Striking a Balance between Patent Rights and Access to Essential Medicines Through the Use of Compulsory Licenses – Comparative Study of Indian and Malaysian Patent Laws

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Abstract

In view of the exorbitant prices charged by pharmaceutical companies as patent monopolists, the economically underprivileged, mostly residents of developing countries, are regularly denied access to essential medicines in as much as the medicines are largely beyond their means. 'Compulsory Licenses' are one of the means for bridging the gap between the high charges imposed by pharmaceutical patent monopolists and the affordability of the economically underprivileged patients. In the pharmaceutical sector, 'compulsory licenses' can be employed by the government to allow generic pharmaceutical companies to produce and sell the patented essential medicines at a fraction of the price being charged by the pharmaceutical monopolists for meeting its twin objectives of ensuring accessibility and affordability of essential medicines for all. In this article, benefits and criticisms of compulsory licenses in the backdrop of the comparative breadth and depth of the Indian and the Malaysian provisions for compulsory licenses have been examined

I. INTRODUCTION

Though scientists have been successful in making inroads into finding cures for some of the deadliest diseases of this century, it is saddening to note that their success has remained largely beyond the reach of the economically underprivileged. Essential medicines, differing from medicines in general, are those which satisfy the priority health care needs of the people[1]. Unfortunately, about one-third population of the developing countries is denied regular access to these medicines.[2] This is because exorbitant prices of essential medicines deter millions from availing their benefits. These prices are further exacerbated by issuance of pharmaceutical patents up to twenty years long, resulting in the sanctioning of monopoly. Pharmaceutical companies, as patent holders, are then uniquely placed to set monopolistic high prices for their patented medicines and thereby advance inequity in distribution of essential, life-saving medicines.

To counter the adverse effects of patents, the medium of compulsory license has been designed to meet the twin objectives of affordability and accessibility of essential

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1 *Essential Medicines*, World Health Organization: http://www.who.int/trade/glossary/story025/en/ Site accessed on 26 July 2015.

2 *Access to Medicines,* World Health Organization: http://www.who.int/trade/glossary/story002/3n/ Site accessed on 26 July 2015.

medicines for all.[3] Compulsory license refers to the license to use patented invention without the permission of the patent holder.[4] It acts as a legal counterweight against patent monopoly by facilitating access to the patented invention at reasonable prices.[5]

Globally, World Trade Organization's Trade Related Aspects of Intellectual Property Agreement, 1995 (TRIPS Agreement) allows its member states to provide for limited exceptions to the exclusive rights conferred to a patent holder,[6] including the provision for use of a patent by the government or by third parties duly authorised by the government, without the authorisation of the rights holder[7]. Accordingly, India and Malaysia as signatories to the TRIPS Agreement have provided for compulsory licenses in their respective patents laws.

In line with the above, Malaysia became the first member state of WTO to grant a compulsory license for an antiretroviral (AIDS) drug.[8] Following unsuccessful price negotiations with the patent holders, GlaxoSmithKline and Bristol-Myers Squibb, the Malaysian Minister of Domestic Trade and Consumer Affairs, at the instance of the Malaysian Ministry of Health, in 2003 granted a two year long 'government use' license for three patented anti-retroviral drugs vis didanosine (ddl), zidovudine (AZT) and lamivudine + zidovudine (Combivir), for their use in the treatment of AIDS[9]. In furtherance thereof, in 2004 the Minister entered into a contract with a generic drug company, Cipla Ltd., to import the three compulsory licensed drugs from India. Where initially the cost of treatment per patient per year with the patented drugs, as charged by the patent holders, was USD10,000 to 15,000 post grant of compulsory licenses, the Minister by way of import of generic medicines from India was able to price the drugs at one seventh of the original price, resulting in the treatment of an additional 2,500 HIV patients. Not that the patent holders were left entirely without any remuneration: remuneration at the rate of 4% of the value of stocks delivered to Malaysia was offered to them.[10]

Nine years behind Malaysia, in 2012, India granted its first ever compulsory license for an anti-cancer drug in favour of an Indian generic pharmaceutical company, Natco Pharma Ltd.[11] Previously, Natco had approached Bayer Corporation for a voluntary license

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3 Raadhika Gupta, "Compulsory Licensing under TRIPS: How Far it Addresses Public Health Concerns in Developing Nations", *Journal of Intellectual Property Rights*, 2010, Vol. 15, pp. 357-363.

4 Article 31, *Agreement on Trade-Related Aspects of Intellectual Property Rights.*

5 Report of the ASEAN Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals, Jakarta, 2-4 May 2000, *The TRIPS Agreement and Pharmaceuticals*, Directorate General of Drug and Food Control and World Health Organization: http://apps.who.int/medicinedocs/pdf/h1459e/h1459e.pdf Site accessed on 26 July 2015.

6 Article 30, *Agreement on Trade-Related Aspects of Intellectual Property Rights*.

7 *Supra* n 4.

8 Marius Meland, *Malaysia Issues World's First Compulsory License*, http://www.law360.com/articles/1035/malaysia-issues-world-s-first-compulsory-license Site accessed on 26 July 2015.

9 *Letter from Minister of Domestic Trade and Consumer Affairs, Malaysia to Director of Operations*, Consumer Project on Technology: http://www.cptech.org/ip/health/c/malaysia/arv-license.html Site accessed on 17 July 2015.

10 Martin Khor, *Compulsory License and Government Use to Promote Access to Medicines: Some Examples*, Third World Network, 2014, pp. 7-9.

11 *Natco Pharma Ltd v Bayer Corporation*, 9 March 2012, Compulsory License Application No. 1 of 2011, Controller of Patents, Mumbai: http://www.ipindia.nic.in/iponew/compulsory_license_12032012.pdf Site accessed on 16 July 2015.

to its patented drug Sorafenib (brand name: *Nexavar*), used in the treatment of liver and kidney cancer, offering to manufacture and sell the drug at a price of about USD155 per month's therapy as compared to the USD4,400 being charged by Bayer at that time. However, Natco's request was resoundingly rejected by Bayer. After a lapse of more than two years, Natco applied to the Indian Controller of Patents ('Controller') to seek a compulsory license for the drug, and on March 9, 2012, the Controller finding that all three grounds for grant of a compulsory license were met by Bayer, granted India's first and only compulsory license to date.[12] Subsequently, Bayer appealed to the Intellectual Property Appellate Board, petitioned the High Court of Bombay and even the Supreme Court of India, to set aside the compulsory license granted to Natco. Nonetheless, all three quasi-judicial/ judicial bodies upheld the order of the Controller.[13] As a result, now thousands of Indian kidney and liver cancer patients have access to *Nexavar* at a fraction of the original price.

