

166

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# Lessons From India's Implementation of Doha Declaration on TRIPS and Public Health

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# RESEARCH PAPER

166

## LESSONS FROM INDIA'S IMPLEMENTATION OF DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH\*

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SOUTH CENTRE

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## ABSTRACT

The major bone of contention between the developed and developing countries in the TRIPS negotiations was patents for pharmaceuticals. The US-led developed countries bloc argued in favour of patents for pharmaceuticals amidst opposition from Brazil, India and other countries. Ample evidence, including patented AZT for HIV/AIDS treatment, showed that patents could make life saving drugs prohibitively expensive. Notwithstanding the effect of patents on access to medicines, Article 27 of the TRIPS Agreement ordained patents for inventions “in all fields of technology”. While the genie was out of the bottle in the form of patents for pharmaceuticals, the developing countries were able to extract some procedural and substantive flexibilities like transition period, parallel importation and compulsory licensing to leverage the IP system to further public health. However, there was uncertainty with respect to the interpretation of TRIPS agreement, scope of the flexibilities and Member States’ rights to use them. It is in this background that the historic Doha Declaration on the TRIPS Agreement and Public Health assumed importance as it reaffirmed the rights of the Member States to take measures to protect public health, reconciled the interpretative tensions in the text of TRIPS Agreement and clarified the scope of some of the flexibilities and attempts to find solutions to the problems faced by countries that do not have sufficient manufacturing facilities. The Declaration which was initially dismissed by some scholars as “non-binding,” “soft law” has been held by WTO Dispute Settlement Body (DSB) to constitute a “subsequent agreement” which must be followed in interpreting the provisions of TRIPS Agreement (Australia-Tobacco Plain Packaging Case).

*La principal manzana de la discordia entre los países desarrollados y los países en vías de desarrollo en las negociaciones de los ADPIC fueron las patentes de productos farmacéuticos. El bloqu de países desarrollados, liderado por Estados Unidos, se mostró a favor de las patentes de productos farmacéuticos en medio de la oposición de Brasil, India y otros países. Numerosas pruebas, como la patente del AZT para el tratamiento del VIH/SIDA, demostraron que las patentes pueden hacer que los medicamentos que salvan vidas sean prohibitivos. A pesar del efecto de las patentes en el acceso a los medicamentos, el artículo 27 del Acuerdo sobre los ADPIC ordenó las patentes para las invenciones “en todos los campos de la tecnología”. Mientras que el genio estaba fuera de la botella en forma de patentes para los productos farmacéuticos, los países en desarrollo pudieron extraer algunas flexibilidades de procedimiento y de fondo como el periodo de transición, la importación paralela y las licencias obligatorias para aprovechar el sistema de PI en favor de la salud pública. Sin embargo, existía incertidumbre con respecto a la interpretación del Acuerdo sobre los ADPIC, el alcance de las flexibilidades y los derechos de los Estados miembros a utilizarlas. En este contexto, la histórica Declaración de Doha relativa al Acuerdo sobre los ADPIC y la salud pública cobró importancia, ya que reafirmó los derechos de los Estados miembros a adoptar medidas para proteger la salud pública, concilió las tensiones interpretativas del texto del Acuerdo sobre los ADPIC y aclaró el alcance de algunas de las flexibilidades e intentó encontrar soluciones a los problemas a los que se enfrentan los países que no disponen de suficientes instalaciones de fabricación. El Órgano de Solución de Diferencias (OSD) de la OMC ha considerado que la Declaración, que en un principio fue tachada de “no vinculante” y de “ley blanda”, constituye un “acuerdo subsiguiente” que debe*

*seguirse al interpretar las disposiciones del Acuerdo sobre los ADPIC (caso Australia-Tobacco Plain Packaging).*

*La principale pomme de discorde entre les pays développés et les pays en développement dans les négociations sur les ADPIC ont été les brevets pour les produits pharmaceutiques. Le bloc de pays développés dirigé par les États-Unis a plaidé en faveur des brevets pour les produits pharmaceutiques, face à l'opposition du Brésil, de l'Inde et d'autres pays. De nombreuses preuves, dont l'AZT breveté pour le traitement du VIH/SIDA, ont montré que les brevets pouvaient rendre prohibitifs les médicaments qui sauvent des vies. En dépit de l'effet des brevets sur l'accès aux médicaments, l'article 27 de l'accord sur les ADPIC prescrit les brevets pour les inventions "dans tous les domaines technologiques". Bien que le génie soit sorti de la bouteille sous la forme de brevets pour les produits pharmaceutiques, les pays en développement ont pu obtenir certaines flexibilités procédurales et substantielles telles que la période de transition, l'importation parallèle et les licences obligatoires afin de tirer parti du système de PI pour promouvoir la santé publique. Toutefois, l'interprétation de l'accord sur les ADPIC, la portée des flexibilités et les droits des États membres à les utiliser restaient incertains. C'est dans ce contexte que la Déclaration historique de Doha sur l'Accord sur les ADPIC et la santé publique a pris de l'importance, car elle a réaffirmé le droit des États membres à prendre des mesures pour protéger la santé publique, a réconcilié les tensions d'interprétation dans le texte de l'Accord sur les ADPIC et a clarifié la portée de certaines des flexibilités, et a tenté de trouver des solutions aux problèmes rencontrés par les pays qui ne disposent pas d'installations de fabrication suffisantes. La déclaration, qui a été initialement rejetée par certains spécialistes comme étant "non contraignante" et "juridiquement souple", a été considérée par l'Organe de règlement des différends (ORD) de l'OMC comme constituant un "accord ultérieur" qui devait être suivi dans l'interprétation des dispositions de l'Accord sur les ADPIC (affaire Australie-Tobacco Plain Packaging).*

## TABLE OF CONTENTS

I. INTRODUCTION .....	1
II. TRIPS, PATENTS FOR PHARMACEUTICAL PRODUCTS AND PUBLIC HEALTH .....	3
III. ASSESSING THE FUNCTIONING OF TRIPS FLEXIBILITIES UNDER INDIAN LAW .....	7
A. <i>Compulsory Licenses</i> .....	8
i. Fault of the patentee .....	8
ii. Emergency situations.....	13
iii. Humanitarian assistance and international cooperation .....	14
B. <i>Patentability Criteria</i> .....	17
C. <i>Opposition Proceedings</i> .....	20
IV. TRIPS AS A PERMISSIVE REGIME: NEED FOR CHANGE AND SOME DEVELOPMENTS .....	24
V. CONCLUSION AND SUGGESTIONS.....	26
ANNEXURE: DATA COMPILED FROM ANNUAL REPORTS OF THE INDIAN PATENT OFFICE FROM 2004 TO 2020 .....	28



## I. INTRODUCTION

India's tryst with patenting of medicines is a semblance of its political reality. The initial imprints of a colonial rule on the patent law were subsequently watered down by an assertive independent Indian State looking for "self-reliance"<sup>1</sup> and then reshaped by globalisation induced harmonization.<sup>2</sup> At the dawn of independence in 1947, the law relating to patents was contained in the "Indian Patents and Designs Act, 1911" that made no mention of field of invention. In the absence of exclusionary clause, patents were granted for chemical substances, medicines and drugs besides others. In fact, medicinal preparations for fighting malaria and other diseases dominated the field of inventions from 1942–1948.<sup>3</sup> However, they were not local inventions; almost all the applications were filed from abroad.<sup>4</sup> Patents were granted for a term of fourteen years<sup>5</sup> and could be extended for another seven or fourteen years in case of a successful determination of inadequate remuneration to the patentee.<sup>6</sup> Under this regime, the Indian need for pharmaceuticals was basically met by imports.<sup>7</sup> Prices of medicines were one the highest in the world.<sup>8</sup> Committees were subsequently constituted to revisit and suggest changes to the Patent Law to make it more conducive to national interest. In 1950, the Bakshi Tek Chand Committee<sup>9</sup> and in 1959 Justice N. Rajagopala Ayyangar Committee<sup>10</sup> recommended that product patents for medicines should not be granted but restricted to process claims only. While an amendment was made in 1952 to make provision for the grant of compulsory licences, product patents for medicines continued to be granted. The overall law was overhauled only in 1970. The new regime made pharmaceuticals ineligible for product patents; only process patents were allowed for a term of seven years. There were provisions on compulsory licenses and "licences of right".<sup>11</sup> This continued till India's accession to the agreement establishing the World Trade Organisation (WTO). In the meantime, the Indian generic industry flourished; it was the golden period for the Indian pharmaceutical industry.<sup>12</sup> One of the consequences of the Patents Act 1970 was "the shortening of the time lag between the introduction of a drug in the global market by the inventor and the marketing of the same drug in the Indian market."<sup>13</sup> India exported low cost

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<sup>1</sup>Suresh D Tendulkar, "Planning for Growth, Redistribution and Self-Reliance in the Fifth Five-Year Plan-I." *Economic and Political Weekly*, vol. 9, No. 1/2, (1974), p. 27.

<sup>2</sup> Amy Kapczynski "Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector", *California Law Review*, vol. 97, No. 6 (December 2009), pp. 1571–1573.

<sup>3</sup> Government of India, "Report of the Patents Enquiry Committee" (1948-1950) pp. 58–59. Available from <https://indianculture.gov.in/flipbook/1592>.

<sup>4</sup> Ibid.

<sup>5</sup> India, Indian Patents and Designs Act, 1911, section 14 (now repealed). Available from [https://legislative.gov.in/sites/default/files/legislative\\_references/1911.pdf](https://legislative.gov.in/sites/default/files/legislative_references/1911.pdf).

<sup>6</sup> India, Indian Patents and Designs Act, 1911, section 15 (now repealed). Available from [https://legislative.gov.in/sites/default/files/legislative\\_references/1911.pdf](https://legislative.gov.in/sites/default/files/legislative_references/1911.pdf).

<sup>7</sup> P. K. Ramachandran and B. V. Rangarao, "The Pharmaceutical Industry in India", *Economic and Political Weekly*, vol. 7, No. 9 (Feb. 26, 1972), p. M27.

<sup>8</sup> Pravin Kamble, Swapnil Ghorpade, Rajesh Kshirsagar, Bhanudas Kuchekar, "Progress of the Indian Pharmaceutical Industry: A Shifting Perspective", *Journal of Intellectual Property Law & Practice*, vol. 7, Issue 1 (January 2012) pp. 48–51.

<sup>9</sup> Supra note 5, p. 112.

<sup>10</sup> Shri Justice N. Rajagopala Ayyangar, "Report on the Revision of Patent Law" (September 1959) p. 39.

<sup>11</sup> Patents in respect of inventions relating to food or medicine or drug or their manufacturing process were endorsed with the words "License of right" after three years from the date of sealing of patent. Such an endorsement entitled any interested person to obtain the license from patent holder to work that invention. See Section 87 and 88 of Patents Act, 1970 prior to amendment Act of 2002.

<sup>12</sup> Prasanta Kumar Ghosh, "Government's Policies and Growth of Pharmaceutical Industry in India 1947-2018: A Review", RIS Discussion Paper, No. 236 (Research and Information System for Developing Countries, New Delhi, January 2019).

<sup>13</sup> Biswajit Dhar and C.N Rao, "Transfer of Technology for Successful Integration into the Global Economy: A Case Study of the Pharmaceutical Industry in India", (United Nations, 2002) pp. 7–8. Available from [https://unctad.org/en/Docs/iteipcmisc22\\_en.pdf](https://unctad.org/en/Docs/iteipcmisc22_en.pdf).

generic medicines across the globe<sup>14</sup>and earned the moniker of being the “pharmacy of the world”. But by agreeing to be a WTO Member State, India had also agreed to be bound by the Agreement on Trade Related Aspects of Intellectual Property Rights (“TRIPS Agreement”).

The implementation of the TRIPS Agreement changed the trajectory of patent law in India. Most importantly, it enabled product patents for pharmaceuticals that India had resisted till then. However, India was cautious in its approach and adopted many patent levers in its law to protect public health. But was it able to implement those policy measures without any hindrances? Or did it face any external or internal obstacles? How has the implementation of these public health levers informed its response to COVID-19 pandemic, particularly the critical shortages of medicines, medical equipment and vaccines? This paper is an attempt to answer some of these and other related questions. The paper is divided into five parts. Part II of the paper gives a historical context of the debate in implementing TRIPS flexibilities leading to the Doha Declaration. Part III discusses patent levers incorporated in Indian Law and traces the trajectory of compulsory licensing, patentability criteria and opposition proceedings from 2005 to 2020. Part IV critically analyses the need to remodel the flexibilities in a defensive way. Part V provides novel solutions that need to be implemented at the domestic and international level to make medicines affordable and available for everyone.

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<sup>14</sup> Ibid. pp. 15–18.

