A RE-LOOK INTO COMPULSORY LICENSING: AFTER NATCO V. BAYER

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I. Introduction

Patent is a legal right granted to an inventor as a reward for disclosing his invention. It is the right of the owner to exclude others from making, selling, importing, or using the product or process without his authorization for a fixed period of time.[1] It is a lawfully gained monopoly right which is justified because the patent holder makes his invention available to the public. If he does not, it will amount to an abuse of the monopoly power granted to him. Abuse can be by way of refusing to grant licences, imposing unreasonable terms on the licensee or restrictive conditions on the use of patented articles or excessive pricing. The provision of compulsory licensing in the Law of Patents prevents such a situation. It is a legal method by which a Government grants either to itself or to a third party the right to produce or to import a patented product without authorization of the patent holder.[2] The object of compulsory licensing is to deter those who obtain patents but try to take advantage of their monopoly power as patent holders.

With TRIPS[3] bringing in a new era of enhanced patent protection, developing economies face difficulties in balancing the rights of patent holders with public needs. In India as well as internationally, the debate

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1 Eugene Maskus, Intellectual Property Rights in the Global Economy 36-37 (Institute for International Economics 1st ed.) (2000).

2 Frederick M. Abbot, Rudolf V. Van Puymbroeck, Compulsory Licensing for Public Health, A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision (World Bank Working Paper No. 61) (2005).

3 Agreement on Trade Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex IC, 33 ILM 1197 (1994) [hereinafter TRIPS].

over compulsory licensing gained momentum after the decision of the Controller of Patents, Mumbai in the case of *Natco* v. *Bayer*[4] on March 9, 2012. The decision allows Natco Pharmaceuticals Ltd, an Indian pharmaceutical company to manufacture and sell a generic version of a drug Nexavar, at a price which is nearly 30 times lower than what was charged by its patent holder Bayer Corporation, a German pharmaceutical company. This decision definitely makes an effort to make drugs more affordable but the question is whether it will discourage investments in future innovations. In this paper we seek to explore the history of compulsory licensing, the friction it creates between developed and developing countries, and further analyse whether the decision by the Controller of Patents is compliant with TRIPS while suggesting safeguards that need to be taken into account before authorizing a compulsory license.

II. Evolution of Compulsory License

The birth of the concept of compulsory license can be traced back to the UK Statute of Monopolies 1623[5] which disallowed monopolies which were mischievous to the state or hurt trade.[6] During that time patents were a tool to bring in foreign inventions into the local market and to boost local industries. Therefore the patent holder had to manufacture/work the invention locally in order to retain his patent rights.[7] This 'working obligation' was based on the idea that an invention to which the privilege of exclusivity is granted should be implemented in such a way that the society also benefits from it.[8] This would result in creation of employment and industrial and technological advancement.

But the later developed Paris Convention for the Protection of Industrial Property, 1883,[9] aimed to reduce the burden on patentees to set

4 Compulsory License Application No. 1 of 2011.

5 Statute of Monopolies, 1623, 21 Jam. 1, c. 3 (Eng.), in 1 STATUTES REVISED (BRITAIN) HENRY III TO JAMES II, 1253-1685.

6 Deli Yang, *Compulsory Licensing: For Better or For Worse, the Done Deal Lies in the Balance*, 17 Journal of Intellectual Property Rights, 76-81 (2012).

7 *Supra* note 5.

8 Hiroko Yamane, Interpreting TRIPS: Globalization of Intellectual Property Rights & Access to Medicines, HART Publishing, 2011.

9 Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, *revised* July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention], The Convention came into force in 1884 with 14 member states. It established principles

up manufacturing facilities in each and every country for getting a patent grant by doing away with the local working requirement. Subsequent amendments [10] to the Convention however brought in the concept of 'compulsory licensing' in case of failure to work the patent. The Hague Revision of the Paris Convention in 1925 introduced this concept. The most recent revision conference was held in 1967 in Stockholm which reaffirmed the concept of compulsory licensing. Thus the working obligation which was originally a condition for granting the patent became a ground for giving a compulsory license.

Presently, The TRIPS Agreement which was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade in 1994 is the most comprehensive international agreement on intellectual property. It sets the minimum standards for intellectual property protection which all member countries have to comply with. In many ways, it signifies a radical departure from earlier standards of patent protection. However in contrast to the Paris Convention, TRIPS does not mention the term compulsory license let alone deal with working requirements.