II. PURPOSE OF COMPULSORY LICENSE

In lieu of public disclosure of the working of the patented invention, patents are granted to legally entitle the holder to exclude others from practicing the patented invention for a pre- determined period.[14] It is believed that through disclosure of the working of a patented invention, the public at large shall benefit from diffusion of knowledge and information whereby others shall be enabled to come up with newer and better inventions. India[15] and Malaysia[16] with the view to achieving technology diffusion under their respective patent laws clearly specify that *inter alia* the right of exclusion of a patent holder shall not extend to acts done in furtherance of scientific research.

However, and especially in the pharmaceutical sector, the advantages of patents are offset by the debilitating effects of patent monopoly on the public welfare. Denial of voluntary licenses for the working of the patented invention, monopolistic prices and supply shortages of the patented medicines are but a few examples of the adverse effects of pharmaceutical patent monopoly. Accordingly, for removal of the disadvantages of pharmaceutical patent monopoly, State intervention is called for. To this end, since patents are privileges granted by the State, the State in situations warranting concessions for preserving public welfare can limit the scope of patents.[17] One such medium through which potential abuse of patents can be limited by the State is that of compulsory license. By way of compulsory licenses the State can authorise others to use the pharmaceutical patent[18] and thus ensure the existence of multiple competitors in the pharmaceutical market.

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12 *Ibid*.

13 Samanwaya Rautray, *Nexavar License Case: SC Dismisses Bayer's Appeal Against HC Decision*, The Economic Times: http://articles.economictimes.indiatimes.com/2014-12-13/news/57012244_1_bayer-s-compulsory-licence-glivec Site accessed on 16 July 2015.

14 Muhammad Zaheer Abbas, "Pros and Cons of Compulsory Licensing: An Analysis of Argument", *International Journal of Social Sciences and Humanity*, 2013, Vol. 3, No. 3.

15 Section 47(3) Indian Patents Act 1970.

16 Section 37(1) Malaysian Patents Act 1983.

17 *Supra* n 14.

18 *Supra* n 4.

India, in particular, mandates that patents must not impede protection of 'public health' and nutrition but instead should endeavour to promote 'public interest', especially in sectors vitally important for socio-economic and technological development.[19] In addition, the Indian Central Government's power to take measures necessary for protection of 'public health' is not in any way deterred by patents.[20] Hence, in line with its emphasis on 'public welfare', India provides for 'compulsory licenses' to *inter alia* secure the fullest commercial working of the patented invention to the extent reasonably practicable[21] and to make the patented invention available to the public at reasonably affordable prices[22].

III. COMPATIBILITY WITH TRIPS AGREEMENT

Notwithstanding the TRIPS Agreement's stipulation for each member state to provide for pharmaceutical product and process patents in their respective patent laws,[23] the Agreement also allows for certain flexibilities to its member states such as the freedom to give effect to the provisions of the agreement and the freedom to choose a customised method of implementation appropriate for the individual domestic legal system.[24] Other flexibilities include the freedom of a member state to take measures necessary for protection of public health and nutrition[25] and the freedom to grant compulsory licenses under Article 31 of the Agreement.[26] Though Article 31 prescribes the procedural and substantive conditions for grant of compulsory licenses yet it does not extrapolate on the scope of the substantive conditions.[27] Instead, the Agreement permits its member states to use their own discretion in framing the grounds for grant of compulsory licenses.[28]

Specifically, in the context of pharmaceutical patents, the Doha Declaration on the TRIPS Agreement and Public Health, 2001 acknowledges the necessity of member states to take measures for protection of public health and promotes the purposive interpretation and implementation of provisions of the TRIPS Agreement for meeting the objectives of accessibility and affordability of essential medicines for all.[29] The Declaration particularly encourages developing countries to fully explore the flexibilities of Article 31 of the TRIPS Agreement[30] and to freely determine the scope of compulsory licenses.[31]

Having incorporated these flexibilities in their respective patent laws, both India and Malaysia should now work towards adopting the most expansive interpretation of

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19 Section 83(d) Indian Patents Act 1970.
20 Section 83(e) Indian Patents Act 1970.
21 Section 89(a) Indian Patents Act 1970.
22 Section 90(3) Indian Patents Act 1970.
23 Article 27, *Agreement on Trade-Related Aspects of Intellectual Property Rights.*
24 Article 1.1, *Agreement on Trade-Related Aspects of Intellectual Property Rights.*
25 Article 8, *Agreement on Trade-Related Aspects of Intellectual Property Rights.*
26 *Supra* n 4.
27 *Ibid.*
28 *Ibid.*
29 Paragraph 4, *Declaration on the TRIPS agreement and Public Health*, 14 November 2001.
30 *Ibid.*
31 Paragraph 5, *Declaration on the TRIPS agreement and Public Health*, 14 November 2001.

the TRIPS provisions as possible for translating the flexibilities of the Agreement into tangible benefits for their economically weak and underprivileged populations.

IV. SCOPE OF COMPULSORY LICENSE

The TRIPS Agreement mandates that the scope and duration of a compulsory license must be limited to the purpose for which it has been authorised.[32] In furtherance thereof, India and Malaysia have included certain limitations with regard to the use of compulsory licenses, including limitations of non-exclusivity and non-assignability of compulsory licenses.[33] While India mandates a blanket prohibition on assignment of compulsory licenses, Malaysia prohibits a beneficiary of a compulsory license to conclude license contracts with third parties[34] but on the other hand allows assignment of compulsory licenses in connection with the 'goodwill' or 'business' or that part of the goodwill or business in which the patented invention is used.[35] Since the terms 'goodwill' and 'business' have neither been defined under the Malaysian Patents Act, 1983 and nor has its meaning been explored by the Malaysian Judiciary, the true interpretation of the scope and extent of this exception remains ambiguous.