## II. TRIPS, PATENTS FOR PHARMACEUTICAL PRODUCTS AND PUBLIC HEALTH

The TRIPS Agreement is one of the annexes to the WTO Agreement. The WTO Agreement was the result of the “Uruguay Round” of trade negotiations that happened between 1986 and 1994 under the auspices of General Agreement on Tariffs and Trade (GATT).<sup>15</sup> Negotiations on Intellectual Property (IP), however, were highly contentious and infamous for not only the “North-South” divide but even intra-North differences.<sup>16</sup> Developing countries were particularly opposed to laying down substantive standards and internal enforcement rules for Intellectual Property (IP) for various reasons. Their chief concerns were that substantive aspects of IP were “marginally trade related”,<sup>17</sup> needed proper alignment with domestic concerns and would deleteriously affect access to affordable medicines.<sup>18</sup> The TRIPS Agreement has been contentious as it commands the WTO Member States to have uniform minimum standards for protection of intellectual property rights (IPRs) regardless of differences in their level of development and socio-economic conditions. Despite their initial resistance during the negotiation phase,<sup>19</sup> the developing countries had to buckle in due to the pressure exerted by a powerful bloc of developed countries amidst geopolitical changes of 1989 and the shift in the domestic economic policies.<sup>20</sup> Accepting the TRIPS Agreement was also made possible as it recognised the right of Members to take some measures to protect public health<sup>21</sup> and incorporated elements of balance and flexibility.<sup>22</sup>

The TRIPS Agreement is the most comprehensive international agreement<sup>23</sup> in the field of IPRs having its own enforcement mechanism.<sup>24</sup> It has been a monumental force in changing the substantive regulatory landscape of intellectual property rights globally. For India and other developing countries, implementing the TRIPS Agreement meant that they could no longer exclude product patents for pharmaceuticals as it obligated patents “for any inventions, whether products or processes in all fields of technology.”<sup>25</sup> The genie was out of the bottle! The technological neutrality clause foreclosed the broad policy space hitherto available to the WTO Member States.

Paradoxically, while the TRIPS Agreement was being negotiated, the human immunodeficiency virus and acquired immune deficiency syndrome (HIV/AIDS) crisis unfolded in the background. From its very early days, this disease forewarned the world about the

<sup>15</sup> Antony Taubman, Hannu Wager and Jayshree Watal, (eds.), *A Handbook on the WTO TRIPS Agreement*, 2nd ed. (Cambridge University Press, 2020) p. 5. e-book. Available from [https://www.wto.org/english/res\\_e/booksp\\_e/trips\\_agree\\_e/history\\_of\\_trips\\_nego\\_e.pdf](https://www.wto.org/english/res_e/booksp_e/trips_agree_e/history_of_trips_nego_e.pdf).

<sup>16</sup> Jayshree Watal, “Patents: An Indian Perspective”, in *The Making of the TRIPS Agreement: Personal insights from the Uruguay Round negotiations*, Jayshree Watal and Antony Taubman, eds. (World Trade Organisation, 2015) 301.

<sup>17</sup> Adrian Otten, “The TRIPS negotiations: An overview” in *The Making of the TRIPS Agreement: Personal insights from the Uruguay Round negotiations*, Jayshree Watal and Antony Taubman eds. (World Trade Organisation, 2015) 61.

<sup>18</sup> A.V. Ganesan, “Negotiating for India” in *The Making of the TRIPS Agreement: Personal insights from the Uruguay Round negotiations*, Jayshree Watal and Antony Taubman eds. (World Trade Organisation, 2015) 213–214.

<sup>19</sup> *Ibid.*, pp. 215–216.

<sup>20</sup> Amit Sengupta, “Globalisation, Intellectual Property Rights and Pharmaceuticals” in *Oxford India Studies in Contemporary Society: Health Care Studies in India*, Purendra Prasad and Amar Jesani, eds. (Oxford University Press, 2018). 127.

<sup>21</sup> World Trade Organisation, Agreement on Trade Related Aspects of Intellectual Property, art. 8.

<sup>22</sup> The Member States had specific transition periods to attune their laws to the TRIPS Agreement. They also had the freedom to determine exhaustion rules, mould their laws incorporating measures to protect public health and nutrition, provide certain exclusions from patentability, issue compulsory licenses and government use, incorporate disclosure related flexibilities, and they could carve out exceptions to the patent rights amongst others.

<sup>23</sup> Keith E. Maskus, “Trade-Related Intellectual Property Rights” in *The Oxford Handbook on The World Trade Organization* Martin Daunton, Amrita Narlikar, and Robert M. Stern eds (Oxford University Press, 2012) 385.

<sup>24</sup> World Trade Organisation, Agreement on Trade Related Aspects of Intellectual Property, art 64.

<sup>25</sup> World Trade Organisation, Agreement on Trade Related Aspects of Intellectual Property, art 27.

impact of patents on access to medicines. When Azidothymidine (AZT), the first (patented) medicine to delay the progression of AIDS, was launched in 1987, its price was set at \$10,000 per patient per year<sup>26</sup> leading to protests against this exorbitant pricing structure.<sup>27</sup> However, AIDS treatment was widely available to most people living with HIV in the developed world by 1999 due to government intervention. The drug was, however, inaccessible to those living in developing countries, particularly Africa.<sup>28</sup> Courtesy to patents, the cocktail of three anti-retroviral drugs that was effective in controlling AIDS cost \$12,000 per patient per year.<sup>29</sup> AIDS had by then become “number one killer in Africa” (World Health Organisation, 1999).<sup>30</sup> It is pertinent to note that it was not the disease but lack of affordable medicines that led to so many deaths in Africa. Around the same time countries, the policy measures undertaken by countries like South Africa,<sup>31</sup> Brazil,<sup>32</sup> Canada<sup>33</sup> and India<sup>34</sup> were disputed before the WTO Dispute Settlement Body (DSB) and they were threatened with trade sanctions. There were clouds on the interpretation of TRIPS Agreement in a pro-health manner amidst increased threat of disputes. Such episodes raised questions on “whether commercial WTO rules would trump the perceived needs of individual countries to pursue public health goals.”<sup>35</sup> Further, provisions of the TRIPS Agreement were inadequate to address the peculiar problem faced by countries that did not have the pharmaceutical manufacturing facilities as compulsory licenses could be issued “predominantly for the supply of the domestic market”.<sup>36</sup> There was a serious threat to global supplies of low cost generic medicines particularly in light of the fact that India, which had a huge export oriented pharmaceutical industry, was required to grant pharmaceutical patents from 1 January 2005.<sup>37</sup> It also had to examine the patent applications for pharmaceuticals that had been collected in its mailbox from 1 January 1995 to 31 December 2004 under transition norms. Pertinently, it was due to Indian generic drug

<sup>26</sup> Gerald Posner, *Pharma: Greed, Lies and the poisoning of America* (New York, Avid Reader Press, 2020) p. 350.

<sup>27</sup> *Ibid.*, p. 351.

<sup>28</sup> Michael R Reich and Priya Bery, “Expanding Global Access to ARVs: The Challenges of Prices and Patents” in *The AIDS Pandemic: Impact on Science and Society* Kenneth H. Mayer and H.F. Pizer eds. (New York, Academic Press, 2004) pp. 32–25. Available from [https://cdn1.sph.harvard.edu/wp-content/uploads/sites/480/2013/01/Reich\\_Bery\\_AIDS\\_drugs.pdf](https://cdn1.sph.harvard.edu/wp-content/uploads/sites/480/2013/01/Reich_Bery_AIDS_drugs.pdf).

<sup>29</sup> *Ibid.*

<sup>30</sup> Avert: Global information and education on HIV and AIDS, “History of HIV and AIDS Overview”. Available from <https://www.avert.org/professionals/history-hiv-aids/overview>.

<sup>31</sup> South Africa enacted Medicines and Related Substances Control Amendment Act, 1997 to provide for compulsory licensing, parallel imports and price transparency. It faced immense pressure from the multinational companies, US and some European Countries to repeal the law. For details see David B. Snyder, “South Africa’s Medicines and Related Substances Control Amendment Act: A Spoonful of Sugar or a Bitter Pill to Swallow?”, *Penn State International Law Review*, vol. 18, No. 1 (1999) p. 175.

<sup>32</sup> USA dragged Brazil to WTO Dispute Settlement Body alleging incompatibility with the TRIPS Agreement of Brazil’s 1996 industrial property law and other related measures that inter alia required ‘local working’ as condition for enjoyment of patent rights and provided for compulsory license in case of failure of working of patented invention. However, the matter was later on mutually settled. See Request for Consultations by United States, *Brazil – Measures Affecting Patent Protection*, WTO Doc. WT/DS199/1 (8 June 2000).

<sup>33</sup> Consultations before WTO Dispute Settlement Body were initiated by EC alleging that Canada’s legislation was not compatible with its obligations under the TRIPS Agreement, because it did not provide for the full protection of patented pharmaceutical inventions for the entire duration of the term of protection envisaged. The panel held that the regulatory review exception provided for in Canada’s Patent Act (Section 55.2(1)) was not inconsistent with Article 27.1 of the TRIPS Agreement. But the stockpiling exception (Section 55.2(2)) was inconsistent with Article 28.1 of the TRIPS Agreement. See Report of Panel, *Canada – Patent Protection of Pharmaceutical Products*, WTO Doc. WT/DS114/13 (adopted 7 April 2000).

In a separate dispute US requested consultations with Canada regarding the term of protection. See Request for Consultations by United States, *Canada – Term of Patent Protection*, WTO Doc. WT/DS170/10 (6 May 1999).

<sup>34</sup> US requested consultations with India concerning the alleged absence of patent protection for pharmaceutical and agricultural chemical products in India. See Request for Consultations by United States, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WTO Doc. WT/DS50/10 (2 July 1996).

<sup>35</sup> Keith E. Maskus, “Trade-Related Intellectual Property Rights” in *The Oxford Handbook on The World Trade Organization*, Martin Daunton, Amrita Narlikar, and Robert M. Stern, eds. (Oxford Handbooks Online, 2012) p. 406, e-book.

<sup>36</sup> World Trade Organisation, Agreement on Trade Related Aspects of Intellectual Property, art 31 (f).

<sup>37</sup> Médecins Sans Frontières, “Will the lifeline of affordable medicines for poor countries be cut? Consequences of medicines patenting in India”, Briefing document, February 2005. Available from <https://www.msf.fr/sites/default/files/2005-02-01-msf.pdf>.

companies<sup>38</sup> that there was a considerable drop in the prices of the triple-drug AIDS therapy.<sup>39</sup> It was feared that under the new regime patents might be granted for anti-retroviral (ARV) drugs used for HIV/AIDS treatment that will hinder their generic production and thwart the imports to African countries.<sup>40</sup>

The consequences of adoption of the TRIPS Agreement on access to essential drugs showed “that the quest for a proper balance and calibration of IPRs has not ended, but was just opened up”<sup>41</sup> leading to the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) in 2001.<sup>42</sup> The Doha Declaration was “the outcome of a carefully elaborated strategy by developing countries”.<sup>43</sup> The immediate spur to the Doha Declaration was the public health problems emanating in developing and least developed countries from HIV/AIDS, tuberculosis and malaria. However, the scope of the declaration was not limited to these mentioned diseases.<sup>44</sup>

An important question, however, arose on the legal status of the Doha Declaration under international law.<sup>45</sup> Some scholars argued that it was binding<sup>46</sup> or a “subsequent agreement” under the Vienna Convention on the Law of Treaties<sup>47</sup> while others dismissed it as non-binding soft law.<sup>48</sup> However, a WTO Panel in the matter of Australia – Tobacco Plain Packaging in 2018 opined that the Doha Declaration was a “subsequent agreement” among WTO Members.<sup>49</sup> It reasoned:

In this instance, the instrument at issue is a "declaration", rather than a "decision". However, the Doha Declaration was adopted by a consensus decision of WTO Members, at the highest level, on 14 November 2001 on the occasion of the Fourth Ministerial Conference of the WTO, subsequent to the adoption of the WTO Agreement, Annex 1C of which comprises the TRIPS Agreement. The terms and contents of the decision adopting the Doha Declaration express, in our view, an agreement between Members on the approach to be followed in interpreting the provisions of the TRIPS Agreement. This agreement, rather than reflecting a particular interpretation of a specific provision of the TRIPS Agreement, confirms the manner in which "each provision" of the Agreement must be interpreted, and thus "bears specifically" (footnote omitted) on the interpretation of each provision of the TRIPS Agreement.<sup>50</sup>

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<sup>38</sup> CIPLA announced in 2001 that it could supply the AIDS cocktail therapy in the form of a single pill at \$350 per patient per year. This single announcement led to considerable drop in the prices of triple-drug AIDS therapy. See Katerine Eban, *Bottle of Lies: Ranbaxy and the Dark Side of the Indian Pharma* (India, Juggernaut Books) 86.

<sup>39</sup> Supra note 30.

<sup>40</sup> Ellen 't Hoen et al., “Driving a decade of change: HIV/AIDS, patents and access to medicines for all”, *Journal of the International AIDS Society*, vol. 14 (March 2011) pp. 14–15.

<sup>41</sup> Thomas Cottier, “Working together towards TRIPS” in *The Making of the TRIPS Agreement: Personal insights from the Uruguay Round negotiations*, Jayshree Watal and Antony Taubman eds. (World Trade Organisation, 2015) p. 80.

<sup>42</sup> World Trade Organisation, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2.

<sup>43</sup> Carols M. Correa, *Implication of the Doha Declaration on the TRIPS Agreement and Public Health* (World Health Organisation, 2002) p. 3. Available from <https://apps.who.int/iris/handle/10665/67345>.

<sup>44</sup> Ibid., p. 5.

<sup>45</sup> Steve Charnovitz, “The Legal Status of the Doha Declarations”, *Journal of International Economic Law*, vol. 5 (2002) p. 207.

<sup>46</sup> Tai-Heng Cheng, “Power, Norms, and International Intellectual Property Law”, *Michigan Journal of International Law*, vol. 28, No. 1 (Fall 2006), pp. 142–143.

<sup>47</sup> Bloche, M. Gregg, “WTO Deference to National Health Policy: Toward an Interpretive Principle” *Journal of International Economic Law*, vol. 5, No. 4 (December 2002) p. 842.

<sup>48</sup> Sekalala S and Masud H, “Soft Law Possibilities in Global Health Law” *Journal of Law, Medicine & Ethics* vol 49 (2021), p. 152.

<sup>49</sup> Report of the Panel, *Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, WT/DS467/23 (adopted 27 August 2018) ¶ 7.2409.

<sup>50</sup> Ibid.

