiding sense of 'mine' and

[10]Robert P. Merges, *Justifying Intellectual Property* (Harvard University Press, 2011) 36(hereinafter *Merges*).
[11]See Andrew R. Sommer, 'Trouble on the Commons: A Lockean Justification for Patent Law', (2005)87 J. PAT. & TRADEMARK OFF. SOC'Y 141.
[12]John Locke, *Two Treatises of Government- First treatise* (Peter Laslett ed., Cambridge Univ. Press, 1988) 170 (hereinafter *First Treatise*).
[13]Carol Rose, 'Canons of Property Talk, or Blackstone's Anxiety', (1998)108 YALE L.J. 601, 608.
[14]*ibid*605.

'yours'.[15] Although he contended that the right to property was widely available, he curtailed its ambit by arguing that when individual appropriation interferes with the rights of others, this right must give way.[16] Thus, despite being necessary for promotion of autonomy and self-development, the right to hold individual property was restricted.[17] The restriction that Kant was referring to was his Universal Principle of Right, about which, he said:

> *Every action is right if it can coexist with everyone's freedom in accordance with a universal law, or if on its maxim the freedom of choice of each can coexist with everyone's freedom in accordance with a universal law.*[18]

Freedom of choice is supreme. Death being the ultimate restriction on autonomy, there can be no freedom of choice once a person dies. The endeavour, to preserve his freedom of choice, should be to ensure that he lives to exercise this freedom. So, when an exclusive claim to a certain property by a person leads to the death of another, his claim is liable to be rejected in light of Kant's Universal Principle.[19] Similarly, the conflict between protection of patent rights and guaranteeing access will necessarily turn on the effect of the patent on the freedom of those suffering from treatable, life-threatening diseases. Giving precedence to patent rights constrains the freedom of patients in such a way that patent rights in life-saving drugs must necessarily give way.

RAWLSIAN PRINCIPLES OF JUSTICE

Rawls recognized the concept of property insofar as he believed that each person should have an equal right to the system of basic liberties compatible with a similar system of liberty for all.[20] This system of basic liberties included, among others, the right to hold some property.[21] He complemented this by arguing that social and economic inequalities should be arranged such that they are both to the greatest benefit of the least advantaged, consistent with the just savings principle.[22] Also referred to as the "difference principle", this serves as a criterion by which permissible differences in the resources available to people in a given society can be

[15]Immanuel Kant, *The Critique of Practical Reason*(Mary Gregor ed., Cambridge Univ. Press 1997) 15 (hereinafter *Kant*).

[16]B. Sharon Byrd & Joachim Hruschka, 'The Natural Law Duty to Recognize Private Law Ownership: Kant's Theory of Property in his Doctrine of Right', (2006) 56 U. TOR. L.J. 217, 219 (hereinafter *Bryd&Hruschka*).

[17]*ibid*221.

[18]*Kant*(n 15) 387.

[19]*Merges*(n 10) 276.

[20]John Rawls, *A Theory of Justice*(Harvard University Press, 1971)302 (hereinafter *Rawls*); *see* Thomas Pogge, *John Rawls: His Life and Thought* (Oxford University Press, 2007) 188.

[21]*ibid*61.

[22]ibid302; *see* Roger Paden, 'Rawls' Just Savings Principle and the Sense of Justice', (1997) 23 SOC. THEORY &PRACT. 27.

measured.[23]

According to him, property is not a 'primary good'; it is a secondary good that occupies a lower level of priority.[24] Primary goods include basic rights, liberties and opportunities, income and wealth, and health and vigour.[25]Given that property is a secondary good, property rights must give way if they gravely threaten someone's very survival. When viewed in proper perspective, it appears that Rawls had a problem similar to the patent vs. access question in his mind when he constructed this system.[26] Even when viewed in the light of his "difference principle", which follows the path of distributive justice to achieve the goal of reallocation, the outcome is unambiguous: Rawls, just like Locke and Kant believes that right to life will take precedence over patent rights.

ENSURING ACCESS TO MEDICINES: THE MIDDLE PATH

When a society grants patent, it benefits from the enrichment of existing knowledge, which propels socio-economic growth, and can be used to invent further and improve the quality of life. This system encourages inventors to disclose their inventions to the public rather than maintaining them as trade secrets. As highlighted in the preceding chapter, patent is a negative right, which provides the patent owner with the legal means to prevent others from making, using, or selling the new invention for a limited period of time, subject to a number of exceptions. Compulsory licensing is one such exception.[27] Another exception exists in the form of parallel imports.[28] They have been discussed in detail below:

COMPULSORY LICENSING- THE SMARTEST WAY OUT?

