NEXAVAR: THE FIRST MARKET-INITIATED COMPULSORY LICENCE

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This article looks at market-initiated compulsory licences issued under patent regimes, the first of which came into force with the grant of the Nexavar licence in India. By classifying the various types of compulsory licences, this article brings out the differences between government-use and market-initiated licences. I argue that market-initiated licences have many advantages over government-use compulsory licences. Although factors like overcoming capacity barriers of local manufacturers and legislative preparedness of the nation seeking to implement the licences are important for the grant of market-initiated compulsory licences, such licences, when granted, can regulate competition, address non-emergency situations like lack of affordability of life-saving drugs by reducing drug prices, facilitate local production and encourage the practice of price discrimination, while simultaneously resolving antitrust concerns that arise out of a refusal to licence by the patent owner.

I. INTRODUCTION

The grant of a compulsory licence on Bayer's patented drug, Nexavar, was the world's first compulsory licence in the real sense of the word.[1] This was the first time a market-initiated compulsory licence was granted by an Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement') compliant patent regime, licensing a patented drug for

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[1] *See* Natco Pharma v. Bayer Corpn. (*Nexavar Licence*) 38–39, Mumbai Patent Office, (2012) *available at* http://www.ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf (citing Bayer's argument that the quantities required in India do not economically justify setting up a manufacturing facility in India) (Last visited on September 19, 2016) ('Nexavar Licence') (describing it as India's first compulsory licence). An intellectual property licence is seen as a competitor's protection from an infringement suit. A government use compulsory licence is granted to an entity the government chooses in order to meet a health emergency. In contrast, a market initiated compulsory licence is made by a competitor who fails to seek the licence as a result of the refusal by the patent holder. If successful, the competitor will be protected from an infringement action by reason of the licence. Thus, market initiated compulsory licences compel the patent holder to licence the patent to the competitor and perform the traditional role of licences in offering immunity from an infringement suit.

a non-epidemic disease in the absence of a national emergency.[2] The Nexavar licence created a new category of market-initiated compulsory licences, which until its grant, existed only in principle.[3]

It was the first compulsory licence granted under the compulsory licensing regime that has existed for more than four decades.[4] Even before the compulsory licence was issued, Nexavar made news when Bayer, the makers of Nexavar (Sorafenib Tosylate), sued Cipla, an Indian generic pharmaceutical company.[5] Cipla, a company which uses proactive infringement[6] as a legal strategy, was selling the generic version of Sorafenib since April, 2010.[7] At the time when Cipla was sued, it was selling the generic version of Sorafenib at about INR 30,000 (USD 555) for a month's treatment, as opposed to INR 2,80,000 (USD 5200) charged by Bayer.[8] This fact had a critical bearing on the Nexavar licence as Bayer had to justify the availability of the drug at an affordable price. This was done by citing Cipla's involvement, against which it had filed an infringement case.[9]

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2 Previous studies on compulsory licences do not make a distinction between market-initiated compulsory licence and government-initiated compulsory licence, as market-initiated compulsory licences were not employed in any jurisdiction before India granted the same to Nexavar. For a comprehensive list of government-initiated compulsory licences issued under the WTO regime, *see* Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9(1) PLoS Med. (2012).

3 Frederick M. Abbott & Graham Dukes, Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow's World 145 (2009) (noting the option of the use of non-voluntary licences in favour of local manufacturers).

4 Nexavar Licence, *supra* note 1, 4.

5 Vikas Bajaj & Andrew Pollack, *India Orders Bayer to License Patented Cancer Drug*, The New York Times, March 12, 2012, available at http://www.nytimes.com/2012/03/13/business/global/india-overrules-bayer-allowing-generic-drug.html (Last visited on September 19, 2016).

6 Proactive infringement is also known as 'launch-at-risk' infringement. It is when a company launches the product in the market before any pending law suit with respect to the patent is resolved. A reason for this step is to garner sales even during the pendency of the suit and ensure a ready market. An example of the use of this method is the case of AstraZeneca v. Apotex, in the Southern District of New York, where Apotex went ahead with the launch of the generic version of AstraZeneca's drug. The district court ruled in favour of AstraZeneca, stating that it was entitled to fifty percent of Apotex's gross profits of the drug sold during 2003- 2007. *See* AstraZeneca AB v. Apotex Corpn., et al., No. 2014-1221, at 5 (Fed. Cir. Apr. 7, 2015).

7 *C.f.* Y.K. Hamied, Chairman, CIPLA, Address at the Sixty-Seventh Annual General Meeting of CIPLA: Patent Protection (September 10, 2003) ("The generic industry has only recently started to fight back aggressively by challenging the validity of patent extensions. The future will see more litigations on this major issue that will, unfortunately, also extend to India in due course."); *See* Nexavar Licence, *supra* note 1, 11.

8 P.T. Jyothi Datta, *Cipla to launch generic version of Bayer's kidney cancer drug*, The Hindu Business Line, April 30, 2010, available at http://www.thehindubusinessline.com/todays-paper/cipla-to-launch-generic-version-of-bayers-kidney-cancer-drug/article988601.ece (Last visited on December 2, 2016).

9 Bayer contended that due to the presence of Cipla in the market, it could not work the invention to the fullest extent that is reasonably practicable, as Cipla undercut its prices. Nexavar Licence, *supra* note 1, 52.

Nexavar is a drug used for the treatment of advanced-stage liver and kidney cancer.[10] It was protected by Patent No. 215758 and was launched in India in 2008.[11] Natco, an Indian generic drug manufacturer, requested Bayer for a voluntary licence of Nexavar, which was rejected by Bayer.[12] Natco developed a process to manufacture Sorafenib and received licence from the Drug Controller of India to manufacture the drug in April, 2011.[13] It filed an application for compulsory licence under §84(1) of the Patents Act, 1970 ('Patents Act') and offered to sell the drug at a price of INR 8,800 (USD 165) for a month's treatment.[14] Natco sought a compulsory licence on all the three grounds in §84, i.e., lack of accessibility, lack of affordability and lack of local working, a fact that would make the licence indefeasible to challenge.

In this background, Part I of this paper seeks to enquire into the advantages of market-initiated compulsory licences over the more popular government-use compulsory licence regime. Part II of this paper examines the balance that compulsory licence creates between accessibility of a patented product on one hand, and the rights of the patent holder on the other. This part also looks into the various methods by which compulsory licences can be classified. Part III of this article addresses the pre-conditions for grant of a market-initiated compulsory licence. Part IV examines the history behind the grant of the Nexavar licence and analyses the grant of the licence. Finally, Part V details the significant features of market-initiated compulsory licences that distinguish it from other forms of compulsory licences. The paper concludes with an analysis that elaborates on reasons about why market-initiated licences are better suited to address the needs of a nation in comparsion to government-use licences.

II. TAXONOMY OF COMPULSORY LICENCES

Compulsory licences are conceptually oxymoronic and fundamentally problematic.[15] It can be seen by breaking down the two terms, where

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[10] The order draws a distinction between live-saving and life-extending drugs. Nexavar, as per the order, is not a life-saving drug but a life extending drug, and it could extend the life of a kidney cancer patient by 4 to 5 years and that of a liver cancer patient by 6 to 8 months. Nexavar Licence, *supra* note 1, 6.

[11] Nexavar Licence, *supra* note 1, 6.

[12] Nexavar Licence, *supra* note 1, 9-10.

[13] Nexavar Licence, *supra* note 1, 5.

[14] Nexavar Licence, *supra* note 1, 6; The Patents Act, 1970, §84(1), states that at any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely:- (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India.

[15] From a strictly contractual perspective, a compulsory licence violates the elements of consent necessary for a valid contract, since the consent is neither free nor mutual when a party

'complusory' refers to something that has to be done without the exercise of choice and 'licensing'refers to something which is usually done at the volition of the parties. Yet, the process of compulsory licensing of patents has evolved as the 'middle path' in international intellectual property law.[16] The significance of compulsory licensing has continued to increase unabated,[17] and it has often been used as one of the yardsticks for computing the failure or success of the TRIPS Agreement.[18] Perceived as an involuntary contract,[19] the grant of such licences undermines patent rights by diluting the exclusivity vested with the patent owner.[20] Compulsory licences aptly signify the proverb "one hand giveth, the other hand taketh away", as the governments that granted the patents in the first place are the ones that issue compulsory licences.[21] These licences attempt to create a balance between accessibility and the patent holder's right of appropriation, giving enough incentive to the right holder to produce more

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is compelled. *See*, *e.g.*, Edmund J. Sease, *Common Sense, Nonsense and the Compulsory Licence*, 55 J. Pat. Off. Soc'y 233 (1973) (defining a compulsory licence as a compelled, non-exclusive licence); Consent or permission is quintessential for licensing — one of the modes of exploitation of intellectual property rights — and its absence defines infringement. The phrase "compulsory licence" is a juxtaposition of two oxymoronic terms — the former denoting the absence of consent and the latter implying its presence; *See also* Daniel R. Cahoy, *Breaking Patents*, 32 Mich. J. Int'l L. 461, 462 (2010) (describing a patent compulsory licence as one of the most contentious legal mechanisms in international law).

16 The two extremes being unrestricted exploitation of the patent and forfeiture of the patent. *See* Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 Cal. L. Rev. 1293, 1295 (1996) (referring to compulsory licence as the "middle path"); *See also* Bajaj & Pollack, *supra* note 5 ("In the entire debate about patents, this is the middle path").