Further limitations include a mandatory requirement of working of the compulsorily licensed patented invention in the respective territories of India[36] and Malaysia[37]. In this endeavour, an Indian beneficiary is barred from importing the patented invention from abroad inasmuch as the importation constitutes infringement of the rights of the patent holder,[38] though conversely no such restriction has been recognised in Malaysia. Additionally, beneficiaries are also bound to remunerate the patent holders for use of their patented invention and the amount of such payable royalty shall be set forth by the Indian Controller[39] and the Malaysian Corporation[40] at the time of fixing the terms of compulsory licenses. Pursuant thereto, the Indian Patents Act, 1970 lays down certain factors to be considered for establishing the value of 'reasonable' royalty viz. the nature of the invention, the expenditure incurred by the patentee in making, developing or obtaining the patent and other relevant factors.[41] *Nexavar* compulsory license being the case in hand, the Controller therein, with due regard to the 'reasonable' royalty factors, directed Natco to pay Bayer Corporation a royalty at the rate of 6% of the net sales value of *Nexavar*, which was later increased by the Appellate Board to 7%.[42] Moreover, under the Indian patents

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32 *Supra* n 4.
33 Section 90(1)(iv) and (v) Indian Patents Act 1970.
34 Section 53(2) Malaysian Patents Act 1983.
35 Section 53(1)(a) Malaysian Patents Act 1983.
36 Section 90(1)(ii) Indian Patents Act 1970.
37 Section 54(2)(b) Malaysian Patents Act 1983.
38 Section 90(2) Indian Patents Act 1970.
39 Section 90(1)(i) Indian Patents Act 1970.
40 Section 52 Malaysian Patents Act 1983.
41 *Supra* n 39.
42 *Bayer Corporation v Union of India*, 4 March 2013, (OA/35/2012/PT/Mum), Intellectual Property Appellate Tribunal: http://www.ipabindia.in/Pdfs/Order-45-2013.pdf Site accessed on 20 July 2015.

Act, 1970, the Controller while setting the terms and conditions of a compulsory license is bound to also ensure that the beneficiary is able to earn a reasonable profit from working of the patented invention without hindering the availability of the patented invention at 'reasonably affordable prices'.[43] Absence of a corresponding provision in the Malaysian Patents Act, 1983 is unfortunate as it may result in discouraging the Malaysian generic pharmaceutical companies from taking the initiative of acquiring compulsory licenses.

In addition, the scope of a compulsory license is also limited by its duration of applicability. Although the three Malaysian 'government use' licenses for antiretroviral drugs were granted for a period of two years[44], the Indian compulsory license for *Nexavar* shall continue to be in force for the remaining lifespan of the patent.[45] Moreover, in case Bayer Corporation, even after two years from the date of grant of the compulsory license, fails to dispel all three of the grounds which formed the basis for grant of the compulsory license to Natco, any interested person, including the Central Government, can approach the Patent Office to seek revocation of the concerned patent. If however Bayer, during the subsistence of the compulsory license, is able to offset all three grounds of the compulsory license, then based on the change in circumstances, upon Bayer's request, the Controller can terminate the compulsory license, provided Bayer is able to first establish non-recurrence of its previous conduct.[46] Similarly, in Malaysia a compulsory license can be amended[47] or cancelled[48] when the circumstances which gave rise to the compulsory license cease to exist. Herein, the inclusion of termination provision in the scheme of compulsory licenses reinforces the proposition that compulsory licenses are in fact not granted for the benefit of the applicant but instead are the medium for ensuring that the patented invention reaches the public.[49]

V. COMPULSORY LICENSE TO IMPORT FROM ABROAD

Ordinarily, a patent holder is entitled to exclude others from importing their patented invention from abroad, however in furtherance of 'public interest' the Indian Central Government can direct the Controller to authorise a beneficiary to import the compulsorily licensed patented invention.[50] As the Indian legislature has not narrowed down the ambit of 'public interest' under this provision by inclusion of any qualifications, in its broadest form 'public interest' can be read to include accessibility and affordability of essential medicines by all, and hence hypothetically in all circumstances where the twin objectives of accessibility and affordability are not met, a beneficiary can be allowed to import the patented medicine from abroad. This exception is notwithstanding the presence or absence of adequate pharmaceutical manufacturing facilities within the territory. Yet,

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43 Section 90(1)(ii) and (iii) Indian Patents Act 1970.
44 *Supra* n 8.
45 *Supra* n 11.
46 Section 94 Indian Patents Act 1970.
47 Section 54(1) Malaysian Patents Act 1983.
48 Section 54(2)(a) Malaysian Patents Act 1983.
49 *Supra* n 42.
50 *Supra* n 22.

this import authorisation need not entirely be unrestricted. The Central Government can, at its discretion, make these imports conditional upon payment of royalty or any other remuneration to the patent holder, and can otherwise stipulate the quantum of imports allowed, the sale price chargeable for the imported patented medicine, the period of importation, and any other condition that it may deem relevant.[51]

India by means of this exception has re-emphasised its pro 'public interest' patent policy which is found to be the common thread running through each provision concerning compulsory licenses under the Indian Patents Act 1970. In this regard, Malaysia lags behind India as it not only lacks an equivalent provision for 'public interest' guiding import authorisation under a compulsory license, but it has also to date not incorporated the WTO decision of 2003, as explained herein below.

VI. COMPULSORY LICENSE TO EXPORT TO OTHER COUNTRIES

Earlier, export under a compulsory license had been restricted under the TRIPS Agreement with only a limited implied exception existing for export of the surplus products upon satisfaction of the domestic demands. Principally, compulsory licenses were granted predominantly for supply to the domestic markets.[52] This restriction on export of patented medicines had a severe impact on accessibility of patented essential medicines, particularly affecting the interests of patients of countries with minimum to no pharmaceutical manufacturing capacities such as Malaysia of 2004, as these countries were left without any reasonable avenue for meeting their immediate demand for these essential medicines. Considering that the said restriction was one of the strongest deterrents against achieving a unanimous WTO approval of the TRIPS Agreement, pursuant to the Doha Declaration on the TRIPS Agreement and Public Health of 2001, a compromise was reached on 30 August 2003 to allow export of compulsorily licensed patented medicines to countries with insufficient or no manufacturing capacities[53] provided the importing countries grant a compulsory license in their territory for the patented medicine,[54] take reasonable measures for blocking re-export of imported medicines to another country[55] and provide for effective legal means for prevention of any inconsistent import or sale of patented medicines within their territories[56].