III. The Case

In India, the Patents Act, 1970 ensures that the monopoly granted to the patent holder does not just benefit him but also contribute to the promotion of technological innovation and the social and economic welfare of the country. It expressly recognises the concept of compulsory licensing under Section 84. Also, non working is an independent ground for granting a compulsory license in India.

In the case of *Natco* v. *Bayer*, [11] M/s. Bayer Corporation, an internationally renowned manufacturer of drugs invented a drug useful in the treatment of advanced stage liver and kidney cancer and obtained a

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and procedures of cooperation among contracting parties of the Paris Union in relation to industrial property such as patents, trademarks, trade names, industrial designs and geographical indications as well as the prevention of unfair trade practices. The Convention was designed to facilitate the ability of inventors of one Union member country to obtain protection in other member countries for their intellectual creations, in the form of industrial property rights.

10 The Paris Convention was subject to six subsequent revisions over the course of 115 years.

11 *Supra note* 4.

patent for it in India in the name Nexavar. This was sold at a very high price of Rs. 2,80,428 for a month's therapy. Natco Pharmaceuticals an Indian drug manufacturer filed an application for compulsory license under section 84 of the Patents Act in respect of the patent granted to Bayer and proposed to sell the drug at a much lower rate of Rs. 8800/-.

The main issue in this case was whether the requirements of Section 84 (1) upon which a compulsory license can be granted were satisfied. On an analysis we find that firstly, Section 84 (1) requires at least three years to have elapsed since the grant of the patent before the license can be applied for. This requirement was satisfied in this case.[12] Further Section 84 (1) of the Act sets out three grounds on which a compulsory license can be granted. These grounds are alternative grounds in the sense that satisfaction of a single ground alone would entitle the applicant to get a compulsory license. Section 84 (1) lays down that a compulsory license can be granted on *any one* of the following grounds *viz.* when the reasonable requirements of the public with respect to the patented invention have not been satisfied *or* when the patented invention is not available to the public at a reasonably affordable price *or* when the patented invention is not worked in the territory of India.

Section 84 (6) prescribes certain factors which have to be taken into account by the Controller while deciding the grant of the application. In this regard, the following circumstances will have to be considered. Firstly, the efforts taken by the patentee, the nature of the invention, the time elapsed since the grant of the patent, and the measures taken by the patentee to make full use of the invention are to be considered. Also, the ability of the applicant to work the invention must be reckoned. Lastly, it must be seen whether the applicant had made efforts to obtain a license directly from the patentee on reasonable conditions. In this regard, Natco had the necessary business experience in the market to work the invention and make it available to the public. Also, the negotiations for getting a license from Bayer to manufacture and sell the drug had failed.

On deciding whether the potential requirements under Article 84 (1) have been satisfied, the Controller, first looked into statistics regarding

12 Bayer had obtained the patent in 2007 by Patent Application No. 1633/MUMNP/2007, available at http://124.124.193.235/patentpublishedsearch/publishApplicationNumber.aspx?application_number=1633/MUMNP/2007.

the existing and projected demands. Only 2% of the affected population had access to the drug and the projected demands were also high. It was therefore concluded that the reasonable demands of the public with respect to the patented invention was not met.

On the subject of whether the price was affordable, Bayer had submitted that it incurs huge costs for developing new drugs. Further it contended that Nexavar has been granted an orphan drug status in various countries which means that it is a drug which treats a rare disease[13]. Another argument was that the drug price was similar to other oncology based drugs. More importantly, it strongly argued that as the inventor of the drug, having invested huge resources in developing the drug, it must have a say in determining the reasonable price of the patented invention. The Controller however reasoned that such high prices were one of the reasons affecting the availability of the drug. Thus the price affecting the availability, the Controller leaned in favour of the conclusion that the patented invention was not available to the public at a reasonably affordable price.

As regards the non working clause, it was submitted by Natco that since the product was imported into India it did not satisfy the working requirement in 84 (1) (c). Bayer however, brought to notice the fact that the phrase "manufactured in India" was specifically removed from the earlier Act through the amendment to Patent Act in 2002, in order to make it comply with Article 27 of TRIPS. Article 27 of TRIPS provides that all patent rights shall be enjoyable regardless of whether products are imported or locally manufactured. The Controller however observed that it was removed from 90 (a) in the earlier act in the context of requirements of public, but was made as a separate ground under Section 84 for granting compulsory licenses.