17 The recent years have witnessed the expansion of the scope and usage of compulsory licences. Paragraph 5 of the Doha Declaration reaffirmed the scope of Art. 31 of the TRIPS Agreement that recognised the authority of member states to grant compulsory licences, to determine the grounds for compulsory licences, to determine what constitutes a national emergency, and to define its own compulsory licensing regime without challenge. *See* Doha WTO Ministerial Declaration, November 14, 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) ('Doha Declaration').

18 *See*, *e.g.*, Donald Harris, *TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing*, 18 J. Intell. Prop. L. 367 (2011). Other yardsticks to measuring compliance includes studying the efforts of a country to correct a violation of the TRIPS Agreement as found by the WTO Dispute Settlement Body; *See* Edward Lee, *Measuring TRIPs Compliance and Defiance: The WTO Compliance Scorecard*, 18 J. Intell. Prop. L. 401, 403 (2010). Some scholars are critical of the above approach. *See*, *e.g.*, Brian Manning & Srividhya Ragavan, *The Dispute Settlement Process of the WTO: A Normative Structure to Achieve Utilitarian Objectives*, 79 UMKC L. Rev. 1, 1–2 (2010) (arguing that the WTO has not efficiently promoted mutually advantageous global relationships and attributing its failure to the structure and functioning of organisations such as the Dispute Settlement Body).

19 *C.f.* Paul Gorecki, Regulating the Price of Prescription Drugs in Canada: Compulsory Licensing, Product Selection, and Government Reimbursement Programs 25 (1981) (defining a compulsory licence as "an involuntary contract between a willing buyer (licensee) and an unwilling seller (patentee) imposed and enforced by the state").

20 The grant of a compulsory licence breaks up the patent monopoly into a duopoly.

21 *C.f.* Jerome H. Reichman & Catherine Hazenzahl, ICTSD-UNCTAD Project on IPRs & Sust. Dev., Non-Voluntary Licensing of Patented Inventions 10 (2003) (defining compulsory licensing as the practice by a government to authorise itself or third parties to use the subject matter of a patent without the authorisation of the right holder for reasons of public policy).

inventions, without hindering the opportunity available to competitors to use them.[22] Despite its relevance, there has not been any serious attempt to classify the different types of compulsory licences that exist in patent law.

A classification of compulsory licences helps distinguish the different types of compulsory licences that exist within the field. It also assists in understanding the qualities that set them apart, so as to better inform the decision makers who grant such licences and the right holders whose patents are subject to such grants. Intellectual property laws create a variety of compulsory licences, some of which rely on courts and administrative agencies to set the rates of compensation, while others are issued at rates set in statutes, rules or notifications.[23] The taxonomy of compulsory licences can be traced by analysing the instances wherein compulsory licences on patents have been issued throughout the world.

A. IDENTIFICATION

In modern patent law, compulsory licences can be seen as a development with a short history.[24] Since a sizeable number of compulsory licences issued so far have been on pharmaceutical products, these grants are viewed

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[22] Some scholars have concluded that the right of appropriation must extend not merely to private appropriation of intellectual property for personal use, but should also include competitive and commercial uses. *See* Jed Rubenfeld, *The Freedom of Imagination: Copyright's Constitutionality*, 112 Yale L.J. 1 (2002); David Lange & Jefferson Powell, No Law: Intellectual Property in the Image of an Absolute First Amendment 179 (2009). Others have offered 'liability regimes' as a legislative approach to compensation for the use of intellectual property akin to the compulsory licences in copyright and patent law; Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 Harv. L. Rev. 1089 (1971–1972) (written more than forty years ago, this essay paved the way for more attractive and sophisticated interpretation of liability regime); *See*, *e.g.*, J.H. Reichman, *Legal Hybrids Between the Patent and Copyright Paradigms*, 94 Colum. L. Rev. 2432 (1994) (interpreting Calabresi's liability regime to encourage incremental innovation); Many similar proposals have come and almost all of them have a provision for "appropriating revenues resulting from competitive appropriation, one that is calculated to preserve the incentives to create the original work without impairing the absolute freedom of others to bend that work to the service of their own further expression."Lange & Powell, *supra* note 22, 181.

[23] *C.f.* Mark A. Lemley, *Contracting around Liability Rules*, 100 Cal. L. Rev. 463, 476 (2012) ("The government has the power to compel licensing of certain patents on reasonable and non-discriminatory terms. These various powers have apparently never been used."); Wendy J. Gordon, *Asymmetric Market Failure and Prisoner's Dilemma in Intellectual Property*, 17 U. Dayton L. Rev. 853, 858 (1991) ("Similarly, a court that allowed an infringing use to continue while awarding a damage remedy or a reasonable royalty would basically be setting up a compelled licence.").

[24] Despite its recent origin, there is some confusion about its actual appearance. One view holds that the idea of compulsory licensing came up at the conference of Vienna in 1873. Edith Tilton Penrose, The Economics of the International Patent System 164 (1951). Others attributed its origin to public proposals in the United Kingdom and Germany around the 1850s. *Id*.

as occurrences in a specialised field, affecting few parts of the world.[25] One of the problems in the identification of compulsory licences is that there is no database under any of the international conventions where member countries need to record the issue of compulsory licences. This leads to an unclear record of the licences issued so far. The primary mode of identification of these licences is based on what is known as compulsory licensing 'episodes'.[26] An episode is an event which involves a grant of a compulsory licence or a threat to grant one.[27]As the episodes illustrate, not every episode leads to the grant of a compulsory licence. These episodes are categorised based on the drug patent and the unique pharmaceutical products involved. By one account, only half of the episodes resulted in the actual grant of a compulsory licence.[28] In 2012 based on public accounts, only eighteen countries had compulsory licensing episodes.[29] Until 2012 all the compulsory licences issued were the ones initiated and issued by the states which are members to the TRIPS Agreement.[30] Even for those episodes involving non-communicable diseases like heart disease, which is not an epidemic and hence may not fall within the traditional category of national emergency, the issued licences were initiated by governments and not by any private party.[31]

B. CLASSIFICATION

Once identified, compulsory licences that emerge from the episodes can be distinguished from each other. The twenty-seven episodes issued until 2011 involved the local government, which initiated and issued the licence.[32] The episode in 2012 was the sole instance of a compulsory licence initiated by a private party.[33] In terms of grounds, some of the episodes involved local non-working[34] as a ground, whereas others involved public interest. Additionally, episodes can be divided based on whether it involves a

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[25] These include compulsory licences issued in Brazil, Ecuador, Eritrea, Ghana, Indonesia, Kenya, Malaysia, Mozambique, South Africa, Thailand, Zambia, and Zimbabwe. Harris, *supra* note 18, 388.

[26] Beall & Kuhn, *supra* note 2, 3.

[27] *Id*.

[28] So far there have been twenty-four verified compulsory licensing episodes in seventeen countries between January, 1995, and June, 2011, of which half resulted in the announcement of a compulsory licence. These episodes involved forty drug patents for twenty-two unique pharmaceutical products. Sixteen of the compulsory licensing episodes involved drugs for HIV/AIDS, four involved drugs for other communicable diseases and another four related to non-communicable diseases like cancer. *Id*., 3-4.

[29] *Id*.; The above study records seventeen countries which have granted compulsory licences by the year 2011. Nexavar licence was issued by India in 2012, which makes the number of countries that have issued compulsory licences eighteen.

[30] Beall & Kuhn, *supra* note 2.

[31] *Id*., 4.

[32] Beall & Kuhn, *supra* note 2.

[33] Nexavar Licence, *supra* note 1.

[34] Local non-working refers to one of the grounds in §84 of the Patents Act, 1970 for granting a compulsory licence. §83(a) states that "patents are granted to encourage inventions and to

compulsory licence for local use or foreign aid. Compulsory licences granted so far have also been classified based on type of medicines (HIV/AIDS, cancer) and the diseases it treats (communicable and non-communicable),[35] although there has been considerable concern regarding the disease-based classification of compulsory licences.[36]

An early attempt classified compulsory licensing systems into three broad types: first, the limited compulsory licence system which issued licences only for failure to work, second, the broader system which issued such licences on specified conditions stated in the law and third, the flexible system of issuing licences whenever public interest required.[37] Recent studies have grouped compulsory licences based on existing state practices that fall within the framework of Articles 31 and 31 *bis* of the TRIPS Agreement.[38] Article 31(a) states that the authorisation of the use of a patent without the express consent of the right holder shall be considered on its individual merits,[39] i.e., applications for compulsory licensing would be done on a case-to-case basis. Hence, a classification based on these grounds is not useful as members are, in principle, free to issue compulsory licences on grounds that are not included in the TRIPS Agreement.[40] From the data available, it is possible to classify compulsory licences into three broad, albeit overlapping, categories.

1. Abuse and Public Interest

This is a conduct-based classification, in which the grant of a compulsory licence depends on the conduct of the patent holder which could

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secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay."

35 Beall & Kuhn, *supra* note 2.

36 Though nothing in the TRIPS Agreement points towards confining the use of compulsory licences to a particular category of diseases, there have been several attempts by countries like the United States to limit them to certain diseases like AIDS, tuberculosis and malaria, or to situations that can be treated as health emergencies. *See* Kevin Outterson, *Should Access to Medicines and TRIPS Flexibilities Be Limited to Specific Diseases?*, 34 Am. J.L. & Med. 279, 280-81 (2008).

37 Penrose, *supra* note 24, 177–84.

38 The Spennemann-Reichman classification identifies six types of compulsory licences based on the substantive grounds on which member states may grant a compulsory licence. These include compulsory licences granted: (1) under antitrust law; (2) to rectify abuses of the patentee's exclusive rights; (3) in the public interest; (4) to allow holders of improvement patents to make use of original patents; (5) for government use; (6) for export of pharmaceutical products under Art. 31*bis* of the TRIPS Agreement. *See* Christoph Spennemann & Jerome H. Reichman, Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide 118–19 (2011).