A compulsory license is license granted by national authorities to companies or individuals other than the patent owner to use the rights of the patent, viz. to make, use, sell or import a product under patent (i.e. a patented product or a product made by a patented process) without the permission of the patent owner.[29] It is one of the flexibilities on patent protection included in the WTO's agreement on intellectual property, the TRIPS (Trade-Related Aspects of Intellectual Property Rights)

[23]JohnRawls, *Justice As Fairness: A Restatement* (Belknap Press of Harvard University, 2001) 43 (hereinafter *Justice as Fairness*).

[24]*Rawls*(n 20) 54.

[25]*ibid* 62.

[26]*Merges*(n 10) 277.

[27]WTO, Philosophy: 'TRIPS Attempts to Strike a Balance'<http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm01_e.htm> accessed15 August 2012.

[28]WTO, Fact Sheet: 'TRIPS and Pharmaceutical Patents- Obligations and Exceptions'<http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm> accessed 17 August 2012.

[29]WTO Glossary, 'Compulsory Licensing' <http://www.wto.org/english/thewto_e/glossary_e/compulsory_licensing_e.htm>accessed 17 August 2012.

Agreement.[30] It is permitted, however, subject to compliance with certain procedure and conditions, provided for in Article 31 of the TRIPS.

CONDITIONS FOR GRANT OF COMPULSORY LICENSE

The Doha Declaration on the TRIPS Agreement and Public Health (*Hereinafter* referred to as Doha Declaration), which recognized the needs of members to take measures to protect public health, affirmed that the TRIPS can be interpreted in a manner consistent with the members' right to protect public health, and ensure access of medicines to all.[31] To meet these ends, the Declaration conferred the right on national governments to grant compulsory licenses, and have the freedom to determine the grounds upon which such licenses are to be granted.[32] Before a compulsory license can be granted, certain basic conditions have to be fulfilled. These conditions are explained below:

1. Before such a license can be granted, the person applying for the license must have attempted to obtain a voluntary licensee from the patentee on reasonable commercial terms, and such efforts must have failed within a reasonable period.[33] In case of national emergencies, other circumstances of extreme urgency, public non-commercial use or anti-competitive practices, Article 31 waives this requirement.[34] The Doha Declaration specifically makes it clear that members have the right to determine what constitutes a national emergency or other circumstance of extreme urgency. For brevity, it clarified that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.[35]

2. Even when a compulsory license is granted, the patent owner is entitled to receive adequate remuneration, keeping in mind the economic value of the authorization.[36] However, there is no procedure for fixing the 'amount' of remuneration, and as such, it is open for the concerned government to decide the same.[37] However, the Patent owner has a right to judicial review or other independent review by a higher authority in the member country in respect of

[30]WTO, 'Compulsory Licensing of Pharmaceuticals andTRIPS',<http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm>accessed 12 August 2012 (hereinafter *Compulsory Licensing of Pharmaceuticals and TRIPS*).

[31]Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 20 November 2001, Para. 4. (hereinafter *Doha Declaration*).

[32]*Ibid*Para.5(b).

[33]Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 31(b) (1994). (hereinafter *TRIPS*).

[34]*Compulsory Licensing of Pharmaceuticals and TRIPS*(n 30).

[35]*Doha Declaration* (n 31) Para.5(c).

[36]*TRIPS*(n 33) Article 31(h).

[37]*Compulsory Licensing of Pharmaceuticals and TRIPS*(n 30).

the remuneration offered.[38]

3. The grant of a compulsory license is without prejudice to the right of the Patent owner to produce, i.e., the use by the licensee of the patent shall be non-exclusive.[39] Also, the decision concerning grant of compulsory license is open to judicial review or other independent review on grounds of legal validity by a higher authority in the member country.[40]

The TRIPS Agreement, under Article 7 recognizes the need for using intellectual property rights to the mutual advantage of producers and users of the technological knowledge, so as to achieve social and economic welfare.[41] Article 8 further recognizes the right of members to adopt measures necessary to protect public health and nutrition, and for socio-economic and technological development.[42] In line with this philosophy, compulsory licensing gives precedence to public health over private patent rights, and promotes the use of inbuilt WTO safeguards to increase access to medicines. The Doha Declaration, which was issued at the behest of the African group also emphasizes on this aspect.[43] In the next section, the authors will discuss how compulsory licensing can be used to make medicines more accessible, building on the recent case of *NatcoPharma Limited v. Bayer Corporation*.[44]

