2017 SPECIAL 301 REVIEW

(Docket No.USTR-2016-0026)

Submission by

INDIAN PHARMACEUTICAL ALLIANCE

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Indian Pharmaceutical Alliance

USTR: 2017 Special 301 Submission

1. My name is Dilip G. Shah and I am Secretary General of the Indian Pharmaceutical Alliance (IPA). I am making this submission to the USTR on behalf of the IPA for the 2017 Special 301 Review.

2. The IPA's membership consists of twenty pharmaceutical companies which collectively account for about 85 percent of private sector investment on pharmaceutical research and development in India, 60 percent of the country's exports of pharmaceuticals and related services and 46 percent of the domestic market. We therefore have a vital interest in the protection of our innovations, not only for developing cost-effective and useful improvements in existing medicines, but also for discoveries of new medicines.

3. This submission is limited to patent issues relevant to the pharmaceutical industry, particularly those which have been noted in the 2016 Special 301 Report and seeks to provide information and perspectives that may aid the USTR in determining whether India denies adequate and effective protection of Intellectual Property Rights (IPR) or denies fair and equitable market access to the U.S. pharmaceutical industry which relies on intellectual property protection.

The IPR environment

4. The 2016 Special 301 Report continued with the placement of India on the Priority Watch List. However, the Report took note of several positives that have contributed to a better environment for the protection and enforcement of IPR including:

   - The 'strong channels of engagement with the United States on IPR issues'.
   - The 'improved communication with industry stakeholders'.
   - The 'increasing public recognition of the importance of IPR and its linkage with India's future development, including 'high-level national initiatives, such as "Make in India" and "Start-up India" [that] have linked the realization of development goals to IPR creation and protection'.
   - The integrity of judicial processes: 'India's courts retain their reputation for providing fair and deliberate treatment of both foreign and domestic litigants'.

5. Subsequent developments reinforce the above assessment:

- The engagement with the U.S. on IPR continues. U.S. Trade Representative, Ambassador Michael Froman and India's Minister of Commerce and Industry Ms Nirmala Sitharaman met in Delhi on October 20, 2016, for the tenth ministerial-level meeting of the India and United States Trade Policy Forum (TPF). In a joint statement[1], they 'agreed that the TPF has greatly strengthened U.S. - India engagement on bilateral trade and has increased trade and enhanced the overall economic relationship'. They specifically 'welcomed the enhanced engagement on intellectual property rights (IPR) under the High Level Working Group on Intellectual Property, and reaffirmed their commitment to use this dialogue to continue to make concrete progress on IPR issues.' The eleventh meeting is slated to be held in the U.S. in 2017.

- The process of improved communications with industry stakeholders has come to stay, in general as well as for IPR. For example, the Department of Industrial Policy and Promotion (DIPP) of the Government of India invited public comments on the Foreign Direct Investment Policy for 2017[2]. A task force for innovation was set up in September 2016 for improving India's ranking in the Global Innovation Index with a specific direction that public comments be invited.[3] DIPP put out a discussion paper for public comments in March 2016 on Standard Essential Patents and their availability on FRAND terms to develop a suitable policy framework.[4]

- There is continued recognition of IPR as vital to the economy. For example, the *Economic Times* has quoted Prime Minister Narendra Modi as having said on January 10, 2017 that 'creating an investment climate is top priority' and that his government 'is strongly committed to continue the reform the Indian economy'. In this context, the newspaper reports that Prime Minister Modi listed several 'historic initiatives' including the 'upcoming goods and services tax (GST), insolvency and bankruptcy rules, the National Company Law Tribunal, the new arbitration framework and the updated intellectual property regime'.[5]

- Fairness and transparency of Indian courts are among the institutional strengths of Indian democracy.

[1] https://ustr.gov/about-us/policy-offices/press-office/press-releases/2016/october/%E2%80%8BIndia-US-Joint-Statement-TPF

[2] http://dipp.nic.in/English/News/Consolidated_FDI_Circular_of_2017_Inviting_Comments_from_Stakeholders_16012017.pdf

[3] http://dipp.nic.in/English/acts_rules/Orders/Order_Task_Force_Innovation_16092016.pdf

[4] http://dipp.nic.in/English/Discuss_paper/standardEssentialPaper_01March2016.pdf

[5] http://economictimes.indiatimes.com/news/economy/policy/pm-modi-hard-sells-india-to-global-investors-at-vibrant-gujarat-summit/articleshow/56446236.cms

Protection and enforcement

6. The 2016 Report noted two positive developments:

   - The 'hiring and training of large numbers of new patent and trademark examiners should help to reduce significant delays new applicants face while also cutting down the backlog of pending applications' and 'actions taken in recent years to improve the operations of its Patent Office, such as digitizing records, upgrading online search and e-filing capabilities'.

