

# *Is the working requirement legitimate?*

**Ritushka Negi and Vineet Rohilla of Remfry & Sagar** look at the legitimacy of the working requirement in the context of the TRIPs Agreement, and whether importation constitutes working

**C**ompulsory licensing has been an integral part of the Indian patent regime since its inception. Its significance, however, was realised when the controller general recently issued the country's first compulsory licence for Bayer's oncology drug, Nexavar (sorafenib), to Natco Pharma, an Indian drug manufacturer. The controller found Nexavar eligible for compulsory licensing on all three grounds available under the Indian Patents Act, 1970 and held that: i) Bayer had made its drug available to only a small percentage (about 2%) of eligible patients, which did not meet the reasonable requirements of the public; ii) priced close to Rs280000 per month (\$5,700), the drug was not reasonably affordable, the term reasonably affordable being construed predominantly with reference to the purchasing power of the public; and iii) Bayer's patent was not being worked in India as Nexavar was not being manufactured in India. Significantly, the controller held that mere importation of sorafenib from manufacturing facilities outside India did not amount to working as envisaged under the Patents Act.



# COMPULSORY LICENSING



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The controller's decision to hold that import does not qualify as working is debatable since the Patents Act does not specifically prohibit importation. Before addressing the issue whether mere importation would or would not constitute working under Indian law, let us examine whether the working requirement is TRIPs compatible.

### Working requirement – what does TRIPs say?

Under article 27 (1) of the TRIPs Agreement, patents shall be available and patent rights enjoyed without any discrimination as to the place of invention, the field of technology and irrespective of whether products are imported or locally produced. Article 27 (1) appears to prohibit member countries from making any laws mandating a local working requirement. However, since article 27 (1) only postulates general protections for patentees' rights, it is imperative to delve into the specific exceptions provided under article 30 and 31 of the TRIPs Agreement. These need to be appreciated against the backdrop of articles 7 and 8, which set out the objectives and principles of the TRIPs Agreement.

Article 7 of TRIPs states that protection and enforcement of IP rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology. It further states that such technology transfer and dissemination should be for the mutual advantage of both producers and users of technological knowledge, in a manner conducive to social and economic welfare and a balance of rights and obligations. Essentially, the provision seeks to balance two sets of competing interests: the public interest of transfer and dissemination of technology to the benefit of society and the private interest of patent holders in maximising the exploitation of their inventions.

All three objectives that lie behind article 7 – technological innovation, transfer and dissemination of technology, and the production and use of technological knowledge – also form the rationale behind the local working requirement. This is because the actual working of a patented invention in a country may be viewed as the most efficient way of accomplishing a transfer of technology to that country.



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Article 8 of TRIPs lays out the public interest principle in the agreement. It allows member countries to adopt measures necessary to protect public health and nutrition, and to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Turning now to article 30 of the TRIPs Agreement, it deals with exceptions to the exclusive rights conferred by a patent. It states that such exceptions should not unreasonably conflict with normal exploitation of a patent and should not unreasonably prejudice the legitimate interests of a patent owner, whilst taking account of the legitimate interests of third parties. Listing the bases for unauthorised use of a patent without pre-negotiation with the patent holder, article 31 of the TRIPs Agreement allows laws of member states to supplement or amplify the conditions under which such unauthorised use is permissible. However, while this article qualifies the manner of unauthorised use of a patent in several ways, including prescrip-

tion of procedural and substantive conditions for grant of a compulsory licence, interestingly, it does not explicitly specify failure to work a patent as a ground for grant of compulsory licence. In fact, it is silent on the grounds on which such a licence may be granted.

It is essential to consider article 2 of the TRIPs Agreement at this juncture. This provision requires member states to comply with, amongst others, article 5 of the Paris Convention dealing with compulsory licences, which ties in with unauthorised use. Article 5(A)(2) of the Paris Convention states that each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licences to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work. The word abuse also comes up under article 8 of the TRIPs Agreement as it talks about the abuse of IP rights by right holders and the adoption of appropriate measures needed to prevent such abuse. The usage of word abuse in article 8 of TRIPs and article 5(A)(2) of the Paris Convention suggests that the "appropriate measures" referred to in article 8 should in-

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clude compulsory licensing consistent with article 31. And as mentioned earlier, article 31 does not list grounds for grant of compulsory licences – it merely seeks to regulate the conditions of use of such a licence.

