NOTES AND COMMENTS

2020 SPECIAL 301 REPORT: PATENTS AND PUBLIC HEALTH

Abstract

The threat of the US to impose unilateral trade sanctions continues with the release of USTR 2020 Special 301 Report for the "TRIPS-plus" patent protection to the US-based pharmaceutical MNCs in India. Waiving a "big stick" with unmerited "concerns" against Government of India to forgo public health safeguard provisions of patents law, coupled with poor implementations of these provisions in the recent past in India, make the provisions more vulnerable and millions of patients in need of critical life saving medicines more susceptible to death. Immediate action of the Government of India to officially reject the Special 301 Report completely and corrective measures to actualise public health safeguard provisions of patents law are needed to make essential medicines more affordable and accessible to protect public health.

I Introduction

THE OFFICE of the United States Trade Representative (USTR), on April 29, 2020, released 2020 USTR Special 301 Report (Special 301). It identifies India on a "Priority Watch List Category" for not resolving long-standing challenges that have negatively affected, *inter alia*, pharmaceutical patent right holders of the United States (US) to receive, maintain, and enforce patents in India.[1] USTR threatens to take actions under section 301 of the US Trade Act, 1974 or pursue the matter to World Trade Organization (WTO); if India fails to address US "concerns." Special 301, from its inception in 1989, has been largely influenced by pharmaceutical multinational corporations (MNCs) lobby groups. Before WTO-Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), it was instrumental in coercing unwilling developing countries to sign the TRIPS, to provide dramatic "minimum" protection to pharmaceutical inventions by changing patent laws of foreign jurisdictions. TRIPS, not a legal but diplomatic agreement leaves many textual "constructive ambiguities" that preserve policy options, flexibilities and public health safeguards to accommodate divergent socio-economic needs of member states without compromising the TRIPS obligations. India accordingly has amended its Patents Act, 1970 which the TRIPS guarantees and the Doha Declaration on TRIPS and public health affirms. After amendment, USTR has continuously raised "concern" over public health safeguard provisions incorporated in the Indian patent law. Legislative intent behind these provisions is to deny unmerited patent applications and make essential medicines more affordable and accessible. USTR

1 United States Trade Representative, *2020 Special 301 Report* 5 (USTR, Washington, 2020), *available at*: https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf (last visited on May 30, 2021).

demands either to amend or not to apply the provisions so as to serve private economic interests of pharmaceutical MNCs. This article analyses the merit of contentious "concerns" raised by Special 301 report over public health safeguard provisions of the Indian patent law. In the backdrop of USTR threats, this article explains the TRIPS Compatibility of those patent provisions and their implementation in India over past few years to know the effects these provisions are creating to protect public health in India.

II Section 3(d)

Special 301 has regularly cited section 3(d) of the Patents Act, 1970 as one of the major concern to the US. It perceives that section 3(d) creates special and additional criteria which can prevent a pharmaceutical invention to get patent even if it is new, involve an inventive step, and is capable of industrial application. Therefore, US opines that section 3(d) is incompatible with article 27.1 of the TRIPS as it violates the non-discrimination clause that patents shall be granted in all fields of technology if an invention satisfies above-mentioned three patentability criteria without pressing for any additional substantive criteria. In the *European Community (EC)-Canada*, WTO panel clarified that the article 27.1 of the TRIPS prohibits discrimination and not differentiation. It suggested that governments are allowed to adopt different rules for particular product areas provided that differences are adopted for bona fide purposes.[2] Therefore, distinction regarding field of technology is permitted under article 27.1 of the TRIPS. Further, the obligation of non-discrimination in article 27.1 applies to the availability and enjoyment of patent rights, meaning that neither the acquisition of patent rights nor the means for enforcement can be subject to discrimination.[3] While article 27.1 mandates member countries of WTO to grant patents when three patentability criteria specified in the article are met, it does not define them. Further, a non-exhaustive patent-exclusionary list of items is provided under article 27 itself. Therefore, the policy space left by article 27 of the TRIPS gives flexibility to member countries of WTO to distinguish between "inventions" that are patentable and other matters that are not.[4] Further, section 3(d) is non- discriminatory according to the terms of article 27.1 of the TRIPS as it does not apply only to pharmaceutical but to any chemical product. For example, it may be applied to examine the patentability of an isomer of an agrochemical product.[5]

---

2 WTO, *Canada – Patent Protection of Pharmaceutical Products*, Report of the Panel, WT/DS114/R, 2000-5 (Mar. 17, 2000), *available at*: http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf (last visited on June 30, 2021).