   - The '2015 passage of the Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Bill may provide an important new tool for right holders in India to efficiently and effectively enforce their rights in the courts.'

7. Further comfort can be drawn from subsequent developments:

   - In April 2016, the secretary, DIPP announced the recruitment of 458 additional patent examiners on tenure basis, and 263 patent examiners on contract basis. This was more than a four-fold increase over the 130 patent examiners that were then in place. An ambitious plan was also announced to reduce the examination period from 5-7 years to 18 months by March 2018.[6] In November 2016, 396 of the 458 examiners had joined work and the government is determined to rapidly reduce the backlog of more than 237,000 patent applications as of November 2016.

   - Though the reduction in patent backlog will begin to be substantially realized only in 2017, the seriousness of government intent cannot be doubted. Administrative measures have been implemented that have already yielded noticeable improvements in 2016 over 2015:[7]

Latest data on patent applications and disposals

	2015 (Apr-Dec)	2016 (Apr-Dec)
Filed	35430	33193
Examined	13011	15649
Grants	**4481**	**6347**
Disposals	**10878**	**15910**
Pendency ('000s)	**246***	**237***
***November data**		**Source: Patent Office**

[6] http://www.livemint.com/Politics/7wlzU21P5FOGvfDa4SolMP/DIPP-looks-reduce-delays-in-clearing-intellectual-property-a.html

[7] Data presented by the Patent Office at a recent meeting with stakeholders

Apart from the administrative improvements noted in the 2016 Report, further measures implemented to improve functioning include re-engineering the process of examination, substantially clearing the arrears of publication, cleaning up the database of applications, hearings through video-conferencing in three of the four offices, and the preparation of a short-term action plan based on suggestions received from stakeholders at several meetings.

- The Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act will undoubtedly reduce litigation time for IPR disputes in the long term. There is, however, another dynamic in play that has already improved matters. The adjudication of patent disputes was in part delayed and hampered as there was little judicial precedent and experience in the past. The Delhi High Court has now become the forum of choice for patent and other IPR disputes, including trade mark disputes. As a consequence, the Delhi High Court has a critical volume of litigation and considerable precedent to facilitate better advocacy and quicker adjudication. In practical terms, the advantages of specialized patent courts are being substantially delivered.

Compulsory licensing

8. The 2016 Report 'welcomed the deliberate and transparent process employed in India's evaluation of a compulsory license application in 2015' which resulted in it its refusal. However, it notes with concern the 'lack of clarity on standards for Sections 85 and 92 compulsory licenses'.

9. There has been only one issue of compulsory license and one refusal in India under Section 85 prior to 2016. The circumstances of the refusal of the compulsory license (for Astra Zeneca's Onglyza™ and Kombiglyze™) and those that occasioned the solitary grant (for Bayer's Nexavar™) are not indicative of any lack of clarity in standards. In both these cases, the application for a compulsory license was made principally because the reasonable requirements of the public for the drug were allegedly not met at a reasonably affordable price. This is a ground for the grant of compulsory licenses under Section 85 the Indian Patents Act.

10. The Controller of Patents refused the license application for AstraZeneca's drugs (for the treatment of Type II diabetes). After a detailed review of the evidence and an oral hearing, the Controller of Patents determined that the applicant had not been able to substantiate its case and rejected its application on January 20, 2016.[8] On the other hand, the applicant for a compulsory license for Bayer's Nexavar™ (for the treatment of advanced cancer) was able to establish its case for the reasons detailed in the order of the Intellectual Property Appellate Board.[9]

[8] Lee Pharma v AstraZeneca, Controller of Patents, available at http://www.ipindia.gov.in/iponew/compulsoryLicense_Application_20January2016.pdf

[9] *Bayer Corp.* vs *Union of India*, OA/35/2012/PT/MUM; judgement available at http://www.ipab.tn.nic.in/045-2013.htm

11. The 2016 Report 'requests further clarification that could increase confidence for patentees such that they better understand the conditions for which a compulsory license would be permitted'. Clearly, whether a drug is adequately available to meet the reasonable requirements of the public at reasonably affordable prices is dependent on the facts of each particular case. The decisions in both cases were made fairly and transparently, after open hearings. We therefore submit that the absence of specific standards for the grant of compulsory licenses under Section 85 ought not to be a matter of concern. More so, as the decisions of the Controller of Patents are subject to judicial review and there is a well-developed judicial approach to determining 'reasonableness' in a variety of circumstances.