In support of this logic, the Controller looked into Section 90 (2) of the Act wherein it is mentioned that no license by the Controller can authorise the importation of a patented product. Using this provision, the Controller concluded that if a licensee cannot import products to satisfy the working condition, it is implied that importing cannot amount to working an invention by the patentee. Further, it was held that a reasonable fetter on the rights of patentees' by compulsory licensing mechanism does not

13 In the United States, Nexavar was granted an orphan drug status because less than two lakh patients met the indications which the drug treats.

violate the provisions of TRIPS. In fact, TRIPS does recognise such a mechanism under Article 30 which provides for limited exceptions to patent rights.

Apart from these provisions, the general principles in Section 83 also turned the decision in favour of the applicant. Section 83 (a) states that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale. 83 (b) clarifies that patents are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article. Section 83 (d) further states that patents should not impede protection of public health and nutrition.

With these in mind, the Controller finally issued the compulsory license in favour of Natco Pharmaceuticals. The license is non exclusive which would be valid till the patent for Nexavar ends in 2021, and the royalty was set at 6 % of total net sales payable by Natco to Bayer Corporation. It is worthwhile to mention here that though the Controller has granted the license on all three grounds under Section 84 (1), it would have sufficed if a single ground alone was satisfied. The huge controversy around the meaning of what amounts to working in India need not exert too much influence on compulsory licensing decisions, as high prices and public demands not being met can independently be a ground for issuing the license.

After this decision, U.S. condemned it calling it a dilution of the international patent regime as it violates TRIPS.[14] But in spite of the strong opposition by U.S, after this decision several developing countries are considering an amendment to their patent laws to include compulsory licensing.[15] India has thus set a trend which many countries could opt for in the future.In the next section, we would like to throw light on the divided opinions which countries have with regard to limitations on patent rights.

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14 Shamnad Basheer, *Compulsory Licensing,: Pot v Kettle* SPICY IP, http://spicyipindia.blogspot.in/2012/05/compulsory-licensing-pot-vs-kettle.html (last updated May 07, 2012) *Also see* C.H. Unnikrishnan, *US steps up lobbying efforts against compulsory license,* Livemint, http://www.livemint.com/2012/07/16203019/US-steps-up-lobbying-efforts-a.html (last updated Jul. 17, 2012).

15 Archana Shukla, *Developing world supports India's compulsory license policy*, CNBC TV18, http://www.moneycontrol.com/news/cnbc-tv18-comments/developing-world-supports-indias-compulsory-licence-policy_746844.html, (last updated Aug. 17, 2012).

VI. Developing and Developed Countries' Perspective

During the Uruguay Round negotiations for TRIPS in 1987, U.S. and other developed countries argued for strengthening of the Paris Convention so that importation would be considered as the working of patents. But developing countries opposed this view and criticized this as a restriction on compulsory licensing.[16]

TRIPS is however conveniently silent on the point. But generally speaking, the standards of patent protection set under TRIPS are more in line with the patent laws of developed nations.[17] The U.S. had enormous influence and considerable power in the world economy to bring nations to agree to such standards of patent protection. Particularly, the U.S. government had vast powers under Section 301 of the Trade Act, 1974.[18] This provision gave powers to the U.S. Government to authorize trade sanctions against countries with inadequate intellectual property protection as it would impose unjustifiable burdens on its commerce.[19] This threat of trade retaliation by the U.S Government against developing economies forced them to conform to the standards set out in TRIPS. Thus developing countries eventually agreed to move in towards stronger intellectual property enforcement.

Although all member nations have now more or less come to an agreement as to the minimum standards of patent protection to be complied with, developing countries often face problems relating to public health due to excessive pricing of patented pharmaceutical drugs. Hence, they seek to carve out an exception to patent rights which is strongly opposed by developed nations.

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16 *Supra* note 8.

17 F M Scherer and Jayashree Watal, *Post-Trips Options for Access to Patented Medicines in Developing Countries,* CMH Working Paper Series 1 (Nov. 20, 2001), http://www.icrier.org/pdf/jayawatal%20.pdf.