COMPULSORY LICENSING IN INDIA: THE NEXAVAR SOLUTION

NatcoPharma's case is the first ever case of compulsory licensing in India. This case concerned a drug invented by Bayer Corporation, Sorafenib (Carboxy Substituted DiphenylUreas), marketed as Nexavar used for the treatment of advanced stages of hepatocellular carcinoma (a type of liver cancer) and renal cell carcinoma (a type of kidney cancer), as highlighted in the introductory chapter.[45] This drug received FDA approval in 2005, and was launched in the world market in 2006. Despite having filed the patent application in India in 2000, the drug was not launched in India until 2009. When it was finally launched, the quantity imported was sufficient to meet only 2 percent of the demand, based on Bayer's own statistics: while the demand for Nexavar was anywhere between 27,000 boxes to 70,000 boxes, the supply was less

[38] *TRIPS* (n 33) Article 31(j).
[39] *ibid* Article 31(d).
[40] *ibid* Article 31(l).
[41] *ibid* Article 7.
[42] *ibid* Article 8.
[43] WTO, 'TRIPS and Pharmaceutical Patents: Obligations and Exceptions'<http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm>accessed 26 July 2012. (Hereinafter *TRIPS and Pharmaceutical Patents*).
[44] *Natco*(n 3).
[45] US FDA, 'Highlights of Prescribing Information- Nexavar'<http://www.accessdata.fda.gov/drugsatfda_docs/label/2007/021923s004s005s006s007lbl.pdf>accessed 28 August 2012.

than 680 boxes.[46] This supply-deficit was a ground for granting compulsory license under s. 84(7)(a)(ii) r/w s. 84(1)(a) of the Patents Act, 1970 as Bayer was unable to meet the demand for the patented product to an adequate extent or on reasonable terms.[47]

Further, even at the limited supply, Bayer priced the monthly therapy of the drug at Rs. 280,428.[48] In a country where a family having a monthly income of Rs. 4805 in urban areas, and Rs. 3924 in rural areas is deemed to be above the poverty line, such pricing can push the affected population into poverty.[49] Given the position of monopoly that Bayer enjoys, this constitutes an abuse of its dominant position. As most people were unable to buy the drug due to its out-of-reach pricing, the invention was not available to the public at a 'reasonably affordable price'. Being in violation of s. 84(1) (b) of the Patents Act, this was a ground for a grant of compulsory license.[50]

Moreover, as the drug was merely imported, and not 'manufactured' in India, the invention was not 'being worked' in the territory of India. This was yet another ground for granting compulsory license as the scheme of s. 84(1)(c) r/w s. 83(c) and (f) r/w s. 84(6)(ii) envisages that 'worked in the territory of India' means, to a reasonable extent, 'manufactured to some extent in the territory of India'.[51]

NatcoPharma made an application before the Controller General of Patents, Designs and Trademarks, requesting him to grant a compulsory license to Natco to manufacture Nexavar. Keeping in mind the aggravating circumstances highlighted above, the Controller General granted a compulsory license to Natco to manufacture Nexavar. Under the terms of the compulsory license, Natco was authorised to sell the drug at Rs.8880 for a pack of 120 tablets, and to compensate Bayer for the costs of drug development, Natco was directed to pay 6 % of the net sales of the drug to Bayer as royalty.[52] Nonetheless, it must be noted that in line with the Doha Declaration, this order is liable to be judicially reviewed,[53] particularly given that it ceases to be a speaking order on the issue of determination of royalty rates.[54]

[46] *Natco*(n 3) 21-22.
[47] *Ibid*23-24.
[48] *Ibid*6.
[49] *ibid* 25.
[50] *ibid* 36.
[51] *ibid* 44-45.
[52] *ibid* 61.
[53] *TRIPS*(n 33) Article 31(j).
[54] *Natco*(n 3) 58-60.