In doing so, the Panel affirmed the pivotal role of Articles 7 and 8 of the TRIPS Agreement in interpretation of provisions of TRIPS Agreement. Previously, in the Canada – Pharmaceutical Patents case,<sup>51</sup> a WTO Panel had observed that in interpreting the terms of Article 30 of the TRIPS Agreement, “both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes”.

The declaration reaffirmed the supreme right of Member States to take actions to protect public health uninhibited by the TRIPS Agreement that “does not and should not prevent members from taking measures to protect public health.”<sup>52</sup> It also clarified the scope of the existing flexibilities under the TRIPS Agreement on rules of interpretation,<sup>53</sup> issuance of compulsory licences,<sup>54</sup> determination of national emergency or other circumstance of extreme urgency<sup>55</sup> and exhaustion regime.<sup>56</sup> It further directed the Council of TRIPS to find solutions to the peculiar problem faced by members with insufficient or no pharmaceutical manufacturing capacities. Consequently, the TRIPS Council in 2003 adopted a decision to waive the requirement under Article 31(f) for developing countries that had insufficient pharmaceutical manufacturing capacities and Least Developed Countries (LDCs).<sup>57</sup> On 23 January 2017, the waiver was incorporated as Article 31 bis of the TRIPS Agreement after two thirds of the WTO members accepted the Protocol amending the Agreement.<sup>58</sup>

The Declaration demonstrated that “some norm change in favour of public health in developing countries was achieved within the WTO”.<sup>59</sup> As pointed out the High Court of Delhi, “The 2005 Decision of the General Council on the amendment of the TRIPS Agreement also impliedly flags the concern of balancing humanitarian and development goals on the one hand, and right-holder interests, on the other, in the public health field.”<sup>60</sup>

The following section discusses how these flexibilities reaffirmed by the Doha Declaration have been used in India since 2005.

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<sup>51</sup> Report of the Panel, *Canada — Patent Protection of Pharmaceutical Products*, WT/DS114/13 (adopted 7 April 2000) ¶ 7.26.

<sup>52</sup> World Trade Organisation, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, paragraph 4.

<sup>53</sup> Article 7 and 8 of the TRIPS Agreement enunciate the objectives and principles respectively. Most importantly protection of public health is one the principles of TRIPS Agreement. However, there was no clarity as to the manner in which these objectives and principles would interact with interpretation of other the parts of the Agreement. Without referring to Article 7 and 8, paragraph 5 (a) of Doha Declaration clarified that “each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.”

<sup>54</sup> Article 31 of the TRIPS Agreement provides for other use without authorization of right holder, detailing the nature of such authorization and saving the right of patentee to receive remuneration but it is silent on the circumstances in which authorization may be granted. In this context, paragraph 5 (b) of Doha Declaration reiterates the right of members to grant compulsory licences and the freedom to determine the ground on which the licences are granted.

<sup>55</sup> Under Article 31(b) of the TRIPS Agreement, one of the preconditions to the issuance of a compulsory license is the requirement of the efforts by proposed user to obtain a voluntary license. However, this requirement is waived of “in case of national emergency or other circumstances of extreme urgency of in cases of public non-commercial use”. Again, these important terms have not defined nor has a mechanism been evolved for their notification. In this regard, paragraph 5 (c) of Doha Declaration saves this interpretative space for Member States.

<sup>56</sup> TRIPS Agreement (art 6) is uncommitted on a uniform rule of exhaustion thereby leaving it to the Member States to determine an appropriate exhaustion doctrine. Paragraph 5(d) of Doha Declaration reiterates the same.

<sup>57</sup> Decision of the General Council, *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health*, WTO Doc. WT/L/540 and Corr.1 (30 August 2003).

<sup>58</sup> World Trade Organisation, “TRIPS: Special Compulsory Licences for Export of Medicines”. Available from [https://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/public_health_e.htm).

<sup>59</sup> Isabel Feichtner, “The Waiver Power of the WTO: Opening the WTO for Political Debate on the Reconciliation of Competing Interests”, *European Journal of International Law*, vol. 20, Issue 3 (August 2009) pp. 615–645.

<sup>60</sup> High Court of Delhi, *Bayer Corporation v. Union of India*, LPA No.359/2017, Order, 22 April 2019.

### III. ASSESSING THE FUNCTIONING OF TRIPS FLEXIBILITIES UNDER INDIAN LAW

India being a developing country had an initial transition period of five years (till 31 December 1999) to comply with the TRIPS Agreement.<sup>61</sup> Further, as it did not have product patents for pharmaceutical products, an additional period of another five years (till 31 December 2004) was available to extend product patent protection to the pharmaceuticals.<sup>62</sup> It was only from 1 January 2005 that India was required to grant product patents to pharmaceuticals. However, there was a catch in the form of pipeline protection.<sup>63</sup> The implementation of the “pipeline protection” entailed the creation of a mailbox mechanism to enable the filing of patent applications for pharmaceutical and agricultural chemicals immediately from the date of entry of WTO Agreement. While the patent applications so received in the mailbox were to be examined only upon the expiry of transition period, that is, after 1 January 2005, the applicants were nevertheless entitled to exclusive marketing rights subject to certain conditions.<sup>64</sup> This warranted an immediate change of the patent regulatory landscape as India followed a dualist system<sup>65</sup> to give effect to international agreements.<sup>66</sup> However, the manner of implementation of mailbox provisions and exclusive marketing rights through administrative instructions rather than a parliamentary law prompted the United States to make a complaint against India before the WTO Dispute Settlement Body.<sup>67</sup> India had to bite the bullet when the panel returned a finding against it and found that there was “lack of legal security in the operation of the mailbox system in India”<sup>68</sup> and that it had “failed to establish a system for the grant of exclusive marketing rights”.<sup>69</sup> India appealed against the panel findings but lost that case too.<sup>70</sup> Pursuant to the panel decision India was coerced to amend its law in 1999. However, this aggressive positioning by developed countries particularly the US and European Communities led to a clarion call for the protection of public health within the trade regime.<sup>71</sup>

The grant of patents to pharmaceutical products in India was an emotive issue. When the transition period ended and it was time for India to be fully TRIPS compliant it tried to tread carefully to ensure that no harm to public health ensued in the process by incorporating through the Patents (Amendment) Act 2005 various flexibilities like provisions against ever-

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<sup>61</sup> World Trade Organisation, Agreement on Trade Related Aspects of Intellectual Property, arts. 65(1) and (2)

<sup>62</sup> World Trade Organisation, Agreement on Trade Related Aspects of Intellectual Property art 65(4).

<sup>63</sup> World Trade Organisation, Agreement on Trade Related Aspects of Intellectual Property art 70(8).

<sup>64</sup> World Trade Organisation, Agreement on Trade Related Aspects of Intellectual Property art 70(9). [Exclusive marketing rights were to be granted if firstly the patent for that pharmaceutical product was granted in another WTO member state; secondly, the product in question should be give marketing approval in another WTO Member State; thirdly, the patent application of that product has been filed in India and fourthly, marketing approval has been granted in India. The exclusive marketing rights were to be granted for a period of five years or till the decision of patent application, whichever was shorter.]

<sup>65</sup> Supreme Court of India, *Union of India v Agricas LLP*, 2020 (9-10) SCJ 557.

<sup>66</sup> Article 253 of the Indian Constitution empowers the Parliament to make laws to give effect to international agreements.

<sup>67</sup> Request for Consultations by United States, *India–Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WTO Doc. WT/DS50/10 (2 July 1996).

<sup>68</sup> Report of the Panel in *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WTO Doc. WT/DS50/R (5 September, 1997)¶ 7.41.

<sup>69</sup> Report of the Panel in *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WTO Doc. WT/DS50/R (5 September, 1997)¶ 8.1.

<sup>70</sup> Report of the Appellate Body in *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WTO Doc. WT/DS50/AB/R (19 December, 1997).

<sup>71</sup> Parliament of India debate. *Combined discussion regarding disapproval of the Patents (Amendment) Ordinance, 1999 and passing of the Patents (Amendment) Bill, 1998* (9 March 1999). Available from [https://eparlib.nic.in/handle/123456789/756351?view\\_type=search](https://eparlib.nic.in/handle/123456789/756351?view_type=search).

greening,<sup>72</sup> pre-grant oppositions,<sup>73</sup> post-grant oppositions,<sup>74</sup> import of medicines or drugs by the government for its own purpose<sup>75</sup> revocation of patents,<sup>76</sup> revocation of patents in public interest<sup>77</sup>, revocation of patents for non-working,<sup>78</sup> compulsory licenses,<sup>79</sup> compulsory license to deal with circumstances of national emergency, extreme urgency or public non-commercial use,<sup>80</sup> compulsory license for export of patented pharmaceutical products,<sup>81</sup> acquisition of patents by the Central Government for public purpose,<sup>82</sup> research exceptions,<sup>83</sup> parallel imports and international exhaustion rule.<sup>84</sup> When the constitutional validity of Section 4 of the Patents (Amendment) Act 2005, that enabled product patents for pharmaceuticals in India was challenged before the High Court of Delhi in 2006 on the ground that it violated the fundamental right to health, the Court dismissed the petition. It agreed with the Government that the presence of flexibilities sufficiently equipped the Government to take action in the public interest.<sup>85</sup> But what has the Indian journey been in implementing these flexibilities? Was it able to sufficiently protect public health and ensure affordability and availability of patented drugs? How did it deal with pressure from multinational pharmaceutical companies and its powerful trading partners?

As the purpose of this paper is to look at the implementation challenges and success stories of public health tools deployed by India, the paper discusses in detail three patent levers: compulsory licenses, patentability criteria and opposition proceedings.

## A. Compulsory Licenses

A compulsory license is the tool deployed by the State, to authorize itself or a third party, to make use of the patented invention without the consent of the patent holder. However, royalty is to be paid to the patent holder. It is Article 31 of the TRIPS Agreement that provides for situations of use of patent “without authorization of the right holder” without using the terms “compulsory license”. The use of compulsory licensing provisions under the Patents Act, 1970 (as amended) is broadly premised on the fault of the patentee, emergency situations and humanitarian assistance to countries with no manufacturing capacities.

### i. Fault of the patentee

Fault grounds mean that the patentee has not been able to meet its obligations vis-a-vis the public. The fault can be in the form of non-availability of the patented invention in sufficient quantity, non-availability of the patented invention at a reasonable price, failure to work the invention in the territory of India or anti-competitive practices.<sup>86</sup> The Patents Act gives a three-year grace period from the date of grant of patent to excuse the fault of the patentee. If the fault persists after this grace period, then any interested person can make an application for grant of a compulsory license. However, it is necessary that before the application is made by the prospective licensee, he/she should first try to obtain a voluntary license from the patent

<sup>72</sup> India, Patents Act, 1970, sec 3(d).

<sup>73</sup> India, Patents Act, 1970, sec 25 (1).

<sup>74</sup> India, Patents Act, 1970, sec 25(2).

<sup>75</sup> India, Patents Act, 1970, sec 47(4).

<sup>76</sup> India, Patents Act, 1970, sec 64.

<sup>77</sup> India, Patents Act, 1970, sec 65.

<sup>78</sup> India, Patents Act, 1970, sec 85.

<sup>79</sup> India, Patents Act, 1970, sec 84.

<sup>80</sup> India, Patents Act, 1970, sec 92.

<sup>81</sup> India, Patents Act, 1970, sec 92a.

<sup>82</sup> India, Patents Act, 1970, sec 102.

<sup>83</sup> India, Patents Act, 1970, sec 107-a (a).

<sup>84</sup> India, Patents Act, 1970, sec 107-a (b).

<sup>85</sup> High Court of Delhi, *Jeevan Jyoti Health & Welfare Society v. Union of India*, W.P. (C) No.: 10634/2006, Judgment, 20 December 2007.

<sup>86</sup> India, Patents Act, 1970, sec 84.

holder. The burden of proof is upon the applicant/prospective licensee to prima facie establish the fault of the patentee.<sup>87</sup> The patentee can oppose the application and is provided with an opportunity of being heard before a compulsory license is granted.<sup>88</sup>

As of now three applications have been considered by the Controller on fault grounds and their status is as follows:

Patented Product for which Compulsory License sought	Use of Patented Product	Patentee	Applicant of Compulsory License	Status of Application
Sorafenib Tosylate (Brand name: Nexavar)	To prolong life in case of advanced stages of kidney and liver cancer	Bayer Corporation	Natco Pharma Ltd.	Granted <sup>89</sup>
Dasatinib (Brand name: Sprycel)	Treatment of Chronic Myeloid Leukaemia	Bristol Myers Squibb Company	BDR Pharmaceuticals International Pvt Ltd.	Rejected <sup>90</sup>
Saxagliptin	Treatment of Type-II Diabetes Mellitus	AstraZeneca AB	Lee Pharma Ltd.	Rejected <sup>91</sup>

A reading of these cases highlights that the following are important considerations for the grant of compulsory licenses:

1. The paramount consideration for grant of compulsory license is the protection of public interest and not commercial interest of the applicant. The High Court of Delhi has held that "The provisions for compulsory licences are designed to prevent the failure of the patentee to satisfy the reasonable requirements of the public as distinct from those of particular individuals. It is this failure which is in terms made the ground for granting a compulsory licence."<sup>92</sup> "Nexavar" remains the only product for which compulsory license has been given. The applicant was able to show that the patentee did not meet the quantitative demand for invention on a reasonable price. The patentee despite having an import and marketing license as early as January 2008 did not import the drug in 2008, and only small quantities were imported in 2009 and 2010. Affordability to the public was also a vital consideration. The patentee was offering the drug at the price of INR 280,000 per patient per month while the patients belonged to economically weaker sections of society and the applicant claimed to make it available at less than INR 10,000 per patient per month.
2. Unsubstantiated claims based on vague assumptions and calculations with respect to requirements of the public or affordability will lead to rejection of the application as was

<sup>87</sup> India, Patents Act, 1970, sec 87 (1).