18 Popularly known as Special 301 provisions.

19 Alan O. Sykes, *Constructive unilateral threats in International Commercial Relations : The limited case for section 301*, 23 Law & Policy in International Business, Georgetown University Law Center 263-330 (1992).

The unrest is in the fact that the patents of developing countries are usually held by patentees' of developed economies.[20] While developing countries need flexibility in patent laws for increased access to technology and more importantly to meet public demands with respect to health and nutrition, developed countries try to protect their interest which is to profit from the patents obtained. A weak intellectual property regime in foreign countries would not serve their purpose as it would mean reduced returns. They fear that such provisions may discourage investments in future research and development or result in new inventions being kept as trade secrets. Thus an ideological divide regarding the measure of patent protection exists even after TRIPS.

Historically, the U.S. has aggressively opposed the use of compulsory licensing by countries.[21] Based on the past record of licensing, countries that elect to take licenses must demonstrate a willingness to endure lawsuits, pressure, and threats of trade sanctions from the U.S.[22] Notably the U.S. has opposed the compulsory licensing laws of Brazil, South Africa and most recently India.

Article 68 of Brazil's Industrial Property law allowed non manufacture of the product locally as a ground for issuing a compulsory license. This was opposed by the United States as a violation of Article 27 of TRIPS and announced its intentions to take up the matter before the WTO. However the two governments entered into a settlement due to political pressure[23]. In 1997, South Africa passed compulsory licensing laws in the wake of high pharmaceutical prices for addressing its growing HIV/AIDS epidemic. The United States responded by threatening the South African government with sanctions and exerting economic pressure on the country. However, it later gave into pressure from public interest groups and the matter never went before the WTO.

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20 Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals hurt Innovation?* , Berkeley Technology Law Journal, (2003).

21 Sara M. Ford, *Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patents*, 15 AM. U. INT'L L. REV 941, 953-54 (2000).

22 *Supra* note 20.

23 *See* Request for the Establishment of a Panel by the United States, Brazil- Measures Affecting Patent Protection, WT/DS199/3 (Jan 9, 2001), *See generally,* Paul Champ and Amir Attaran, *Patent Rights and Local Working under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute,* 27 THE YALE JOURNAL OF INTERNATIONAL LAW 365, (2002).

At this point, we would like to point out that although it is a common belief that developing countries are strong advocates for compulsory licensing, one can find such provisions even in the statutes of industrially advanced economies. In the United Kingdom compulsory licensing may be ordered if the demand for the patented product is not being met on reasonable terms or if the refusal to grant a licence prejudices the establishment or development of commercial or industrial activities. In Japan a license may be ordered if a patent is not worked for three years or where it is in public interest to do so. In Canada, a compulsory licence may be granted if three years after the grant the demand for the patented article is not being met to an adequate extent and on reasonable terms or the trade or industry of Canada is prejudiced and it is in public interest. In Germany, licensing can be ordered if it is in public interest or if it is necessary to ensure adequate supply of the patented product in the domestic market.

In the U.S., there is no legislation which sets out the various grounds on which a compulsory license can be issued. But the concept of compulsory licensing has been judicially endorsed. Although compulsory licensing is frequently resorted to as a remedy for antitrust violations, there have also been instances where compulsory licensing have been granted in public interest.[24]

Further, 28 U.S.C. § 1498[25] gives immunity to the U.S. Government to use patents without the permission of the patentee. The only remedy available to the patentee in such cases would be to claim for 'reasonable and entire compensation'. This effectively limits a patentee's remedy for infringement by the government or a government contractor to reasonable compensation and strips off the remedy by way of an injunctive relief. Additionally, there have been cases where injunctions are denied on the basis of overriding public interests. The power to grant injunctions can be decided in accordance with the principle of equity as per 35 U.S.C. § 283[26]

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24 *City of Milwaukee* v *Activated Sludge* 69 F.2d 577 (7th Cir. 1934), *Johnson & Johnson* v *Ciba Vision* 712 F. Supp. 2d 1285 (M.D. Florida 2010) wherein injunctions were not granted against the infringer due to public interests. *See generally* James Packard Love, *Recent examples of the use of compulsory licenses on patents*, http://keionline.org/content/view/41/1 (last updated Mar. 8, 2007).