Nonetheless, WTO's laudable move has not escaped its fair share of criticisms. Its policy of requiring prior notification by a member state of its intention to import[57] or

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51 *Ibid.*

52 Article 31(f), *Agreement on Trade-Related Aspects of Intellectual Property Rights*.

53 Paragraph 6, *Declaration on the TRIPS agreement and Public Health*, 14 November 2001.

54 Article 2(a)(iii), *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,* 30 August 2003.

55 Article 4, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,* 30 August 2003.

56 Article 5, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,* 30 August 2003.

57 Article 1(b), *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,* 30 August 2003.

export[58] patented medicines; prior establishment of a website specifying the details of the imported/ exported patented medicines;[59] and employment of distinguishing features like special packaging and/ or special colouring/ shaping for the patented medicines[60] have been criticised for being time consuming, cumbersome and unnecessary hindrances to effective importation of patented medicines.[61]

Though India has ratified the WTO decision of 30 August 2003,[62] Malaysia, favouring supply within its domestic territory,[63] has refrained from incorporating this decision despite previously having taken advantage of the flexibilities of this decision for importing patented antiretroviral drugs from India.[64] Unlike Malaysia, India not only allows exports to countries with insufficient or no pharmaceutical manufacturing capacities but also allows exports for supply and development of export markets in general.[65]

Another exception against prohibition of export has been devised for remedying the 'judicially or administratively determined' anti-competitive practices of a patent holder.[66] Ergo if denial of a voluntary license for meeting of external demands is found to be an anti-competitive refusal on part of the patent holder, then a compulsory license for export can be granted. Interestingly, considering that here the very act of an anti-competitive refusal is sufficient for permitting export of the patented invention, the scope of 'external demands' herein may even be wider than that of WTO decision of 2003 to additionally include demands of countries with adequate pharmaceutical manufacturing capacities[67]. Yet again, even though India has incorporated this additional exception of the TRIPS Agreement in its patent laws,[68] Malaysia has not.

VII. GROUNDS FOR CLAIMING A COMPULSORY LICENSE

An application for a compulsory license in India must satisfy any of the following three grounds, namely:

(i) non-satisfaction of the reasonable requirements of the public;
(ii) non-availability of the patented invention at reasonably affordable prices; or
(iii) non-working of the patented invention in India.[69]

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58 Article 2(c), *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,* 30 August 2003.

59 Article 2(b)(iii), *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,* 30 August 2003.

60 Article 2(b)(ii), *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,* 30 August 2003.

61 *Supra* n 3.

62 Section 92A Indian Patents Act 1970.

63 Section 53(1)(b) Malaysian Patents Act 1983.

64 *Supra* n 9.

65 Section 90(1)(vii) Indian Patents Act 1970.

66 Article 31(k), *Agreement on Trade-Related Aspects of Intellectual Property Rights.*

67 Ng-Loy Wee Loon, "Exploring Flexibilities within the Global IP Standards", *Intellectual Property Quarterly*, 2009.

68 Section 90(1)(ix) Indian Patents Act 1970.

69 Section 84(1) Indian Patents Act 1970.

Separately, in Malaysia, a person can apply to the Registrar for a compulsory license where any of the following circumstances arise without a legitimate reason:

(i) non-meeting of public demand;
(ii) non-availability of the patented product for sale in any of the domestic markets;
(iii) unreasonably high prices of the patented product; or
(iv) non-production of the patented product or application of the patented process in Malaysia.[70]

Comparing the two sets of grounds, it is apparent that though the same are couched in different words, both India and Malaysia construe eligibility of compulsory licenses in similar circumstances. While the Indian Judiciary, in keeping with the spirit of the Doha Declaration of 2001, has liberally interpreted the scope of these grounds in the *Nexavar* case, the Malaysian Judiciary has not yet been approached to review the legality and scope of these grounds. In view of the similarities between the compulsory licensing regimes of the two countries, Malaysia is open to borrow the Indian learnings in this regard.

A. Meeting Reasonable Requirements of the Public

While patent holders have the prerogative to refuse a license for their patented invention, they are also bound to meet the 'reasonable requirements of the public' for their patented invention. With the view to balance the two competing interests, the Indian Patents Act, 1970 specifies that if a reasonably termed license to a patented invention is refused and in consequence an existing trade/ industry or other commercial activities or development thereof is prejudiced or establishment of a new trade or industry is prejudiced, or demand for the patented invention with regard to both quantity and price,[71] is not adequately met, or establishment or development of a market for export is prejudiced[72] or for that matter anti-competitive terms like exclusive grant back, waiver of right to challenge the validity of the patent, coercive package licensing etc. are mandatorily included in the license agreement[73], then the patent holder shall be considered to have not met the 'reasonable requirement of the public'.

Independently, in case a patent holder even after expiry of three years from the date of grant of patent does not work the patented invention to an adequate commercial extent or to the fullest extent that is reasonably practicable[74]or otherwise hinders the working of the patented invention in India by way of importing the patented invention,[75] then again the reasonable requirements of the public shall be deemed to be not met. In the context of essential medicines, working the patented medicines to an 'adequate commercial extent' refers to meeting the 100% demand, with no patient being left in want of a patented

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70 Section 49(1)(a) and (b) Malaysian Patents Act 1983.
71 *Supra* n 42.
72 Section 84(7)(a) Indian Patents Act 1970.
73 Section 84(7)(c) Indian Patents Act 1970.
74 Section 84(7)(d) Indian Patents Act 1970.
75 Section 84(7)(e) Indian Patents Act 1970.

medicine.[76] As in the case of Bayer Corporation, its act of making the patented medicine available to less than 3% of the eligible patients was determined by the Controller to be insufficient for meeting the reasonable requirements of the public.[77]

B. Making the Patented Invention Available to the Public at Reasonably Affordable Prices

'Reasonably affordable price' has neither been defined under the Indian Patents Act 1970 nor under the Malaysian Patents Act 1983. Its scope instead was determined by the High Court of Bombay in the *Nexavar* case wherein the court held that the reasonably affordable price of a patented drug is dependent on *inter alia* the evidence led by the applicant and the patent holder on their proposed respective prices; the relative price of the applicant in comparison to the patent holder; and the research and development costs incurred for the patented drug.[78] When Bayer priced *Nexavar* at about USD4400 for one month of therapy and on the other hand Natco offered to supply *Nexavar* at a much reduced price of about USD155 for a month long therapy, the High Court of Bombay after considering the purchasing ability of the public determined that the price being charged by Bayer was *'unreasonable for a very large section of the public'*. Even though Bayer had offered differential pricing under its Patient Assistance Program, and *Nexavar* provided it at subsidised prices to the economically weaker patients, the Court found that the cost of the medicines was itself so prohibitive that in spite of the subsidies the medicine remained unaffordable by the public at large. Consequently, the Court upheld the compulsory license granted by the Controller to Natco.[79]

Much as Bayer had failed to satisfy the Court as to the affordability of *Nexavar*, the mode of 'differential pricing' of patented medicines for the different economic stratum of a population is a viable alternative for pharmaceutical companies to recoup their costs and simultaneously ensure accessibility and affordability of the patented medicines by all. As explained later in this article, through differential pricing, pharmaceutical companies by charging in accordance with the paying capacity of the patient can equalise their high, low or even forgone profits on sale of patented medicines.