<sup>88</sup> India, Patents Act, 1970, sec 87 (2).

<sup>89</sup> Controller of Patents, *Natco Pharma Limited v. Bayer Corporation*, Compulsory License Application No. 1 of 2011, Order, 9 March 2012.

<sup>90</sup> Controller of Patents, *BDR Pharmaceuticals International Pvt Ltd v. Bristol Myers Squibb Company*, Compulsory License Application No. 1 of 2013, Order, 29 October 2013.

<sup>91</sup> Controller of Patents, *Lee Pharma Ltd v. AstraZeneca AB*, Compulsory License Application No. 1 of 2015, Order 19 January 2016.

<sup>92</sup> High Court of Delhi, *Novartis AG v. Cipla Ltd*, I.A. No. 24863/2014 in CS (OS) 3812/2014, Judgement, 9 January 2015, 96.

illustrated by rejection of Lee Pharma's application for a compulsory license for Saxagliptin.

3. The presence of alternative drugs for the treatment of an indicated disease is also an important consideration in determining the unmet need of the public in the grant of a compulsory license.
4. Despite having "public interest" at the heart of the compulsory license process, primacy is given to market-based solutions in the form of voluntary negotiated license than State based intervention in brokering an involuntary deal. The compulsory license mechanism can neither be used as a bridge to bypass the voluntary negotiation process nor a sword to avenge the failure to obtain a voluntary license without any actual public need. In fact, the Controller will not adjudicate the matter on merits unless the "applicant has made efforts to obtain a license from the patentee." An endless negotiation process is, however, not contemplated and the efforts must be made within a reasonable time. The reasonable time is "six months" under the Indian Law.<sup>93</sup> A compulsory license was denied to BDR Pharmaceuticals as it did not make efforts to negotiate with the patentee. Mere making of an initial offer or sending a letter requesting for a voluntary license without engaging in any kind of dialogue/clarification process even when sought by patentee does not amount to "effort."<sup>94</sup>
5. Non-working of patented invention in the territory of India is also a ground for the grant of a compulsory license despite its doubtful compatibility with the TRIPS Agreement.<sup>95</sup> In the matter of Bayer and Natco, the Controller held that importation could not amount to working and that "'worked in the territory of India' means 'manufactured to a reasonable extent in India'".<sup>96</sup> IPAB disagreed with it. According to IPAB:

As we have already seen, TRIPS says that the authorization and other uses must be dealt with on a case-to-case basis. Therefore, we cannot decide that "the working" totally excludes import, or that "working" is synonymous to "import" and that if there is no manufacture in India, then there is no working. The repeated use of the words, 'in the territory of India' does indicate local working, but as the Controller has observed, the word 'working' has not been defined...So, with regard to Section 84(1) (c), we find that **the word 'worked' must be decided on a case to case basis and it may be proved in a given case, that 'working' can be done only by way of import, but that cannot apply to all other cases. The patentee must show why it could not be locally manufactured.** A mere statement to that effect is not sufficient there must be evidence. Therefore, while we are of the opinion that the word 'worked' has a flexible meaning, and to that extent we differ from the Controller. (emphasis supplied).<sup>97</sup>

That manufacture in India is not a necessary precondition was also confirmed by the Bombay High Court in appeal by Bayer. It held that:

<sup>93</sup> Explanation to Section 84(5) of Patents Act, 1970 reads as follows: "For the purposes of clause (iv), "reasonable period" shall be construed as a period not ordinarily exceeding a period of six months."

<sup>94</sup> In this case the applicant made the request for a voluntary license on 2 February 2012 to the patentee, who, by letter dated 13 March 2012 raised some queries. The queries were never replied to and application for a compulsory license was made one year thereafter. This inaction by the applicant was regarded as intention to not engage in any kind of dialogue.

<sup>95</sup> Prashant Reddy, "'Working' a Patent under the Indian Patent Act, 1970 – Does importation of a patented invention count?", Spicy IP, 22 April 2010. Available from <https://spicyip.com/2010/04/working-patent-under-indian-patent-act.html>.

<sup>96</sup> Controller of Patents, *Natco Pharma Limited v. Bayer Corporation*, Compulsory License Application No. 1 of 2011, Order, 9 March, 2012, pp. 42–43.

<sup>97</sup> Intellectual Property Appellate Board, Chennai, *Bayer Corporation v. Union of India, The Controller of Patents and Natco Pharma Limited*, OA/35/2012/PT/MUM, Order, 4 March, 2013, 51.

Manufacture in all cases may not be necessary to establish working in India as held by the Tribunal. However, the patent holder would nevertheless have to satisfy the authorities under the Act as to why the patented invention was not being manufactured in India keeping in view Section 83 of the Act. This could be for diverse reasons, but it would be for the patent holder to establish those reasons which makes it impossible/ prohibitive for it to manufacture the patented drug in India. However, where a patent holder satisfies the authorities, the reason why the patented invention could not be manufactured in India then the patented invention can be considered as having been worked in the territory in India even by import.<sup>98</sup>

Pertinently, even in two other cases where a compulsory license was rejected, the patented invention was not manufactured in India. While the BDR Pharmaceuticals' application was not heard on merits, Lee Pharma was not able to establish the exact quantitative requirement for the patented invention so as to warrant a query on manufacturing necessity in India.

The successive rejections of compulsory license applications especially on technical grounds have apparently discouraged the generic makers. Even when suggested by the Courts, the generic companies have not filed applications for compulsory license. An example is the dispute between Novartis and Cipla. Novartis had patents over Indacaterol for the treatment of respiratory diseases such as chronic obstructive pulmonary disease, but Cipla launched the product without obtaining any authorization or license from Novartis, inviting an infringement suit. It had however requested the Government to revoke the five patents held by Novartis, but that application was pending.<sup>99</sup> During the hearing of interim injunction, Cipla pleaded that the injunction should not be granted as it would cause prejudice to the public interest. Nevertheless, as infringement was established, an interim injunction was granted but the court advised Cipla to file a compulsory license, in the absence of which it was an infringer. The interim injunction was to be vacated in case the Controller granted the compulsory license. The Court also directed the Controller that if such an application for compulsory license was to be filed by Cipla then it must be decided within the period of six months.<sup>100</sup> Despite this Cipla did not file for a compulsory license and instead went in an appeal against that order. The division bench upheld the interim injunction.<sup>101</sup>

As this saga unfolded, it was widely reported in the media that the Indian Government had privately assured the US–India Business Council that it would not use compulsory licenses for commercial purposes.<sup>102</sup> However, the government vehemently denied these reports as factually incorrect and issued a clarification through a press release to the following effect:

[U]nder the Doha Declaration on the TRIPS Agreement Public Health, each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. Even as Government of India is conscious of

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<sup>98</sup> Bombay High Court, *Bayer Corporation v. Union of India*, Writ Petition No. 1323 of 2013, Judgment, 15 July 2014, 14.

<sup>99</sup> PTI, "Cipla asks government to revoke Novartis' patent; launches its drug", *The Economic Times*, Oct 30, 2014. Available from, <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/cipla-asks-government-to-revoke-novartis-patent-launches-its-drug/articleshow/44984486.cms?from=mdr>.

<sup>100</sup> High Court of Delhi, *Novartis AG v. Cipla Ltd*, I.A. No. 24863/2014 in CS (OS) 3812/2014, Judgement, 9 January 2015.

<sup>101</sup> High Court of Delhi, *Cipla Ltd v. Novartis AG*, FAO(OS) 21/2015 and CM Nos. 731, 1288, 2090/2015, Judgement, 9 March 2017.

<sup>102</sup> Amit Sengupta, "India Assures the US it Will Not Issue Compulsory Licences on Medicines", *The Wire*, 12 March 2016. Available from <https://thewire.in/health/india-assures-the-us-it-will-not-issue-compulsory-licences-on-medicines>.

the need to spur innovation and protect individual rights, it retains the sovereign right to utilize the flexibilities provided in the international IPR regime.<sup>103</sup>

Incidentally, just before these reports came the application of Lee Pharma for compulsory license had been rejected in January 2016. The Government was perhaps signalling that it was unwilling to issue compulsory license as a matter of routine to protect public health. Compulsory license was to be issued only in exceptional cases. Consequently, no application has been made thereafter to the controller for grant of a compulsory license on the basis of fault of patentee.

One more disincentive for the industry to file for the grant of compulsory license is that there is a general limitation on export. The compulsory license is primarily granted with a “predominant purpose of supply in the Indian market.”<sup>104</sup> Exports however are not totally prohibited. Exports can be made if “a market for export of the patented article manufactured in India is not being supplied or developed.”<sup>105</sup> But exports purely for purpose of commercial advantage cannot be made. Natco which has been granted a compulsory license for Sorafenib Tosylate on the conditions inter alia “solely for the purposes of making, using, offering to sell and selling the drug covered by the patent for the purpose of treating HCC and RCC in humans within the territory of India”, faced much opposition from Bayer as it attempted to export the patented drug to China. Bayer filed a writ before the High Court of Delhi seeking directions to the Customs Authorities to seize the consignments for export containing products manufactured by Natco under the compulsory license.<sup>106</sup> Natco claimed that it did not export the products to any party outside India for commercial purpose. It claimed that the exports were for generation or submission of regulatory permission. The question before the court was whether the grant of a compulsory license in any way affected the provisions relating to research and non-commercial use. Holding that Section 107 A was “an independent provision with a specific history” the division bench of the High Court categorically stated that “Natco’s status as compulsory licensee did not place it under any additional statutory bar from exporting the product, as long as the underlying condition in Section 107A was satisfied”.<sup>107</sup> So export of patented products under compulsory license can be made for research purposes.

Except for the situations enumerated above, there is a general restriction on export of patented articles manufactured by a compulsory licensee. It is problematic on many counts. It makes the manufacture economically unviable especially for drugs which have limited patients in India. It hinders the achievement of economies of scale and interacts unclearly with the doctrine of exhaustion. While under the TRIPS Agreement Member States have the freedom to determine an appropriate level of exhaustion, the limitation on compulsory license for domestic use hints towards a de-facto national exhaustion rule at least with respect to compulsory licensed products

If products under compulsory license are required to be predominantly exported for commercial purposes outside the country, then they must satisfy the conditions for grant of special license in terms of the paragraph 6 solution of Doha Declaration.

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<sup>103</sup> Government of India, Ministry of Commerce & Industry, “Clarification on Media Reports regarding Compulsory licence” Press Information Bureau, 22 March 2016, Available from <https://pib.gov.in/newsite/PrintRelease.aspx?relid=138271>.

<sup>104</sup> India, Patents Act, 1970, sec 90 (1) (vii).

<sup>105</sup> India, Patents Act, 1970, sec 84 (7) (a)(iii).

<sup>106</sup> High Court of Delhi, W.P.(C) No.1971/2014.

<sup>107</sup> High Court of Delhi, *Bayer Corporation v. Union of India*, LPA No. 359/2017, Judgment, 22 April 2019.

## ii. Emergency situations

Fault of the patentee is not required to be proved in “circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use.”<sup>108</sup> There is no need to even seek a voluntary license in the first place.<sup>109</sup> A notification by the Central Government of the need for a compulsory license will suffice. Unfortunately, even in the times of the COVID-19 pandemic this section has not been used despite the suggestions by the High Court of Delhi and the Supreme Court of India. In the wake of shortage of medicines during the second wave of COVID-19 in India, the High Court of Delhi reminded the Government of its powers under the Patents Act to invoke compulsory licensing to save people's lives and said:

There are a number of other drugs which are being used for treatment Covid-19 patients, such as *Tocilizumab*, *Favipiravir*, *Ivermectin*, *Dexamethasone*, *Methylprednisolone*, *Dalteparin*, *Enoxaparin*, *HCQ* and *Baricitinib*. As per news reports, there are shortages of some, if not all, of the aforesaid drugs. Looking to the emergent situation, we direct the Central Government to immediately reach out to the manufacturers/ patent holders/ licensees so as to forthwith ramp up the production capacities of the above, and all such other medications, as are essential for treatment of Covid positive patients. We may take note of the fact that the Patents Act provides for Compulsory Licenses under Section 84, and Special Provision for Compulsory Licenses or Notifications by the Central Government, under Section 92. Section 100 provides the power of the Central Government to use inventions for purposes of the Government.

28. Looking to the present-day situation, there can be no doubt that a case is made out for exercise of its power by the Central Government/ Controller under the previously mentioned provisions of law. At the same time, the interests of the Patent holders/ licensees should be kept in mind, since it on account of their investments, inventions and hard work that such like medicines are made available to the public at large. The best course would be encouraging the existing manufacturers to ramp up their production on a war footing. They should also be encouraged to grant voluntary licenses to other entities to manufacture the requisite drugs. However, if such efforts do not fructify soon enough, the Government/ Controller should not hesitate to invoke their jurisdiction and powers under the aforesaid provisions of the Patents Act, since the lives of thousands of people are being lost each day in the country due to COVID. The lives of the people take priority over everything else.<sup>110</sup>

In a similar vein, the Supreme Court of India proposed to the Central Government adopting compulsory licensing for vaccines and essential drugs to address the shortage of patented drugs used for COVID treatment like Remdesivir, Tocilizumab and Favipiravir. The Court also referred to the relevant provisions of the Indian Patent Law including Section 92, Section 100 and Section 102. It assuaged the concerns of the Government regarding the legitimacy of its action under these provisions by averting to TRIPS and Doha Declaration. The Court observed:

The utilization of these flexibilities has also been detailed in the Trade Related Aspects of Intellectual Property Rights Agreement. Even as TRIPS obliges countries to ensure a minimum level of patent protection, it creates a permissive regime for the carving out of exceptions and limitations that further public health objectives. This is evident from

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<sup>108</sup> India, Patents Act, 1970, sec 92.

