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AN ANTI-DISCLOSURE AMENDMENT THAT HITS PUBLIC HEALTH

Relevant for: Developmental Issues | Topic: Health & Sanitation and related issues

The central government recently published the Patent (Amendment) Rules, 2020, amending the format of a statement that patentees and licensees are required to annually submit to the Patent Office disclosing the extent to which they have commercially worked or made the patented inventions available to the public in the country. The amendment has significantly watered down the disclosure format, and this could hamper the effectiveness of India's compulsory licensing regime which depends on full disclosure of patent working information. This in turn could hinder access to vital inventions including life-saving medicines, thereby impacting public health.

In exchange of a 20-year patent monopoly granted to an inventor, India's patent law imposes a duty on the patentee to commercially work the invention in India to ensure that its benefits reach the public. In fact, the purpose of granting patents itself is to not only encourage innovation but also ensure that the inventions are worked in India and are made available to the public in sufficient quantity at reasonable prices.

Comment | Patents and protecting public health

A failure of this duty could trigger compulsory licensing or even subsequent revocation of the patent under the Patents Act, 1970. Further, courts have refused an interim injunction in cases alleging infringement of a patent which has not been worked in India. Thus, the information on the extent of the working of the invention in India is critical for the effectiveness of these public interest measures provided by law to check abuse of patent monopoly (e.g. excessive pricing or scare supply of the invention). Accordingly, section 146(2), a unique provision not found in patent laws of most other countries, requires every patentee and licensee to submit to the Patent Office an annual statement explaining the extent to which they have worked the invention in India. The disclosure is to be made in the Form 27 format as prescribed under the Patent Rules, 2003. This statement is meant to help the Patent Office, potential competitors, etc. to determine whether the patentee has worked the invention in India and made it sufficiently available to the public at reasonable prices.

Unfortunately, patentees and licensees as well as the Patent Office have blatantly disregarded this statutory requirement. Also, there has been significant pressure from multinational corporations and the United States government to do away with this requirement.

The recent amendment to the form was made pursuant to a PIL filed by Shamnad Basheer before the Delhi High Court in 2015. The PIL brought to the Court's attention the rampant non-filing and defective filing of Form 27 by patentees/licensees and sought a direction to the government to strictly enforce the patent working disclosure rules and take action against the violators. The PIL also called for a reform of Form 27, arguing that the information it sought was grossly insufficient to ascertain the extent of the working of the patent.

Comment | Needed: a pandemic patent pool

The government acknowledged that the Form 27 format was problematic and provided an undertaking to the court to effect appropriate amendments. The court accordingly disposed of the PIL in 2018, directing the government to complete the amendment process within the timelines mentioned in the undertaking. However, in non-compliance of the court's order, the

government published the amended form recently after a delay of almost two years. More importantly, instead of strengthening the form, the amendment has significantly weakened it further, thereby defeating the entire purpose of the amendment exercise.

Instead of calling for more elaborate details of the information already sought in the Form as suggested in the PIL, the amended form has removed the requirement of submitting a lot of such important information altogether, thus damaging the core essence of the patent working requirement and the Form 27 format. The form now requires the patentees and licensees to provide only for the following information: whether the patent has been worked or not; if the invention has been worked, the revenue or value accrued in India from manufacturing and importing the invention into India; and if it has not been worked, reasons for the same and the steps being taken towards working. They are no longer required to provide any information in respect of the quantum of the invention manufactured/imported into India, the licenses and sub-licenses granted during the year and the meeting of public requirement at a reasonable price.

How will the data on merely the revenue/value accrued from manufacturing/importing the invention enable one to determine the extent to which it has been worked and its public requirement has been met? The most basic data required for this assessment is the quantum or the total units of the invention manufactured/imported in India. It is the disclosure of this data by Bayer in Form 27 that played a crucial role in grant of India's first compulsory license to Natco for the anti-cancer drug Sorafenib/Nexavar. The deletion of the requirement of its disclosure is thus shocking and defeats the very purpose of this Form.

The removal of the requirement of submitting any licensing information, including the disclosure of even the existence of licenses (instead of seeking further details such as names of licensees/sub-licensees and the broad terms of the licenses as suggested in the PIL), means that the patentees/licensees can just self-certify that they've worked the patent without having to support the claim with the data on how they've done so, including through licensing/sub-licensing the patent.

Further, the omission to mandate disclosure of details such as the price of the invention, its estimated demand, the extent to which the demand has been met, details of any special schemes or steps undertaken by the patentee to satisfy the demand, etc., as recommended in the PIL, makes it extremely difficult to ascertain whether the invention has been made available to the public in sufficient quantity and at an affordable price.

To conclude, the government has significantly weakened the critical duty imposed by the law on patentees/licensees to disclose patent working information, so much so that it has defeated the very purpose of it. The lack of this information could prevent invocation of compulsory licensing and other public interest measures in cases of patent abuse and make certain inventions inaccessible to the public. Such lack of accessibility in case of patented medicines could in turn have adverse consequences for public health of the country. Therefore, the government must reconsider its amendments to the form taking into account the PIL recommendations and re-amend it to restore as well as strengthen its spirit.

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