C. Working the Patented Invention in the Territory

Patents are not granted to merely enable patent holders to monopolise imports of the patented invention.[80] Rather, patents are granted to create a sound technology base and to contribute to the promotion and transfer of technological innovation and dissemination of knowledge in a manner which is conducive to the social and economic welfare of the

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76 *Bayer v Union of India*, AIR 2014 Bom 178.
77 *Supra* n 11.
78 *Supra* n 76.
79 *Ibid.*
80 Section 83(b) Indian Patents Act 1970.

people.[81] The question then arises as to how these objectives of patent protection can be secured.

As the hotly debated Article 27(1) of the TRIPS Agreement stipulates that patents shall be enjoyed without discrimination as to the place of invention, be it foreign or local,[82] accordingly, any requirement of local production of a patented invention shall run contrary to Article 27(1). But then the Agreement also acknowledges 'technology transfer' as one of the objectives of patent protection;[83] and local manufacture of a patented invention is most conducive for enabling transfer of technology in a territory. Consequently, these conflicting requirements under the TRIPS Agreement can only be resolved by harmonising the principle of exhaustion with the local working requirement. Take India, for instance, despite emphasising on the local working of a patented invention[84], it does not impose a mandatory obligation on patent holders to locally work their patented inventions, especially where it may not be feasible for a patent holder to work his invention in India.[85] While determining the extent of the working of *Nexavar* in India, the High Court of Bombay held that local manufacture is not necessary for establishing the working of a patented invention if the patent holder is able to satisfy the Controller as to why the patented medicine is not being manufactured in India, and if the Controller's concerns are alleviated, the patented medicine can be considered to be worked in India by way of imports.[86]

Moreover, in case the patent holder is found to have promptly taken adequate or reasonable steps to work the invention, but as on the date of application for a compulsory license, the patented invention has not adequately, or on a commercial scale, or to the fullest extent reasonably practicable, been worked in India, then if the Controller is of the mind that the time elapsed since sealing of the patent has been insufficient for working the invention, he can adjourn the proceedings for a maximum period of twelve months to allow the patent holder to fulfil his obligation of working the patented invention.[87] Further, if the patent holder is able to establish that he was unable to work the patented invention in India due to imposition of any State or Central Government's Act, Rule, Regulation, or Order, not being a condition for working the invention in India, then the period of adjournment shall be reckoned from the date of expiry of the preventive Act, Rule, Regulation or Order.[88]

Next, the question of determining the extent of local working of the patented invention shall depend on *inter alia* commercial scale of working and the resultant mutual advantage to technological advancement of producers as well as users of technology.[89]

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81 Section 83 (c) Indian Patents Act 1970.
82 *Supra* n 23.
83 Article 7, *Agreement on Trade-Related Aspects of Intellectual Property Rights.*
84 Section 83(a) Indian Patents Act 1970.
85 *Supra* n 76.
86 *Ibid.*
87 Section 86(1) Indian Patents Act 1970.
88 *Ibid.*
89 *Supra* n 76.

Hence, working of a patented invention is not formulaic and can be determined only on a case-to-case basis.

VIII. PROCEDURE FOR GRANT OF COMPULSORY LICENSE

At any time after expiration of three years from the date of grant of a patent (or four years from the date of filing of a patent application in Malaysia[90]), any person, including licensees of the patent holder, may apply to the Indian Controller/the Malaysian Registrar for a compulsory license on a patent.[91]

The procedure in India for processing an application for a compulsory license is that upon receipt of such an application, as a first step the Controller shall determine whether any of the grounds for claiming compulsory license have been satisfactorily proven by the applicant.[92] To that end, he shall consider the nature of the invention; the time elapsed since the sealing of the patent and the measures taken by the patent holder and/or his licensee for fully utilising the patented invention.[93] Next, he shall consider the ability of the applicant to work the invention to the public advantage and his capacity to undertake the risk of providing capital for working the invention.[94] Lastly, he shall consider if the applicant has made prior efforts for a reasonable period, ordinarily not exceeding six months, to obtain from the patent holder a voluntary license on reasonable terms and conditions.[95]

In so far as the extent of 'prior efforts' that are required of an applicant is concerned, the issue has been previously determined by the Controller in the case of *BDR Pharmaceuticals International Pvt. Ltd v Bristol Myers Squibbs Company*[96]. In this case, BDR Pharmaceuticals had initially requested Bristol Myers Squibbs to grant a voluntary license to itself, and in response, Bristol Myers had questioned BDR on its ability to continuously supply high volumes of the drug, capacity for maintenance of the requisite quality, capacity for compliance with regulatory standards, capability as to maintenance of a safe profile, and its litigation history. Instead of addressing these queries, negotiating or even seeking a settlement with Bristol Myers, BDR, assuming the queries to be "*clearly indicative of rejection of the application for voluntary license",* did not immediately pursue the matter. Only after almost a year, BDR preferred an application for compulsory license before the Controller of Patents. The Controller, finding that BDR had made no efforts to negotiate a voluntary license from Bristol Myers, rejected BDR's application for a compulsory license. In making this decision, the Controller held that during negotiations a patent holder is entitled to satisfy himself regarding the credentials and capability of the applicant as well as the terms and conditions of a voluntary license

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90 Section 49 Malaysian Patents Act 1983.