3 Carlos M. Correa, *Trade Related Aspects of Intellectual Property Rights* 282 (Oxford, New York, 2007).

4 Carlos M. Correa, "Is Section 3(d) Consistent with TRIPS?" 48 (32) *EPW* 50 (2013).

5 *Ibid.*

Special 301 states:[6]

> In the pharmaceutical sector, section 3(d) of the India Patents Act, 1970 also remains problematic. One implication of its restriction on patent-eligible subject matter is the failure to incentivize innovation that would lead to the development of improvements with benefits for Indian patients.

Section 3 of the Patents Act, 1970 lists non-patentable inventions. Section 3(d) specifically declares new form of a known substance including derivative or pro-drug of known molecule or compound not enhancing known *therapeutic* efficacy as non-patentable.[7] Further, rejection of different claims within a patent application on the basis of different patentability criteria is quite possible. Moreover, patent examiners rarely use section 3(d) alone as ground of rejection of claim.[8] They use it along with other conventional grounds. These grounds in most of the cases are lack of novelty, lack of inventive step, not having synergistic effect for combination of known molecules and method of treatment. Poor quality of first examination reports make it difficult to find out that which patentability criteria is the sole reason for rejection of a particular claim.[9] Therefore, assertion of Special 301 that section 3(d) alone restricts patent-eligible subject matter to get patent is based on unfounded assumption.

Special 301 while citing section 3(d) as "problematic" asserts that it fails to incentivise innovation beneficial for Indian patients. The pharmaceutical MNCs holding blockbuster patents often try to block the competition by getting secondary patents on trivial variations. Section 3(d) prevents such "evergreening" of patents and provides avenue for generic pharmaceutical companies to offer biosimilar drugs at competitive prices. In fact, section 3(d) does not incentivise innovators by rejecting applications for secondary patents. So, it functions as significant public health safeguard by reducing drug prices as much as 95%.

"Concern" of Special 301 over "expansive application of patentability exceptions to reject pharmaceutical patents" is also baseless."[10] Baseless because 72% of pharmaceuticals patents granted are secondary patents mostly in contravention of

---

6 *Supra* note 1 at 50.

7 *Novartis Ag* v. *Union of India* (Civil Appeal 2706-2716/2013, SC, April 1, 2014) para.181-182, *available at*: https://indiankanoon.org/doc/165776436/ (last visited on June 30, 2021).

8 B.N. Sampat and K.C. Shadlen, "Indian pharmaceutical patent prosecution: The changing role of Section 3(d)" 13 (4) *Plos One* 7 (2018), *available at*: https://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0194714&type=printable (last visited on June 30, 2021).

9 *Ibid.*

10 *Supra* note 1 at 52.

section 3(d) for trivial improvements over earlier known drugs for which primary patents exist.[11]

III Pre and post-grant opposition

India incorporated both pre and post-grant opposition in its Patents Act, 1970 through Patents (Amendment) Act, 2005. Without derogating from the TRIPS norms, grounds of opposition proceedings provide effective mechanism to filter out frivolous claims of a patent applicant especially when patent office fails to do so during examination of patent applications.