<sup>109</sup> World Trade Organisation, Agreement on Trade Related Aspects of Intellectual Property, art 31(b).

<sup>110</sup> High Court of Delhi, *Rakesh Malhotra v. Government of National Capital Territory of India*, W.P.(C) 3031/2020, Order, 20.04.2021.

a conjoint reading of Articles 7, 8, 30 and 31 of TRIPS. Article 7 outlines the objectives of the TRIPS as being to ensure the effective enforcement of intellectual property in a way that, *inter alia*, is “conducive to social and economic welfare”. Article 8 gives member countries the freedom to take measures that protect public health and nutrition. Article 8(2) allows for the taking of TRIPS-compatible measures aimed at preventing the abuse of intellectual property rights. Articles 30 and 31 deal with exceptions to the rights of patent owners, by allowing grant of compulsory licenses. It leaves countries with significant breathing space to determine how the compulsory licensing or government-use levers can be triggered. While such determinations must be made on the individual merits of each case, the aforesaid caveat does not apply when the compulsory license grant is for national emergency, extreme urgency or public non-commercial use.

45. According to the 2001 Doha Declaration, TRIPS should be interpreted in a manner supportive of the right of members to protect public health and to promote access to medicines. It recognizes the right of WTO members to use the full extent of the TRIPS flexibilities to secure this objective. Para 5(b) of the Doha Declaration provides the freedom to each member to grant compulsory licenses and to determine the grounds on which the licenses are granted. Para 5(c) leaves it up to each nation to determine what constitutes a national emergency or extreme urgency. In the context of the COVID-19 pandemic, we note that several countries such as Canada and Germany have relaxed the legal regimes governing the grant of compulsory licenses. (Footnotes omitted).<sup>111</sup>

Despite these exhortations from two constitutional courts, the Central Government did not budge an inch to make use of the patent law flexibilities even in the midst of a public health emergency. Subsequently, compulsory license under emergency provisions was sought by Natco for Olumiant<sup>®</sup>, a patented drug used in COVID-19.<sup>112</sup> The threat of a compulsory license under emergency provisions led to a royalty free, voluntary agreement between Natco and Eli Lilly, the assignee of patent, for the drug Baricitinib (Brand name: Olumiant<sup>®</sup>).<sup>113</sup> Eli Lilly has also entered into voluntary licensing agreements to manufacture Baricitinib with Cipla, Sun, Lupin, Dr. Reddy’s Laboratories, Torrent and MSN Labs.<sup>114</sup> But it refused to license its drug to Bajaj Healthcare Ltd, which is now seeking a compulsory license for the same under Section 92.<sup>115</sup> It will be interesting to see if a compulsory license will be granted in this case to Bajaj Healthcare Ltd as the dispute now encompasses questions not only of emergency but also of a patentee’s alleged right of refusal.

### iii. Humanitarian assistance and international cooperation

Special compulsory licenses can be granted to export patented pharmaceutical products to countries having insufficient or no pharmaceutical manufacturing capacity under Section 92A, Patents Act, 1970. However, before a compulsory license is granted in India, a compulsory license should have been granted in the country of import or a notification should have been issued allowing such importation. While it was widely expected that India would make use of

<sup>111</sup> Supreme Court of India, *In Re: Distribution of Essential Supplies and Services during Pandemic*, Suo Motu Writ Petition (Civil) No.3 of 2021, Order, 30.04.2021.

<sup>112</sup> Swaraj Paul Baroah, “Natco Files Compulsory Licence Application for Covid Drug Baricitinib” *Spicy IP*, 5 May 2021. Available from <https://spicyip.com/2021/05/natco-files-compulsory-licence-application-for-covid-drug-baricitinib.html>.

<sup>113</sup> The Hindu, “Natco Pharma signs pact with Eli Lilly for Baricitinib”, 17 May 2021. Available from <https://www.thehindu.com/business/natco-pharma-signs-pact-with-eli-lilly-for-baricitinib/article34582342.ece>.

<sup>114</sup> *Ibid*.

<sup>115</sup> Sohini Das, “Bajaj Healthcare seeks compulsory licence for Covid-19 drug Baricitinib: Eli Lilly has granted voluntary license to 6 Indian drugmakers for Baricitinib”, *Business Standard*, 28 June 2021. Available from [https://www.business-standard.com/article/current-affairs/bajaj-healthcare-seeks-compulsory-license-for-covid-19-drug-baricitinib-121062801439\\_1.html](https://www.business-standard.com/article/current-affairs/bajaj-healthcare-seeks-compulsory-license-for-covid-19-drug-baricitinib-121062801439_1.html).

this mechanism to export the drugs to African and other countries, it has been dented by the cumbersome and bureaucratic formalities.<sup>116</sup> Only two applications have been made under Section 92A. Applications were made by Natco to produce two drugs for export to Nepal. The drugs in question were: Erlotinib, (Brand name: Tarceva<sup>®</sup>) a lung cancer drug, patented by Roche and Sunitinib (brand name Sutent<sup>®</sup>) for cancer, patented by Pfizer.<sup>117</sup> The applications had to be withdrawn by Natco<sup>118</sup> as there was no proper documentation from Nepal to import the drugs.

The Section 92A mechanism is in accordance with the paragraph 6 solution of Doha Declaration which itself has been riddled with various problems. While the purpose of paragraph 6 solution was to provide succour to least-developed countries or any country with insufficient pharmaceutical manufacturing facilities, it is too formalistic. Both the exporting member and importing member have to make numerous notifications to the TRIPS Council, in addition to the need to specify the name and expected quantity to delivered, deploy special labelling for products in question and take measures to prevent re-diversion of goods in the country of export. The licensee is also required to put up information on its website. The patent holder is entitled to royalty, but double remuneration is avoided; payment is to be made only in exporting Member “taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member.” However, as of now very few notifications by importing and exporting members have been made to make use of this system as shown by the tables below:

Notifications of Intention to Use the Special Compulsory Licensing System as an Importing Member			
Notifying Member	Date of Notification	Limitations	Pharmaceutical Product
Antigua and Barbuda <sup>119</sup>	12 May 2021	Use of the System in the case of a national emergency or other circumstances of extreme urgency	-
Bolivia <sup>120</sup>	17 February 2021	Use of the System in the case of a national emergency or other circumstances of extreme urgency	15 million doses of COVID-19 vaccines.

<sup>116</sup> World Trade Organisation, Council for Trade-Related Aspects of Intellectual Property Rights, *Annual review of the decision on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Report*, WTO Doc. IP/C/69, 26 November 2014. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/69.pdf&Open=True>.

<sup>117</sup> Tatum Anderson, “India Considers Compulsory Licences For Exportation Of Drugs”, Intellectual Property Watch, 20 February 2008. Available from <https://www.ip-watch.org/2008/02/20/india-considers-compulsory-licenses-for-exportation-of-drugs/>.

<sup>118</sup> C.H. Unnikrishnan, “Natco withdraws plea on making patented cancer drugs”, *The Mint*, 28 September 2008. Available from <https://www.livemint.com/Companies/ptTTNsQ4InCP8Y8avJ305J/Natco-withdraws-plea-on-making-patented-cancer-drugs.html>.

<sup>119</sup> World Trade Organisation, Council for Trade-Related Aspects of Intellectual Property Rights, *Notification under the amended TRIPS Agreement: Notification of intention to use the special compulsory licensing system as an importing member*, WTO Doc. IP/N/8/ATG/1, 17 May 2021. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/N/8ATG1.pdf&Open=True>.

<sup>120</sup> World Trade Organisation, Council for Trade-Related Aspects of Intellectual Property Rights, *Notification under the amended TRIPS Agreement: Notification of intention to use the special compulsory licensing system as an importing member*, WTO Doc. IP/N/8/BOL/1, 19 February 2021. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/N/8BOL1.pdf&Open=True>.

Rwanda <sup>121</sup>	17 July 2007	-	260,000 packs of TriAvir, a fixed-dose combination product of Zidovudine, Lamivudine and Nevirapine
Notifications of Intention To Use The Special Compulsory Licensing System As An Exporting Member			
Notifying Member	Date of Notification	Limitations	Pharmaceutical Product
Canada <sup>122</sup>	4 October, 2007	For export to Rwanda	A fixed-dose combination product of Zidovudine, Lamivudine and Nevirapine

In practice, only Rwanda has been able to use this solution of special compulsory licenses to import medicines for HIV/AIDS, calling for deeper introspection. The system is criticized for being overly burdensome and inefficient. In this regard, India has echoed the concerns of generic manufacturers who pointed out that:

There was no way to achieve economies of scale because of the limited quantities of medicines to be procured by the importing countries. He also noted requirements like special labelling and markings and the need for the generic company to host a special website and to pay remuneration to the patent holder. According to him, there was so much red tape built into the System that it was difficult for the Paragraph 6 Mechanism to achieve its intended purpose. Unless the procedures were simplified, his company would never use the System.<sup>123</sup>

While India had been clamouring for change of paragraph 6 solution at the international level, it faced the brunt of the cumbersome process when it faced its worst health crisis in the decade. During the second wave of COVID-19 India faced critical shortages of oxygen and medical supplies including remdesivir.<sup>124</sup> Russia promised to help send remdesivir to India<sup>125</sup> but it could not do so promptly. This was because in January 2021, Russia had issued a compulsory license for remdesivir<sup>126</sup> permitting Pharmasintez JSC to use the corresponding invention patents, owned by Gilead Sciences, Inc. and Gilead Pharmasset LLC, for one year.<sup>127</sup> According to MSF, “Russia’s compulsory license was issued under its national law in

<sup>121</sup> World Trade Organisation, Council for Trade-Related Aspects of Intellectual Property Rights, *Notification under paragraph 2(a) of the decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. IP/N/9/RWA/1, 19 July 2007. Available from <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/N/9RWA1.pdf&Open=True>.

<sup>122</sup> World Trade Organisation, Council for Trade-Related Aspects of Intellectual Property Rights, *Notification under paragraph 2(c) of the decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc. IP/N/10/CAN/1, 8 October, 2007, <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/N/10CAN1.pdf&Open=True>.

<sup>123</sup> World Trade Organisation, Council for Trade-Related Aspects of Intellectual Property Rights, *Annual review of the decision on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Report*, WTO Doc. IP/C/76, 18 November 2011. Available from [https://www.wto.org/english/tratop\\_e/trips\\_e/ta\\_docs\\_e/3\\_ipc61\\_e.pdf](https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/3_ipc61_e.pdf).

<sup>124</sup> Remdesivir is an antiviral medication patented by Gilead Sciences. It was approved for emergency use for treatment of Covid-19 in India and many other countries.

<sup>125</sup> N. Ravikumar, “Russia, Uzbekistan offer Remdesivir to India”, *The Hindu*, 27 April 2021. Available from <https://www.thehindu.com/business/Industry/russia-uzbekistan-offer-remdesivir-to-india/article34425185.ece/>.

<sup>126</sup> “Decree of the Government of the Russian Federation dated 31 December 2020 No. 3718-r”. Available from <http://publication.pravo.gov.ru/Document/View/0001202101050003>.

<sup>127</sup> “Russian Government issues first compulsory pharmaceutical licence”, *CMS Russia*, 11 January 2021. Available from <https://www.lexology.com/library/detail.aspx?g=ee05c5b9-3973-4012-90ca-2bb6dff5b417>.

compliance with Article 31 of TRIPS Agreement, which means generic formulations produced under the license are meant predominantly for domestic use, limiting exports, even for humanitarian assistance".<sup>128</sup> There were concerns that export by Russia of a product under compulsory license would invite patent infringement suits in India or a dispute under the TRIPS agreement. Russian pharmaceutical firm Pharmasynthez confirmed that it was willing to send the shipment but wanted to find a legal basis on which to act. The legality of the shipment could have been either in the shape of a license for the export of a drug authorised by the Russian Government at India's request, or the shipment could be sent as humanitarian aid.<sup>129</sup> Since no compulsory license was issued by India for remdesivir as contemplated under Article 31bis of TRIPS Agreement the first option was not available. Moreover, it was doubtful if India could invoke Article 31bis. It perhaps would not have qualified as a country having insufficient manufacturing capacity as Gilead had already granted voluntary licenses to four generic firms based in India to manufacture the drug.<sup>130</sup> Consequently, after a month of dilly-dallying Russia had to declare the supply of generic version of the remdesivir to India as part of its humanitarian aid contributions.<sup>131</sup> This episode calls for an urgent overhaul of Art 31bis mechanism and the limitation on the export of compulsory licensed products.

## **B. Patentability Criteria**

While the TRIPS Agreement mandates the grant of patents for inventions irrespective of their field of technology, it does not define the term "invention". It thereby leaves room for different interpretations.<sup>132</sup> India has used this flexibility in detailing what it does not consider as "invention".<sup>133</sup> In order to assuage the concerns of ever-greening<sup>134</sup> of pharmaceutical products Section 3(d) of Patents Act 1970, takes out from the definition of invention "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant" thereby making them ineligible for patent protection.

