

AIPLA



INTERNATIONAL HEADLINES NEWSLETTER

April 2018

**The Quest for Clarity – Stakeholders’ view on India’s Working Requirement, by
Pankaj Soni and Surendra Sharma of Remfry & Sagar**

Introduction

A Public Interest Litigation (PIL) was filed before the Delhi High Court in 2015, asserting that, patentees were not complying with India’s *Statement of Working* (SOW)¹ requirement and the patent office was being complicit by not enforcing the requirement strictly. In January of this year, the Court, expressing its concern on the current state of affairs, asked the patent office to explain the process it follows and to set out any proposed amendments or changes in the existing SOW requirement. Pursuant to the directions of the Court, the patent office invited comments from stakeholders to try and

¹ India’s *quid pro quo* for a patentees right of exclusivity in his invention is that the patentee should also “work the patent”, i.e., commercialize the invention to the fullest extent. Embodying this policy, the Statement of Working requires that the patentee must file a document – Form 27 – with the patent office, every year before March 31, starting with the year after patent grant, and identify in the document whether the patent is worked in India, the quantum of working (units/revenue), licenses granted and whether the requirements are being met or not. The Patents Act prescribes a fine of upto USD 20,000 (approximately) for refusal or failure to file a SOW. Further, “[i]f any person furnishes information or statement which is false, and which he either knows or has reason to believe to be false or does not believe to be true, he shall be punishable with imprisonment which may extend to six months, or with fine, or with both.”

understand differing perspectives on the SOW requirement – as many as 64 stakeholders submitted their comments – subsequent to which a meeting was held on April 6, 2018, where the views submitted were discussed and deliberated.

This article provides a summary of the suggestions put forth by industry associations, public interest groups, innovators, law firms and academicians.

1. Abolishing the SOW requirement

The SOW requirement was inserted in the Indian Patents Act upon the suggestion of the Justice N. Rajagopala Ayyangar Report of 1959 and has since remained largely unchanged. Several stakeholders questioned whether this requirement was relevant in the present day. Approximately 10% suggested its outright abolition for the primary reason that the information being sought is unduly burdensome and, many a times, not obtainable. Innovators and industry organisations also noted that while the requirement was TRIPS compliant, its imposition was contrary to the global trend of harmonization of laws and might even discourage innovators from filing for patents in India. It was also noted that the difficulty in strict compliance with the SOW requirement is amplified in the case of multinational corporations that own patents across a breadth of technologies, or when multiple patents are incorporated in a single product – for, how does one quantify monetary contribution or explain if an invention has met local requirements?

However, abolishing the working requirement is, simply put, not a feasible option in India. This would require an act by the legislature, and (almost) everyone in the IP fraternity in India recognises that the government is unlikely to amend the Patents Act.. The more practical and achievable suggestion is to simplify the requirement. As one stakeholder suggested, the only information that ought to be asked is whether a patent is “worked” or “not worked”. The opposing view, vehemently suggested by public interest groups was that any dilution in the existing Form 27 would be detrimental to the country, perhaps because it creates hurdles in dissipation of technological know-how.

Further, in its current avatar, the SOW requirement is linked to the compulsory license provisions – if a patent is not worked for years from the date of grant, then an applicant can request a compulsory license – Stakeholders expressed that one should not be used as a tool for the other. Even looking at it from an “information required for compulsory license” perspective, at least three stakeholders suggested that frequency for filing SOW must be reduced to once every three years rather than annually because a compulsory license application cannot be filed on a patent before expiry of three years from the grant of patent.

2. Quantum or Value of Products covered by patent sold

More than 90% of the innovators, industry groups and law firms also suggested that the requirement under Form 27, to submit the quantum/ value of product sold each calendar year in relation to a subject patent being worked, is unreasonable and either needs to be done away with or, at the very least, requires significant modification. The comments pointed out the following difficulties in collecting data for the “quantum” requirement:

- a) It is difficult to maintain records of sales of all products covered by a patent.
- b) The quantum related information could be confidential, or protected by a pre-existing non-disclosure agreement.
- c) There are patents on intermediate products which are not for sale, but are rather used in manufacturing another product (for sale) of the same company. In such a scenario, how should the quantum requirement be fulfilled?
- d) How do you quantify the quantum for multiple patents incorporated in a single product?

Almost everyone asked for greater clarification on the calculation of the “quantum” requirement. Some suggested that the requirement be modified by introducing a declaration from the patentee explaining the extent of working of a patent rather than the precise quantum sold of a ‘patented product’. The quantum requirement, they added, could be sought (under Section 146) only in cases where a compulsory license request has been filed against the patent.

3. Confidentiality of Licenses

Confidentiality clauses are a norm in licensing agreements. They are meant to protect sensitive information and provide a competitive edge to businesses. Laying licenses bare in a Form 27 submission negates business dealings between parties and invalidates confidentiality clauses. The issue of confidentiality has been appreciated by the Delhi High Court in the spate of recent Standard Essential Patents (SEP) lawsuits and it has even set up confidentiality clubs to review Fair Reasonable and Non Discriminatory (FRAND) licenses.