91 Section 84(1) Indian Patents Act 1970 and section 49(1) Malaysian Patents Act 1983.

92 Section 84(4) Indian Patents Act 1970.

93 Section 84(6)(i) Indian Patents Act 1970.

94 Section 84(6)(ii) and (iii) Indian Patents Act 1970.

95 Section 84(6)(iv) Indian Patents Act 1970.

96 *BDR Pharmaceuticals v Bristol Myers Squibb Company*, 29 October 2013, C.L.A. No. 1 of 2013, The Controller of Patents, Patents Office, Mumbai: http://ipindia.nic.in/iponew/Order_30October2013.pdf: Site accessed on 24 July 2015.

and even if the applicant believes the patent holder to be engaging in dilatory tactics, he must, in accordance with the scheme of law, continue the deliberations with the patent holder for a period of at least six months before applying for a compulsory license; excepting where there is an emphatic rejection from the patent holder in which case the applicant is not required to keep repeating the requests for a voluntary license.[97] Further, the Controller stressed upon the requirement of an applicant to establish 'prior' efforts and held that any attempts made subsequent to filing of an application shall unduly advantage the applicant by empowering him to pursue a compulsory license while simultaneously negotiating with the patent holder, and hence shall not be considered.[98]

Finally, if the Controller upon consideration of all the aforesaid factors is satisfied that a *prima facie* case for grant of a compulsory license has been made out by the applicant, he will then notify the patent holder(s) or any other interested party/parties[99] and provide them with an opportunity to present their respective case. [100] Upon conclusion of the hearing, the Controller after finding that any one or more grounds for a compulsory license exist can grant a compulsory license to the applicant on such terms and conditions as he deems fit. [101] Thereupon the patent holder may challenge the decision of the Controller before the Intellectual Property Appellate Board and/or the High Court but all the same, in the absence of a contrary condition, untill that time as when the decision of the Controller is stayed/ set aside by a higher quasi-judicial/ judicial authority, the beneficiary shall not be barred from taking the benefit of the granted compulsory license.

Conversely, the Malaysian procedure for grant of a compulsory license is not as elaborate as that of India. Although the Malaysian Corporation for deciding on the application for compulsory license[102] allows the applicant to present his case, furnish any relevant document or lead evidence to prove that prior efforts have been made to obtain a reasonably termed authorisation from the patent holder,[103] in striking contrast with India, the Corporation has no corresponding obligation to provide an opportunity to the patent holder for opposing the said application. Instead, the patent holder is permitted to approach the Corporation only subsequent to the grant of a compulsory license to seek cancellation[104] or amendment[105] thereof. This procedural defect can lead to far reaching consequences for the Malaysian patent holders as the imminent threat of applicants exploiting the compulsory licensing provisions by maximising the use and/ or manufacture of the patented invention during the period it takes for the patent holder to stay the operation of the compulsory license cannot be discounted. Hence, there is an urgent need to impress upon the Malaysian law makers to rectify such defect.

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97 *Supra* n 42.
98 *Supra* n 96.
99 Section 87(1) Indian Patents Act 1970.
100 Section 87(4) Indian Patents Act 1970.
101 Section 84(4) Indian Patents Act 1970.
102 Section 51(1) Malaysian Patents Act 1983.
103 Section 49(2) Malaysian Patents Act 1983.
104 Section 54(2) Malaysian Patents Act 1983.
105 Section 54(1) Malaysian Patents Act 1983.

IX. GOVERNMENT AUTHORISED COMPULSORY LICENSE

'Government authorised' compulsory licenses have been included in the TRIPS Agreement as an alternative to the ordinary mode of grant of compulsory licenses.[106] In situations of national emergency, other circumstances of extreme urgency and for public non-commercial use[107] in India and respectively during national emergency or during threat to public interest or threat to national security or threat to the development of vital sectors of the economy such as nutrition and health[108] or in case of anti-competitive exploitation of a patented invention in Malaysia[109] (non-inclusion of this additional criterion is a remiss on India's part), the Governments of both countries are empowered to grant 'government authorised' compulsory licenses.

The importance of 'government authorised' compulsory licenses lies in the fact that these licenses are equipped with an expeditious response action time. Particularly in relation to public health crises when urgent intervention is incumbent to prevent a full-blown epidemic, government authorised compulsory licenses for patented medicines aid in expeditiously securing adequate supply of requisite essential medicines.

Under the alternative expeditious mode of grant of government authorised compulsory licenses, the Indian Central Government can *suo motu* dispense with the prerequisite waiting period of three years and the requirement of six months of prior negotiations, and can without any delay issue a declaration in the Official Gazette to the effect that it authorises the grant of compulsory licenses to all applicants for the identified patents.[110] Whereupon the Controller can waive the ordinarily prescribed hearing for challenging the application and instead immediately proceed to grant compulsory licenses[111] on such terms and conditions that are favourable to achieving the lowest price of the invention without impinging on the patent holder's right to derive a reasonable advantage from his patent.[112] Separately, Malaysia also forgoes its ordinary procedure for grant of compulsory licenses in favour of the decision of the Minister.[113] Though the Malaysian patent holder has no say in the Minister's decision of grant of compulsory licenses, he or any other interested party can make their submissions with regard to the expected remuneration for exploitation of the patent.[114] While the Indian Government provides for grant of government authorised compulsory license to 'any person',[115] the Malaysian Government limits the beneficiaries of government authorised compulsory licenses to government agencies or the designated third parties.[116] Previously, following the 2001 Doha Declaration's affirmation that crises relating to HIV/ AIDS, tuberculosis, malaria and other epidemics represent national emergencies or other circumstances of

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106 *Supra* n 4.
107 Section 92(1) Indian Patents Act 1970.
108 Section 84(1)(a) Malaysian Patents Act 1983.
109 Section 84(1)(b) Malaysian Patents Act 1983.
110 *Supra* n107.
111 Section 92(3) Indian Patents Act 1970.
112 *Supra* n 107.
113 Section 84(1) Malaysian Patents Act 1970.
114 Section 84(3) and (4) Malaysian Patents Act 1983.
115 *Supra* n 107.
116 *Supra* n 113.

extreme urgency,[117] Malaysia had granted three 'government authorised' compulsory licenses for patented antiretroviral medicines.

