

ABA Section of Intellectual Property Law - International Action Group

International IP Legal Updates

Welcome to our IAG May 2018 Newsletter

Dear ABA-IPL Members;

Welcome to the May edition of the International Associates Action Group Newsletter. We are still looking for contributors so please get in touch with me at david@gearhartlaw.com. All articles are welcome, long or short. If interested in becoming an editor or just want to get involved in our Action group please do let myself or Matthias Berger know. See you next Month!

Yours,

David Postolski

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Working Of Patents In The Indian Perspective - What Should 'Work'?

Of late, there has been a flurry of activity regarding India's requirement for *working of patents*. In an order issued on January 10, 2018, the Delhi High Court, hearing arguments in a Public Interest Litigation (PIL) filed in 2015, directed the government to take expeditious steps for the enforcement of statutory provisions pertaining to the working of patented inventions and relook changes required in the statute, rules and prescribed forms.

But what is this provision and why is it such a big issue?

The Genesis of India's Working Requirement

In many patent regimes across the world, a government's 'quid pro quo' for a patentee's right of exclusivity in his invention includes a requirement that the patentee will also "work the patent", i.e., not just sit on the fruits-of-his-labour but commercialise the invention to the fullest extent. The intent behind this is to help the country by spurring growth in the domestic industry, generating employment and dissipating technological know-how.

Internationally, there was little consensus on the issue of patent working before the Paris Convention for the Protection of Industrial Property, 1883 was signed. Article 5 of the Paris Convention (as amended after the Hague Conference in 1925) prohibited forfeiture of a patent merely on the ground of non-working of a patent except for cases where grant of a compulsory license did not prove to be an adequate relief.

On the Indian front, being technologically underdeveloped as India was after independence, the government appointed a committee in 1957, headed by the legal stalwart Justice N. Rajagopala Ayyengar, to review India's patent laws and to suggest changes commensurate with India's new beginnings as an independent nation. The committee submitted its 'Report On The Revision Of The Patents Law' in 1959, which has become the bedrock of India's ideological position on patent protection. Relevant to this report, the Ayyengar committee considered the vices of not commercialising inventions embodied in a patent in great detail, and finally recommended that India should retain *compulsory licensing* as well as "compulsory" *working* of a patent in its laws. As a penalty for continued non-working of a patent, the report advocated the sanction of revocation noting that "[i]f a country with the industrial progress of the U.K. is unwilling to drop the provision as to revocation for non-working in her law, the need for such provision in the circumstances of our country requires no elaborate argument".

The Ayyengar committee's ideology continued to prevail over decades of India's technological growth and the most recent change to the Patent Act, 1970, (the "Act") also embodies the *working* requirement. Although the term 'working' has not been defined in the Act, there is sufficient indication of its importance in our regime. For example, Section 83 (a) stipulates 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*". Leaning towards "working" by way of manufacturing, Section 83 (b) clarifies that patents are "*not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article*".

Procedurally, compliance with the working requirement is monitored through Section 146 of the Act, which requires patentees and licensees (whether exclusive or otherwise) to furnish annual statements – on Form 27 – elaborating the extent to which the patented invention has been worked on a commercial scale in India.

The Consequences of Non-Working of a Patent

The consequences of non-working of a patent are that (i) a compulsory license may be granted, and (ii) the patent may be revoked for continued non-working. Specifically, Section 84 (1)(c) provides a non-patent holder the right to seek a compulsory license on the ground that the patent has not been worked for 3 years since the date of grant of the patent. Thereafter, if a compulsory license is granted, then the patent in question may be revoked under Section 85, if the invention is not worked in India even after grant of a compulsory license.

In addition to the above, non-working of a patent may adversely affect chances of obtaining an interim injunction during an infringement proceeding. This result came to light in the case of *Franz Xaver Huemer vs. New Yash Engineers*, where the Delhi High Court addressed the issue of non-working and held that the plaintiff who had obtained a patent 12 years ago but had not worked the patent in India could not, in equity, seek a temporary injunction against the defendant.

Further, and relevant to the PIL currently being heard by the Delhi High Court, not reporting the working (or not working) of a patent also has its own consequence. Under Section 122 of the Act, failure or refusal to furnish information regarding working of an

invention could invite a penal action, which includes a fine of up to approximately US\$ 20,000. Furnishing false information is also punishable with imprisonment up to 6 months, or a fine, or both.

Does Importation Satisfy Working Of Patents?