IMPORTING UNDER COMPULSORY LICENSING: INCREASING ACCESS

Although compulsory licensing is an effective means to increase access to medicines, it is workable only when the WTO member country has the means to manufacture generic forms of the drug. Many countries sought to import these generic forms, but under an uncertain legal regime, it was difficult to find a willing exporter.[55] Article 31(f) of TRIPS was ambiguous, insofar as it stated that drugs made under compulsory licensing must be "predominantly for the supply of the domestic market".[56]

This ambiguity was resolved by General Council in its Decision on the Implementation of Paragraph 6 of the Doha Declaration.[57] This decision embraced the need for increasing access to medicines, and allowed members to import generic varieties of drugs, if they were unable to manufacture the same themselves.[58] Exporting countries are, in exchange, waived from the requirements of Article 31(f) of TRIPS.[59] However, to protect the rights of patent owners, this decision mandates the exercise of certain safety measures. Exporting countries, for instance, must export only in the quantities required in the importing country, and the drugs such imported must be clearly identifiable as being exported under this system by way of specific packaging.[60] On the other hand, the importing country must, in all capacity, take all measures reasonable to prevent the re-exportation of the products imported under this system.[61] Other members have the obligation to prevent the importation of such materials into their territory, if they are not designated for its territory.[62] Also, the liability to pay remuneration to the patent holder under TRIPS Article 31(h) is on the exporting country alone.[63]

PARALLEL IMPORTS: GOING BEYOND COMPULSORY LICENSING

Parallel or grey import is a situation when a product made legally (i.e. not pirated) abroad is imported without the permission of the intellectual property right-holder (e.g. the trademark or patent owner).[64] They are widely used to prevent market

[55] *Doha Declaration* (n 31) Para. 6.
[56] *TRIPS and Pharmaceutical Patents* (n 43).
[57] WTO General Council Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 and Corr.1 (30 August 2003).
[58] *ibid* Para. 2(a)(ii).
[59] *Ibid* Para.6(I).
[60] *ibid* Para. 2(b)(ii).
[61] *ibid* Para. 4.
[62] *ibid* Para. 5.
[63] *ibid* Para. 3.
[64] WTO Glossary, 'Parallel Imports' <http://www.wto.org/english/thewto_e/glossary_e/parallel_imports_e.htm>accessed20August 2012.

division and price discrimination on a regional or international scale.[65]

The principle behind parallel imports is "exhaustion", which is the idea that once a company has sold a batch of its product, its patent rights are exhausted on that batch and it no longer has any rights over what happens to that batch.[66] This is because the patent holder has been remunerated through the first sale of the product and his further control over the resale of the product would unreasonably restrain trade and stifle competition.[67] Under parallel import, a distributor obtains a product in a low price country and transports it to an unauthorized distributor in a high-price country, who competes directly with the patent holder or the authorized distributor in the country.[68] This scheme is indirectly endorsed by the TRIPS regime, which provides under Article 6 that "*For the purposes of dispute settlement.....nothing in this agreement shall be used to address the issue of the exhaustion of intellectual property rights.*" This provision has been clarified in Doha Declaration to imply that WTO Members are free to choose their own regime of exhaustion of rights without challenge.[69]

PARALLEL IMPORTS IN INDIA

The concept of parallel imports was first introduced in India by Section 107A (b) of the Patents Act, 1970, as amended in 2002. It provided for parallel imports of products patented in India, provided the importer was duly authorized under the law by the patentee to sell or distribute the product. It required the foreign exporter to be endorsed by the patentee to sell and share out the product. So, the fundamental logic on which the law proceeded was the consent of the patentee. With the 2005 amendment to the Patents Act, the law relating to parallel imports has changed drastically.

From being based on the consent of the patentee, the law has been amended to allow parallel imports when the importer is one 'who is duly authorized under the law to produce and sell or distribute the product.' The effect of this amendment is that the capacity for governmental intervention is now predominant. Additionally, the financial revenues of pharmaceutical firms will suffer as the effect of the provision is to allow sale of generic products without the consent of the patent-holder.[70] Hence, in spite of permitting access to drugs, the effect of the amendment in the long run

[65]Elizabeth Verkey, *Law of Patents* (2nd edn, Eastern Book Company,2012) 569.

[66]*TRIPS and Pharmaceutical Patents* (n 43).

[67]ibid.

[68]Barfield Claude E. &Groombridge Mark A., 'Parallel trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare and Health Policy', (1999)10 FORDHAM INTELL. PROP. MEDIA &ENT. L.J. 185

[69]"The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge." *Doha Declaration* (n 31) Para.5(d).