12. We submit that the conditions for issue of compulsory license under Section 92 are clearly specified in the section itself and are exceptional in nature. They can only issue 'in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use'.

13. There was no grant of compulsory license in 2016 under Section 85. We are not aware of any compulsory license having been granted under Section 92 in the past.

Patent Revocation under Section 66

14. The 2016 Report has expressed concern about the lack of clarity on standards for revocation of a patent under Section 66 of the Patents Act.

15. Section 66 enables revocation by the Central Government if 'a patent or the mode in which it is exercised is mischievous to the State or generally prejudicial to the public' after hearing the person who may be aggrieved by the decision. This is a provision applicable only when exceptional circumstances prevail; i.e. when the sovereign interests of the State or those of the general public are adversely affected. For example, Section 157A grants an overriding power to the Central Government to revoke a patent prejudicial to the security of India such as patents for fissionable material, arms and military supplies, among others. The revocation will be under Section 66.

16. We are not aware of the revocation of any patent under Section 66 in the past. We submit that there is no cause of concern on this score.

Section 3(d)

17. We acknowledge that the U.S. has serious concerns on Section 3(d) of the Patents Act which denies patents to inventions that are new forms of known substances, unless there is an increase in efficacy. We also acknowledge that such inventions are patentable in the U.S. and several other countries.

18. The 2016 Report implies that the limitation in Section 3(d) goes beyond the established criteria set out in the TRIPS Agreement – that a product or process is patentable if it is novel, non-obvious and capable of industrial application. As is well known, India believes that Section 3(d) is in conformity with the TRIPS Agreement. We do not propose to elaborate the legal basis of India's position, but focus on pragmatic considerations that may be relevant to the USTR's assessment of whether the Section 3(d) operates in a manner that denies adequate and effective protection of IPR or denies fair and equitable market access to U.S. persons who rely on intellectual property protection.

Preliminary

19. At the outset, we would like to comment on certain issues arising from the 2016 Report, in the interest of clarity:

- Section 3(d) does not discriminate between Indian and foreign applicants for patents. Market access, to the extent it is influenced by patent protection, is neither unfair nor inequitable to U.S. persons as compared to Indian persons or those domiciled elsewhere. The question that remains, however, is whether Section 3(d) denies U.S. persons adequate patent protection in India.

- The 2016 Report notes 'irregularities in the application of Section 3(d) of India's Patents Act' and the 'unpredictable application' of Section 3(d) creating 'considerable uncertainty for patent applicants and patent holders'. We acknowledge that there have been a few instances in the past of misapplication of the law relating to Section 3(d) that needed remediation through judicial processes. However, there can be no doubt that the Patent Office is committed to correct, consistent and transparent application of the law. We are not aware of any glaring misapplication of the law relating to Section 3(d) in the last year.

- The 2016 Report adds that the above uncertainty 'is exacerbated by the ability of third parties to use Section 3(d) as the basis for challenging patents, either before or after they are granted, which can potentially lead to revocation or delays that result in an extremely costly reduction in patent term that cannot be recouped'. While revocation may be a necessary consequence of the application of Section 3(d) for new forms of known substances which do not result in enhanced efficacy, any delay caused by oppositions that *fail* does not result in any reduction in the patent term. The delay also does not result in any reduction in damages if the patent is infringed. The reason is that the Patents Act in India ensures that even if there are procedural delays in the grant of a patent, whether by reason of examination or opposition, there is no erosion in the effective life of the patent, which remains 20 years from the date of first filing (Section 53). Further, there is no substantive damage to the patentee due to delays in grant, as the Indian statute provides for damages *from the date of publication of the patent application* in the event of infringement of a granted patent (Section 45(3)).

Extent of limitation on patentability imposed by Section 3(d)

20. We acknowledge that the limitation imposed by Section 3(d) needs to be carefully evaluated for assessing the adequacy of patent protection to U.S. persons in India. It is therefore important to examine the extent of the limitation, particularly what is *not* limited by Section 3(d):

    - Section 3(d) does not deny patents to new substances, only to *new forms of known substances*, though even such new forms are patentable in India if they enhance efficacy.