25 United States Code Title 28- Judiciary and Judicial Procedure.

26 United States Code Title 35- Patents; 35 U.S.C. § 283- The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the

even in cases where the infringer is not a government entity. Equitable principles that traditionally govern the appropriateness of injunctive relief include within it considerations of public interest.[27] Therefore, it is not necessary that in all cases where infringement is proved, an order of injunction would automatically ensue. Money damages would be the sole remedy in such cases.[28] In effect, a de facto license would be issued in these cases.

Thus, developed countries including the U.S. which is known for opposing compulsory licensing provisions of other countries , have some mechanism or otherwise to deal with overriding public interests.

V. Compliance with Trips

As seen earlier, the decision of *Natco v. Bayer* created a furore in the International scenario as the United States alleged that it violated TRIPS. On this issue we would like to establish that the decision is in compliance with TRIPS.

Though TRIPS is still ambiguous on issues relating to compulsory licensing, leaving it open to interpretation, Article 30 and 31 of TRIPS do provide an exception to patent rights in a language implying compulsory licensing. Article 30 lays down that limited exceptions may be granted to the exercising of the rights of the patent holder if they do not unreasonably conflict with the normal exploitation of a patent or prejudice the legitimate interests of the patent holder taking into account the legitimate interests of third parties. This gives some leeway to member countries to allow the use of a patent without authorization from the patentee. Article 31 talks about certain aspects which need to be respected while member countries choose to adopt the right under Article 30. Firstly, prior negotiations with the patentee must have occurred and failed before an authorization to use the

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principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.

27 The four equitable factors that traditionally govern the appropriateness of injunctive relief: (1) whether the plaintiff will suffer irreparable harm if an injunction does not issue, (2) whether the plaintiff has an adequate remedy at law, (3) whether the balance of hardships tips in the plaintiff's favour and (4) whether an injunction is in the public interest as affirmed in *eBay Inc. v. Merc Exchange L.L.C* 126 S. Ct. 1837 (2006).

28 *Id.*

patent can be given.[29] Further the granting of right to use without authorization should be subject to judicial review by an independent higher authority. Also, unauthorized use must be non-exclusive, non-assignable, mainly for supply to the domestic market and reasonable remuneration is to be paid to the patentee.

Due to the broad and general nature of Article 30, controversies involving the Paris Convention and TRIPS arose after several countries incorporated local working requirements in their national laws. Some countries claimed that this requirement violates Article 27 of the TRIPS which provides that all patent rights shall be enjoyable irrespective of whether products are imported or locally manufactured.

The right given to the patentee under Article 27 is an obligation on all member nations not to curtail the rights of a patentee if the patented product is only imported and not locally produced. This is in direct contradiction to Article 5A (2) of the Paris Convention which recognised failure to work the patent locally as an independent ground for issuing a compulsory license thus allowing a discrimination on the basis of whether a product is locally manufactured or imported. Thus Article 5A (2) of Paris Convention allows what is prohibited by Article 27 of TRIPS. The importance of Article 5A (2) of the Paris Convention is that it is incorporated by reference into TRIPS by Article 2 of TRIPS which requires all Member nations to comply with Articles 1-12 and 19 of the Paris Convention.

It is also debatable whether Article 27 can override the rights of member nations under Article 30 which allows use of a patent without authorization of the patent holder. While some countries believe in Article 27 being absolute, others argue that it is subject to the exceptions under Article 30.

It cannot be easily concluded that Article 27 terminates the 'working obligation' which was originally an essential condition for grant of a patent. The language used in Article 27 is not clear enough to support such an unequivocal conclusion. Article 27 is a general right of a patentee to enjoy all his rights without any discrimination based on the place he

29 This condition may be waived in cases of extreme urgency and when the authorization is for public non commercial use.

chooses to manufacture the patent. Article 30 is however a specific exception to all general rights. According to established principles of legal construction when a general legal provision conflicts with a specific legal provision, the specific legal provision takes precedence.[30] Therefore Article 31 would take precedence over and derogate from Article 27.