So why should license terms be disclosed in a statement of working? This was a question almost all stakeholders put forth along with a suggestion for removal of such a condition. As one pointed out, SEPs are licensed to numerous parties under different licensing arrangements, and it is extremely difficult to have accurate information on all the licenses for submission on Form 27. Further, as stakeholders from the industry pointed out, under Section 69(4) of the Patents Act patentees can request the Patent office to maintain confidentiality of license terms during the term of registration of a patent. However, the provisions related to the working of patents do not contain such a rule implying a contradiction within the Patents Act. Prominent academicians, including the petitioner of the PIL for the enforcement of SOW requirements, recognized the need to address the confidentiality issue in one way or another.

Many law firms and innovators also pointed out a possible unintended consequence of the disclosure of license terms. Due to this mandate, innovators may decide to not license patents in India if it would result in breach of obligations of confidentiality under a global license. In this way, public interest in having access to better technology might get hampered due to a requirement which was actually meant to further public interest, not to mention – as one industry stakeholder elucidated – the possibility that a licensee bound by a confidentiality clause actually runs the risk of an action of breach by a licensor if it discloses the terms of a license on Form 27. A best practice would possibly be to have the patentee identify “if” a license/sub-license has been granted and leave the option of getting further details as and when required by a third party, e.g., when requesting a compulsory license.

4. Meeting requirements of the public at a reasonable price

Several stakeholders noted that what would satisfy fulfilment of reasonable requirements of the public is unknown and ambiguous. Their suggestion was that this detail should not be required as it plays directly into the compulsory licensing provision and, therefore, perpetuates the argument that the SOW is fashioned to help compulsory license seekers in their due diligence. Nevertheless, if a compulsory licensing application is filed against a patent, the patentee would have to defend against assertions that reasonable requirements of the public were not met, and the details are more pertinent at that stage.

However, at the other end of the debate, two academicians argued that identifying whether the reasonable requirement has been met acts as useful information for parties who wish to apply for compulsory licensing in individual patents which, in turn, satisfies the purported intent behind the SOW requirement of spurring growth in the domestic industry, generating employment and dissipating technological know-how.

5. Pharmaceutical Industry and Standard Essential Patents (SEP)

The non-pharma stakeholders strongly made the point that the SOW requirement has been devised to help the generics industry. Therefore, this requirement should only be limited to such patents. A few others suggested that SEP patents should be identified separately especially since SEPs are such an area of contention in India.

6. The Next Steps

As mentioned above, a stakeholder meeting followed post submission of comments by various stakeholders. During the meeting, especially with regard to point 5 above, a technology/industry neutral perspective was asserted by many stakeholders. Whether the SOW requirement should stay or go or have a certain level of exactitude, should be determined irrespective of the technology/industry. Singling out a specific area is something that did not find favour. In order to collate the proposed requirements in a framework that is less theoretical, the patent office has asked the stakeholders to submit a format of Form 27 that they feel should be used in India.

We believe that proposed formats will cover many/all of the points discussed above. But what is finally implemented is a waiting game, so we all must wait with baited breath to see if there is any respite (for players on either end of the spectrum) with respect to India's working requirement.

Addendum:

There is a brand new development to report concerning the working requirement/Form 27 issue. On April 23, the Delhi High Court dismissed the public interest litigation because the Indian Patent Office had effectively responded by seeking comments from stakeholders, holding a well-attended stakeholders meeting, and most importantly, committing to reconsider the issues related to the working requirement, Form 27, and the associated penal provisions. This result can be seen as a win-win for all parties: the litigation called attention to the importance that India places on ensuring that patented inventions are worked in the country, but both the Delhi High Court and the Indian Patent Office demonstrated that they are responsive to the needs of patent applicants.

A copy of the order follows. A copy of the affidavit that the Deputy Controller submitted to the court is available [here](#).

Order dated 23.04.2018

It appears that several issues related to working of patents under Section 146, Rule 131 including Form 27 and penal provisions under Section 122 are under dispute. The Controller General has initiated an exercise to consider the same and invited inputs from stakeholders.

In this regard, stakeholders were invited to file comments and we are informed that perusant thereto, a meeting was conducted on 6th April, 2018.

Pursuant to the directions of this Court, an affidavit of S S Singh Deputy Controller, has been filed, along with a detailed timeline. He is also present in the court. Amit Mahajan,

Counsel for Respondent has taken us through the Affidavit and a timeline has been stated at Para 3 of the Affidavit.

As per schedule and the minutes of the stakeholders meeting dated 6th April, 2018, we accept the timeline. However, we direct that the Respondent to ensure that there is no delay and the matter is treated with the urgency it deserves. The Respondent will place a report at the end of consultation process.

Thus, the writ petition is disposed in above terms.