Special 301 states that "patent applicants continue to confront costly and time-consuming pre and post-grant oppositions."[12] As per annual reports of office of the Controller General of Patents, Designs, Trademark and Geographical Indications (CGPDTM), a total of 2,62,239 patent applications were published under section 11A of the Patents Act, 1970 and 1,574 pre-grant oppositions were made during the period of 2012-2018. These comprised only 0.60% of total patent applications published. 23.06% pre-grant oppositions were disposed of for the same period.[13] However, the low rate of disposal is not because of apathy of the Indian patent office. As per rule 55(2) of the Patent Rules, 2003, a pre-grant opposition is considered only after request for examination of patent application by the applicant. Rule 24 says that request for examination shall be made within 48 months from priority or filing date of the application, whichever is earlier. Further, applicant may delay request for examination up to six months if files any divisional application as per Rule 24B(1)(iv). Furthermore, applicants repeatedly hinder pre-grant opposition by constantly amending the claims made in complete specification.[14] About three-quarter of the patent applicants are

---

11 Feroz Ali, Sudarsan Rajagopal, *et. al*., *Pharmaceutical Patent Grants in India: How Our Safeguards Against Evergreening Have Failed, and Why the System Must Be Reformed* 6 (Accessibsa, Durbanville, 2018), *available at*: https://accessibsa.org/media/2018/04/Pharmaceutical-Patent-Grants-in-India.pdf (last visited on May 30, 2021).

12 *Supra* note 1 at 50.

13 Controller General of Patents, Designs, Trademark and Geographical Indications, *2012-13 Annual Report* (CGPDTM Mumbai 2013); Controller General of Patents, Designs, Trademark and Geographical Indications, *2013-14 Annual Report* (CGPDTM Mumbai 2014); Controller General of Patents, Designs, Trademark and Geographical Indications, *2014-15 Annual Report* (CGPDTM Mumbai 2015); Controller General of Patents, Designs, Trademark and Geographical Indications, *2015-16 Annual Report* (CGPDTM Mumbai 2016); Controller General of Patents, Designs, Trademark and Geographical Indications, *2016-17 Annual Report* (CGPDTM Mumbai 2017); Controller General of Patents, Designs, Trademark and Geographical Indications, *2017-18 Annual Report* (CGPDTM Mumbai 2018), *available at*: http://www.ipindia.nic.in/annual-reports-ipo.htm (last visited on June 30, 2021).

14 Veena Johri, K.M. Gopakumar, *et. al*., *Policy Brief on Patents and Pre-Grant Opposition in India* 7 (TWN, Penang, 2019), *available at*: https://twn.my/title2/briefing_papers/No100.pdf (last visited on June 30, 2021).

non-residents.[15] Therefore, largely foreign applicants become impediment for the disposal of pre-grant oppositions by constantly amending the claims and not filing the request for examination at the earliest. To remedy the situation, restrict amendments in claims to only one or two times, clear timeline for the speedy disposal of pre-grant opposition representations, and disposal of pre-grant opposition without a request for examination; is needed.[16]

As per annual reports of the CGPDTM, a total of 43,549 patents were granted and 66 post-grant oppositions were made during the period 2012-2018. These comprised only 0.15% of total patent grants. 51 post-grant oppositions were disposed of for the same period.[17] Moreover, post-grant oppositions do not put any restriction to exploit patent rights by the patentee.

The number of pre and post-grant opposition are insignificant. However, it has significant effect on accessibility and affordability of medicines. It allows early rectification to filter out frivolous and legally invalid claims, in contravention of patentability or other statutory requirements which improve the quality and validity of the patents granted.[18] The provisions of pre and post-grant opposition acquires more significance as a public health safeguard when the Indian patent office is operating at an error rate as high as 72% while granting pharmaceutical patents which should not have been granted because of likely contravention of the statutory exceptions under section 3(d), 3(e) and 3(i) of the Patents Act, 1970.[19]

IV Working of patents

Article 27.1 of the TRIPS provides that patents shall be available and patent rights enjoyable without discrimination whether products are imported or locally produced. However, article 5A.2 of the Paris Convention mentions failure to work the patent in the patent granting country as ground of compulsory licence.[20] By virtue of article

15 Controller General of Patents, Designs, Trademark and Geographical Indications, *2017-18 Annual Report* 37 (CGPDTM Mumbai 2018), *available at*: http://www.ipindia.nic.in/writereaddata/Portal/IPOAnnualReport/1_110_1_Annual_Report_2017-18_English.pdf (last visited on June 30, 2021).

16 *Supra* note 14.