    - The interpretation of 'efficacy' as 'therapeutic efficacy' has given rise to the apprehension that Section 3(d) 'as interpreted, may have the effect of limiting the patentability of potentially beneficial innovations'. Several examples have been cited in the 2016 Report. Two of these examples, most relevant to the interpretation of 'efficacy' is 'drugs with fewer side effects [and] decreased toxicity'. The interpretation of 'efficacy' as 'therapeutic efficacy' was made in the context of Gleevec™ of Novartis[10], where the question of fewer side effects and decreased toxicity did not arise. To our knowledge, there is no judicial precedent to suggest that the bar of Section 3(d) would be applicable to instances where the claim is for a new form of a known substance with fewer side effects or decreased toxicity.

    - *Processes* for manufacture as well as specific new *formulations* of new forms of known substances are patentable, if they are novel and involve an inventive step, even if they do not result in increased efficacy. It is therefore unclear how it can be said that that Section 3(d) limits the patentability of 'improved delivery systems, or temperature or storage stability' as stated in the 2016 Report.

What Section 3(d) really prohibits

21. While patents for new substances are often known as *primary* patents, the patents for new forms of the same substance are often termed *secondary* patents. These secondary patents for the same substance are expected to increase patent monopoly for a novel drug – the so-called 'evergreening' of patents. This is best explained by the Report of the Commission on Public Health, Innovation and Intellectual Property Rights,[11] which noted that:

> 'As usually understood, "evergreening" occurs when, in the absence of any apparent additional therapeutic benefits, patent-holders use various strategies to extend the length of their exclusivity beyond the 20-year patent term. President Bush, in 2002, provided a working definition while announcing reforms in response to a Federal Trade Commission report on the delays of the entry of generic products onto the market……..Evergreening can occur in a

[10] *Novartis* v *Union of India*, Supreme Court, Civil Appeal Nos. 2706-2716 of 2013 (arising out of SLP(C) Nos. 20539-20549 of 2009)

[11] World Health Organization: Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health, Geneva, April 2006 available at http://www.who.int/intellectualproperty/documents/thereport/CIPIH23032006.pdf

> number of ways but typically, as noted by President Bush, it arises when companies file and obtain patents, subsequent to the original patent, on other aspects of the same compound or reformulations of the original compound in ways that might be regarded as of no incremental therapeutic value, but which are nevertheless patentable."[12]
>
> 'Countries can adopt legislation and examination guidelines requiring a level of inventiveness that would prevent evergreening patents from being granted. The TRIPS agreement gives freedom to WTO Members to determine the hurdle required for the inventive step…….The intention [of Section 3(d)] is to rule out from patentability variations on a known drug, by treating them all as the same substance, except where it can be demonstrated that a drug has superior efficacy. In that sense, the legislation is trying to make a distinction in law between evergreening (where there are no additional therapeutic benefits) and incremental innovations (where there are).'[13](Internal citations omitted)

In practice, the benefits of extended monopoly from secondary patents are often limited in the U.S.

22. The expectation of an extended patent monopoly from secondary patents is however not necessarily realized as secondary patents are often 'weak'. A telling illustration is the well-known case of Gleevec™ of Novartis, the generic name of which is imatinib mesylate. The primary patent was set to expire in the U.S. in July 2015, including the period of extension it received. Novartis, however, obtained a number of secondary patents that further extended patent protection till June 2022. Patent monopoly for Gleevec™ was extended for over four years by secondary patents for polymorphic forms of imatinib mesylate and a further three years for the use of the product in a new indication.[14]

23. It is easy to see why the further period of monopoly achieved through secondary patents is valuable to Novartis. Gleevec™ was the bestselling drug of Novartis, clocking $ 4.7 billion in global sales in 2015,[15] with about half the sales coming from the U.S. alone. Such an extension of monopoly would have been prevented in India – the secondary patent for the 'new' β-polymorphic form of imatinib mesylate was indeed refused in India because of the prohibition of Section 3(d).

24. The expectation of an additional *seven years* of monopoly generated by secondary patents has, however, not been realized. Sun Pharma introduced its generic version of Gleevec™ in the U.S. on 1 February 2016, just *seven months* after the expiry after the primary patent. How did this happen?

[12] *Ibid*, p149-150
[13] *Ibid*, p151-152
[14] Source: Orange Book
[15] https://www.novartis.com/investors/financial-data/product-sales

25. Sun Pharma was the first to file an Abbreviated New Drug Application (ANDA) for imatinib mesylate with a paragraph IV certification – implying that Sun Pharma believed that the patents so certified were either invalid or non-infringed by their product. The primary patent was not challenged and Sun Pharma proposed to launch its generic after its expiry. While details are not publicly available, it is almost certain that the paragraph IV certification was with respect to the two patents for crystalline forms of imatinib mesylate. Gleevec™ is presently approved for use in ten indications in the U.S.[16] Sun Pharma 'carved out' two indications presumably covered by Novartis' secondary use patent and one indication which may have been subject to orphan drug exclusivity. Their product is approved and marketed for use in the remaining seven indications.[17] Sun Pharma was awarded the incentive of 180 days of exclusivity for their generic product as an incentive for having incurred the risk and cost of successfully litigating the patents of Novartis. Other generics followed after the expiry of 180 days.