However, Section 3(d) has been in the eye of storm since it was first introduced in the statute book in 2005. The United States continues to flag this section while putting India under its priority watch list under Section 301.<sup>135</sup> Its scope has been put to test by Novartis AG in a long litigation battle when the salt of its anti-cancer drug Gleevec "Imatinib Mesylate in its beta crystalline" was denied a patent. A patent was claimed for the beta crystal form of Imatinib

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<sup>128</sup>MSF, "Compulsory licenses, the TRIPS waiver and access to COVID-19 medical technologies: Briefing Document", May 2021. Available from [https://msfaccess.org/sites/default/files/2021-05/COVID\\_TechBrief\\_MSF\\_AC\\_IP\\_CompulsoryLicensesTRIPSWaiver\\_ENG\\_21May2021\\_0.pdf](https://msfaccess.org/sites/default/files/2021-05/COVID_TechBrief_MSF_AC_IP_CompulsoryLicensesTRIPSWaiver_ENG_21May2021_0.pdf).

<sup>129</sup> Reuters and Polina Nikolskaya, "Russian firm awaits government approval to ship remdesivir to India" 26 April 2021. Available from <https://www.reuters.com/world/india/russias-pharmasynthez-ready-ship-1-mln-packs-remdesivir-india-2021-04-26/>.

<sup>130</sup> Gilead, *Voluntary Licensing Agreements for Remdesivir*. Available from <https://www.gileadchina.cn/en/news/press-releases/2020/5/voluntary-licensing-agreements-for-remdesivir>. Also see, PTI, "Four Indian firms ink licensing pact with Gilead for COVID-19 drug Remdesivir", The New Indian Express, 14 May 2020. Available from <https://www.newindianexpress.com/business/2020/may/14/four-indian-firms-ink-licensing-pact-with-gilead-for-covid-19-drug-remdesivir-2143054.html>.

<sup>131</sup> Reuters, "Russia ships remdesivir drug to India as part of humanitarian aid" 25 May 2021. Available from <https://www.reuters.com/world/india/russia-ships-remdesivir-drug-india-part-humanitarian-aid-2021-05-25/>.

<sup>132</sup>Carlos. M Correa, "Interpreting the Flexibilities under the TRIPS Agreement" in *Access to Medicines and Vaccines: Implementing Flexibilities under Intellectual Property Law*, Carlos M. Correa ad Reto M. Hilty eds. (Springer, 2022) pp. 2–4. e-book.

<sup>133</sup> India, Patents Act, 1970, sec 3.

<sup>134</sup> Ever greening refers to the strategic tactics adopted by a patentee to extend its patent over a compound by filing new patent applications on its variations.

<sup>135</sup> United States of America, the Office of the United States Trade Representative, *Special 301 Report, 2020* (April 2020). Available from [https://ustr.gov/sites/default/files/2020\\_Special\\_301\\_Report.pdf](https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf).

Mesylate. On the date of the patent application non-crystalline Imatinib Mesylate was already a part of the “Zimmermann patent”. When the case reached the Supreme Court of India in 2013, the court upheld the application of Section 3(d) to deny the patent. The court held that, “As beta crystalline form of Imatinib Mesylate, is a new form of a known substance, i.e., Imatinib Mesylate, of which the efficacy was well known it must be shown that there was enhanced therapeutic efficacy of the new form.” When the court looked for enhanced therapeutic efficacy of the beta crystalline form of Imatinib Mesylate to clear the hurdle of Section 3(d), it found none. Therapeutic efficacy had nothing to do with better physico-chemical properties of beta crystalline. Increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy. Better therapeutic efficacy needs to be established by research data.<sup>136</sup>

A study of 1723 pharmaceutical patent applications that were rejected by the Indian Patent Office between January 2009 and January 2017 found that the Indian Patent Office increased application of Section 3(d) after this judgement.<sup>137</sup> Section 3(d) either alone or in combination with other provisions was raised in “69 per cent of the cases where the exceptions to patentability were cited”.<sup>138</sup> These objections also led to a higher number of applicants abandoning or withdrawing their application.<sup>139</sup> Another study showed a sharp increase in the prevalence of 3(d) in the First Examination Report.<sup>140</sup> Despite this, occasionally secondary patents are granted for marginal improvements over previously known drugs for which primary patents exist<sup>141</sup> even in the absence of relevant submissions of clinical data to demonstrate therapeutic efficacy.<sup>142</sup> One of the reasons for these spurious patents is the lack of adequate manpower in the patent office. A perusal of the annual reports of Indian Patent Office from 2005 to 2020 shows that there was always a yawning gap between the sanctioned and the actual working strength in Group A posts<sup>143</sup> as illustrated in Chart 1.

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<sup>136</sup> Supreme Court of India, *Novartis AG v. Union of India*, Civil Appeal Nos. 2706-2716 of 2013 arising out of SLP(C) Nos. 20539-20549 of 2009, Judgement, 1 April 2013.

<sup>137</sup> Dr. Feroz Ali, Dr. Sudarsan Rajagopal, Mohamed Mustafa and Chinnasamy Prabhu, “Rejected in India: What the Indian Patent Office got Right on Pharmaceuticals Patent Applications (2009–2016)” (Aziz Premji University, December 2017), pp. 6–8. Available from <https://accessibsa.org/media/2017/12/Rejected-in-India.pdf>.

<sup>138</sup> Ibid.

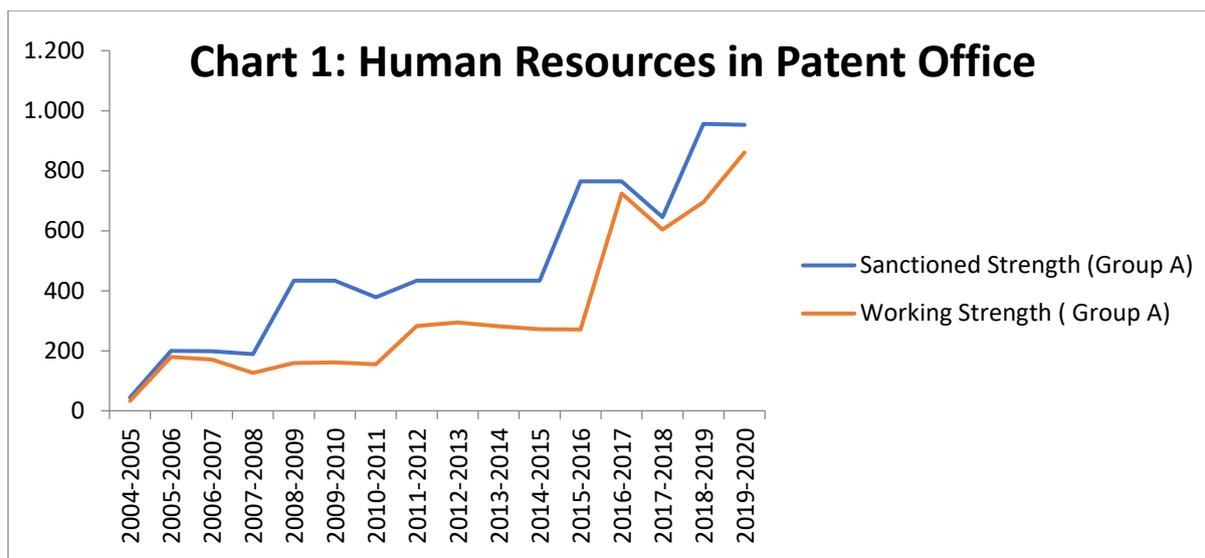
<sup>139</sup> Ibid.

<sup>140</sup> Bhaven N. Sampat and Kenneth C. Shadlen, “Indian pharmaceutical patent prosecution: The changing role of Section 3(d)”, *PLOS ONE*, vol. 13, No. 4 (2 April 2018).

<sup>141</sup> Dr. Feroz Ali, Dr. Sudarsan Rajagopal, Dr. Venkata S. Raman and Roshan John, “Pharmaceutical Patent Grants in India: How our safeguards against evergreening have failed, and why the system must be reformed in 2018” (Aziz Premji University, April 2018), pp. 5–8. Available from <https://accessibsa.org/media/2018/04/Pharmaceutical-Patent-Grants-in-India.pdf>.

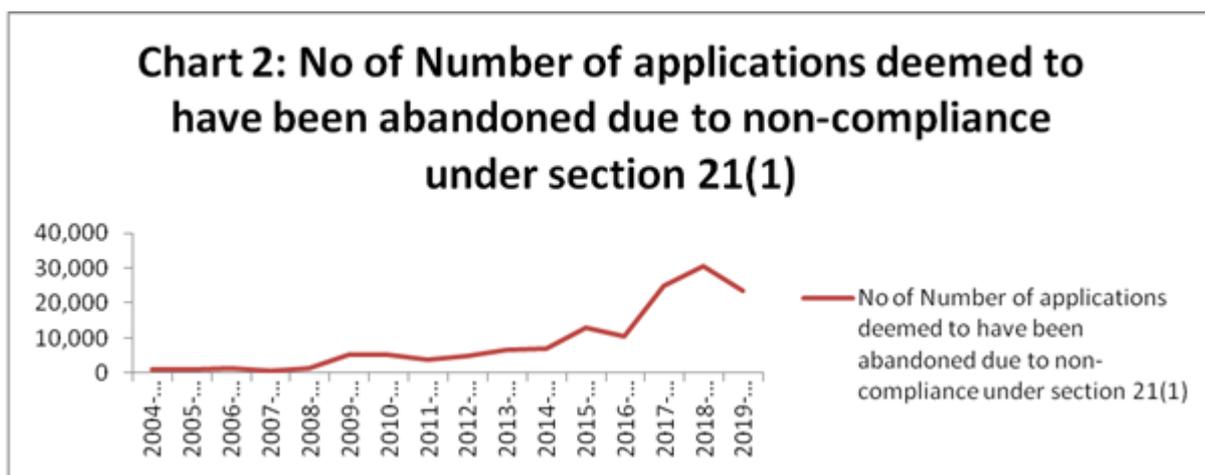
<sup>142</sup> Ibid.

<sup>143</sup> Group A posts includes the following posts: Senior Joint Controller of Patents & Designs, Joint Controller of Patents & Designs, Director, Deputy Secretary, Deputy Controller of Patents & Designs, Principal System Analyst, Assistant Controller of Patents & Designs, Senior System Analyst, Senior Administrative Officer, Examiner of Patents & Designs, Assistant Director(CL), Senior Finance & Accounts Officer, Administrative Officer, Accounts Officer and Computer Programmer. For the purpose of this article, Group B and C officers have not been included as it is only Group A officers who are responsible for examination of patent applications.



Source: Annual Reports of The Office of the Controller General of Patents, Designs, Trademarks and Geographical Indications, Government of India, Ministry of Commerce & Industry, Department of Industrial Policy and Promotion.<sup>144</sup>

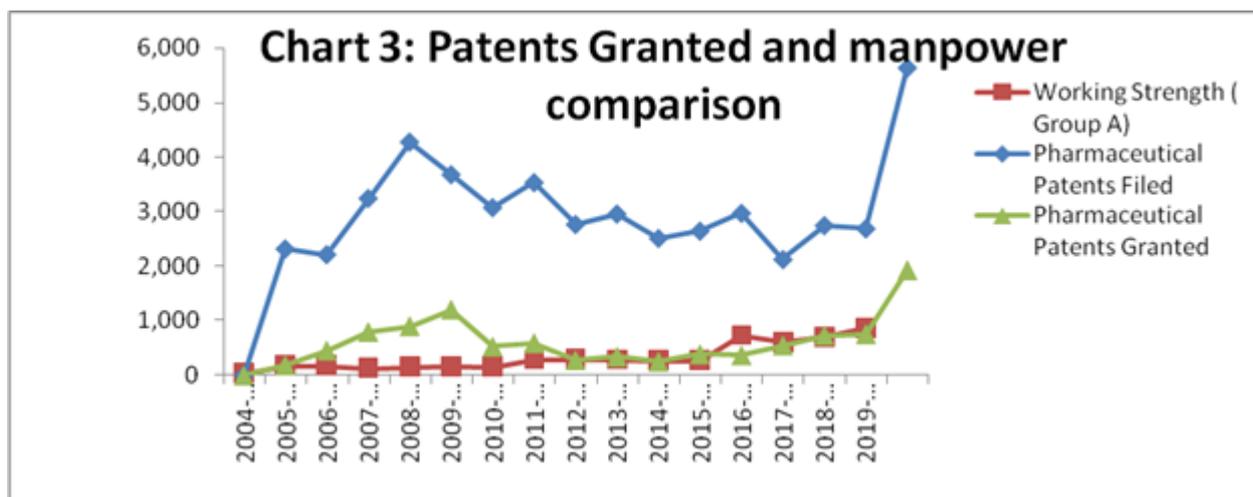
As the strength increased every year so did the objections and consequent abandonment of overall patent applications as shown in Chart 2:



Source: Annual Reports of The Office of the Controller General of Patents, Designs, Trademarks and Geographical Indications, Government of India, Ministry of Commerce & Industry, Department of Industrial Policy and Promotion

The actual manpower in the patent office also affects the number of pharmaceutical patents granted as, shown in chart 3. The patents granted from 2010 to 2019 show that number of patents granted have a direct relationship with the working strength.

<sup>144</sup>The data for each year has been obtained from the annual report for that respective year prepared by the Office of the Controller General of Patents, Designs, Trademarks and Geographical Indications, Government of India, Ministry of Commerce & Industry, Department of Industrial Policy and Promotion. Available from <https://ipindia.gov.in/annual-reports-ipo.htm>. See annexure 1.



Source: Annual Reports of The Office of the Controller General of Patents, Designs, Trademarks and Geographical Indications, Government of India, Ministry of Commerce & Industry, Department of Industrial Policy and Promotion

### C. Opposition Proceedings

While it is the duty of the patent office to scrutinize the applications properly and ensure that requirements for grant of patents are strictly met, it is only human that some mistakes will inadvertently creep in the process. To ensure that no harm is caused to the public by grant of an undeserved monopoly, the Indian Patent Law provides for both pre-grant<sup>145</sup> and post-grant oppositions.<sup>146</sup> The opponent can contest the grant of patent to an applicant for filing a defective, incomplete application, non-conformity with the requirement of patentability criteria, inadequate disclosures amongst other grounds as mentioned in section 25.