In 2012, the Controller General of the Indian Patent Office, while rendering a decision in the compulsory licensing matter of *Natco Pharma vs Bayer Corporation*, set the cat among the pigeons by adopting the view that “[t]he term ‘work the invention’ does not include imports as a [sic] compulsory license holder has to necessarily work the patent by manufacturing the patented invention in India....” The Controller General went on to state that, “I am therefore convinced that ‘worked in the territory of India’ means ‘manufactured to a reasonable extent in India’”.

The Intellectual Property Appellate Board (the “IPAB”), while hearing an appeal against the Controller General’s decision, disagreed. It recognised that there may be circumstances, such as low demand for the patented product, which may make setting up a factory in India impracticable. It held that working neither excludes ‘import’, nor is it synonymous with ‘import’. Rather, whether importation qualifies as working has to be determined on a case-to-case basis. In a subsequent writ petition filed in the same case, the Bombay High Court upheld this view of the IPAB. The Court noted that in Form 27 there is clear indication that ‘import’ is relevant for the purpose of working since the details of import are furnished under the head “worked”. It was also observed that onus was on the patentee to satisfy the authorities as to why the patented invention was not being manufactured in India keeping in view Section 83 of the Act.

In preliminary injunction matters before courts, the issue of importation was first addressed in detail in the matter of *F. Hoffmann-La Roche Ltd. & Anr. vs. Cipla Ltd.* (2009), where the Delhi High Court refused an interim injunction on the ground that the plaintiff was importing the patented product and not manufacturing the patented drug in India. The Court was of the view that “[i]n case interim injunction is granted in favour of the plaintiffs, the manufacturing and marketing network of the defendants so far as the drug is concerned would be dismantled. If due to any problem, the plaintiffs cannot make available the drug in required quantity in India, it obviously will be disastrous for patients. This consequence is foreseeable, therefore in my opinion, the Court should not pass any interim order which may possibly lead to such a situation.”

This view prevailed until 2015, when the landscape from the lens of a patentee became a little brighter because the Delhi High Court clarified that setting up of a manufacturing unit in India cannot be imposed as a condition precedent to patent protection. In its judgment passed in *Novartis AG & Anr. vs. Cipla Ltd.*, the Delhi High Court unequivocally held that “the requirement of law is limited to working the patent in India so that the same is available to public at large. It is not essential that the patent must be worked by manufacturing the patented product in India..... The Act does not mandate that no patent protection would be granted to a patentee unless local manufacture is undertaken”. As affirmation of this reasoning, in 2017, the Division Bench of the Delhi High Court confirmed that patents can be worked through imports, holding that “all that has to be seen is that the imports are of a sufficient quantity so as to meet demands for the product.”

The Current State of Discontentment

So, where is the discord? While several patentees decry that the working requirement is anti-patent, the PIL mentioned at the beginning of this article complains that the Patent Office is not fulfilling its duty as the gate keeper of the working requirement in India. Particularly, the PIL asserts that until now, the Patent Office has not initiated action against patentees who have not complied with the statement of working requirement mandated by the Act.

Fig. (i)

	2011-12	2012-13	2013-14	2014-15	2015-16
Patents in force	39,989	43,920	42,632	43,256	44,524
Form-27 received	27,825	27,946	33,088	31,990	39,507
Reported as working	7,431	6,201	8,435	7,900	8,589

Statistics published in the annual report of the Office of the Controller General (*Fig. (i) above*) reflect that while compliance of filing a statement of working has increased considerably over the last five years, the percentage of patents being worked *vis-à-vis* the number of patents in force has remained static over the same period, as shown in *Fig. (ii)* below.

Fig. (ii)

	2011-12	2012-13	2013-14	2014-15	2015-16
Patents worked (out of total number of active patents)	18.6%	14.1%	19.8%	18%	19.3%
Cases where statement of working has not been filed	30.4%	36.4%	22.4%	26%	11.3%

The PIL is sub-judice and hopefully, we will see some clarity emerge in the next few months, as the Patent Office (and the Court) decides the importance of the ideological requirement of *working of patents* in India, the procedural steps for compliance with the requirement and the consequences of non-compliance. To aid this process, the Patent Office has even issued a notification seeking comments from stakeholders on the issues that have been raised in the PIL. Whatever the outcome, it is almost certain that the finality will bring about far reaching changes with respect to the working requirement.

Practically, until further clarification issues, it will be prudent for patentees, especially in the pharmaceutical domain to meet the statement of working (Form 27) requirements by filing annual statements indicating the working of their inventions in India or alternatively, filing a statement that the patent is not worked – along with the reasons for non-working.

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