17 *Supra* note 13.

18 Carlos M. Correa, *Tackling the Proliferation of Patents: How to Avoid Undue Limitations to Competition and the Public Domain* 9 (South Centre, Geneva, 2014), *available at*: https://www.southcentre.int/wp-content/uploads/2014/09/RP52_Tackling-the-Proliferation-of-Patents-rev_EN.pdf (last visited on June 30, 2021).

19 *Supra* note 11 at 32.

20 Paris Convention in its art. 5A (2) reads as: "Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work", *available at*: http://www.wipo.int/treaties/en/text.jsp?file_id=288514#P123_15283 (last visited on May 30, 2021).

2.1 of the TRIPS, article 5A.2 of the Paris Convention is part of the TRIPS as exception which overrides general provision regarding patent rights mentioned in article 27.1 of the TRIPS.[21] Consequently, patent working requirement of the Patents Act, 1970 is fully complied with the TRIPS.

Special 301 states that India is trying to resolve "burdensome patent reporting requirements" by considering revisions to Form 27 on patent working.[22] In the recent past, all multinational pharmaceutical manufacturers associations, *United States Patent and Trademark Office* and the US government have demanded to eliminate the annual requirement to file Form 27 citing it as "burdensome." It is pertinent to note that in the dispute of Natco-Bayer, the first and only successful compulsory licence case in India, information furnished in Form 27 by the Bayer in 2011 played significant role in favour of Natco- the compulsory licence applicant.[23] In the absence of such reporting, it will be impossible for any domestic pharmaceutical company (potential compulsory licence applicant) to know that the patented invention is attracting grounds to issue compulsory licence under section 84 (1)(a) and (c) or not.

Section 146(2) of the Patents Act, 1970 read with Rule 131 of Patent Rules, 2003 require every patentee to furnish annual statement in Form 27 regarding working of patented invention in India on a commercial scale. Failure to do is punishable with fine subject to maximum 10 lakh rupees. Despite non-submission of Form 27 by most of the patentees over the years, no penalties have been imposed by the Controller of Patents till date. Out of total 56,764 patents in force in India, only 12,246 which is about 22%, were reported by the patentee as working.[24] Pharmaceutical patents share 5-6% of total patents in India.[25] Therefore, a large number of pharmaceutical patents were not working in 2018. Moreover, in April 2018, High Court of Delhi while disposing of a public interest litigation directed the Government of India to take expeditious steps within a timeline to effectuate working of patents in India.[26] Nevertheless, Central Government has not taken any step to revoke these non-working patents on the basis that mode of exercising patents were generally prejudicial to the public having regard to the Principles of the Patents Act, 1970 enunciated in section 83(a),(c),(d) and (f).

Non-application of these statutory provisions by the Indian patent office as well as Central Government and a positive hope expressed by the USTR in its report regarding revision of Form 27 is an indication that the Indian government shall continue to bow

21 Keith E. Maskus and Jerome H. Reichman (eds.), *International Public Goods and Transfer of Technology Under a Globalised Intellectual Property Regime* 240 (Cambridge, New York, 2005).

22 *Supra* note 1 at 51.

23 In the matter of Natco Pharma Ltd. and Bayer Corporation, Compulsory License Application No. 1 of 2011.

24 *Supra* note 15 at 31.

25 *Id.* at 40

26 *Samnad Basheer* v. *Union of India* (WP 5590/2015, High Court of Delhi, Apr. 23, 2018).

down to the US pressure and facilitate pharmaceutical MNCs to enjoy monopoly without any obligation and detriment to public-health safeguard provisions of the Patents Act, 1970.

V Compulsory licensing

Article 31 of the TRIPS is related to compulsory licence. It proposes "other use" of a patent without authorisation from the patent holder, implicitly supporting the freedom of member countries to issue compulsory licences.[27] It does not attempt to specify or limit in any way the grounds upon which such licences may be granted.[28] However, a member country is authorised to secure such option only when terms and conditions of article 31 are completely met and fulfilled.[29] The Declaration on the TRIPS Agreement and Public Health affirms that "Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."[30] Chapter XVI of the Indian Patents Act, 1970 which contains provisions of compulsory licences fully complies with article 31 of the TRIPS while using flexibilities provided by it.