Pre-grant oppositions can be filed by “any person” including civil society, researchers and academicians. It is not required that such a person should have some commercial interest in the matter. In fact, most of the important oppositions in India have been filed by civil society and NGOs. In this regard the Madras High Court has pertinently observed:

Advisedly right to object at a pre-grant stage has been given to ‘any person’ by the said amendment. This is an illustration of statutorily broadening the concept of locus standi and widening the scope of objection procedure by giving access to ‘any person,’ who has a concern for public interest in the area of public health and nutrition, to raise an objection. The grant of patent is virtually a grant of monopoly right against the whole world and that is why such wide-ranging right of objection has been designedly given at a pre-grant stage.<sup>147</sup>

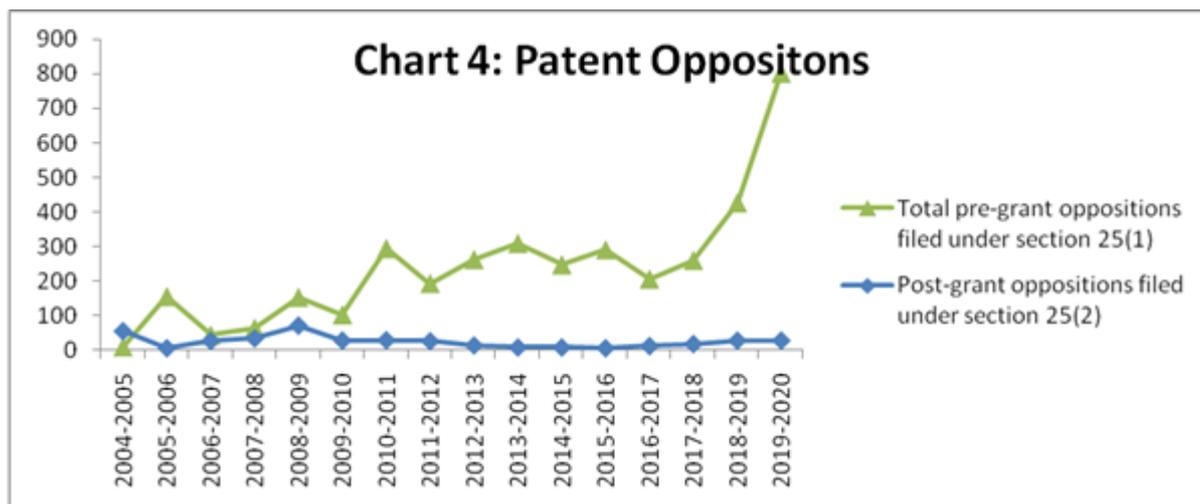
However, post-grant applications can be filed only by “any person interested.” As held by the Supreme Court of India, “However, Section 25(1) is wider than Section 25(2) as the latter is available only to a ‘person aggrieved’”.<sup>148</sup> Data shows that in recent years there has been a spate in pre-grant oppositions while the post-grant oppositions have remained stagnant as depicted in chart 4. Also, for any given year the number of pre-grant oppositions exceed the number of post-grant oppositions.

<sup>145</sup> India, Patents Act, 1970, sec 25(1).

<sup>146</sup> India, Patents Act, 1970, sec 25(2).

<sup>147</sup> Madras High Court, *Indian Network for People living with HIV/AIDS v. Union of India*, Writ Petition No. 24904 of 2008, Judgment December 2, 2008.

<sup>148</sup> Supreme Court of India, *J. Mitra & Co Pvt Ltd v. Assistant Controller of Patents & Designs*, S.L.P. (C) No.15727 of 2008, Judgment, 21 August 2008.



Source: Annual Reports of The Office of the Controller General of Patents, Designs, Trademarks and Geographical Indications, Government of India, Ministry of Commerce & Industry, Department of Industrial Policy and Promotion.

Studies show that the “patent oppositions by civil society and generic pharmaceutical companies have been instrumental in increasing access of drugs to the public by preventing patent ever-greening and bringing in earlier generic drug entry”.<sup>149</sup> By using opposition proceedings India has been able to deny patents to some notable HIV/AIDS medicines such as Valcyte by Roche,<sup>150</sup> Viread by Gilead,<sup>151</sup> Kaletra by Abbott.<sup>152</sup> Companies also withdrew their patent applications for fear of getting them rejected.<sup>153</sup> These HIV/AIDS drugs were nevertheless patented in other countries. However, as India exported these drugs to other Latin American and African nations, it invited the ire of multinational pharmaceutical companies. As the drugs were sent via Europe, these companies complained of patent infringement when drugs were in transit. Subsequent to the complaints, the customs authorities in the Netherlands seized a substantial number of consignments of generic drugs from India in transit through the Netherlands. The seized drugs included clopidogrel (patent in Netherlands by Sanofi-Aventis), abacavir (patent in Netherlands to GlaxoSmithKline), olanzapine (patent in Netherlands to Eli Lilly & Co), rivastigmine (patent in Netherlands to Novartis AG), losartan (patent in Netherlands to E.I. Du Pont de Nemours and Co. Inc., Merck & Co. Inc. and Merck Sharp & Dohme B.V).<sup>154</sup> Notably, abacavir used in the treatment of HIV/AIDS, meant for use in Nigeria, was purchased by the Clinton Foundation through UNITAID.<sup>155</sup> There were protests by civil society, WHO, India and Brazil. India raised a dispute in WTO and requested consultations with the European Union and the Netherlands, where the shipments were detained.<sup>156</sup> However, the matter did not go before the WTO Dispute

<sup>149</sup> Sandeep K. Rathod, “Patent Oppositions in India”, in *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law*, Carlos M. Correa and Reto M. Hilty eds. (Springer, 2022), p. 151, e-book.

<sup>150</sup> Ibid., pp. 158–159.

<sup>151</sup> Supra note 154 at 163–164.

<sup>152</sup> Supra note 154 at 164–165.

<sup>153</sup> KHN Morning Briefing, “GlaxoSmithKline Withdraws Patent Applications for Antiretrovirals Abacavir, Trizivir in India”, 11 January 2009. Available from <https://khn.org/morning-breakout/dr00049303/>.

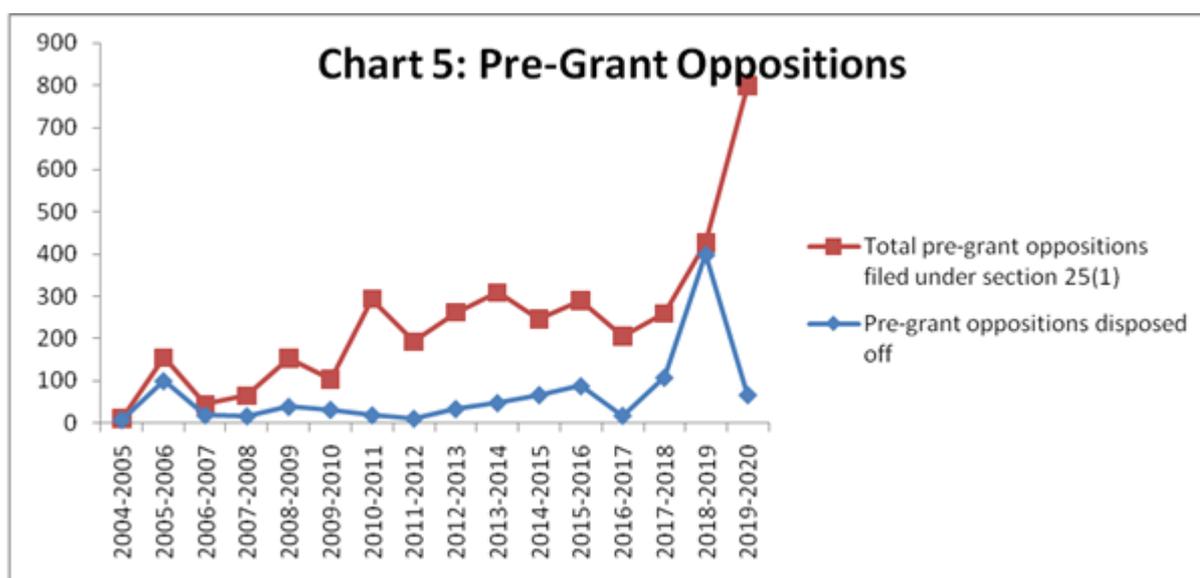
<sup>154</sup> Request for Consultations by India, *European Union and a member state – seizure of generic drugs in transit*, WTO Doc. WT/DS408/1 (11 May 2010). Available from [https://trade.ec.europa.eu/doclib/docs/2011/january/tradoc\\_147464.pdf](https://trade.ec.europa.eu/doclib/docs/2011/january/tradoc_147464.pdf).

<sup>155</sup> Radhika Pandeya, “UN agency protests Dutch seizure of Indian HIV drugs” Live Mint, 6 March 2009. Available from <https://www.livemint.com/Companies/Ufe1ntEsvQX0ZnhJy4pwwK/UN-agency-protests-Dutch-seizure-of-Indian-HIV-drugs.html>.

<sup>156</sup> Supra note 159.

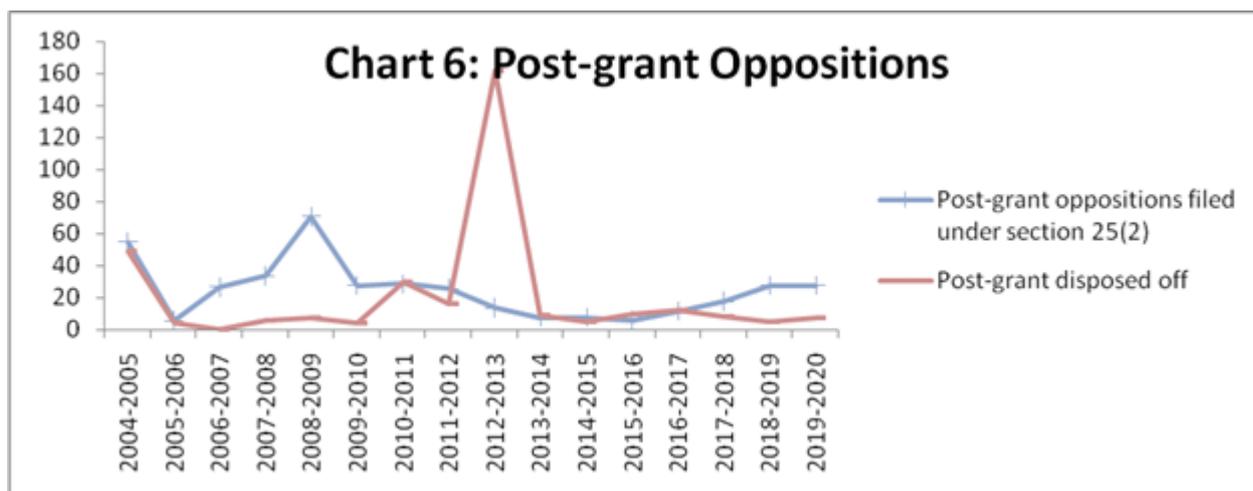
Settlement Body as the parties amicably settled the dispute. They reached an understanding that the EU would no longer intercept generic medicines in transit unless there is adequate evidence to satisfy customs authorities that there is a substantial likelihood of diversion of such medicines to the EU market and that the EU would amend the relevant laws accordingly.<sup>157</sup> This episode in India's attempt to use TRIPS flexibilities and provide access to generic versions, however highlights the potential of (mis)use of the border enforcement measures and need for having a common principle of international harmonisation.

The use of opposition proceedings to improve the quality of patents is also dependent upon the manpower in the patent office as the opposition applications are finally adjudicated by the Controller of Patents. It has been observed that any given time there is a huge pendency of opposition applications with the Controller. Charts 5 and 6 depict the variance between filing and disposal of pre and post grant opposition applications, respectively.



Source: Annual Reports of The Office of the Controller General of Patents, Designs, Trademarks and Geographical Indications, Government of India, Ministry of Commerce & Industry, Department of Industrial Policy and Promotion.

<sup>157</sup> Press Trust of India, "EU offers out of WTO settlement on drug seizure row", Business Standard, January 21, 2013. Available from [https://www.business-standard.com/article/economy-policy/eu-offers-out-of-wto-settlement-on-drug-seizure-row-110120100190\\_1.htm](https://www.business-standard.com/article/economy-policy/eu-offers-out-of-wto-settlement-on-drug-seizure-row-110120100190_1.htm). Also see, UNCTAD's Intellectual Property Unit, "European Union and a Member State – Seizure of Generic Drugs in Transit: Request for Consultations by India (DS408/1) and Brazil (DS409/1)", 19 May 2010 WTO, Dispute Settlement Body". Available from <https://unctad.org/ippcaselaw/sites/default/files/ippcaselaw/2020-12/WTO%20DS408%20DS409%20India%2C%20Brazil%20v%20EU%20on%20seizure%20of%20goods%20in%20transit.pdf>.



Source: Annual Reports of The Office of the Controller General of Patents, Designs, Trademarks and Geographical Indications, Government of India, Ministry of Commerce & Industry, Department of Industrial Policy and Promotion.