26. The seven-month reprieve from generic competition obtained for Gleevec™ was because Novartis and Sun Pharma settled the matter out of court. It is clear that the outcome for Gleevec™ in the U.S. (which follows the Hatch-Waxman Act) and in India (which has Section 3(d)), is not that different.

27. The question that arises is whether the Gleevec™ instance can be generalized. Amy Kapczynski and her colleagues studied the patents of 432 new molecular entities (with at least one patent) approved by the U.S. Food and Drug Administration (FDA) between 1985 and 2005.[18] Instances of 'PIPES' patents, i.e. secondary patents for polymorphs, isomers, pro drugs, esters and salts, without any compound claims, similar to the patents prohibited by Section 3(d) in India, increased from 13% to 23% in the period.[19]On an average, these secondary patents appeared to add 6.3 years of patent protection for each product, beyond the term of the primary patent.[20] Though secondary patents appeared to add significantly to *nominal* patent life, the *actual* additional life was limited as they were prone to invalidation or designing-around:[21]

> 'Secondary patents may be more vulnerable to attack than chemical compound patents, and if they are frequently invalidated or designed around, they will in practice have less effect on market exclusivity than their effects on nominal patent life suggest. There is reason to suspect that this is the case. Although industry groups reject the suggestion that secondary patents are weaker than chemical compound patents, in practice companies that seek such patents

[16] http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/021588s042lbl.pdf
[17] http://www.imatinibrx.com/
[18] Kapczynski A, Park C, Sampat B. Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of ''Secondary'' Pharmaceutical Patents. *PLoSONE*,December 2012, Volume 7, Issue 12, p 8, available at http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0049470
[19] *Ibid*. p4, Col 2
[20] *Ibid*. Table 3, p7
[21] *Ibid*. p7, Col 2-p 8, Col 1

> often appear to hold this view. Previous empirical work shows that drugs with non-active ingredient patents, particularly those that generate incremental patent life, are much more likely to attract patent challenges in the U.S. A European Commission study of the sector recently concluded that generic litigation ''mainly concerns secondary patents,'' and that generic companies have high success rates in cases involving secondary patents.' (Internal citations omitted)

28. One of the empirical studies cited by Kapczynski and colleagues was an analysis of new molecular entities that were subjected to generic competition between 2001 and 2010 which concluded that later expiring patents were successfully (and disproportionately) challenged, limiting the effectiveness of 'evergreening' of pharmaceutical patents in the U.S. <u>While there are differences in individual cases, overall, there is no significant increase in average patent life despite secondary patents</u>:

> "The average nominal patent term is 16 years for drugs with first generic entry between 2001 and 2010. By comparison, average effective market life for these drugs is 12 years, not much different than in the previous decade, and greater than in the decade before Hatch–Waxman. Patent challenges are the key driver of the gap between nominal patent term and effective market life."[22] (Internal citation omitted)

Section 3(d) is merely an appropriate alternative in the Indian context to the Hatch-Waxman provisions.

29. The legal framework in the United States mitigates the problem of non-meritorious secondary medicinal patents by providing the incentive of exclusivity to successful generic challengers but India does not have a comparable provision in its law. Nor is it feasible to have one as India does not have mandatory generic substitution (and the consequent rapid substitution of generics) as in the U.S. to make the incentive meaningful. Section 3(d) in India's Patents Act provides an alternative. It is perhaps a more efficient way than to grant weak patents in the first instance and then impose the burden of litigation to set matters right. Kapczynski *et al* say it best[23]:

> 'Furthermore, litigation as a means to invalidate weak secondary patents is a far less plausible policy outcome in countries without robust incentives for generics to undertake the expense of challenging these patents. Insofar as the policy response to the rise of secondary patents relies on litigation and rigorous patent examinations as a means to ensure that only truly inventive secondary patents issue, resource-limited settings are likely to be at a substantial disadvantage. This may help to explain why countries like India have sought to adopt clear statutory bars on certain types of secondary patent claims….' (Internal citations omitted)

30. Section 3(d) is thus an effective way in the Indian context to achieve similar outcomes as the Hatch-Waxman provisions in the U.S. Innovator companies doubtless benefit from the delays in generic entry occasioned by litigation in the U.S. However, we respectfully submit that the denial of such litigation benefits in India ought not to be considered a denial of adequate and effective patent protection for U.S. companies.