Affirmation of Special 301 that "the pharmaceutical industry reports concerns as to India's continued use of the threat of compulsory licensing to coerce right holders to lower pharmaceutical prices" is contrary to the fact.[31] For example, Drugs (Prices Control) Amendment Order, 2019 by substituting paragraph 32(i) of the Drugs (Prices Control) Order, 2013 mandated that all patented new drugs and medical devices shall be out of the purview of price control for a period of five years from the commencement date of its commercial marketing in India. Therefore, pharmaceutical MNCs may directly import and sell the patented drug with exorbitant prices without any fear of price control. This shall have devastating effect on those poor Indian patients who are in need of critical drugs. The amendment gives severe blow to all the clauses of Principles of the Patents Act, 1970. The exemption through amendment order also makes grounds to issue compulsory licence under section 84 vulnerable.

After issuance of first-ever compulsory licence to Natco Pharma, for an anti-cancer drug sorafenib tosylate, in 2012, India has witnessed a series of rejections for all compulsory licence applications either by the Indian Patent Office or by the Ministry

27 Thomas Pogge, Matthew Rimmer, *et.al.*, *Incentive for Global Public Health: Patent Law and Access to Essential Medicines* 411 (Cambridge, New York, 2010).

28 UNCTAD-ICTSD, *Resource Book on TRIPS and Development* 462 (Cambridge, New York, 2005).

29 Nattapong Suwan-in, "Compulsory License, A Long Debate on TRIPS Agreement Interpretation: Discovering the Truth of Thailand's Imposition on Pharmaceutical Patents" 7 (1) *Asian J. WTO & Int'l Health L. & Pol'y* 242 (2012).

30 WTO, *Declaration on TRIPS and Public Health*, WTO Ministerial Conference (Nov. 20, 2001). WT/MIN(01)/DEC/2., *available at*: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf (last visited on June 30, 2021).

31 *Supra* note 1 at 52.

of Central Government. The grounds of rejections of compulsory licence applications were based either erroneous interpretation of the Patents Act, 1970 or clearly erroneous assessment of the facts. Moreover, in recent years, many developing and even developed countries have issued compulsory licences to protect public health in spite of facing threats of the US retaliation.[32] It appears that government of India is committed to its insidious promise that "it would not use compulsory licences for commercial purposes."[33]

In fact, the position of the US on compulsory licence is complex. The US extensively uses compulsory licences to protect health. However, it tries to handcuff foreign countries to issue compulsory licences, primarily to protect private interest of the US pharmaceutical MNCs. The US, in the last 15 years, has witnessed at least 15 compulsory licences to protect public health which is much higher than any other country. Recently, on April 24, 2020, Federal Circuit affirmed the decision of Court of Northern District of California to grant compulsory licence to *Ariosa Diagnostics, owned by Roche, over US patent* (trade name Harmony) used for commercial diagnostic testing.[34] The US District Court issued compulsory licence because patent was not in practice.[35] Claim of the US that India threatens to issue compulsory licence to coerce patent holders to lower pharmaceutical prices, is nonsensical. In fact, the US has successfully employed the tactics of threat to issue compulsory licences to cut the prices of patented drugs. For example, in 2001, the US Secretary of Health and Human Services threatened to issue compulsory licence for Bayer's antibiotic drug Ciprofloxacin to respond to anthrax scares. Similarly, in 2017, the Health Secretary of Louisiana threatened Gilead to provide hepatitis C drugs, Sovaldi and Harvoni, at much lower cost or face compulsory licence to provide a lower-priced version of the same drugs.

VI Definition of inventive step

As stated, article 27.1 of the TRIPS mentions three requirements of an invention to get a patent. These are new, involve an inventive step and are capable of industrial application. However, it does not define these terms. Therefore, TRIPS gives flexibility to member countries to define these terms as per their national interest. After the TRIPS, legislature defined the term "inventive step" in the Patents Act, 1970 applying a conservative approach towards patentability.

