Erga Omnes

Blog of the Weeramantry Centre for Peace, Justice and International Law

#10/2021 | 24 May

www.weeracentre.org

Patent and the Pandemic: The Indian Story

*M R Shamshad**

*Mohammad Umar***

Backdrop

The US recently expressed a willingness to consider a waiver of intellectual property protection for COVID related vaccines. On the other hand, on 30.04.2020, after considering the existing legal position in India, the country's Supreme Court (SC) has recorded detailed advisory observations for the Union of India to follow. In the COVID related *suo moto* proceedings, the order appears to be advisory in nature but there cannot be a better occasion for the Central Government to read these observations of Public Importance as binding directions of the Court and invoke applicable provisions of Patents Act, 1970 in the larger public good.

World Intellectual Property Organisation defines a patent as 'an exclusive right granted for an invention' that in general 'provides a new way of doing something, or offers a new technical solution to a problem'. These exclusive rights pertain to using, making, selling or importing the invention; hence, giving almost a blanket monopoly to the owner of the invention to economically exploit the invention. The rationale of granting these rights stems from the need to incentivising creativity which, arguably, helps in accentuating R&D culture in the country. However, this hypothesis stands challenged when we look at statistics. A survey of 5.1 lakh patent applications filed in India between 2005 and 2018 shows that 76 percent of the total applications were filed by foreigners. Naturally, an overwhelming majority of the patent regime beneficiaries are foreigners, not the locals.

* Shamshad is Advocate on Record practicing at the Supreme Court of India. ✉mrshamshadoffice@gmail.com

**Umar is an Assistant Professor of Law at Bennett University, India and the Founder Advisor of Weera Centre. ✉mdumar2417@gmail.com

Patent Protection in India and Trickling Down of TRIPS

In India, patents are governed by the Patents Act of 1970 which authorises the Controller General with the power of processing the patent applications. As a member of the World Trade Organisation, India also became a party to the binding *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS) in 1995.

A look at the pre-WTO negotiations shows that India was never comfortable with being imposed upon a certain 'universal idea' of intellectual property protection. A V Ganesan, who was negotiating for India wrote in a paper that all developing countries, including India, thought an agreement like TRIPS 'would seriously intrude into their domestic policy space and constrain their freedom to pursue economic and social policies best suited to their individual needs'.

Ultimately, India gave in to the external pressures and was bullied into signing the TRIPS Agreement along with other developing countries. It was compelled to change domestic intellectual property laws, including the Patents Act, to bring them in conformity with the requirements of the TRIPS Agreement. The amendment in 2005, for instance, allowed for product patents in food and pharmaceuticals, which was hitherto prohibited under Section 5 of the Patents Act. It meant that henceforth generic pharmaceutical companies in India like CIPLA, Sun or NATCO would not be able to make cheaper versions of expensive foreign drugs. It was possible earlier because the generic companies had the liberty to choose alternative processes in order to create a generic version of an otherwise expensive medicinal product.

This development was a threat to the constitutionally guaranteed right to life and health of millions of Indians. The opportunity to have access to cheaper medicine was now radically reduced. Expressing anguish on these developments, famous Indian Supreme Court judge- late Justice Krishna Iyer had famously remarked- 'deleteriousness of TRIPS' cannot be allowed to truncate or trample upon the fundamental rights and aspects of social justice.

Way Forward

Despite the changes brought after signing the TRIPS Agreement, few provisions remain in the Patents Act allowing for the issuance of an involuntary license to the generic companies in certain conditions. This is technically called- compulsory license (CL). According to the scheme, Controller General of Patents or the Central Government can, by fixing a certain amount of royalty, force the patent owner, which is usually a big pharmaceutical company based outside India, to give a license to a generic Indian

company for making and selling cheaper versions of the medicine. Accordingly, under the present circumstances, the advice of the SC is that the Indian government should seriously consider invoking these liberties implicit in the Patents Act. Another option highlighted in the judgment is the usage of patents for governmental purposes. If the Central Government so wishes, Indian companies can begin manufacturing generic drugs while negotiating the royalties with the patentees. If parties fail to reach an agreement on royalty, the High Court has the authority to fix it on a reasonable basis. Another alternative available to the Central Government is the acquisition of patents under Section 102. Again, if the Central Government and the patentee are not able to reach a consensus on the price of the patents, it is up to the High Court to fix the compensation. Additionally, under Section 66 of the Patents Act, the Central Government is also entitled to revoke a patent in the public interest.