[22] Hemphill S, Sampat BN. Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals. *Journal of Health Economics*, 2012, 31(2): 327–339 p 336, Col 2

[23] Kapczynski A, Park C, Sampat B. *Op. Cit.* p8

Patent opposition procedures

31. The 2016 Report notes with concern that 'under India's patent regime, the same interested party may, at minimal cost, challenge a patent through both pre-grant and post-grant opposition proceedings on any of 11 enumerated grounds, including by citing the same grounds in both pre- and post-grant challenges. As a result, applications can be tied up in costly challenge proceedings for years, all the while running the potential term of the patent, which begins from the application filing date.'

32. We have pointed out in paragraph 19 above that under the Indian Patents Act, an infringer will be liable for damages from the date of publication of the patent application, which mitigates the loss, if any, because of delays in grant of the patent caused by pre-grant opposition. Post-grant oppositions are available in many jurisdictions.

33. The possibility of the same person filing pre- and post-grant oppositions on the same grounds appears remote. The Supreme Court of India had occasion to consider whether the multiple options available to challenge the validity of patent under the Indian Patents Act – by way of post-grant opposition under Section 25(2), revocation proceeding before the Intellectual Property Appellate Board or as a counter-claim in a suit for infringement before a High Court under Section 64- could be pursued. By a judgement of 2 June 2014, the Supreme Court effectively ruled that a person can choose only one option to pursue from among the three to avoid multiple litigations.[24] The same reasoning would act as a deterrent for the same person filing pre- and post-grant oppositions.

34. We are not aware of abusive pre- and post-grant oppositions filed by the same person on the same patent.

Data protection and data exclusivity

35. The 2016 Report notes 'the lack of an effective system for protecting against unfair commercial use, as well as the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products'.

36. At the outset, we submit that unauthorized disclosure of undisclosed test data by government regulatory agencies of confidential information submitted by applicants for regulatory approval would be actionable under the Official Secrets Act.

[24] *Dr.AloysWobben*v *Yogesh Mehra*, Civil Appeal No. 6718 Of 2013, Supreme Court of India, particularly para 26, available at http://supremecourtofindia.nic.in/outtoday/ac671813.pdf

37. We have in the past elaborated on India's stand that the prohibition on unfair commercial use mandated by the TRIPS Agreement does not extend to a regulator in India relying in part on the approval of a new drug by a foreign regulatory agency such as the U.S. FDA or the European Medicines Agency for regulatory approval of a generic version. We do not propose to reproduce the reasoning of India here; instead we will dwell pragmatically on whether the lack of data exclusivity makes a material difference to the adequacy and effectiveness of intellectual property protection to U.S. persons in India.

38. Data exclusivity confers a period of protection from generics for new drugs independent of patent protection and runs concurrently with the patent term in the U.S. The period of protection varies depending on its approval requirements. For certain new drug products requiring new clinical investigation it is three years, for new chemical entities it is five years, for orphan drugs it is seven years and for biologicals it is twelve years. Data exclusivity benefits drug companies in the U.S. only if there is no patent for a new drug or the patent term is less than the data exclusivity period.

39. From a pragmatic perspective, the extent of benefit that would be available for U.S. companies if India were to provide for data exclusivity is uncertain. Firstly, not all drugs developed for U.S. companies are introduced in India for commercial reasons, as is the case with many biologicals, or drugs which are granted orphan drug exclusivity. Further, it would be a rare occurrence for the patent term to expire before a period of data exclusivity for new chemical entities. It is also uncertain how many drugs with new clinical trial investigation exclusivity or orphan exclusivity would find a market in India. We therefore submit that it would be reasonable to require a realistic, data-driven estimate of the extent of actual and potential injury occasioned by the lack of data exclusivity, before concluding that U.S. companies are denied adequate and effective intellectual property protection in India.

Amendment in patent rules

40. The 2016 Report expresses concern that the 'Patent Rule Amendments would introduce concerning new incentives to pressure patent applicants to localize manufacturing in India'. The concern was possibly in the context of the Draft Amendments issued for public comment in October 2015.[25] The proposed insertion of Rule 24C would have enabled expedited examination of patent applications if specified conditions were satisfied. One of these conditions was the requirement of manufacture in India. After consideration of public comments, the amendments to the Rules have been finalized and notified on May 16, 2016.