32 Prabhat Kumar Saha and Aditi Mukherjee, "Compulsory Licensing of Pharmaceutical Patents in India: A Policy Shift" 54 (5) *EPW* 12-13 (2019).

33 US-India Business Council, *USIBC Hearing Statement to the Office of the USTR Concerning the 2016 Special 301 Review* 5 (USIBC, Washington, 2016).

34 *Verinata Health* v. *Ariosa Diagnostics* (CN 2198/2018, US Court of Appeals for the Federal Circuit, Apr. 24, 2020) 19, *available at*: http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/18-2198.Opinion.4-24-2020_1576415.pdf (last visited on Aug. 30, 2021).

35 *Verinata Health* v. *Ariosa Diagnostics* (CN 12-cv-05501-SI /2012, District Court of Northern District of California, July 19, 2018) para. 63, *available at*: https://www.keionline.org/wp-content/uploads/Verinata-v.-Ariosa.pdf (last visited on July 30, 2021).

Apart from section 3(d), "concern" of Special 301 regarding "narrow patentability criteria" mainly relates to the definition of "inventive step".[36] The definition of "inventive step" in the Patent Act, 1970 was incorporated by the Patents (Amendment) Act, 2002. Section 2(1)(ja) of the Patents Act, 1970 defined it as "inventive step means a feature that makes the invention not obvious to a person skilled in the art." The definition was further amended by the Patents (Amendment) Act, 2005. The definition reads as "inventive step means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art." Now, the definition has two alternative features—"invention that involves technical advance as compared to the existing knowledge" or "invention having economic significance." The term "or" makes it clear that inventive step criteria can be satisfied by having economic significance without having technical advancement. The term economic significance has not been defined and exact connotation of it is not clear. However, insertion of the term economic significance has certainly liberalised the fundamental criteria of inventive step used as higher layer than novelty in the form of technical advancement. Therefore, the term economic significance may become a blessing in disguise for the applicants of pharmaceutical patents. It remains to be seen that how Indian patent office shows its ability to withstand pressure from USTR regarding use of the term economic significance in near future.

VII Data exclusivity

According to article 39.3 of the TRIPS, member countries of WTO are required to protect undisclosed test or other data of the originator against unfair commercial use and disclosure when member countries require it as a condition for marketing approval of pharmaceutical or agricultural chemical products. TRIPS waives the requirement where disclosure is necessary to protect the public. It is disputed whether the reliance on the originator's test data for subsequent marketing approval amounts to an "unfair commercial use" under article 39.3 of the TRIPS. It is pertinent to note that article 39.3 of the TRIPS does not prevent the State or its agencies from relying on the originator's clinical trial data to provide subsequent marketing approval to any subsequent applicant. It only prohibits the third party to take clinical trial data unfairly and independently submit it for marketing approval.[37] Hence, there is no obligation for a member country to grant data exclusivity under article 39.3 of the TRIPS.

Special 301 mentions lack of any effective system to protect undisclosed test or other data to obtain marketing approval by pharmaceutical companies.[38] Motive of USTR

36 *Supra* note 1 at 50.

37 Biswajit Dhar and K.M. Gopakumar, "Data Exclusivity in Pharmaceuticals: Little Basis, False Claims" 41 (49) *EPW* 5076 (2006).

38 *Supra* note 1 at 50.

raising such "concern" is to put pressure on India to provide exclusivity of 10 years to the data generated during clinical trial of a drug treating it as "property". Therefore, it argues that any subsequent marketing approval to generic pharmaceutical company relying on originator's data is "unfair commercial use." Granting such market exclusivity to clinical trial data shall prevent drug regulatory authority to rely on such data of originator for marketing approval to manufacture bio-equivalence product by generic pharmaceutical firms even if the patent on that drug is revoked for any reason or expires. Small and medium size domestic pharmaceutical firms shall hesitate to conduct clinical trials because that needs prior permission of drug regulatory authority, involves burdensome procedures and requires considerable time as per the New Drugs and Clinical Trail Rules, 2019. Consequently, data exclusivity will delay the entry of generic drug companies into the market resulting in high price and less accessibility of drugs. Further, such exclusivity would make compulsory licence and government use provisions ineffectual because Controller of Patents takes into account the ability of the compulsory licence applicant to work the invention.