X. COMPULSORY LICENSING OF INTERDEPENDENT PATENTS

In addition to the aforesaid grounds for grant of compulsory licenses, the TRIPS Agreement also provides compulsory licenses for interdependent patents i.e. those patents which cannot be exploited without infringing the other.[118] Both India and Malaysia respectively have incorporated the provisions for compulsory licensing of interdependent patents, but the scope of the parallel provisions in the two countries is at variance, with Malaysia focussing more on the 'priority' of the interdependent patents.

India stipulates that if a patented invention substantially contributing to the establishment and development of commercial or industrial activities of India[119] is prevented from being efficiently and most advantageously worked because the same would result in infringement of another patented invention, then a compulsory license for the other patented invention can be granted,[120] provided the patent holder of the other patented invention is able to secure a compulsory license for the concerned patented invention also.[121] This being the more general provision for compulsory licensing of interdependent patents, specifically India also recognises that in case of a single patent holder's bundle of patents consisting of two sets, with one set of patents meeting the reasonable requirement of the public and the other set qualifying for grant of a compulsory license, if the Controller finds that the second set of patents cannot be efficiently or satisfactorily worked without infringing the first set of patents and involves technical advancement of considerable economic significance in relation to the first set of patents, then along with the second set of patents he can grant a compulsory license for the first set of patents also, irrespective of the priority of the patents.[122]

On the other hand, Malaysia provides that if a later invention, constituting an important technical advance of considerable economic significance in relation to a patent with an earlier priority date (earlier patent) cannot be worked without infringing such earlier patent, then the Corporation can grant a compulsory license for the earlier patent to the extent necessary for the later invention to be worked without infringing the same,[123] and vice versa also grant a compulsory license for the later invention to the patent holder, licensee or beneficiary of the earlier patent.[124] Therefore, it is apparent that unlike India, Malaysia lays more importance on the priority of interdependent patents for grant of compulsory licenses, and in consequence, restricts patent holders of earlier

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117 *Supra* n 31.
118 *Supra* n 4.
119 Section 91(2)(ii) Indian Patents Act 1970.
120 Section 91(1) Indian Patents Act, 1970.
121 Section 91(2)(i) Indian Patents Act 1970.
122 Section 88(3) Indian Patents Act 1970.
123 Section 49A(1) Malaysian Patents Act 1983.
124 Section 49A(2) Malaysian Patents Act 1983.

patents from being the first to approach the Controller for seeking a compulsory license for an interdependent later invention.

XI. DEBUNKING CRITICISMS AGAINST COMPULSORY LICENSE

In spite of its obvious contribution towards achieving accessibility and affordability of essential medicines, compulsory licenses have been severely criticised by developed countries, home to all the major pharmaceutical companies.[125] The developed countries claim that interference with the exclusivity enjoyed by a patent holder may deter pharmaceutical companies from investing in research and innovation for new medicines. Pharmaceutical companies themselves allege that by being forced to reduce their prices under the threat of compulsory licenses, they will not be able to recover their costs of research and development, currently claimed to be USD5 billion per drug, and that in consequence they will face insurmountable losses.[126] Their asserted claims may have had force if pharmaceutical companies had been genuine in pricing their medicines. Instead, at the prices the medicines are being sold, the patients end up paying about twice the actual cost of the medicines while the global pharmaceutical companies earn a humungous profit margin of about 20-40%.[127] Shockingly, over a period of ten years from 2003 to 2012, the largest pharmaceutical companies have collectively earned a profit of USD711.4 billion.[128] Not all of their staggering profits have been dedicated to research and development. Rather, pharmaceutical companies spent about one-third of their sales revenue on marketing.[129] Plus pharmaceutical companies at the time of proclaiming costs to the tune of USD5 billion do not account for the substantial research subsidies and tax deductions which are offered to them by the State.[130] Lack of clarity on the net expenditure incurred on research and development cloaks pharmaceutical companies' practice of continuing to charge supernormal profits from the patients, even after recovery of their entire research and development cost.[131] In fact, the prices of essential medicines rarely reflect their 'fair value' but manifest the value that can be fetched from the market from 'grateful victims' who, left without any alternatives, pay the exorbitant prices of the medicines for their survival.[132] Not that the pharmaceutical companies should entirely

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125 *Supra* n 14.

126 Matthew Herper, *The Cost of Creating a New Drug Now $5 billion, Pushing Big Pharma to Change*, Forbes: http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/ Site accessed on 26 July 2015.

127 Richard Anderson, 6 November 2014, *Pharmaceutical Industry Gets High on Fat Profits*, BBC News: http://www.bbc.com/news/business-28212223 Site accessed on 26 July 2015.

128 Ethan Rome, *Big Pharma Pockets $711 Billion in Profits by Robbing Seniors, Taxpayers*, The Huffington Post: http://www.huffingtonpost.com/ethan-rome/big-pharma-pockets-711-bi_b_3034525.html?ir=India&adsSiteOverride=in Site accessed on 26 July 2015.

129 *Pharmaceutical Industry*, World Health Organization: http://www.who.int/trade/glossary/story073/en/ Site accessed on 26 July 2015.

130 *Rx R&D Myths: The Case Against The Drug Industry's R&D "Scare Card"*, Public Citizen's Congress Watch: http://www.citizen.org/documents/ACFDC.PDF Site accessed on 26 July 2015.

131 *Supra* n 11.

forgo 'healthy profits', but rather that their practices of 'profiteering' from the sale of essential medicines must be curbed. In this regard, compulsory licenses play a key role.

Having said that, the genuine concerns of the pharmaceutical companies can be mitigated, especially in countries where medical expenses are privately borne, through differential pricing of patented medicines on the basis of the varying economic abilities of the patients.[133] By charging higher prices from persons belonging to the higher income bracket, the subsidised prices offered to those with lower incomes can be offset so that not only every strata of the population is able to access the essential medicines but the pharmaceutical companies are also able to recoup their legitimate costs in accordance with the paying capacity of the patients. Despite the burden of complications in implementing the scheme of differential pricing, the shortcomings do not detract from its ability to improve the overall accessibility to essential medicines.[134]

XII. CONCLUSION

Developed countries, at the behest of their pharmaceutical companies, have been increasingly pressurising developing countries to strengthen their allegedly weak intellectual property laws. Through Bilateral Agreements and Multilateral Free Trade Agreements, developed countries to discourage the grant of compulsory licenses, and are increasingly threatening developing countries with trade sanctions.[135] Unfortunately, seeing that in spite of TRIPS compatibility, to date only a handful of compulsory licenses have been granted by developing countries, the developed countries have been successful in their threats to a certain degree.