39 Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, 1869 U.N.T.S. 299, Art. 31(a), ('TRIPS Agreement').

40 Jayashree Watal, Intellectual Property Rights in the WTO and Developing Countries 319 (2001).

either mean not using the patent, or using the patent right in an abusive manner.[41] Though Article 31 of the TRIPS Agreement does not classify compulsory licences, most compulsory licences issued so far are initiated by Member States on the ground of public interest.[42] The inability of the Member States to distinguish their routine exercise of issuing government-use licences from the grant of other compulsory licences contributed to the breadth of Article 31 of the TRIPS Agreement.[43] Article 31 contains clauses (a) to (k) stipulating the scope, kind of remuneration and provisions for cross-licening, to name a few. The public interest grounds could be used to address issues like government use, blocking patent and anticompetitive practices.[44] The public interest ground is employed predominantly for domestic use.[45] But, as mentioned above, such use need not be confined to an epidemic as can be seen in the case of Thailand's threat to use compulsory licences for heart disease, where Thailand widened the use of compulsory licensing provisions to cover non-epidemic diseases.[46]

2. Local and International

This is a territory-based classification. Compulsory licences can be classified on the basis of the countries involved in the granting process. Most licences are granted by the local government to address local needs. Government-initiated licences are tools with which governments bargain with the originator pharmaceutical companies. On many occasions, governments that bargain under the shadow of compulsory licences have been able to get into agreements with major pharmaceutical companies.[47] In the United States, one such instance involved the threat to issue a compulsory licence on Bayer's Cipro (ciprofloxacin) in 2001 for stockpiling in the event of anthrax outbreak.[48] In Europe, the French government extended its *ex-officio* compulsory licensing regime to cover genetic diagnostic patents in 2004 in response to excessive

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41 *See* Michael Halewood, *Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law*, 35 OSGOODE HALL L.J. 244, 260 (1997) (classifying compulsory licences into three categories based on the situations in which they are granted, i.e., non-working, abuse and public interest).

42 Beall & Kuhn, *supra* note 2.

43 WATAL, *supra* note 40, 34 ("By insisting on the same set of conditions for both types of non-voluntary use of patent rights, the Indian negotiating tactic, supported by EC, Japan and Canada, forced some dilution of conditions and achieved considerable flexibility for developing countries in having no restriction on the ground of such authorization.").

44 CYNTHIA M. HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS 132–33 (2011). Article 8(1) of the TRIPS Agreement deals with measures to protect public health.

45 TRIPS Agreement, *supra* note 39, Art. 31(f).

46 Roger Bate, *Thailand's Patent Attack*, THE NEW YORK SUN, February 13, 2007, available at http://www.nysun.com/opinion/thailands-patent-attack/48499/ (Last visited on September 19, 2016).

47 FEROZ ALI, THE ACCESS REGIME: PATENT LAW REFORMS FOR AFFORDABLE MEDICINES 128 (2016).

48 Jill Carroll & Ron Winslow, *Bayer Agrees to Slash Price for Cipro Drug*, WALL ST. J., October 25, 2001, available at http://www.wsj.com/articles/SB1003966074330899280 (Last visited on September 19, 2016).

price and restrictive licensing conditions on patented diagnostic test kits for breast and ovarian cancer.[49] Often strong compulsory licensing regimes and measures, such as the one in France, which have not yet seen any compulsory licence being issued under them, are used to bring pressure on non-cooperative patent holders.[50]

International compulsory licences are issued by countries which do not have the local capacity to produce a drug, and necessarily involve the laws of another country where these drugs are manufactured.[51] Rwanda was the first country to utilise the waiver provisions under Paragraph 6 of the Doha Declaration in 2007[52] when it applied for assistance from Canada and issued a compulsory licence for HIV/AIDS drug on the ground that it could not locally produce the same.[53]

3. Government-use and Market-initiated

This is a need-based classification. Compulsory licences can be classified on the basis of the need for which they were issued, i.e., those issued to meet an essential need such as a health emergency and those issued to meet a market-initiated need. Compulsory licences issued for use by the government are essential licences granted to meet a perceived national emergency or a looming health crisis.[54] A national emergency could be characterised by the contagious nature of the disease, the speed of its spreading, as well as the absence of any readily available and universally accessible cure.[55] An example of national emergency could be what happened during the great plague[56] or more

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[49] Esther van Zimmeren & Gilles Requena, *Ex-Officio Licensing in the Medical Sector: The French Model* in Gene patents and public health 133-134 (Geertrui van Overwalle, 2007).

[50] *Id*., 137. The French example illustrates that even the governments of the developed countries employ the compulsory licensing regime to make patented products more acessible even under non-emergency situations.

[51] Olasupo Ayodeji Owoeye, *Compulsory Patent Licensing and Local Drug Manufacturing Capacity in Africa*, 92(3) Bulletin of the World Health Organization 214, 216 (2014).

[52] *See* Doha Declaration, *supra* note 17.

[53] Paige E. Goodwin, *Right Idea, Wrong Result - Canada's Access to Medicines Regime*, 34 Am. J.L. & Med. 567, 569 (2008).

[54] The Patents Act, 1970, §92(1), a special provision for compulsory licences states that "If the Central Government is satisfied, in respect of any patent in force in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, that it is necessary that compulsory licences should be granted at any time after the sealing thereof to work the invention, it may make a declaration to that effect, by notification in the Official Gazette, and thereupon the following provisions shall have effect[…]"

[55] Associated Press, *US Declares State of Emergency in Puerto Rico over Zika Epidemic*, The Guardian, August 13, 2016, available at https://www.theguardian.com/world/2016/aug/12/zika-virus-epidemic-puerto-rico-state-of-emergency-mosquito (Last visited on December 20, 2016).

[56] *See generally* A. Lloyd Moote & Dorothy C. Moote, The Great Plague: The Story of London's Most Deadly Year (2004) (stating that "an emergency public health subcommittee of the king's council called on the most elite body of London medicine, the College of Physicians, to put a stop to that evil as far as [they] could by some remedies.").

recently, in case of the Zika virus, where a state of emergency was declared in some South American countries.[57] The system was designed to be triggered by the government depending on the needs of the government: if it felt the need to compel a patentee to licence its invention, a compulsory licence would be granted. 'What' triggered the compulsory licence is not as relevant as 'who' triggered it, as it is ultimately a government response to a crisis, and the decision to grant is made without much consultation or negotiation.[58] To this effect, much of the scholarly focus[59] has been on unauthorised government use or sanction of the use of patents, where the government would grant a compulsory licence authorising someone to make the patented product.[60]

Since the right to grant compulsory licences does not depend on the state of emergency or other circumstances of emergency, there have been some instances of market-initiated licences.[61] One of the defining features of a market-initiated compulsory licence is that it is not necessarily triggered by an emergency but by an act of a market competitor requesting for a licence and the consequent denial by the patent holder.[62] In other words, a market-initiated compulsory licence is the functional opposite of a government-use compulsory licence.

However, even though the right of member countries issuing compulsory licences need not be confined to emergency situations, there have not been enough instances to treat market-initiated licences as a class of its own.[63] Further, scholars have scarcely analysed market-initiated compulsory licences in their works.[64] This may be due to the absence of any attempt to classify compulsory licences based on their purpose. When they are identified, described and classified, market-initiated licences emerge as instruments that are substantially different from government-use licences in the ways in which they are triggered, granted, maintained and challenged.

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57 Associated Press, *supra* note 55.

58 Beall & Kuhn, *supra* note 2, 3.

59 *C.f.* Reichman & Hazenzahl, *supra* note 20, 10 (defining compulsory licensing as the practice by a government to authorise itself or third parties to use the subject matter of a patent without the authorisation of the right holder for reasons of public policy); J.P. Love, *Recent Examples of the Use of Compulsory Licenses on Patents*, 8 Knowledge Ecology International (2007).

60 *See, e.g.*, Cynthia M. Ho, *Unveiling Competing Patent Perspectives,* 46 Hous. L. Rev. 1047, 1094 (2009) (describing compulsory licences as including 'government use' of patents,"whereby use of patented inventions by government contractors are subject only to remuneration, but never injunctions.").

61 *C.f.* Spennemann & Reichman, *supra* note 38, 127.

62 Ali, *supra* note 47, 129.

63 *C.f.* Spennemann & Reichman, *supra* note 38, 127.

64 *See e.g.*, Abbott & Dukes, *supra* note 3 (noting that the use of non-voluntary licensing in favour of local manufacturers is an option open to developing countries to lower the prices of drugs).

III. PRECONDITIONS FOR THE GRANT

Though any country could in principle provide for the issue of compulsory licences under Article 31 of the TRIPS Agreement when drugs are needed at lower prices, the ability to issue a market-initiated compulsory licence will depend on the willingness of competitors to initiate the process. This is in turn dependent on the capacity of manufacturers in the local market or their ability to obtain the key active ingredient. When countries lack these capabilities, the mere presence of such provisions in the law will not lead to any move for grant of a compulsory licence, which partly explains why the use of such licences is limited. Thus, factors such as overcoming capacity barriers and legislative preparedness will be relevant if such provisions in the local law are to be effective.