VIII Concluding observations

India has shown the ability to craft a public-health oriented patent law with the help of "constructive ambiguity" of the TRIPS which led the foundation for new interpretative disagreements over the policy space which the TRIPS provides. Nevertheless, in the recent past, India has not been successful in utilising patent law provisions to protect public health. "Concerns" which the US has been raising through Special 301 from last few years are being mitigated by the Indian government either directly or indirectly. Misinterpretation, underutilisation and non-utilisation of provisions discussed above either by the Indian patent office or central ministry has frustrated the legislative intent to give priority to public health over monopoly of pharmaceutical patent holders. Such practises have helped to advance the mischief of pharmaceutical patent holders instead of suppressing it. In sum, one can easily draw inference that Indian patent law in the recent past has been dramatically different in theory and practice. This contrast defeats the Objectives (article 7) and Principles (article 8) of the patent system incorporated in the TRIPS which are mostly reflection of Indian submission during Uruguay round of negotiations.[39] Simultaneously, it also effectively neutralises Principles (section 83) of "development-oriented" Indian Patents Act, 1970. Moreover, section 83 can be used as "shield" to justify any action taken by the government to protect public health. It can also be used as "sword" to curb monopolistic behaviour of pharmaceutical patent holders to maintain the balance of the patent system.

---

39 GATT, *Standards and Principles Concerning the Availability, Scope and Use of Trade-Related Intellectual Property Rights*, Communication from India 5 (July 10, 1989). MTN.GNG/NG11/W/37, *available at*: https://www.wto.org/gatt_docs/English/SULPDF/92070115.pdf (last visited on May 30, 2021).

Although, executive has failed to protect and advance public health safeguards available under Patent Act 1970, it is only the executive which can remedy the situation. Leaving it to the judiciary may invite unpredictable outcome. Court while exercising judicial discretion to adjudicate "constructive ambiguities" in the Patents Act, 1970 may get influenced by "strict textual approach" or "innovation-oriented" patent laws of developed countries. Failure of the Supreme Court to say that section 3(d) prohibits grant of patent for all incremental inventions of pharmaceutical substances in the *Novartis* case, and interpretation of the word "working" includes even importing in the Natco-Bayer[40] dispute by the High Court of Bombay are such examples.

To counter Special 301 Report, Indian government may prepare its own report. The report shall identify the patent and related provisions of the TRIPS as well as Doha Ministerial Declaration which provide "flexibilities" or "constructive ambiguities" for the member states. The report shall further state the provisions of the Patent Act, 1970 which can protect public health either directly or indirectly and use of those provisions in last ten years to know that to what extent these provisions have been utilised to protect public health. The report shall further identify the countries that have pressurised, through report like Special 301 or bilateral trade talks or otherwise, not to use such provisions. It shall further state action plan to utilise the provisions in a better way and declare the sovereign right of India to use the TRIPS compliant provisions of Patents Act, 1970 to protect public health so as to create a balance in the patent system. Engaging national and international public health organisations in preparing the report shall increase the credibility of the report.

Government of India must officially reject the Special 301 Report and make use or allow using provisions of the Patents Act, 1970 to protect public health through affordability and accessibility of drugs. In current global health crisis due to coronavirus pandemic most of member states shall support such action. Moreover, it is the constitutional duty of the state to protect life and health of its people, keeping aside all other factors including arm-twisting tactics of the US to influence government decision–making for reshaping Indian patent law to serve private interests of pharmaceutical MNCs through a public law.

B.N. Pandey[*]
Prabhat Kumar Saha[**]

40 *Bayer Corporation* v. *Union of India* (WP 1323/2013, High Court of Bombay, July 15, 2014).

* Former Head and Dean, Faculty of Law, Banaras Hindu University, Varanasi (India).

** Assistant Professor of Law, Faculty of Law, Banaras Hindu University, Varanasi (India).