In 2012, when India granted its first compulsory license for Bayer's patented medicine, *Nexavar*[136], developed countries raised a collective outcry against India and made tall allegations of misuse of compulsory licensing provisions,[137] culminating in demotion of India's position on the United States of America's Global Intellectual Property Index.[138] Still India, secure in its stance on maintaining accessibility and affordability of

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132 *The Price of Drugs for Chronic Myeloid Leukemia (CML); A Reflection of the Unsustainable Prices of Cancer Drugs: From the Perspective of a Large Group of CML Experts*, Blood Journal: http://www.bloodjournal.org/content/bloodjournal/early/2013/04/23/blood-2013-03-490003.full.pdf?sso-checked=true Site accessed on 26 July 2015.

133 *Supra* n 76.

134 Patricia M. Danzon and Adrian Towse, "Differential Pricing for Pharmaceutical: Reconciling Access, R&D and Patents", *International Journal of Health Care Finance and Economics*, 2003, Vol. 3, pp. 183-205.

135 Patralekha Chatterjee, 12 March 2013, *Leaked IP Chapter of India –EU FTA Shows TRIPS Plus Pitfalls for India, Expert Says*, Intellectual Property Watch: http://www.ip-watch.org/2013/03/12/leaked-ip-chapter-of-india-eu-fta-shows-trips-plus-pitfalls-for-india-expert-says/ Site accessed on 26 July 2015.

136 *Supra* n 11.

137 Amiti Sen, 27 March 2012, *US Protests Patent Issuance to Natco to Sell Copied Versions of Nexaver*, The Economic Times: http://articles.economictimes.indiatimes.com/2012-03-27/news/31245102_1_compulsory-licence-patent-owner-indian-patent-office Site accessed on 25 July 2015.

138 *Measuring Momentum*, GPIC International IP Index, First Edition, 2012, Global Intellectual Property Centre: http://dev.theglobalipcenter.com/wp-content/uploads/2013/01/020119_GIPCIndex_final.pdf Site accessed on 25 July 2015.

essential medicines, continued to stand steady against the relentless onslaught.[139] Rather, in 2013 the Union Ministry of Health approached the Department of Industrial Policy and Promotion (DIPP) in pursuit of 'government authorised' compulsory licenses for three anti-cancer drugs, namely Herceptin, Ixabepilone (both used in the treatment of breast cancer) and Dasatinib (used in the treatment of leukaemia), on account of the drugs being priced far above the reach of the common man.[140] With this admirable show of strength in the past, it is now unfortunate to note that with the advent of a new government at the centre, apprehensions are being raised that India is beginning to bow to the insistent pressure from the developed countries.[141] Two years since the Union Ministry of Health first sought compulsory licenses for the three anti-cancer drugs DIPP continues to demur in processing its request.[142] Taking note of this regrettable turn of events, *Medecins Sans Frontieres*, an international humanitarian aid organisation for providing emergency medical assistance,[143] recently launched a campaign calling for the Indian Prime Minister, Mr Narendra Modi, to remain steadfast against the intensifying pressure from the developed countries. The campaign cautions the Prime Minister against narrowing the scope of Indian patent laws and policies as any such action shall immediately impact India's ability to manufacture generic medicines at affordable prices.[144]

Contrastingly, Malaysia's stance on compulsory licenses remains ambiguous. Since the grant of its three compulsory licenses in 2003, Malaysia has not granted any other compulsory license to date. Moreover, Malaysia has also held back from incorporating the import/export flexibilities of WTO's decision of 2003 in its patent laws. More clarity in this regard will be gained only once the Ministry of Health determines the viability of Malaysian AIDS Council's request for 'government use' compulsory licenses for patented antiretroviral medicines, Lopinavir and Ritonavir, sold under the brand name of Kaletra, for use in the second line treatment of HIV/ AIDS.[145]

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139 Chidanand Rajghatta, 12 July 2013, *Don't let Rhetoric Trump Reason, Chidambaram tells US*, The Times of India: http://timesofindia.indiatimes.com/business/india-business/Dont-let-rhetoric-trump-reason-Chidambaram-tells-US/articleshow/21043653.cms Site accessed on 25 July 2015.

140 Sushmi Dey, 30 March 2013, *Government Begins work on 3 more compulsory licenses*, Business Standard: http://www.business-standard.com/article/companies/govt-begins-work-on-3-more-compulsory-licences-113032900230_1.html Site accessed on 25 July 2015.

141 G Pramod Kumar, 28 January 2015, *Will Modi Give up India's Intellectual Property Stand Just to Please Obama?,* Firstpost: http://www.firstpost.com/business/obamas-pressure-on-india-over-intellectual-property-rights-betrays-his-double-standards-2067809.html Site accessed on 25 July 2015.

142 Rituparna Bhuyan, 11 March 2014, *Health Minister's compulsory license proposal hits DIPP hurdle*, Moneycontrol: http://www.moneycontrol.com/news/cnbc-tv18-comments/health-mins-compulsory-license-proposal-hits-dipp-hurdle_1052711.html Site accessed on 26 July 2015.

143 *'What we do'*, Medecins Sans Frontieres: http://www.msfindia.in/ Site accessed on 25 July 2015.

144 *Don't Shut Down the Pharmacy of the Developing World*, Medecins Sans Frontieres: http://handsoff.msf.org/ Site accessed on 25 July 2015.

145 Malaysian AIDS Council, *Application for a Compulsory License for Kaletra*, 1 May 2012, Don't Trade our Lives Away: https://donttradeourlivesaway.files.wordpress.com/2012/05/here1.pdf Site accessed on 25 July 2015.

In this prevailing climate, it is necessary to realise that the fear of losing foreign investments is not a sound basis for sacrificing access to essential medicines. Economic development at the expense of public health is unsustainable. Therefore, it now falls upon developing countries, like India and Malaysia, to place the welfare of their people ahead of the threats made by the developed countries and to meet their opposition with a united front and collective strength. For this purpose both India and Malaysia should not only learn from the lessons of the other, but also emulate the other's pro public-health inclusion and interpretation of compulsory licensing provisions. Both countries should pro-actively grant compulsory licenses for overcoming the adverse effects of patent monopoly and/or for strengthening their domestic technical base. Otherwise, access to essential medicines shall remain a luxury for many.