A. CAPACITY BARRIERS

These barriers include the financial, technical and legal expertise to apply for compulsory licence. The ability to issue a market-initiated compulsory licence depends on the absorptive capacity of the market to manufacture the drug locally. The capacity to manufacture is crucial as the initiation of the compulsory licence is dependent on the market. Capacity also implies that competitors in the market, who are likely to initiate the process, have the technical, financial and administrative capacity that would eventually bring the drug into the market. Therefore, capacity barriers often include lack of production capacity, absence of distribution networks and absence of buying power required to effectively use the compulsory licensing provisions.[65] To implement the regime, developing countries therefore need to become self-reliant by increasing their capacity to produce low-price medicines.[66]

To put the regime into effect, the market needs to play a significant role. Countries without the capacity to manufacture may not be able to avail full benefits of having market-initiated compulsory licences in their laws.[67] Thus, such licensing regimes can take off only in countries with a robust generic industry.[68] If the above factors are present, then the country may not be

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[65] Frederick M. Abbott, WTO TRIPS *Agreement and Its Implications for* Access *to* Medicines *in* Developing Countries, 13-14, available at http://www.iprcommission.org/papers/pdfs/study_papers/sp2a_abbott_study.pdf (Last visited on September 19, 2016).

[66] *Id*., 65.

[67] *C.f.* Randall Kuhn & Reed F. Beall, *The Time for Pharmaceutical Compulsory Licensing Has Expired,* 18 Nature Medicine 1168 (2012) (noting that compulsory licensing activity has been especially rare in low-income countries that were purported beneficiaries of Doha Declaration).

[68] The generic industry needs to be multi-tiered to protect the country from the hostile acquisitions by originator companies. This is especially true in the generic pharmaceutical industry in India which is not only multi-tiered, with various manufacturers operating at different level each waiting to move up the tier, but also has a long tail of manufacturers ready to serve

threatened with the consequences of withdrawal by the patent holder or by the risk of non-introduction of future drugs.[69]

B. LEGISLATIVE PREPAREDNESS

Apart from capacity barriers, the issuance of market-initiated compulsory licences could be hindered by the lack of legislative provisions in the local laws or by a procedure-ridden regime that is laborious.[70] One of the key prerequisites for functioning of a market-initiated compulsory licensing regime is the working requirement[71] in the patent law without which it would be hard to justify and defend the issue of those licences in times of normalcy.[72] For the market-initiated compulsory licensing regime to work, the patent law should have provisions wherein third-party competitors can initiate the process based on the refusal to licence by the patent holder. Countries have been reluctant to introduce new legislations affecting pharmaceutical companies for the fear of backlash from the developed countries as well as from the pharmaceutical industry.[73] The failure of the Rwanda-Canadian compulsory licensing effort initiated under Article 31*bis* of the TRIPS Agreement was a low-point in the history of compulsory licences where local government laws and provisions of the WTO trade regime became hurdles in the issuance of the licence.[74] Rwanda

different market segments. There was a spate of acquisitions in India soon after the regime change, when India started to grant patents for pharmaceutical products. *See* Madhur Singh, *India May Issue Compulsory Licences to Control Drug Prices,* 27 BNA INT'L TRADE REP. 1349 (2010).

69 This was done by Abbott in Thailand. Abbott retaliated to Thailand's compulsory licence on its drug lopinavir/ritonavir (trade name 'Kaletra') by withdrawing all of its new products from the market. Thomas Fuller, *Thailand takes on Drug Industry, and may be Winning*, NEW YORK TIMES, April 11, 2007, available at http://www.nytimes.com/2007/04/11/world/asia/11iht-pharma.4.5240049.html?pagewanted=all&_r=0 (Last visited on September 19, 2016). This may not be an issue in India as it has earlier relied on foreign market approvals (under the special 'Exclusive Marketing Rights' provisions of the Patents Act, 1970) as valid drug approvals. They could do the same to ensure that the drug is supplied by a generic drug supplier; *C.f.* FEROZ ALI KHADER, THE LAW OF PATENTS: WITH A SPECIAL FOCUS ON PHARMACEUTICALS IN INDIA 233–34 (2007).

70 *See* Kuhn & Beall, *supra* note 2, 62.

71 The criteria for reasonable requirement of the public will not be considered to be satisfied if the patented invention was not being worked in India on a commercial scale to an adequate extent or if it is not being so worked to the fullest extent that is reasonably practicable. Therefore an applicant making an application on the above ground will have to establish the demand expected for the patented invention and the extent to which it has not been satisfied. *See* KHADER, *supra* note 69, 722.

72 *C.f.* G.H.C. BODENHAUSEN, GUIDE TO THE APPLICATION OF THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY, AS REVISED AT STOCKHOLM IN 1967, available at http://www.wipo.int/edocs/pubdocs/en/intproperty/611/wipo_pub_611.pdf (noting that in some countries the local working requirement is essential to justify the grant of patents).

73 *See* ABBOTT, supra note 3, 51-54 (describing the reactions to the South African legislation, Medicines and Related Substances Control Amendment Act of 1997 (South Africa), by the United States and the pharmaceutical companies).

74 Frederick M. Abbott & Jerome H. Reichman, The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS

had to thus go through implementing a labrynth of complex legislations which consited of requirements in addition to those laid out in the Waiver Decision.[75] Politically speaking, there is much at stake for a country that issues a compulsory licence as it could provoke retaliatory action in the form of withdrawal of products from the market by the patent holder or informal pressure from foreign trade ministries or formal action at the WTO Dispute Settlement Body.[76] For the system to work, countries have to provide more scope for compulsory licences by making the process of their issue easy, thereby reducing some of the inefficiencies associated with the current system.[77]

Both the above conditions came into perfect play when India granted the world's first, post-TRIPS Agreement, market-initiated compulsory licence.

IV. THE GRANT OF THE LICENCE

The chapter on compulsory licensing was introduced into the Patents Act pursuant to the recommendations made by the Ayyangar Committee ('Committee').[78] The Committee identified the abuse of patent rights as a common concern for many countries and observed, "India is not unique in having to face this problem of patents for vital inventions being owned by foreigners who evince no desire to work them within the country."[79] The problem is common to all under-developed countries which have adopted the patent system of rewarding inventors. Two means for redressing this handicap have generally been adopted: *first*, compulsory working,[80] with revocation of the patent in the event of non-working; and *second*, compulsory licensing on terms of royalty settled by an outside authority where the parties do not agree.[81] The recommendations made by the Committee became the precursor for the provisions on compulsory licensing that later became a part of the TRIPS Agreement.[82]

Provisions, 10 J. Int. Economic Law 921, 941-942 (2007).

75 *Id*. The 'Waiver Decision' also called the WTO Decision of 30th August 2003, established a waiver of certain obligations under the TRIPS Agreement for the purpose of permitting exports of exports of patented medicines under government use and other compulsory licences that might otherwise be prevented by the terms of the TRIPS Agreement.

76 Paul Champ & Amir Attaran, *Patent Rights and Local Working under WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute*, 27 Yale J. Int'l L. 365, 380–91 (2002) (analysing the legality of local working in the context of its Industrial Property Law).

77 Claude Henry & Joseph E. Stiglitz, Intellectual Property, Dissemination of Innovation and Sustainable Development, 1 Global Policy 237, 245 (2010).

78 *See* Justice N. Rajagopal Ayyangar Committee, *Report on the Revision of the Patent Laws*, 125-167 (September 14, 1959).

79 *Id*., 125.

80 Ali, *supra* note 47, 170. The concept of working encompasses two things: use of the patent by the patentee and licensing of the patent to a third party.

81 *Id*.

82 *See* Watal, *supra* note 40, 33–34. In fact, it has often been remarked that there is no country which has utilised the flexibilities in the TRIPS Agreement in a way in which India has done it. *See also* V. Venkatesan, *The Current Patent System is Deeply Flawed,* Frontline (Kolkata)

A. STATUTORY PROVISIONS

Chapter XVI of the Patents Act classifies compulsory licences into four categories, namely – market-initiated compulsory licence (§84), compulsory licences for related patents (§91), special compulsory licences for emergency situations and government use (§92) and compulsory licences for export of pharmaceuticals (§92A).[83] Any interested person is allowed to make an application before the Patent Office setting out the nature of his interest, and the terms and conditions that he will accept.[84] The person seeking the compulsory licence is required to establish a *prima facie* case.[85] The Patents Act provides for a process of opposition by which the patentee or any interested persons intending to oppose the application may give notice of opposition to the Controller, stating the grounds of such opposition.[86] On receiving the notice of opposition, the Controller will notify the applicant and give the applicant and the opponent a hearing.[87] Chapter XVI of the Patents Act also lists the relevant factors to be considered in determining an application for compulsory licence.[88] A market-initiated compulsory licence could be granted on any of the three grounds: *first*, that reasonable requirements of public interest with respect to the patented invention have not been satisfied; *second*, that the patented invention is not available to the public at a reasonably affordable price; *third*, that the patented invention is not worked in the territory of India.[89] Thus, apart from public interest grounds, compulsory licences can also be used as sanctions for non-working.[90]

The Patents Act has working requirements for all granted patents, which is a variation of the compulsory working requirement. All patents are granted subject to the conditions stipulated under the Patents Act.[91] The Patents Act also requires patents to contribute to the "promotion of technological innovation and to the transfer and dissemination of technology."[92] This is stated as one of the general considerations applicable to the working of patented

April 21, 2012. ("My own view is that India strategically exploited TRIPS' flexibilities to the hilt. It introduced higher standards for pharmaceutical patentability, a very potent opposition mechanism where any member of the public could effectively oppose a patent grant and some of the widest compulsory licensing norms that the world has ever known.").

83 KHADER, *supra* note 69 (noting the kinds of applications for compulsory licences).

84 *See* The Patents Act, 1970, §84; *See also* The Patents Rules, 2003, Rule 96.