Reading the above provisions together, it is implicit that member countries have the discretion to impose compulsory licensing on wide ranging grounds including the failure to work a patent. Therefore, working requirements would not contravene TRIPs especially in light of the inclusive reference to the Paris Convention in article 2. However, no one can infer from the TRIPs Agreement that import does not qualify as working.

### Local working requirement

The term working or local working is not defined under the Indian Patents statute. However, by a combined interpretation of various provisions of the Act, one can determine what constitutes working. Section 83(a) specifies that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale to the fullest extent that is reasonably practicable, without undue delay. Section 83(b) states that patents are not granted merely to enable the patentees or patent licensees to enjoy a monopoly for importation of the patented article. Further, section 83(c) stipulates that the grant of patent rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology. Clause (f) of section 83 goes on to state that patent rights should not be abused and the patentee should not resort to practices that unreasonably restrain trade or international transfer of technology.

Section 84 of the Act specifically pertains to compulsory licences and subsection (7)(e) provides that the reasonable requirement of the public is deemed to have not been satisfied if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation of the patented article.

While section 83 may be viewed as merely postulating a general guiding principle that is not enforceable by any court of law, section 84(7) deals with the circumstances under which reason-



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able requirements of the public are deemed to not have been met, which forms a separate ground for grant of a compulsory licence. Nevertheless, section 84 (7)(e) does not require a patentee to locally manufacture the patented article and does not even bar importation of patented article – however, if the importation of the patented article hinders the working of an invention, then the same may become a basis for reasonable requirements of the public not being met. The hindrance in working could be due to low availability of the product.

Section 90 sets out terms and conditions for the grant of compulsory licences. Barring exceptional circumstances covered by subclause (3), it states that “no licence granted by the controller shall authorise the licensee to import the patented article....made by a patented process from abroad where such importation would, but for such authorisation, constitute an infringement of the rights of the patentee”. The exclusion made for import of a patented article by a licensee has led many scholars (and even the controller while issuing compulsory li-

cence) to argue that if import does not amount to working for a compulsory licensee, it implies that import cannot amount to working even for a patentee. This argument appears to be bizarre, since a patentee and licensee cannot be put in the same bracket. The rights of a patentee are certainly on a higher pedestal than those of a compulsory licensee. No one will disagree that a compulsory li-

**The controller's decision to hold that import does not qualify as working is debatable**

### Protection and enforcement of IP rights should contribute to the promotion of technological innovation

cence confers only limited rights, which are for the advantage of the public, wherein the pricing of the product has to be kept reasonably affordable. Furthermore, as opposed to a patentee, the rights of such a licensee are non-assignable and the licence granted is non-exclusive.

Based on the foregoing discussion, it is evident that there is nothing in the Patents Act which requires the patentee to work the invention only by way of local manufacture and not by importation. The Patents Act requires every patentee or licensee to furnish periodical statements listing the extent to which the patented invention has been

commercially worked in India. Such a statement on Form 27 is required to be filed for every calendar year within three months of the end of such calendar year, that is, by March 31. The patentee is required to state whether or not the patent has been worked and if worked, the quantity and value of the patented product manufactured in India as well as imported from other countries must be declared in the form of turnover.

Such a requirement for furnishing details of importation into India under the caption If Worked in Form 27, clearly indicates that importation would fall within the ambit of working. Form 27 is a statutory form and cannot be considered divorced from the scheme of the statute. Thus, the proposition that mere importation would not satisfy the mandatory working requirement within the meaning of the Act appears to defy logic.

#### **The Apex Court will rule**

Bayer has filed an appeal against the grant of a compulsory licence to Natco before the appellate authority, and the matter is expected to reach the Apex Court. It will be interesting to see how the Court interprets the provisions of the Act and settle this important question, which will be significant for future strategies of multinational companies seeking protection of patent rights in India, especially in the pharmaceutical sector.



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