SC has asked the government to consider giving a CL for critical COVID medicines such as -Remdesivir, Tociluzumab and Favipiravir. In the past, CL was granted in the dispute between Bayer (German company) and NATCO (Indian company). The issue was regarding the extraordinary pricing of NEXAVAR- a cancer drug, the prescribed dosage of which cost around ₹2,80,000 per month. NATCO was awarded the CL as it demonstrated the capacity to come up with a generic version of the drug making it available at a price as low as ₹ 30,000 per month.

It is strange that despite strongly acknowledging the need for CL or government use license the court fell short of issuing orders to invoke Section 92 or Section 100 to enable manufacturing of COVID-related generic drugs. Constitutionally, it is all empowered to do so in the public interest. But the final call to use either of the two provisions was delegated to the Central Government only.

There could have been a direction to float a voluntary license for the indigenously developed COVAXIN since the Central Government is the owner of its patent. This would have helped disperse the manufacturing load on the present proprietors and would have brought down the price of vaccination. In a recent piece published by Forbes-India, Professor V K Unni of IIM Calcutta has argued:

> GoI [Government of India] should do everything possible to bring many more vaccine/pharma companies from India and abroad to manufacture the vaccine on the basis of technology transfer. Even in the case of Covishield, GoI can encourage AstraZeneca-Oxford/ Serum Institute to rope in more manufacturers on the basis of technology transfer/know-how.

But in the court's order, the 'advise' was mostly limited to procurement related matters only. Since the matter is pending; one may expect such direction in one of the future

hearings. In any case, it is not happening anytime soon as one of the judges in the case is infected by COVID and the case is now deferred till his recovery.

From the action and inaction of the government, it appears to be reluctant to use its powers under the Patents Act. The answer may be found in the pressures exerted by big pharma giants, but a part of it also finds genesis in the desperation of pandering to the corporate interests. Even if there was no active applicant for CL, nothing stopped the government from making a general declaration encouraging the submission of applications. Coincidentally, on 5 May itself, NATCO has approached the Central Government for CL so that it can make a generic version of Baricitinib, a European drug considered useful for COVID treatment. The per tablet cost of this sparsely available drug is currently ₹ 3,230. In the event of acceptance of the application, NATCO can deliver it at a meagre ₹ 30 per tablet.

This CL application is thus a litmus test for the government. It will be seen whether the present dispensation has the necessary gumption to navigate through international pressures. If recent pointers are to be believed, even those who are usually conservative in relaxing their monopoly rights, are expressing agreement to a softer approach in these distressing times. As mentioned in the beginning, after a week of holding discussions with Astrazeneca and Pfizer, the US administration has announced in principle support to the waiver of IPR for COVID vaccines. Read with the exhortation of the SC in the *suo moto* case, this news should further shed the inhibitions that the government might have regarding the scrutiny of its affirmative decision on CL.

Final Remarks

Given the joint submission at the WTO, it is time for India to walk the talk. In the face of agony and unprecedented misery, health cannot allowed to be held hostage to profit. Article 47 of the Indian Constitution makes improvement of public health a primary duty of the government. Section 92 of the Patents Act clearly provides for the issuance of CL in a national emergency or extreme urgency. Currently, the official figures put the number of COVID deaths closer to 4000 daily. The National Disaster Management Authority of India declared COVID a pandemic long back in March 2020 itself. Thousands are gasping for oxygen and struggling to get affordable medicines. Black marketing and hoarding of COVID drugs are at an all-time high. The health care system is crippled and overstretched like never before. If this is not a national emergency, what else is?

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