85 The Patent Rules, 2003, Rule 97.

86 The Patents Act, 1970, §87(2), 87(3).

87 The Patents Act, 1970, §87(4).

88 The Patents Act, 1970, §84(6).

89 The Patents Act, 1970, §84(1).

90 *C.f.* PENROSE, *supra* note 24, 161 (arguing that the compulsory working requirements are not very effective, and in so far as they are effective, they are likely to force an uneconomic location of industry; and further that compulsory licensing as a sanction for non-working is, therefore, based upon a false approach to the treatment of foreign patents).

91 The Patents Act, 1970, §48.

92 The Patents Act, 1970, §83(c).

inventions in India which, if not satisfied, could lead to the issue of compulsory licences. Local working, which the Patents Act refers to as "worked in the territory of India", is another requirement.[93] The Patents Act requires every patentee to submit annual working statements to the Patent Office.[94] This is done by filing Form 27 of the Patents Rules before the Patent Office.[95] Form 27 requires information to be submitted annually on the working of a patented invention on a commercial scale in India, including information on importation.

These provisions, however, were not put into effect even once during the first four decades of its existence. As a result, in 2010 the government of India sought suggestions to work the compulsory licensing regime for formulating a new policy on the issuance of compulsory licensing in the pharmaceutical sector.[96]

A question that has often been asked pertains to the time taken for the regime to take off.[97] Why did the generic industry, which has been active in challenging patents by way of opposition, not show similar enthusiasm in seeking compulsory licences? Some argued that oppositions combined with the subject-matter exceptions and the new standard of inventive step offered a better way to challenge patents than using the compulsory licensing process.[98] These processes are used before a patent is granted, thereby making them easier, cost effective and appropriate, as they are done before the granting authority, i.e., the Patent Office. However, that does not offer a complete explanation. Applications or patents that are challenged are the ones that mostly come under

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93 The Patents Act, 1970, §83(a). The phrase "worked in the territory of India" has not been defined in the Act. *See* Nexavar Licence, *supra* note 1, 42.

94 *See* J. Sai Deepak, *Working of Patents: Public Notice Issued by Patent Office to Patentees and Licencees*, Spicy IP Blog, January 5, 2010, available at http://spicyipindia.blogspot.com/2010/01/working-of-patents-public-notice-issued.html (Last visited on September 19, 2016).

95 *See* The Patents Act, 1970, §146; The Patent Rules, 2003, Rule 131; For a critical perspective of India's working requirement, *see* Feroz Ali Khader, *Making Patents Work*, Spicy IP Blog, March 11, 2010, available at http://spicyipindia.blogspot.com/2010/03/guest-post-by-feroz-ali-making-patents.html (Last visited on September 19, 2016) (noting that the requirement of furnishing a statement with regard to working of patented inventions on a commercial scale in India is mandated under the Patents Act, 1970, only in the context of compulsory licences; and criticising the scale of cost, time and resources involved in requiring all patentees to file regular worksheets to the Patent Office in the first three years of the patent).

96 Bindu D. Menon, *Compulsory licensing of patented drugs under study*, Hindu Business Line, August 24, 2010, available at http://www.thehindubusinessline.com/todays-paper/tp-marketing/compulsory-licensing-of-patented-drugs-under-study/article1002281.ece (Last visited on September 19, 2016).

97 Shamnad Basheer & Prashant Reddy, *Build Patents Regime on Fortified Law*, The Economic Times, October 7, 2010, available at http://economictimes.indiatimes.com/policy/build-patents-regime-on-fortified-law/articleshow/6703241.cms (Last visited on September 19, 2016).

98 Amy Kapczynski, *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 Cal. L. Rev. 1571, 1594 (2009) (arguing that using these flexibilities, governments can render a substantial portion of medicines open to generic competition without ever needing to consider a compulsory licence).

some kind of exception, like §3(d), which deals with patenting known substances.[99] The fact that the generics were vigilant in challenging new patents for known substances does not explain the non-use of compulsory licensing provision, which can be used for new molecular entities that are beyond the purview of provisions like §3(d). Others argued that the trend of the mergers and takeovers of generics by the originator pharmaceuticals could have played a role.[100] This, too, is not the precise reason as the Indian generic pharmaceutical industry is a highly tiered industry with a long tail, one in which the top rank will quickly be filled when the first-tier companies are acquired, such acquisitions being far and few. The second tier is comprised of those companies which are not capable of being acquired or merged into bigger originator companies, as the companies in this tier are smaller and do not have scale or products that appeal to originator phramaceuticals companies. Did the cumbersome process of compulsory licences divert the generics away from the regime?[101] The difficulties involved in the process of obtaining compulsory licences is also often cited as a deterrent for initiating new applications.[102] That again could not have been the reason as generics did not initiate any compulsory licence in the first four decades of the patent law, and also, there has been no instance of a market-initiated compulsory licence under §84 that had to be abandoned later due to the cumbersome procedure. What, then, could have been the reason for the delayed start of the compulsory licensing regime in India?

Under the old patent regime, India did not grant protection for pharmaceutical products which enabled generics in most cases to freely make those drugs, either by a non-infringing process where a process patent existed or by any method when the drug was not protected by any patent. Since the new regime came into effect in 2005 the applications made during the transition period, especially the mail-box applications for pharmaceutical products, were taken up for examination.[103] When these applications were taken up and granted, which normally took between three to five years, the generic companies which were keen on applying for a compulsory licence had to wait for a

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[99] Khader, *supra* note 69, 57–98 (explaining the scope and operation of §3(d) of the Patents Act, 1970).

[100] *See* Basheer & Reddy, *supra* note 97. In the last decade, six Indian generic companies were merged with or acquired by foreign entities: Matrix Lab, Dabur Pharma, Ranbaxy Labs, Shanta Biotech, Orchid Chemicals, and Piramal Healthcare. The total cost of the takeover is estimated at USD 1.58 billion. Ranbaxy was purchased by Japan-based Daiichi Sankyo Co. in June 2008; Piramal Healthcare was bought by U.S. based Abbott Laboratories, Matrix Lab was acquired by Mylan Inc. and Dabur Pharma was acquired by German Fresenius Kabl. *See* Singh, *supra* note 68.

[101] *See* Basheer & Reddy, *supra* note 97.

[102] Jakkrit Kuanpoth, Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future 171 (2010) (noting that the cumbersome process eventually led Natco to discard its application for compulsory licence under §92A of the Patents Act, 1970).

[103] Khader, *supra* note 69, 14 (describing "mail-box" applications as patent applications filed for pharmaceuticals and agricultural chemicals between 1995 and 2005, on the condition that they would be examined after 2005).

mandatory three years period after the grant, before it could apply for a compulsory licence.[104] Thus the total waiting period – the time for taken for grant combined with the three year time period after the grant – in some cases extended the timeline for making an application for compulsory licence by six to eight years from 2005.[105] This explains why there was no activity on compulsory licences during the first five years since 2005, and also hints at the cause for a spate of recent moves for new licences.[106]

B. THE NEXAVAR LICENCE

The Nexavar licence has the distinction of being the first compulsory licence granted in India under the compulsory licensing regime that has been in existence since 1970.[107] Despite being a proceeding conducted at the Patent Office, the events that led to the grant of the licence resembled court proceedings. In court proceedings, one of the causes for the delay in rendering justice could be the non-adherence to procedural time frames.[108] Delay plays a significant role as a strategy in cases where the patent holder will stand to lose in the event of an adverse decision. The compulsory licensing proceedings were protracted with the exploitation of every foreseeable procedural technicality, as has been the norm in cases filed between originator and generic pharmaceutical companies in India.[109] Nonetheless, the order of the Controller of Patents granted the compulsory licence on all the three grounds raised by Natco:

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104 The Patents Act, 1970, §84.

105 *See* Venkatesan, *supra* note 82.

106 *See* Viswanath Pilla, *Natco Targets Drugs Ripe for Compulsory Licensing*, Livemint, July 19, 2012, available at http://www.livemint.com/Companies/ZR7YHsT0xTb6e9ppKDIAuN/Natco-targets-drugs-ripe-for-compulsory-licensing.html (Last visited on September 19, 2016) (noting the number of new compulsory licences that are being sought); C.H. Unnikrishnan, *Compulsory Licences may Spur More Voluntary Licensing Deals*, Livemint, January 24, 2013, available at http://www.livemint.com/Home-Page/f0R9060osU7bENFNwlnx5O/Compulsory-licences-may-spur-more-voluntary-licensing-deals.html (Last visited on September 19, 2016) (predicting the pre-emptive move by originator companies to enter into licensing deals to avoid a compulsory licence).

107 Nexavar Licence, *supra* note 1, 4.

108 Brajesh Ranjan, *What causes judicial delay? Judgments diluting timeframes in Code of Civil Procedure worsen the problem of adjournments*, Times Of India Blogs, August 25, 2016), available at http://blogs.timesofindia.indiatimes.com/toi-edit-page/what-causes-judicial-delay-judgments-diluting-timeframes-in-code-of-civil-procedure-worsen-the-problem-of-adjournments/ (Last visited on December 1, 2016).

109 Nexavar Licence, *supra* note 1, 6-8; *See also* ET Bureau, *Pharma MNCs Use RTI Law to Protect Market for Patented Drugs & Delay Entry of Generics*, Economic Times, January 24, 2013, available at http://economictimes.indiatimes.com/news/news-by-industry/healthcare/biotech/pharmaceuticals/pharma-mncs-use-rti-law-to-protect-market-for-patented-drugs-delay-entry-of-generics/articleshow/18159392.cms (Last visited on September 19, 2016) (describing the pre-emptive legal action taken by originator companies to delay the entry of generics in India).