Local working is one of the primary means by which transfer of technology can be achieved. This is one of the objectives of TRIPS as reflected in Article 7.[31] But there is no obligation on the patentee to work a patent locally as protection can be sought under Article 27. However, Article 27 must be interpreted in light of Article 7, the objectives and Article 8, the Principles of TRIPS. These provisions state that protection of intellectual property rights should ensure technological innovation and the transfer of technology and should be conducive to social and economic welfare so as to balance rights and obligations. Article 8[32] of TRIPS allows a member nation to prevent abuse of intellectual property rights by resorting to measures consistent with the provisions of TRIPS. An appropriate measure in the form of compulsory licensing when refusal to work the patent locally leads to an abuse of rights would thus be supportive of the purposes and objectives of TRIPS.[33]

Article 27 cannot be isolated from the rest of the TRIPS Agreement and be read alone. It has to be read along with the exceptions provided under Article 30, the objectives and principles contained in Article 7 and 8,

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30 *Lexspecialis derogate legigenerali.*

31 TRIPS art. 7, The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

32 TRIPS art. 8(1) Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. (2) Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

33 Paul Champ and Amir Attaran, *Patent Rights and Local Working under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute,* 27 THE YALE JOURNAL OF INTERNATIONAL LAW 365, 386-388, (2002).

and also Article 5A (2) of the Paris Convention which is incorporated into TRIPS by reference. Though there is a view that the TRIPS agreement prohibits the necessity of local working requirements, they are based on a narrow reading of the TRIPS agreement without regard for the document as a whole or its context.

Amidst this controversy surrounding the TRIPS and Paris Convention, the Doha Declaration[34] was tabled which confirmed the right of countries to issue compulsory licenses[35] and allowed member nations to take measures to protect public health and to promote access to medicines.[36] The legal status of the Declaration is however controversial since it is not a decision, but it contains an agreement among the members as to how the TRIPS should be interpreted. Nevertheless, it ensures a balance between the rights of Members to implement policies intended to safeguard public health and the rights of the patent holder. Once again, this is in tune with Article 8 (1) of TRIPS which provides that Members may adopt measures necessary to protect public health and nutrition provided that such measures are consistent with the other provisions of TRIPS.

In conclusion we see that though TRIPS does not expressly provide for compulsory licensing, reading it as a whole and in regard to the Paris Convention and the Doha Declaration, member countries may resort to use of the patent without authorization of the patent holder in certain cases. The decision in the case of Natco ensured that the drug is affordable and therefore is in tune with TRIPS and Doha Declaration to protect public health.

VI. Conclusion

Thus though TRIPS creates a strict intellectual property compliance, it does address the concern of developing nations to promote their public health. The principal opposition to the Natco decision from critics seems to stem from the fact that it violates Article 27. But critics fail to notice the fact that, even if Bayer had indeed set up a manufacturing unit in India, and Nexavar was locally produced, the astronomical rates charged

34 Declaration on the TRIPS Agreement and Public Health: WTO, Ministerial Conference, Fourth Session, WT/MIN(01)/DEC/2, November 14, 2001.

35 *Id* ¶ 5(b).

36 *Id* ¶ 6.

(at least in the context of the Indian economy) could alone be a ground for issuing a compulsory license.

Now, there is absolutely nothing in TRIPS to suggest that high prices and non availability of a patented product should not be a ground for issuing a license. While there is an Article 27 to part rebut local working requirements in national laws, there is no such thing which is against high prices being a ground for issuing a compulsory license. That is to say there is nothing in TRIPS which says patent rights shall be available irrespective of the cost at which the patented product is sold. The Doha declarations have in fact only strengthened the movement towards high prices being a ground for issuing compulsory licenses.

On a final note, it is impossible to harmonize world patent law under TRIPS without the mechanism of compulsory licensing. It could have been quite possible that when TRIPS was being negotiated, the provisions regarding compulsory license were made deliberately vague. This vagueness itself brings out the fact that there was no consensus among world nations regarding this issue. Thus we have only general guidelines, while each country is free to charter its own course for the substantial conditions upon which a license can be issued. If the international law in this regard within the TRIPS framework has to take shape, it is not possible without high prices and non availability being grounds for issuing a compulsory license. Presently, it is still the most practical way to prevent misuse of monopoly power granted by patents. In conclusion, "*One should not forget that patents represent an interventionist instrument, ultimately for the sake of community welfare. Thus intervention to restrict some of the effects of patents may be required, when the community welfare is no longer served.*[37]

37 Michael Kern, *Frequently asked questions about compulsory licenses,* http://www.cptech.org/ip/health/cl/faq.html (last updated Jan. 20, 1999).