41. The Rules as notified do not have a requirement for local manufacture for expedited examination of patent applications.[26]

[25] http://www.ipindia.nic.in/writereaddata/Portal/IPORule/1_4_1_patent-rules-29october2015.pdf

[26] See the Amended Rule 24C in para 11 available at http://www.ipindia.nic.in/writereaddata/Portal/IPORule/1_42_1_Patent__Amendment_Rules_2016_16May2016.pdf

Notification of interested parties of marketing approvals for generic pharmaceuticals

42. We acknowledge that India does not have a formal system of notifying patent holders of marketing approvals of generics. In our opinion, it is infeasible for such a system to be adopted in India as it would require a major overhaul of the legislative framework within which the Drugs Control General (India) functions as well as substantial changes in the organizational structure, functional expertise and staffing of the Central Drugs Standard Control Organization.

43. However, interested parties are invariably aware of marketing approvals for generics. Clinical trials are normally required for the introduction of a new generic and notification of 'no objection' of all clinical trials is periodically made public.[27] This does provide the needed notice well in advance, for it usually takes a long time to complete clinical trials and the regulatory application for approval. New drugs that are approved are also periodically notified.[28]

44. In practical terms, normal market intelligence enables pharmaceutical companies to keep track of competing drug approvals. We are not aware of any instance where the patent-holder was unable to sue because of the lack of notification, or where an interim injunction was refused on account of the patent-holder delaying the institution of the suit occasioned by delayed knowledge of an alleged infringement.

Section 8 and Form 27

45. The 2016 Report notes with concern that patentees who do not comply with the 'burdensome' requirement of furnishing information under Section 8 or in Form 27 'face the serious consequence of possibly having their patent revoked or subject to a compulsory license if they fail to meet the standard.' Our 2014 Special 301 submission provided the context and commented on the implications. It bears repetition.

46. Section 8 requires a statement from the patent applicant, whether Indian or foreign, giving particulars of applications made for the same or similar subject matter in jurisdictions outside India and updates on them till the grant or rejection of the patent in India. The intent of the provision appears to be to ensure that Indian patent examiners have the benefit of being informed by the prosecution of the application elsewhere to aid their examination.

47. By way of mitigation, it may be noted that India does not have long experience in the examination of pharmaceutical patents. About three-quarters of the patent examiners have been newly appointed and would possibly appreciate the ready availability of information on examination - whether it results in grant or refusal – in other jurisdictions.

[27] http://www.cdsco.nic.in/forms/list.aspx?lid=2173&Id=11
[28] http://www.cdsco.nic.in/forms/list.aspx?lid=2034&Id=11

48. It may also be reassuring to note that the mere omission to provide information as required by Section 8 will not lead to revocation of the patent. The omission must be both material and willful, which is a high bar. [29, 30]

49. Form 27 is an annual statement required to be submitted by all patentees, whether Indian or foreign, providing brief information related to the working of the patent in India. The information may be as useful for the Patent Controller to refuse a compulsory license, as much as to grant it.

National IPR Policy

50. The National IPR Policy was released on 12 May 2016. We are mindful of the comment in the 2016 Report that a 'lackluster policy that does not reflect or provide the ability to act upon Prime Minister Modi and high-level officials' stated commitment to improve the climate for IPR in India would be an unfortunate missed opportunity.'

51. The USTR will doubtless be making its own assessment of the policy. We would only point put some aspects of its impact that may not be obvious. Substantial changes in patent laws cannot be made in a robust democracy like India without public support. The assessment of the National IPR Policy must therefore take into account its impact on public attitudes, however fuzzy, in addition to objective aspects.

52. India has had patent protection, including for medicines, since 1911. The result of this decade long 'incentive' for innovation did not produce any innovation in medicines in India; nor did it foster the development of indigenous capability. Foreign companies operated in India very profitably with the monopoly granted by patents, but few new medicines were available and that too at prices that were not affordable for the vast majority of Indians. After several expert committees had deliberated upon the issue and faced with a stark crisis, the government decided to abolish patents for medicines in 1970. This, coupled with other far-reaching measures, averted the looming crisis. Public perceptions were that patents were one of the root causes of the problem. The situation changed dramatically in just about two decades and generic medicines became available at very affordable prices. Nevertheless, the government had a herculean task in 1995 to generate consensus on the signing of the TRIPS Agreement and in 2005 to amend the patent law to reintroduce patents for medicines.