1. Lack of accessibility

The order of the Controller identified importation of Nexavar as the key reason for the unavailability of the drug in high volume.[110] The order also noted the neglect of the Indian market by Bayer.[111] While the drug was released around the world in 2006 (earning revenue of USD 165 million), the drug was not introduced in India until 2009, when about 200 bottles were imported,[112] though the Indian patent was granted in 2008.[113]

Natco argued that the number of patients who needed the drug stipulate the demand for the drug and not the number who can afford.[114] When the drug is not supplied in adequate quantities or if the drug is priced above the reach of the masses, the demand is not being met on reasonable terms. Bayer countered this argument by stating that cancer patients required to be supervised by oncologists and hence, the argument that it is not made available in villages is of no consequence as the drug was made available in 278 cancer hospitals and institutes in fifty places.[115] Bayer further argued that access to a patented invention is not identical to affordability and that the purpose of §84(1)(a) was to enhance access.[116] Bayer stated that the cancer patients were required to be supervised by oncologists and hence the argument that it was not made available was irrelevant as the drug was made available in 278 cancer hospitals and institutes in fifty places.[117] Intriguingly, Bayer cited Cipla's infringement of its patent and stated that the combined sales of Bayer and Cipla would ensure availability of the drug in India.[118] Rejecting Bayer's arguments, the order held that reasonable requirements of the public with respect to the patented invention were not satisfied.[119]

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[110] Nexavar Licence, *supra* note 1, 13-14. The order notes that while there is a demand of around 16000 bottles per month only about 200 (worth around INR 16 crores, USD 3 million approx.) were imported by Bayer in 2009, a year in which Bayer's global sale of Nexavar was USD 843.5 million. *Id*.

[111] *Id*., 48.

[112] *Id*., 13.

[113] Bayer received the licence for importing and marketing the drug from the Drug Controller (the regulatory authority) in India on August 1, 2007, and the licence from the Directorate General of Health Sciences for importing and marketing the drug on January 22, 2008. *Id*., 53.

[114] *Id*., 31.

[115] *Id*.,18.

[116] *Id*., 27.

[117] Nexavar Licence, *supra* note 1, 18.

[118] *Id*., 19.

[119] *Id*., 23-24; The Patents Act, 1970, §84(7), mentions the situations in which the reasonable requirements of the public shall be deemed not to have been satisfied.

2. Lack of affordability

Nexavar's high price was another reason for it being considered as not available to the public at a 'reasonably affordable price'.[120] Bayer raised the classic arguments on Research & Development ('R&D') expenditure and argued that such high prices were required for it to sustainably fund further research in areas of unmet medical needs, where the research is carried out in public interest.[121] It was pointed out that replacing the innovation based product with a generic will damage India and Indian patients in the long run as the patentee as an originator provides more than just the product, for example, it invests in education of practitioners on the use of the product, pharmacovigilance, etc.[122] As the innovator of the drug, Bayer demanded that the discretion to decide on what would constitute a 'reasonably affordable price' for its product should be vested in itself.[123]

Bayer hinted at its inability to tackle the free-rider problem and argued that different classes of society should be treated differently.[124] Bayer argued that 'public' denotes different sections of the public such as 'the rich class', 'the middle class' and 'the poor class'.[125] A blanket compulsory licence cannot be granted, thereby giving the patented drug to all sections of 'public' at the same price. Bayer wanted the licence to devise a method of differential pricing which would make it 'reasonable' for the patentee and make it 'reasonably affordable' for the different sections of the 'public'.[126] On 'the rich class' and 'the lower class' being placed in the same category, Bayer argued that it was unreasonable to treat unequals as equals, at the expense of the patentee.[127] It opined that to protect its R&D efforts, the device of differential pricing had to be introduced in the licence.[128] Bayer expressed its apprehension about the 'bargaining rich' and argued that it cannot be the intention of the legislature to lower the price for those patients who can afford its drug.[129] Citing health insurance as a means that could make the drug affordable, Bayer concluded that af-

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120 The Patents Act, 1970, §84(1)(b).

121 Nexavar Licence, *supra* note 1, 29. *See*, *e.g.*, Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The price of innovation: new estimates of drug development costs*, 22 Journal of Health Economics 151–185 (2003), available at http://www.sciencedirect.com/science/article/pii/S0167629602001261 (Last visited on December 1, 2016).

122 Nexavar Licence, *supra* note 1, 29.

123 *Id*.; *C.f.* Mark A. Lemley, *A New Balance Between IP and Antitrust*, 13 Sw. J. L. & Trade Am. 237, 245 (2007) ("Indeed, in order for the IP laws to succeed in giving authors and inventors an incentive to create, the law must give them at least some power over price, though not always monopoly control.").

124 Nexavar Licence, *supra* note 1, 35.

125 *Id*., 30.

126 *Id*. Bayer also came up with a proposal for differential pricing.

127 *Id*.

128 *Id*., 31.

129 *Id*., 30. Bayer was hinting at the problem of the 'bargaining rich', the rich who could afford to buy Nexavar but choose not to do so and *bargain* by buying the cheaper generic version supplied by Natco.

fordability has to be judged from the cost to be incurred on the insurance cover and the question of affordability changes from whether the patient can afford the drug at a given cost to whether the patient can afford the insurance cover.[130]

Though Bayer argued that the cost of R&D incurred by it has to be taken into account while fixing royalty, it failed to give the break-up of the costs.[131] While agreeing with Bayer that the issue of 'affordability to the public' should be considered as 'affordability to different classes of public', the Controller questioned as to why Bayer did not execute this concept by offering differential pricing for different classes of public in India.[132] The order observed that the patented drug was not bought by the public due to only one reason, i.e., its price was not reasonably affordable to them and concluded that the patented invention was not available to the public at a reasonably affordable price.[133]

3. Lack of Local Working

The order granted the Nexavar licence on the ground that it was not worked in the territory of India.[134] In reaching this conclusion, the Controller relied, among other things, on the working statement filed by Bayer which showed that the patent was not worked in India.[135] The quantum of working was put to issue: whether working would be satisfied by 'minimal working' or whether working meant working to the fullest extent.[136] Bayer argued that local working means that the invention has to be supplied to the Indian market, which could be through importation.[137] It argued unsuccessfully that local working cannot mean local manufacturing as it would be beyond the scope of the Patents Act.[138] Bayer attempted to make the local working subservient to the other two grounds of lack of accessibility and lack of affordability. It argued that local working would be relevant where the patentee was not supplying the patented product to the market. If the drug is made available by other means such as importation, local working would be irrelevant.[139]

Bayer relied on the argument of economies-of-scale for not locally manufacturing the drug.[140] Manufacturing the drug required huge investment in terms of infrastructure and logistics. Natco, in turn, argued that Bayer was

130 *Id*., 31.

131 Bayer merely submitted that the cost of making the invention and developing a new medical entity like Nexavar works out to about EUR 1.8 billion. *Id*., 59.

132 *Id*., 35 (the order notes that Bayer offers Nexavar at a similar price to patients all over the world).

133 *Id*., 36.

134 The Patents Act, 1970, §84(1)(c).

135 Nexavar Licence, *supra* note 1, 10.

136 *Id*.

137 *Id*., 38-39.

138 *Id*., 40.

139 *Id*., 39.

140 *Id*., 38.

manufacturing other oncology drugs in India through its existing facilities.[141] According to Bayer, Nexavar had a small global demand and hence, was required to be produced in small capacities. To achieve economies-of-scale with a small-volume produce and keep manufacturing costs at a reasonable level, Bayer decided to consolidate both chemical API synthesis and pharmaceutical bulk production of the product covered by patent within its manufacturing facilities in Germany.[142] Though Bayer argued that the quantities required in India do not economically justify setting up a manufacturing facility by Bayer in India, it conceded that due to the local nature of their sales, the drug could be manufactured on a contractual basis with those manufacturers who were experienced in the process of manufacturing the drug in the correct dosage forms.[143]

The Controller observed that local working ('worked in the territory of India') cannot be restricted to mean "worked in India on a commercial scale", as argued by Bayer.[144] The order holds that a combined reading of clauses (c) and (f) of §83 obliges the patentee to contribute towards the transfer and dissemination of technology, nationally and internationally, so as to balance the rights with the obligations.[145] The Controller observed that this could be achieved by either manufacturing the product in India or by granting a licence to any other person for manufacturing in India.[146] The order holds that unless such an opportunity for technological capacity building domestically is provided to the Indian public, they will be at a loss as they will not be empowered to utilise the patented invention after the patent right expires, which certainly could not have been the intention of Parliament.[147] Hence, the Controller concluded that 'worked in the territory of India' implies manufactured in India to a reasonable extent, so that the principles enumerated in §83 are satisfied.

Addressing Bayer's argument that importation would amount to working, the Controller observed that the term 'work the invention' under §84(6) did not include imports, as a patent holder had to necessarily work the patent by manufacturing the invention in India. Thus, the order held that if importing will not amount to working for the compulsory licencee, by the

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141 *Id*., 37.

142 *Id*., 38.

143 *Id*., 39.

144 *Id*., 42-43. The Controller relied on §83(b) which he described "the key to decoding the various provision of Chapter XVI" of The Patents Act, 1970, dealing with compulsory licences. It states that patents are not granted merely to enable patentees to enjoy a monopoly for importation of the patented article, and that mere importation cannot amount to working of a patented invention. The Patents Act, 1970, §83(b); §83(c) further states that the grant of a patent right must contribute to the promotion of technological innovation and to the transfer and dissemination of technology. The Patents Act, 1970, §83(c); §83(f) states that the patent right should not be abused and the patentee should not resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology. The Patents Act, 1970, §84(f).

