

October 12, 2023

# A 'Captured' Patent Office?

#### By: Prashant Reddy T

Three proposed amendments to the Patent Office Rules of 2003 reveal the power of business lobbying groups to bring about changes in India's rules. If implemented, they will significantly dilute rights of patient groups, impact patent quality and reduce transparency of the patent system.

The Department for Promotion of Industry and Internal Trade (DPIIT), under which the Patent Office functions, has published for consultation a set of proposed amendments to the Patent Rules, 2003. Two of the provisions slated to be amended have a direct impact on the quality of patents granted by the Patent Office. The third impacts the transparency of the patent system in India.

The more worrying aspect of this exercise is that all provisions have featured on the lobbying agenda of three powerful foreign advocacy groups representing some of the most powerful corporations in the world.

We know this because these advocacy groups have complained about exactly these provisions, in public comments addressed to the United States Trade Representative (USTR) which prepares the Special 301 report. This report which is mandated under American law and placed before the US Congress, requires the USTR to conduct a review of the intellectual property (IP) laws and enforcement policies of American trading partners in order to identify those laws or practices which maybe detrimental to American interests. The USTR Special 301 report is then used as the basis of American diplomacy to lobby other countries to change their laws and practices, sometimes at the threat of unilateral American trade sanctions, as experienced by India in the early 1990s during the negotiations leading up to the signing of the World Trade Organisation (WTO) Agreements.

#### Pre-grant opposition

The first proposal relates to amending the pre-grant opposition mechanism, which allows patent applications to be opposed before the Patent Office officially "grants" the patent. This provision has existed in different forms in Indian patent law since 1911,

In its comments to the USTR in 2022, the United States Chambers of Commerce had complained about the pre-grant opposition mechanism in Indian law. In its own words: "For many years, pre-grant oppositions from "any interested party" caused undue delays in the granting of patents in India. This has allowed parties with political, ideological, and other non-technical opposition to patent applications to unduly delay the process by raising a series of pre-grant challenges."From a policy perspective, pre-grant oppositions are excellent policy. This is because they allow competitors to the patent applicant, who are more likely to be more familiar with the invention sought to being patented, to contribute to the examination process by bringing forth the latest "prior art" to the attention of the Patent Office.

#### From a policy perspective, pre-grant oppositions are excellent policy.

Between 1911 and 2005, Indian patent law allowed any person to "oppose" a patent application within a three-months window, after the patent application had been examined and found fit to be granted but before the patent was "sealed." In 2004, as the deadline to comply with the WTO Agreement on Trade-Related Intellectual Property Rights (TRIPS) was drawing to a close, the United Progressive Alliance (UPA) government issued the Patent (Amendment) Ordinance, 2004 which deleted the existing pre-grant opposition mechanism. The new legal mechanism did not guarantee any person who filed a pre-grant opposition, a right to be heard by the Patent Controller.

This was surprising because this amendment was not required by TRIPS and the TRIPS deadline was the main reason for the ordinance to be promulgated. There is some speculation that an anonymous note delivered to the cabinet secretary by the Indian ambassador to the United States in 2004 influenced this decision.

However, since the ordinance would lapse, Parliament had to necessarily enact a law to amend the Patents Act. This time round, the CPI(M), which was providing support to the UPA, made pre-grant opposition a major issue during negotiations with the government on support for the bill in Parliament. The government agreed to make some concessions and the amendment brought about by the



ordinance was further amended to include this specific phrase in the provision dealing with pre-grant opposition: "the Controller shall, if requested by such person for being heard, hear him and dispose of such representation."

Pre-grant oppositions have been on the radar of advocacy groups like the US Chambers of Commerce, which have complained the process is resulting in delay of grant of patents because those with "ideological" and "political" objections are filing "serial" pre-grant oppositions.

Despite the express wording providing persons filing a pre-grant opposition a specific right to be heard, the Patent Office refused to play ball when patient groups started filing pre-grant oppositions against pharmaceutical patent applications.

In 2008, a patient group took up this issue to the Madras High Court in a case involving a patent application for an AIDS drug. The court ruled that it was mandatory for the Patent Office to give a hearing to every opponent who filed a pre-grant opposition, including patient groups. Since then, pre-grant oppositions have been on the radar of advocacy groups like the US Chambers of Commerce, which have complained the process is resulting in delay of grant of patents because those with "ideological" and "political" objections are filing "serial" pre-grant oppositions.

The amendment to the Patent Rules, under discussion, has responded to these complaints. If carried through, it will give the Patent Controller the power to decide the "maintainability" of any pre-grant opposition, that is, whether the opposition should even be heard by the Patent Controller.

