



# **COMMENTS RELATING TO WORKING OF PATENTS**

*Submission by*

**INDIAN PHARMACEUTICAL ALLIANCE**

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**Mumbai**

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## **Indian Pharmaceutical Alliance**

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 Controller General Patents, Designs & Trade Marks on behalf of the IPA. The submission is in response to Circular dated 1 March 2018 calling for comments on Section 146 and 122 of the Patents Act, 1970 and Rule 131 and Form 27 of the Patents Rules, 2003 relating to the working of patents.
2. 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, 80 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 manufacture of generic medicines for India and the world. We also have an 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. The statutory provisions relating to the working of patents cover domestic as well as foreign patentees in all fields. However, our comments are limited to the perspective of the pharmaceutical industry.
4. Though the IPA represents a segment of the pharmaceutical industry in India, it is deeply conscious of its larger responsibilities and has always endeavoured to provide inputs relevant to policy making in the national interest, including in the area of Intellectual Property Rights. This submission is no exception.

### **The context**

5. The power of the Controller to call for information S. 146(1) and the mandatory requirement for patentees to periodically submit the prescribed information under S. 146(2) read with R. 131 and Form 27 assumes significance in the context of Chapter XVI of the Patents Act (the Act) dealing with the working of patents, compulsory licensing and revocation. For the purposes of this Chapter the terms 'patent' and 'patentee' are in relation to 'patented articles' and 'any article made with a patented process' (S. 82). The term 'patentee' includes a licensee. The terms 'patent' and 'patentee' are used in the same sense in this submission, unless the context requires otherwise.
6. Chapter XVI confers power to the Controller to grant compulsory licences on application by any person (S. 84) or on notification by the Central Government (S. 92) and to revoke patents for non-working (S. 85). The 'general considerations' for the exercise of these powers are set out in S. 83 extracted below:

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- (a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;
  - (b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;
  - (c) that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;
  - (d) that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;
  - (e) that patents granted do not in any way prohibit Central Government in taking measures to protect public health;
  - (f) that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and
  - (g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.
7. It may be noted that subsections (c) to (g) were added by the Patents (Amendment) Act, 2002 with effect from 20 May 2003. These additions were clearly intended to safeguard public health, prevent abuse of patent rights and ensure that patents contribute to the transfer and dissemination of technological knowledge. They were also intended to strike a balance between the grant of monopoly rights to incentivize innovation and the imperatives of public health, consistent with the Doha Declaration and the TRIPS Agreement.
8. Public health objectives are furthered by the availability of medicines at reasonable prices. When medicines are under patent, it is imperative that patents are adequately worked. Compulsory licences are a powerful mechanism to ensure adequate availability at reasonable prices. Contrary to general perception, the use of compulsory licencing is not unusual. A recent study shows that there were 100 instances of compulsory licences (including for public non-commercial or government use) for pharmaceutical products between 2001 and 2016, and six of these instances were in developed countries. These licences were largely for HIV (73), but were also issued for cancer (12) and other (15) diseases.<sup>1</sup>

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<sup>1</sup> Ellen FM 't Hoen, Jacquelyn Veraldi, Brigit Toebes & Hans V Hogerzeila: *Medicine procurement and the use of flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016*, Bulletin of the

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9. India has been very circumspect in exercise of powers under Chapter XVI. The first and only issue of compulsory licence under S. 84 (for Bayer's Nexavar<sup>TM</sup>) was in March 2012. No compulsory licence has been issued in the last five years. On the contrary, applications for compulsory licences (for AstraZeneca's Onglyza<sup>TM</sup> and Kombiglyze<sup>TM</sup>) have been rejected in 2016. No patent has ever been revoked under S. 85 and no notification of patents for grant of compulsory licence under S. 92 has ever been made. In addition, it may also be mentioned that no use of a patented invention by Government has ever been resorted to under S. 100.
10. The mandatory requirement for patentees to furnish information annually on the working of patents under S. 146(2) read with R. 131 in Form 27 has to be reviewed in the above context.
11. It may be noted that a writ petition in the public interest is pending before the High Court at Delhi.<sup>2</sup> Based on an analysis of Form 27 filings between 2009 and 2012 in three fields – pharmaceutical drugs, telecommunications and publicly funded research – the writ petition alleges that about a third of the patentees did not disclose the status of patent working and even for the disclosures made, about a third were defective and incomplete. The writ petition seeks a directive to the Government and the Controller to compel patentees and licensees to declare information on the working of their patents as required under the Act.
12. As Government is well aware, PhRMA (Pharmaceutical Research and Manufacturers of America) and BIO (Biotechnology Innovation Organization) have consistently made a grievance of the requirements under S. 146(2) and Form 27 in their annual Special 301 submissions to the USTR (United States Trade Representative). Their apprehension is that this information will be used to grant compulsory licences and further, that it imposes an unreasonable administrative burden on them. The USTR has consistently noted this grievance while continuing to place India on the Special 301 Priority Watch List.