145 *Id*., 43.

146 *Id*.

147 *Id*.

same reasoning, it would not amount to working if done by the patentee.[148] The Controller concluded that 'worked in the territory of India' means 'manufactured to a reasonable extent in India', noting that the patentee failed to manufacture the invention even after four years of the grant and also failed to grant a voluntary licence on reasonable terms to anyone including the applicant.[149]

During the proceedings, Bayer came up with a proposal of differential pricing.[150] It offered to supply the drug at the existing price of INR 2,80,000 (USD 5200) in the open market to the patients who can afford it and offer the product to deserving patients through its Patient Assistance Program ('PAP') at a reduced price of INR 30,000 (USD 555) per month.[151] Natco countered this proposal by stating that the scope of §84 is to ensure that the product is available in the open market at a reasonably affordable price and not to consider the merits of the PAP.[152] The Controller rejected the proposal under §84(6) – which prohibits the Controller to take account of matters subsequent to the making of the application – as the PAP was made after the filing of the application.[153]

The terms of the Nexavar licence stated that Natco shall manufacture the generic version of Sorafenib for a price not exceeding INR 8,880 (USD 167) for a pack of 120 tablets, required for one month's treatment. The terms also stated that the licence shall be a non-exclusive, non-assignable licence, solely for the purpose of treating patients afflicted with the disease within India, with no right to import the drug for the balance term of the patent.[154] The royalty was fixed at the rate of six percent of the net sales of the drug by Natco.[155]

The Nexavar licence brought the spotlight onto local working. Soon after the Nexavar order, other originator companies such as Hoffmann La-Roche, apprehending similar proceedings, entered into contract manufacturing with Emcure, a local generic manufacturer to satisfy the working requirement for their drugs.[156] The most significant impact was on the price of patented drugs. Soon after the grant, Cipla brought down the price of the generic version of Sorafenib to INR 6,840 (USD 130) for a monthly dose, which was below

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148 *Id*., 44.
149 *Id*., 45.
150 *Id*., 52.
151 *Id*., 46, 49.
152 *Id*.
153 *Id*., 54-55.
154 *Id*., 61.
155 The Patents Act, 1970, earlier provided for a ceiling of four percent royalty to be paid to the patentee in case of compulsory licence, which was later removed by the Patents (Amendment) Act, 2002. *Id*., 58.
156 Jeanne Whalen, *Cancer Drugs Get Cheaper, in India*, Wall Street Journal, March 23, 2012, available at http://online.wsj.com/article/SB10001424052702303812904577297673910205972.html (Last visited on September 19, 2016).

the price that Natco had agreed to sell under the compulsory licence.[157] Other originator companies too reduced or offered to reduce the prices of their drugs: for example, Roche's drugs Herceptin and MabThera were subject to price reductions.[158] The impact of the Nexavar order was such that it evoked varied reactions, either supporting or denouncing it, from politicians and bureaucrats in the United States to pharmaceutical industry observers, and activist lawyers in India.[159]

C. APPEAL BEFORE THE IPAB

Bayer filed an appeal against the order before the Intellectual Property Appellate Board ('IPAB') but the same was rejected, making minor modifications to the order passed by the Controller.[160] In its order, the IPAB observed that the provisions of the compulsory licences are well founded in both national legislation and International treaties and noted that patent rights were created "not in the interest of the inventor, but in the interest of the national economy."[161] On the issue of local working, drawing a distinction between revocation (forfeiture) of a patent and a compulsory licence issued on a patent, the IPAB observed that the "prohibition of discrimination in the grant of patent under the International Conventions which bar forfeiture of patent for not manufacturing locally will not come in the way of the Controller granting a compulsory licence."[162] It noted that 'worked' in §84(1)(c) must be decided on a case-to-case basis and that in a given case, it may be proved that 'working' can be done only by way of import.[163] The IPAB observed that the patentee had to show why it could not be locally manufactured and pointed out that a mere statement to that effect would not be sufficient in the absence of any evidence.[164] It held that the word 'worked' had a flexible meaning and to that extent it differed from the order of the Controller.[165]

On the issue of royalty, though the IPAB observed that the six percent royalty fixed by the Controller was based on United Nations Development Program ('UNDP') recommendations, it agreed with the grievance of the

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[157] Kaustubh Kulkarni, *Cipla cuts generic Nexavar price by 75 pct in India*, Reuters, May 3, 2012, available at http://www.reuters.com/article/2012/05/03/india-cipla-bayer-idUSL4E8G359N20120503 (Last visited on September 19, 2016).

[158] Whalen, *supra* note 156.

[159] *See*, *e.g.*, Divya Rajagopal, *US ups the Ante on Nexavar Generic, Threatens to Take India to WTO,* Economic Times, July 5, 2012, available at http://articles.economictimes.indiatimes.com/2012-07-05/news/32551753_1_compulsory-licence-patent-office-patent-order (Last visited on September 19, 2016).

[160] *See* Intellectual Property Appellate Board (Chennai), Bayer Corpn. v. Union of India, 2013 SCC OnLine IPAB 25.

[161] *Id*., ¶1.

[162] *Id*., ¶51.

[163] *Id*.

[164] *Id*.

[165] *Id*.

appellant that the distributors and stockists were getting a margin of thirty percent, while the appellant got only six percent, as a genuine reason for revision of royalty and ordered an increase of one percent to the royalty fixed by the Controller.[166] Barring the above two interventions, the IPAB upheld the order of the Controller. Bayer agitated the matter further before the High Court of Bombay where it filed a writ petition questioning the findings of the IPAB.[167]

D. APPEAL BEFORE THE HIGH COURT

Dismissing the appeal filed by Bayer, the Bombay High Court upheld the observation of IPAB that the compulsory licence proceedings are in public interest and further held that "public interest is and should always be fundamental in deciding a lis between the parties while granting a compulsory licence for medicines/drugs."[168] The Court also upheld the finding of the IPAB that the 'working' needs to be decided on case-to-case basis.[169] Further, the Court made some pertinent observations on access to medicines. It observed that the "medicine has to be made available to every patient and this cannot be deprived/scarified at the altar of rights of patent holder."[170] The Court regarded access to medicines as the reason behind the Parliament providing for compulsory licensing and opined that such a mandate was in accordance with the Doha Declaration which *inter alia* reiterates the flexibility granted to member countriess to ensure access to medicines for all.[171] TheCourt concluded that it found no reason to interfere with the orders of the Controller and the IPAB.[172]

In light of the string of decisions upholding the compulsory licence granted to Natco, Bayer finally approached the Supreme Court of India.[173] The Supreme Court of India dismissed the Special Leave Petition filed by Bayer but curiously observed that all the questions of law shall remain open.[174]

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166 *Id*., ¶53.

167 Khushboo Narayan & C.H. Unnikrishnan, *Bombay HC Upholds IPAB Order on Nexavar's Generic Copy,* Livemint, July 15, 2014, available at http://www.livemint.com/Companies/feivYXISXb6XBMhELJD6LJ/Bombay-HC-upholds-Nexavar-compulsory-licensing-decision.html (Last visited on September 19, 2016).

168 Bayer Corpn. v. Union of India, 2014 SCC OnLine Bom 963 : AIR 2014 Bom 178, ¶19.

169 *Id*., ¶15.

170 *Id*., ¶13.

171 *Id.*

172 *Id*., ¶20.

173 Samanwaya Rautray, *Nexavar Licence Case: SC Dismisses Bayer's Appeal against HC Decision*, The Economic Times, December 14, 2013, available at http://articles.economictimes.indiatimes.com/2014-12-13/news/57012244_1_bayer-s-compulsory-licence-glivec (Last visited on September 19, 2016).

174 Bayer Corpn. v. Union of India, SLP (C) No. 30145 of 2014, decided on 12-12-2014 (SC) (UR). When a Special Leave Petition ('SLP') is dismissed, it is done by a summary order of dismissal. This is not regarded as a dismissal on merits. A dismissal on merits happens when the SLP is admitted and numbered separately as a civil appeal. A dismissal of a civil appeal will be an order on merits as it would happen after hearing the parties. When the civil appeal is dismissed, it will be right to say that the questions of law have been decided. However, this is

V. THE DISTINGUISHING FEATURES OF MARKET-INITIATED COMPULSORY LICENCE

The countries that issue market-initiated compulsory licences can wield more power than those that issue government-use compulsory licences. They can regulate competition, set a downward spiral in drug prices, facilitate local production and promote price discrimination, in addition to offering solutions to antitrust issues that arise out of a refusal to licence by the patent owner. Market-initiated compulsory licences are different from government-use licences in significant ways.

A. TRIGGER: MARKET FORCES

Market-initiated licences are defined by what commences them. Like an antitrust action, they are triggered by a competitor when the patent holder refuses to offer a licence over a patented invention.[175] Issuing such a compulsory licence no longer requires an emergency – a mere refusal to licence by the patent holder will suffice. The trigger is now shifted from the government to a private party. These licences allow the market to maintain vigilance on antitrust practices, thereby transferring to the market the government function of monitoring whether inventions are locally worked and made available and accessible in the local market. This is done by incentivising the competition to check the patent holders and by making allowance for a compulsory licence. Thus, they are significantly different from the traditional government-use compulsory licences, which are devoid of a third-party initiation and of any procedure to hear them.

