

## Patents and protecting public health

A new chapter on the access to medication debate in India began when Shamnad Basheer filed a public interest litigation before the Delhi High Court. The petition pointed out the importance of “working requirements” in the Patents Act, 1970; the need to amend Form 27; and the lapses by patentees in furnishing information. The importance of Form 27 on the question of access to health cannot be underestimated. In essence, Form 27 seeks information to ensure that the patented material is adequately supplied in India. If the supply of the patented invention does not cater to the demands, statutorily the reasonable requirement of the public with regard to the patented invention is deemed as not met. This will be a ground to seek compulsory licensing of the product within India. The underlying rationale is to protect public health.

Patent law grants to the patentees the privilege of enjoying a limited monopoly in order to achieve the objective of public benefit. Thus, the quid pro quo for getting patent monopoly is patent disclosure. As part of the disclosures, patentees are required to disclose if they are locally working their patented invention in exchange for the conferred benefits. Thus, Section 83 of the Patents Act states 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” and that the monopoly granted to the patentees is not merely to import the invention. Historically, laws in India have considered “working” the invention as being so crucial to the enjoyment of the monopoly that non-working in India entitled a third party to apply for a compulsory license.

In streamlining the local working requirement, especially in the field of pharmaceuticals, India is in line with its international trade obligations. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provides flexibilities and underscores the sovereign rights of countries to weave in the ground realities of each country while honouring their international trade commitments. Paragraph 5(2) of the Doha Declaration outlines the right of national governments to compulsorily license patents and the “freedom to determine the grounds upon which such licences are granted”, including the use of grounds not explicitly specified in Article 31 of TRIPS. Thus, lack of local working of the patent can be grounds for granting a compulsory licence along with other grounds such as high prices and non-supply of the patented invention locally. In doing so, the Doha Declaration allows the exercise of sovereign rights to define when exclusive rights could be curtailed to achieve a larger public interest result.

Seeking local working information is part of India’s use of its sovereign rights. The state is obligated to protect the right to life of its citizens under Article 21, and this duty is heavier than any duty that the state may owe the patentees. The state should ensure that patentees perform their duties as monopoly holders. This means that the grant of patents must contribute to the promotion of technological innovation and to the transfer and dissemination of technology in a manner conducive to social and economic welfare and to a balance of rights and obligations.

Currently, Form 27 requires patentees to submit a statement “regarding the working of the patented invention on a commercial scale in India”. But as the Form is bereft of crucial details, India’s next step is not to abjure it, but to revise it in a way that the conditions subject to which the patent privilege is granted are complied with. In this regard, the Indian Patents Act (Section 146) empowers the Controller to require a patentee or a licensee to furnish statements of how the invention has been commercially worked in India. It also requires the patentees and every licensee to furnish the prescribed statements regarding the invention. The Controller also has the right to publish the information received. This is the law. The law requires transparency and patentees and licensees should know that they are bound by this law. In this regard, requiring licensees to make a full disclosure of the patent working information through Form 27 would not be considered out of the norm. The liability for non-compliance with Form 27 must be strict civil liability.

India needs to appreciate that the World Trade Organisation (WTO) rules do not prohibit getting information on the local working. After all, TRIPS Article 27 does not apply to this situation. The Article 27 prohibition against discrimination based on whether the goods are locally manufactured or imported applies to the grant of a patent and not to grounds for issuing a compulsory license. Further, the WTO's jurisprudence in Canada Pharmaceuticals states that the word "discrimination" does not ban all forms of differentiation and that it refers to "results of the unjustified imposition of differentially disadvantageous treatment."

Countries like India signed up to the intellectual property bandwagon to maximise opportunities for technology transfer. Part of this exercise involves allowing local firms to compete and improve innovation, especially on life-saving pharmaceuticals. There is no wisdom in enacting patent laws that mainly enable foreign companies to import into a jurisdiction, without using it as a tool to foster scientific and technological progress at home. Thus, disclosures under Form 27 are required as part of a national strategy to improve innovation and further technology transfer into India, to maintain public health and to ensure supply of pharmaceuticals nationally.

The U.S. has set a precedent with its America First approach, leading to an imposition of 25% steel tariffs. Article XXI of the General Agreement on Tariffs and Trade that allowed the U.S. to impose the steel and aluminium tariffs to prevent importation will also justify India's position in requiring local working to ensure access to medication. In any case, the use of Section 301 of the U.S. Trade Act, 1974 to unilaterally impose trade pressures stands on shaky legal grounds. India has been subjected to this unwanted bullying regularly. The amendment of Form 27 presents a great opportunity for India to reiterate the limits and limitations of the unilateral approach, should the U.S. choose to take unilateral action.

Kaushik Sunder Rajan has rightly asserted that in a world in which the structure of monopolistic drug development is the norm, there are consequences for both health and democracy, since the initial rationale of patents as a purely instrumental monopoly in public interest is subverted and forgotten. The patent system is misconstrued as serving the patent owner. Similarly, there is wide misconception by trade lobbyists that trade obligations are subservient to sovereign rights. Neither of these propositions is correct. That is why the question raised in the petition filed by Professor Basheer is not to be lightly taken. It is not only about the right to health but also about the state's sovereign right to preserve public health and duty to fulfil a Constitutional mandate.

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