### IPA comments

13. Section 146(1): The subsection confers power on the Controller to call on patentees and licensees to furnish such information or periodical statements that may be specified on the extent to which a patent has been worked on a commercial scale for specified period(s).

IPA submits that this power is necessary and justified.

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World Health Organization, 2018;96:185–193 accessible at <http://www.who.int/bulletin/volumes/96/3/17-199364.pdf>

<sup>2</sup> *Shamnad Basheer v Union of India*, WP(C) 5590 of 2015, Delhi High Court

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14. Section 146(2): The subsection requires the submission as prescribed (currently at annual periodicity in Form 27) by every patentee and licensee of statements on the extent to which the patented invention has been worked on a commercial scale in India.

IPA believes that information pertaining to working of a patent is crucial to assessing whether the balance that is sought to be achieved by the Act, between incentivising innovation and promoting public health by ensuring adequate availability of medicines at reasonable prices, is achieved. The exercise of the power (and the concomitant obligation) under Chapter XVI will be stultified without such information. When the product patent regime for pharmaceuticals was incorporated into the statute to conform to the TRIPS Agreement, the assurance that public health will be safeguarded was backed partly by the amendments to Chapter XVI in 2002.

IPA submits that the requirement mandated by this subsection is justified and should continue.

15. Section 146(3): The subsection provides that the Controller may publish information received by under subsections (1) and (2).

Patents are in the public domain. Our understanding is that Form 27 filings are made available under the Right to Information Act. Civil Society and NGOs can play a constructive role in aiding assessment of the extent to which patents are worked on a commercial scale if the information is made available routinely and efficiently.

S. 100 confers power on the Government to use an invention for the purposes of Government. Information on the working of a patent can be advantageous should Government exercise this power for the furtherance of public health without losing sight of imperative of preserving the incentive for engaging in such much-needed innovation.

The Controller has previously made public the filings of Form 27 for two years – 2012 and 2013 – in a searchable database.

IPA submits that the Controller may consider routinely digitising all Form 27 filings and placing them in a searchable database designed to permit convenient analysis and scrutiny by all persons.

16. Rule 131: The rule merely specifies that the statement filed under S. 146(2) shall be filed in Form 27 for every calendar year, within three months of the close of the calendar year. IPA submits that no change is needed.
17. Form 27: The primary purpose of submission of the Form is for the Controller and Government to exercise their powers (and the concomitant obligations) under the Act. It is for them to decide on what best serves their purpose, taking into consideration the views of all stakeholders.

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The content of the Form has invited criticism from several quarters. The main issues seem to be:

- Lack of clarity on what should be the definition of ‘quantum’, as several filings have aggregated supplies under Patient Assistance Programmes with commercial sales. IPA submits that the Form should provide for separate reporting of commercial sales and supplies under Patient Assistance Programmes.
  - Lack of clarity on the manner of computation of value; IPA submits that the value should represent the aggregate value of commercial sales to wholesalers/distributors net of discounts, direct sales to patients and institutional sales. Free supplies under Patient Assistance Programmes need not be ascribed any value.
  - Vagueness in Sl. No. 3 of the Form (‘public requirement’, ‘met partly/adequately’, ‘reasonable price’). Clearly, these terms are subjective and difficult to define in general. It may serve no purpose to require such information as they have to be determined through a case-by-case assessment.
  - Confidentiality of commercial information relating to quantum, value and licensees. Information of quantum and value re provided in aggregate and may not materially compromise commercial confidentiality. Licensees are also required to file Form 27, so their identity is known.
18. Section 122: S. 122(1)(b) provides for punishment that may extend to Rs. Ten Lakhs for failure to furnish information under S. 146 and S. 122(2) provides for punishment that may extend to six months imprisonment, or fine, or both for furnishing false information. IPA does not see any reason to modify the penalty.
19. Administrative burden: All patentees (and licensees) of a patented article or an article made by a patented process are required to file Form 27, without any limitation of field. The primary purpose of such filings is to enable the Controller to make an assessment of working of the patent for the purpose of granting a compulsory licence (S. 84), revoking a patent (S. 85), termination of a compulsory licence (S. 94) and the Government to make a declaration by notice that it is necessary to grant a compulsory licence (S. 92).

The primary administrative burden is therefore that of the Controller to scrutinize all the Form 27 filings for the purpose of exercising powers under Chapter XVI the Act and of Government for the purposes of S. 92 and S. 100. The Controller may also decide to undertake the burden of publishing all Form 27s in a searchable database.

It may be noted that the majority of patents would be in fields or for articles where their working or non-working are of no consequence to public health or public interest. The Controller and Government may wish to examine the possibility of reducing the administrative burden on themselves, without in any way compromising public health and public interest.

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