#### IV. TRIPS AS A PERMISSIVE REGIME: NEED FOR CHANGE AND SOME DEVELOPMENTS

A perusal of the TRIPS flexibilities as incorporated under the Indian law suggests that they are at best permissive in nature. Even the Supreme Court of India has observed that TRIPS creates a permissive regime and remarked:

The utilization of these flexibilities has also been detailed in the Trade Related Aspects of Intellectual Property Rights Agreement. Even as TRIPS obliges countries to ensure a minimum level of patent protection, it creates a permissive regime for the carving out of exceptions and limitations that further public health objectives. This is evident from a conjoint reading of Articles 7, 8, 30 and 31 of TRIPS. (Footnotes omitted).<sup>158</sup>

This permissive regime, however, gives too much importance to the rights of the patentee. It leaves public health at the mercy of the market forces. While this permissive regime may still seem to work during normal times it is utterly inadequate to address the issues of access to lifesaving medicines especially for those diseases where no alternative treatment is available. In such a scenario a cue can be taken from criminal law which permits the defence of necessity even to individual persons. It will be therefore useful to have a defence of public necessity to excuse the actions of an infringer but subject to damages or continuous royalty being paid the patentee. In this context it is useful to recall the observations of the Supreme Court of India in *Union of India v. Mool Chand Khairati Ram Trust*.<sup>159</sup>

In the wake of globalisation, we are in a regime of Intellectual Property Rights. **Even these rights have to give way to the human rights.** It is an obligation of the Government to provide life-saving drugs to have-nots at affordable prices so as to save their lives, which is part of Article 21 of the Constitution of India (emphasis added).

Scholars have argued that the compensatory liability model is a better alternative to the intellectual property rules especially in cases of life saving drugs.<sup>160</sup> The Indian Judiciary did attempt the compensatory liability model by building the public interest defence in infringement suits. It is a kind of “judicial compulsory licenses”.<sup>161</sup> In the sense that when a court adjudicates a patent injunction then besides the three traditional factors of prima facie case, balance of convenience and irreparable injury, an additional fourth factor of “public interest” is considered. The High Court of Delhi had famously invoked “public interest” in the case of *F. Hoffmann-LA Roche Ltd v. Cipla Ltd* and remarked

[t]hat in a country like India where question of general public access to life saving drugs assumes great significance, the adverse impact on such access which the grant of injunction in a case like the instant one is likely to have, would have to be accounted for...the public interest in greater public access to a lifesaving drug will have to outweigh the public interest in granting an injunction to the patent holder.

However, there has been inconsistency in the approach of the courts in bringing public interest into play while deciding an interim injunction. There has been no case whereby injunction has been denied solely on the ground of public interest. Public interest is an important

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<sup>158</sup> Supra note 113.

<sup>159</sup> Supreme Court of India, *Union of India v Mool Chand Khairati Ram Trust*, Civil Appeal No. 3155 of 2017, Judgment, 9 July 2018.

<sup>160</sup> Shamnad Basheer, “The End of Exclusivity: Towards a Compensatory (Patent) Commons”, *IDEA- The Journal of the Franklin Pierce Centre for Intellectual Property*, vol 58, No. 2 (2018) p. 229.

<sup>161</sup> Ibid.

consideration but not the only factor. A single Judge of the Delhi High Court in *Novartis v. Cipla*<sup>162</sup> held:

There is line of authorities emerging from United States stating that public interest is fourth ground to refuse the injunction if the injunction to be granted in a given case is oppressive or extremely harsh to the society or the affected industry. This Court is of the view that on the sole ground of public interest is the one which can be said to be an offshoot of balance of convenience and the comparative damage as one has to see comparative inconvenience of the plaintiff vis-a-vis the defendant and the other affected parties...**Therefore to say that public interest is a complete exception to the patent would not be correct as otherwise the rights granted by the sovereign towards monopoly would be undermined by too broadly interpreting the public interest (emphasis added).**

Further, a Division Bench of the High Court in an injunction case of *Merck Sharp and Dohme Corp v. Glenmark*<sup>163</sup> clarified that while the public interest is a vital factor to be considered while granting an injunction, the Court can overlook the public interest in maintaining the integrity of the patent system itself, so that a legitimate monopoly is not distorted. It opined that "In a case where a strong case of infringement is established, there is an interest in enforcing the Act." It was further held that "The victory for the patentee therefore should not be pyrrhic but real."<sup>164</sup>

Ironically, there are many injunction orders from the same court in which public interest has not been discussed at all. For instance, in *Bristol-Myers Squibb Holdings Ireland Unlimited Company v. BDR Pharmaceutical International Pvt Ltd*<sup>165</sup> the impact of the grant of an injunction on public interest has not been discussed. There is no reference to the four factor tests. Only the triple tests have been mentioned. Similarly, in *Novartis AG v. Natco Pharma*<sup>166</sup> the interim injunction was granted only on the basis of prima facie case in favour of the patentee.

One of the reasons for this anomaly is that courts in India have conducted mini trials at the stage of interim injunctions and have therefore given decisions which could have been passed only after full trial. Perhaps the judiciary needs to streamline its approach and ingrain the concept of public interest more fundamentally in its approach to protect public health.

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<sup>162</sup> Supra note 94.

<sup>163</sup> High Court of Delhi, *Merck Sharp and Dohme Corp v. Glenmark*, FAO (OS) 190/2013, Judgment, March 20, 2015.

<sup>164</sup> Ibid.

<sup>165</sup> High Court of Delhi, *Bristol-Myers Squibb Holdings Ireland Unlimited Company v. BDR Pharmaceutical International Pvt Ltd*, CS(COMM) 27/2020 Judgment, 30 January 2020.

<sup>166</sup> High Court of Delhi, *Novartis AG v. Natco Pharma*, CS(COMM) 256/2021 & I.A. 6980/2021, Judgment, 13 December 2021.

## V. CONCLUSION AND SUGGESTIONS

The Indian experience shows that access to medicines does not only require a law that incorporates policy levers but a robust presence of civil society to counter international pressure from trading partners, an aggressive and competent local pharmaceutical industry and a polity committed to the welfare of people. The Doha declaration has only been the start of the process of aligning the international trade laws with the public health agenda but there is a lot that still needs to be done. While the flexibility of issuing compulsory licenses is an important safeguard to protect public interest, it has major limitations. Compulsory licensing presupposes the presence of a robust domestic industry. The players in the domestic pharmaceutical industry should have adequate capacity, capability, capital and willingness to lock horns with innovator firms. But with capital incoming in the form of foreign direct investments it is doubtful that the investor sentiment will let it take the route of compulsory licenses. The States need to look into the particular impact of foreign investment regulations on public health and deploy other tools like competition policy to promote public health.<sup>167</sup> The consolidation in the pharmaceutical industry, acquisition of Indian firms by multinational companies has reduced competition in the pharmaceutical market. On the other hand, there are increasing tie-ups between multinational companies and generic manufactures but not necessarily for manufacturing. The multinational companies have strategically entered into exclusive marketing licenses<sup>168</sup> with generic manufacturers for marketing and sale of patented medicines. By entering into profitable business associations with potential competitors, the competition is nibbed in the bud. However, marketing licenses do not increase the product availability, nor do they reduce cost. While these marketing licenses may increase the availability of the product, they do not necessarily translate to lower costs for the public leaving the question of affordability unanswered. Even voluntary manufacturing licenses do not ensure enhanced affordability for patients and there are serious cross-border ramifications as there are geographical limitations for supply of patented articles.<sup>169</sup> It is high time that competition authorities wake up and undertake a scrutiny of these tactics.

Further, compulsory license does not entail technology transfer and the licensee needs to reverse engineer the product. Even if a competitor takes that risk, there are serious economic disadvantages for the holder of a compulsory license. The limitation on the marketing of the patented goods so produced due to general prohibition on exports of patented goods needs urgent revisitation. It is therefore suggested that, firstly the limitation for domestic use should not apply especially in times of public health emergency. Article 31(f) of the TRIPS Agreement should be deleted or if it is too ambitious to ask for then a proviso must be attached that “the limitation on supply of the domestic market will not apply in case of international health emergency or in case of public non-commercial use by other States.” It is time to learn from the Russian fiasco on sending remdesivir to India. To support this suggestion, we can take a cue from Article 31(b). It waives the requirement to obtain voluntary licenses in case of emergency or public non-commercial use.

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<sup>167</sup> In 2011, the High-Level Committee Report on Foreign Direct Investments in Existing Indian Pharma Companies headed by Arun Maira observed that the Competition Act is not adequately equipped to regulate mergers in the pharmaceutical sector.

<sup>168</sup> See for instance, Cipla entering into an in-licensing deal with Roche for distribution and sale of Actemra (Tocilizumab) and Avastin (bevacizumab) Tocilizumab was in high demand during second wave of the COVID-19 pandemic in India but was not readily available. One Tocilizumab injection of 162 mg is sold for Rs 92,672 as per data available with National Pharmaceutical Pricing Authority last checked on 8 December 2021.

<sup>169</sup> Medicines Sans Frontiers Access Campaign, “Access To Sofosbuvir, Ledipasvir And Velpatasvir Analysis & Key Recommendations On Gilead’s Voluntary License” (March 2015). Available from [https://msfaccess.org/sites/default/files/MSF\\_assets/HepC/Docs/HEPC\\_Analytistics\\_GileadHepCLicense\\_ENG\\_2\\_015.pdf](https://msfaccess.org/sites/default/files/MSF_assets/HepC/Docs/HEPC_Analytistics_GileadHepCLicense_ENG_2_015.pdf).

Secondly, there is an urgent need to overhaul the Article 31 bis mechanism to address the issue of shortage of patented medicines in countries having no manufacturing capacities and least developed countries. At the best it is an enabling mechanism, but it does not confer any right on countries having no manufacturing capacities or least developed countries. This lack of right is responsible for the current "vaccine apartheid". If TRIPS can establish minimum norms of protection of IP it must also enlist minimum commitments of right holders to ensure social justice.

Thirdly, it is imperative to revisit the manner in which compulsory licensing applications are adjudicated by the appropriate authorities. Arguably, a compulsory licensing application is maintainable only after the efforts to obtain a voluntary license have failed. An overemphasis on compliance with a requirement such as this one might actually harm the public health agenda as it has a chilling effect on the prospective applicants. The main plank of a compulsory license is to address the unmet need of public on reasonable terms. However, rejection of the application on technical grounds defeats that avowed purpose. It is suggested that even if it is shown that an applicant has not been diligent in efforts to obtain a voluntary license, its application should not be summarily rejected. There should be a prima facie evaluation of contention relating to reasonable public requirement. If the authority prima facie thinks that the need of the public is not met on reasonable terms, then it must send the parties for mediation. In case of failure of mediation, the application for a compulsory license must be decided on merits. While alternative means of dispute resolution have been adopted in patent infringement suits, it is time for incorporating them in adjudication of compulsory license applications.

Fourthly, there is a need to have an intersectional approach to patent laws. The signalling by India so far has been that it will not use compulsory licenses and instead wait for market initiatives to solve the issues of access to drugs. This reluctant attitude is perhaps an attempt to woo investors, improve its ranking in ease of doing business, and avoid coercive unilateral trade measures like the "Special 301" by the United States. The process of compulsory licensing is inextricably intertwined with political and other trade considerations and India must stand against illegal trade practices of other countries and resort to using the WTO dispute settlement mechanism, if need be, like it did against European Communities following the seizure of drugs in transit.

Lastly, the States should increase the manpower in patent offices or adopt technological measures to improve the quality of patents granted. There is much to benefit by investing in the capacities of patent offices. The number of people should be commensurate to the total number of applications and be adequately trained. Their training should be indigenised and there should not be an overreliance on foreign patent offices to provide training and modernization as the standards for grant of patents differ varies across countries. Over the years, it has been observed that the trilateral offices, the European Patent Office (EPO), Japan Patent Office (JPO) and United States Patent and Trademark Office (USPTO), have been at the forefront of providing technical assistance, IP training and modernization services to developing countries, including India, leading to the build-up of technocratic trust between the trainer office and trainees.<sup>170</sup> However, this is problematic, as Drahos notes that "technocratic trust thus fosters a circle of decision-making in which the EPO trains developing country examiners to make decisions in their own countries that predominantly benefit foreign companies, including European companies."<sup>171</sup> It is high time that developing countries evolve their own training manuals and procedures.

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<sup>170</sup> Peter Drahos, "Trust me": *Patent Offices in Developing Countries*, Working Paper (November 2007) The Australian National University.

<sup>171</sup>Ibid., p. 17.

## ANNEXURE: DATA COMPILED FROM ANNUAL REPORTS OF THE INDIAN PATENT OFFICE FROM 2004 TO 2020

Year	Working Strength (Group A)	Pharmaceutical Patents Filed	Pharmaceutical Patents Granted	Total pre-grant oppositions filed under section 25(1)	Pre-grant oppositions disposed off	Post-grant oppositions filed under section 25(2)	Post-grant disposed off	No of Number of applications deemed to have been abandoned due to non-compliance under section 21(1)
2004-2005	33	2316	192	10	8	55	49	775
2005-2006	179	2,211	457	155	100	6	4	894
2006-2007	171	3,239	798	44	19	27	0	1,121
2007-2008	126	4,267	905	64	17	34	6	479
2008-2009	159	3,672	1,207	153	39	71	7	1,075
2009-2010	161	3,070	530	103	32	28	4	5,171
2010-2011	155	3,526	596	294	19	29	30	5,186
2011-2012	282	2,762	282	193	11	26	16	3,800
2012-2013	294	2,954	344	262	34	14	162	4559
2013-2014	281	2,507	256	309	48	8	9	6,418
2014-2015	272	2,640	389	247	67	8	5	6,970
2015-2016	271	2,966	370	290	88	6	10	12,782
2016-2017	724	2,122	551	206	18	12	12	10,408
2017-2018	604	2,741	733	260	108	18	8	24,922
2018-2019	695	2,683	761	426	399	28	5	30,458
2019-2020	861	5,622	1,930	800	67	28	7	23,291

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