[29] *Koninklijke Philips Electronic* vs *SukeshBehl* , para 14; available at http://www.indiankanoon.org/doc/21642064/
[30] *Fresenius Kabi Oncology v Glaxo*, IPAB, July 27,2013, paras 34-52; available at http://www.ipab.tn.nic.in/162-2013.htm

53. The building of public consensus on the value of innovation and the need to incentivize it with strong IPR is work-in-progress. The task is not easy, given fears of monopoly pricing, particularly as medicines are still paid for out-of-pocket by the vast majority of people in India. The National IPR Policy aims to build such consensus and the government is committed to implementing it. For example, Minister Nirmala Sitharaman took several steps in 2016, immediately after the policy was released. She followed this up last August by commencing wide-ranging consultations with 28 industry bodies.[31] The very announcement of a national policy on IPR and stimulating awareness of its benefits, as well as its linkage with innovation and development, are important steps in generating public consensus on incentivizing innovation with strong IPR.

54. In the past, the USTR has drawn attention to lax enforcement of IPR. The adoption of the National IPR Policy is creating an environment of strict and effective enforcement. For example, the Federation of Indian Chambers of Commerce and Industry, with the support of DIPP, released a 'tool-kit' on 6 January 2017 to aid police personnel in prosecuting trademark and copyright offences under the penal provisions in Indian law. In his prefatory message, Ramesh Abhishek, Secretary, DIPP said '[t]his IPR Enforcement Toolkit for Police is an initiative to strengthen the enforcement regime of IPRs in the country and thereby take forward the clarion call of "Creative India; Innovative India" enshrined in the National IPR Policy.'[32]

Concluding comments

55. We have alluded to the deals struck by innovation-led U.S. pharmaceutical companies with Indian companies to gain access not only to the Indian market but also to the developing world in our submission for the 2015 Out-of-Cycle Review as well as the 2016 Review. Such deals included those by Amgen Inc., Gilead Sciences Inc. and AstraZeneca (whose subsidiary is incorporated in the U.S.). Significantly, in yet another deal, Merck Inc. agreed to grant world-wide marketing rights of a novel drug candidate to an Indian company for an up-front payment and reimbursement of the continuing costs of development. The trend continues in 2016.

56. The increasing commercial collaboration between U.S. and Indian pharmaceutical companies is indicative of the ways in which U.S. companies are increasing their revenues from India and spreading their development costs. It must, however, be noted that the Indian market for expensive medication under patent is small.

[31] http://www.business-standard.com/article/pti-stories/sitharaman-convenes-meeting-of-industry-bodies-on-ipr-tomorrow-116082201174_1.html

[32] http://ficci.in/past-events-page.asp?evid=23153

57. We therefore respectfully submit that there is a case for reviewing the continuance of India on the Priority Watch List. In summary:

- The improvements demonstrated in 2015 have been sustained and accelerated in 2016. These include improvements in the IPR environment through dialogue and consultation as well as adoption of the National IPR Policy, quadrupling of patent examiners and consistent judicial enforcement in accordance with Indian law.

- There has been no grant of compulsory license in 2015 and 2016 or revocation under Section 66. We are also not aware of any abusive patent opposition.

- Section 3(d) has caused considerable apprehension in the past that it would limit the patentability of useful innovations. We have shown that it only limits secondary patents that do not enhance efficacy and typically result in 'evergreening'. We have also shown that Section 3(d) and Hatch-Waxman provisions are not dissimilar in terms of outcomes. Therefore, Section 3(d) ought not to be of concern.

- The proposed provision in the Patent Amendment Rules noted in the 2016 Report which gave rise to the apprehension that patent applicants would be pressurized into local manufacture has been dropped.

- We are unclear about the extent of adverse impact of the lack of data exclusivity on U.S. companies. Though general assertions have been made, no specifics have been provided in past submissions by U.S. companies. We do not expect that the impact will be significant. Our expectation is also borne out by the simulation studies conducted by the United States International Trade Commission (USITC) that the likely increase in employment in the U.S. if India provided for TRIPS-plus IPR on par with the prevalent standard in the U.S. indicated 'employment gains of less than 10,000 jobs' for all U.S. sectors put together.[33] The pharmaceutical industry would account only for a fraction of this.

58. The removal of India from the Priority Watch List would be recognition of the strides that India has made in promoting, protecting and enforcing IPR and sustain its forward momentum.

59. We thank you for the opportunity to make this submission.

[33] USITC, Trade, Investment, and Industrial Policies in India: Effects on the U.S. Economy, December 2014 https://www.usitc.gov/publications/332/pub4501_2.pdf, p 89