[70]ArghyaSengupta, 'Parallel Imports in the Pharmaceutical Sector: Must India be More Liberal?', (2007)12 J. INTELL. PROP. RTS.400, 406.

appears gloomy. The research and development capabilities of domestic firms will be gradually truncated, leading to an extreme reliance on imports and generics.[71] Further, as this provision does not contemplate an exhaustion of rights but merely allows imports into India if they are authorized under the law of the exporting country, it may fall foul of Article 6 of the TRIPS Agreement r/w Article 5(d) of the Doha Declaration.[72]

Therefore, to mitigate the damage, it is recommended that in accordance with Locke's Charity Proviso,[73] Kant's Universal Principle of Right,[74] and Rawls' Principles of Distributive Justice,[75] parallel imports should be permitted in case of life-saving drugs alone. For all other drugs, it is advisable to stick to the scheme prevailing before the 2005 Amendment, i.e., subject to the consent of the patentee.

CONCLUSION

The objective of this article was to determine if the economic rights of patent holders can be reconciled with the public's right to access in the event of life-threatening diseases. It involved finding if the right to access at all exists in such cases and if yes, what are the modalities with which, the interests of the various stakeholders can be balanced?

After embarking on a thorough examination of all viewpoints, the authors conclude that in situations where the very existence of an individual is at threat, there does exist a definite right to access, which takes precedence over the patent rights of the individual intellectual-property owners. At the same time, it must also be borne in mind that the rights of patent holders must be respected and protected. The need of the hour, in such circumstances, is to strike a delicate balance between these ostensibly warring objectives. Compulsory licensing and parallel imports are two means by which this can be done. However, given the stakes at play, we should be mindful of not making one right subservient to the other. The grant of a compulsory license to NatcoPharma to manufacture a generic version of Sorafenib was not necessarily a move in this direction.

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[71] *ibid.*

[72] ShamnadBasheer, 'India's Tryst with TRIPS: The Patents (Amendment) Act, 2005', (2005)1 INDIAN J. L. & TECH. 30, 31.

[73] "God the Lord and Father of all, has given no one of his Children such a property, in his peculiar Portion of the things of this world, but that he has given his needy brother a right to the Surplusage of his Goods; so that it cannot be justly denied him, when his pressing Wants call for it. And therefore no Man could ever have a just Power over the life of another." *First Treatise*(n 12).

[74] "Laws secure our right to external freedom of choice to the extent that this freedom is compatible with everyone else's freedom of choice under a universal law." *Byrd &Hruschka*(n 16) 219-221.

[75] "Property is a secondary good; rights and liberties, powers and opportunities, income and wealth are primary goods and there is little doubt that property rights must give way in the face of a claim in which someone's survival is threatened." *Justice as Fairness*(n 23).

One of the grounds on which this compulsory licence was granted was that Bayer 'failed to work the invention' in the territory of India and thereby, violated Section 84(1)(c) of the Patents Act as it did not manufacture the drug in India. This interpretation, although innovative, comes with a substantial cost. More than 90 percent of the drugs marketed in India are not manufactured locally, and hence, are susceptible to compulsory licensing.[76] This impending fear can drive existing pharmaceutical companies out of India, in addition to discouraging the introduction of new drugs in the Indian market.

Another contentious issue is the determination of royalty rates. The viewpoint taken by the Controller General of Patents, Designs and Trademarks was that Section 87(1) of the Patents Act did not envisage a hearing for the patentee while passing an order concerning royalty rates further increases the threat-perception of pharmaceutical companies: compulsory license coupled with a low rate of royalty can stifle invention.

The overriding fact that has to be kept in mind is that pharmaceutical R&D is enormously expensive. Patent Protection can in many ways be argued provides the incentive to create and produce marketable drugs. Therefore, the need is to draw an equitable balance between protecting the interest of the innovators and the general public good of ensuring access. The answer probably does not and cannot be a straightjacket one. The Government has to ensure that the usage of Compulsory Licensing and Parallel Imports remain exceptional such as in cases of national emergency or in cases of life-threatening diseases. Generally efforts should be made to convince and take the consent of patent holder as access aspirations should not happen at the cost of owners of intellectual property. Efforts should be made to enforce stricter standards itself at the very stage of granting of patents. And in all endeavours, a balance must be maintained between the interests of all stakeholders.

[76]Shamnad Basheer, 'A Life Saver'*The Indian Express* (New Delhi, 15 March 2012) <http://www.indianexpress.com/news/a-life-saver/923764/> accessed 11 September 2012.