B. PROCEDURE: ADVERSARIAL

Market-initiated licences follow an adversarial procedure of adjudication, which differs from the unilateral grants witnessed in government-use licences. The competitor who initiates the licence has to make a *prima facie* case, after which the patent holder is allowed to file its opposition to the application. Both the competitor and the patent holder get an opportunity to state the

not so when an SLP is dismissed. This is a fine distinction. The questions of law are still open. For instance, the dismissal of the SLP does not stop Bayer from challenging the vires of the Patents Act, 1970, §84 through a writ of declaration as Novartis did in the case of §3(d) of the Patents Act, 1970. It is to be noted that there were two writ petitions that Novartis had filed: one challenging the order of the controller, and the other challenging the constitutional validity of §3(d) of the Patents Act, 1970. The Supreme Court has indirectly indicated that the latter option is still open for Bayer. I am of the view that the court did that to avoid any ambiguity that could arise in future.

[175] *C.f.* Ian Forrester & Katarzyna Czapracka, *Compulsory Licensing in European Competition Law: The Power of the Adjective* in Intellectual Property and Competition Law: New Frontiers 142 (1st ed., 2011) (noting that the European Union's response to refusal to licence was by granting compulsory licences under competition law).

terms on which they would agree for a licence. After considering their respective arguments, the Controller of Patents either allows or rejects the application of the competitor. The adversarial process allows the patent holder to negotiate the terms of the licence and to have a say in fixing the royalty rate of the licence.

C. SITUATION: NON-EMERGENCY AND NON-POLITICAL

Much of the government-use compulsory licences have political overtones. For example, the compulsry licence granted by the government of Thiland was a part of its commitment to its universal health program.[176] This move was also considered to be used to increase its political capital and transforming the country into a hub for the manufacture and export of medicines.[177] The issuing countries have become vocal, and use these cases as a means to grab the attention of the world, in the way they make the grants.[178] Since the option of compulsory licence is considered when the negotiation with patent holders breaks down and is used more as a threat to make the patent holder fall in line, such threats or expressions of intention are often made publicly. The last decade saw Thailand's public health authorities issue two compulsory licences on HIV/AIDS drugs and one on clopidogrel bisulfate (Plavix) for a non-communicable disease.[179] This was done with a lot of fanfare and with a follow-up list of candidates for further compulsory licences.[180] Even Brazil, a country which until 2007 had deftly negotiated settlements with foreign companies without issuing a compulsory licence,[181] made its declaration of intent more explicit. The President signed the order for compulsory licence for governmental use of Merck's Sustiva (efavirenz) in a public ceremony that was broadcasted worldwide.[182] The politicised nature of some compulsory licences, especially the ones granted by Thailand, has been the subject of criticism.[183] In contrast, market-initiated compulsory licences are devoid of political overtones that punctuate government-use licences, as these licences are granted

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[176] V. Kuek et al., *Access to Medicines and Domestic Compulsory Licensing: Learning from Canada and Thailand*, 6 Global Public Health 111, 117 (2011).

[177] *Id.*

[178] Jon Cohen, *Brazil, Thailand Override Big Pharma Patents*, 316 Science 816 (2007) (noting that Brazilian President Luiz Inácio Lula da Silva signed the decree to issue a compulsory licence over a HIV/AIDS drug in a televised ceremony).

[179] Beall & Kuhn, *supra* note 2.

[180] Kristina M. Lybecker & Elisabeth Fowler, Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules, 37 J.L. Med. & Ethics 222 (2009).

[181] Abbott & Reichman, *supra* note 74, 921.

[182] Cohen, *supra* note 178.

[183] *See, e.g.*, Richard A. Epstein & F. Scott Kieff, *Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents,* 78 U. Chi. L. Rev. 71, 93 (2011) ("The Thai CL was a matter of political fiat, unrestrained by law. It sets a dangerous precedent that other nations should avoid, given that they have other sensible methods, in the form of direct and bulk purchases, to help their own vulnerable populations.").

in situations that do not involve a health emergency. Also, non-governmental organisations do not play a significant role in these licences.. Since market-initiated licences are solely determined by the forces of demand and supply, the market failure caused by drugs which are inacessible due to high price or unavailable due to meagre production can be resolved by allowing competitors to seek such complusory licences.

D. TERM: LIFE OF THE PATENT

Since the grant of the licence is neither triggered nor tied to an emergency situation, its term could potentially exist for the remaining term of the patent. Though the TRIPS Agreement states that "the scope and duration of such use shall be limited to the purpose for which it was authorized", the absence of an emergency or a specific situation makes it difficult to limit the term of the licence.[184] This is due to the deficiency in the language of the TRIPS Agreement which foresees compulsory licences as situation-specific and stipulates that the "authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur."[185] If the market-initiated licence is granted for the rest of the term of the patent as it was done in the Nexavar licence, the patentee would have to move the Controller for reviewing its decision on the ground that the circumstances for the grant have ceased to exist.[186]

E. COMPENSATION: NEGOTIATED

Unlike a government-use licence, a market-initiated licence offers the patent holder an opportunity to stipulate the rate of royalty, as the licences are initiated at the request of the third party who is willing to manufacture the patented product. Though Bayer requested for fifteen percent royalty, considering its R&D expenditure, the Controller awarded six percent, as Bayer did not give the details of the R&D costs for Nexavar.[187]

F. GROUNDS: MULTIPLE

The three grounds for the grant of a market-initiated compulsory licence often overlap, making it potentially indefeasible when issued on multiple grounds. For instance, the order found that Bayer had failed to fulfil the demand for adequate quantities of the drug, which attracts the ground under §84(1)(a) by linking it with the duty to work locally, imposed under §84(1)

[184] TRIPS Agreement, *supra* note 39, Art. 31(c).
[185] *Id*., Art. 31(g).
[186] *Id*.
[187] Nexavar Licence, *supra* note 1, 60.

(c).[188] The effect of such linkage is that even if Bayer succeeds in making a case in appeal that importation would satisfy the requirement of working under §84(1)(c), it would still find it hard to avoid the continuance of the licence on the grounds mentioned in §84(1)(a) and §84(1)(b), which are essentially public interest grounds. Local working is just the first step to ensure the availability of the drug in the market. Even if the drug is locally manufactured, there could be instances where the price is not within the reach of the masses, thereby attracting the grounds in §84(1)(a) and §84(1)(b).[189] Though a government-use licence could also be issued on similar grounds, it is unlikely that non-working would be cited as one of them, as raising such a ground would necessitate the capacity of locally working the invention, a factor that can only be demonstrated by a locally manufacturing pharmaceutical company.

G. RETALIATION: NO WITHDRAWAL OF DRUG

The grant of government-use licences often leads to retaliatory measures, such as withdrawal of drugs by the patent holder.[190] However, in a market-initiated regime, there is no merit in the patent holder threatening to withdraw its products from the local market, as the interest shown by the competitor in preferring an application for compulsory licence is a certain indicator that the product will be locally produced.[191] The threat of withdrawal is not a material one as these licences are granted in countries that have the local capacity to produce the drugs.

Market initiated compulsary licences thus have these distinct features, as detailed above.

VI. CONCLUSION

The compulsory licence regime has largely evolved as a regime that aims to strike a balance between the right of the patent holders and the issue of accessibility of the patented product. However, the scholarship surrounding compulsory licences has shown a lack in the categorisation of compulsory licences based on the conduct of the patent holder that triggers it, the territory granting the licence or the need that makes the issuance of licence a necessity. The categorisation of compulsory licences gains significance when one

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[188] *Id*., 14 (equating local working to a duty owed under The Patents Act, 1970).

[189] The mandate of the law goes beyond mere supply in the market, and it extends to making the drug available in a manner such that a substantial portion of the public is able to reap the benefits of the invention.

[190] Cohen, *supra* note 178.

[191] The Patents Act, 1970, §84(6), requires the Controller of Patents to take into account the ability of the person making the application for compulsory licence to work the invention to public advantage. The ability to work the invention will ensure that the product will be locally produced.

enquires into the advantages of market-initiated licences over government-use licences.

While a government-use licence is mostly issued to address a situation of national emergency or public healthcare crisis, a market-initiated licence is not necessarily initiated by an emergency, but by an act of a market player applying for a licence and the subsequent refusal by the patent holder to grant a voluntary licence. Even though, theoretically, Article 31 of the TRIPS Agreement empowers member nations to issue a market-initiated compulsory licence even in the absence of a national emergency, the effectiveness of such a licence depends on the capacity of the competitors to manufacture and sell the patented product locally. Also, the domestic laws governing the patent regime need to have provisions where a private party can initiate the process based on the refusal to licence by the patent holder.

The Nexavar licence became a turning point in the history of compulsory licences. It is the first market-initiated licence that was issued in 2012 despite the fact that there was no national emergency or public health crisis. The main reason for the licence was the refusal by Bayer, the originator company to provide a voluntary licence to Natco, an Indian generic drug manufacturer. Natco sought a compulsory licence on all the three grounds in §84 of the Patents Act – lack of accessibility, lack of affordability and lack of local working, making the application indefeasible.

The Nexavar licence essentially demonstrtated the multitude of advantages that a market-initiated compulsory licence has over a government-use compulsory licence. A market-initiated compulsory licence helps regulate competition in the market, reduces drug prices to affordable levels, facilitates the local manufacture of the patented product, prevents abuse of the dominant position by the originator company and also facilitates price discrimination. While keeping in mind the interests of the market players and the consumers at large, a market-initiated compulsory licence also protects the rights of the patent holder by providing him with an opportunity to stipulate the rate of royalty. The other area of concern that a market-initiated compulsory licence addresses is the issue of withdrawal of drugs by the patent holder. In case of a government-use compulsory licence, there is a risk of withdrawal of the drug from the market by the patent holder. However, since a competitor who has already demonstrated his ability to produce the drug locally has triggered a market-initiated compulsory licence, the risk of withdrawal of the drug from the market by the patent holder is reduced.