The fear of patient groups is that the Patent Office will use this untrammelled power to reject their pre-grant oppositions and that the patent will be granted by the time they can seek redress from an appellate forum.

The "maintainability" requirement makes no sense in context of pre-grant oppositions where the law has deliberately not laid down any criteria on who can file it as long as it is filed before the patent application is granted. Legally speaking, a determination about "maintainability" makes sense only in those legal proceedings which limit the right to file legal claims to certain people or where the law imposes time limits on initiating legal action or where there are doubts about the jurisdiction of the forum.

Without the law specifying any specific criteria to determine maintainability, the Patent Controller will have complete unfettered discretion to decide whether to admit or reject a pre-grant opposition. The fear of patient groups is that the Patent Office will use this untrammelled power to reject their pre-grant oppositions and that the patent will be granted by the time they can seek redress from an appellate forum.

The more important question is whether this requirement will stand a legal challenge since Section 25(1) of the Patents Act is very clear that "the Controller shall, if requested by such person for being heard, hear him and dispose of such representation." The Patent Rules notified by the government cannot go against the language of the Patent Act enacted by Parliament. There is a high likelihood if challenged before court, the proposed amendment will be struck down as illegal because it undermines the right guaranteed in Section 25(1) by allowing the Patent Controller to refuse a hearing to some persons who do file pre-grant oppositions.

### Disclosure of actions by foreign patent offices

A second proposed amendment is aimed at diluting Section 8 of the Patents Act. This provision gives the Patent Controller the power to demand from the patent applicant copies of examination reports prepared by foreign patent offices examining corresponding patent applications for the same invention. The logic is that the Patent Controller can benefit from these foreign patent office reports while deciding upon the grant of the Indian patent application.

This provision has been in the sight of American advocacy groups like the Pharmaceutical Research & Manufacturers of America (PhRMA). In submissions to the USTR, the group had complained that Section 8 "creates heightened and unduly burdensome procedures that mainly impact foreign patent applicants" and that "much of the information sought is now publicly available on patent office websites in most major jurisdictions."

If powerful corporations with their armies of lawyers are finding this requirement "burdensome," how are over-burdened Patent Controllers going to have the time to access this information by themselves just because it is available on public databases?



The actual reason for the opposition to Section 8 is because patentees do not want to disclose adverse reports of foreign patent offices, which may lead to the Indian Patent Office rejecting their patent application. A failure to disclose these foreign reports can also lead to trouble for the patentee later during patent infringement proceedings. Indian courts have been known to deny injunctive relief on the grounds that the patentee failed to approach the court with clean hands.

The proposed amendment will require patent controllers to use publicly available databases to access information from foreign patent offices. This requires more time and effort by Patent Controllers in India.

In any event, the proposed amendment fulfils PhRMA's demand, by deleting the existing Rule 12(3) of the Patent Rules, 2003 that allows the Patent Controller to summon "information" relating to objections raised by foreign patent offices, in respect of novelty and patentability of the invention" and also "any other particulars" including "claims of application". This provision was generally interpreted by the Patent Office to summon examination reports prepared by specific patent offices in relation to the same invention.

The proposed amendment will require patent controllers to use publicly available databases to access information from foreign patent offices. This requires more time and effort by Patent Controllers in India. As per this proposed amendment, Patent Controllers can now summon only a "fresh statement and undertaking in Form 3." This information is largely inconsequential since it involves only the identifying details of the foreign patent application filed in foreign patent offices such as the application number, status, date of filing etc. This is very different from the existing rule which allowed the Patent Controller to summon entire examination reports of foreign Patent Offices.

This proposed amendment will be tough to challenge in court because the Patents Act delegates to the government the power to determine, via the rules, the kind of information that can be summoned by the Patent Controller pursuant to Section 8(2) of the Patents Act.

#### Reporting requirements on earning per patent

A third proposed amendment, is aimed at a requirement in Section 146 of the Patents Act that requires patentees to disclose their earnings from the sale of the patented invention.

This commercial information is invaluable to the Patent Controller in compulsory licencing proceedings. It helps to assess whether the legal threshold for the grant of compulsory licences has been met. Courts can use this information to calculate damages in patent infringement cases. For academics, this information helps understand the workings of the patent system and its impact on the economy.

American advocacy groups have for long been lobbying against this provision. In its submission to the USTR, the Intellectual Property Owners Association (IPOA) had this to say about Form 27 which implements Section 146:

Form 27 is also extremely burdensome, including requests concerning the value of the products worked and the licenses or sub-licenses that are granted for a given patent. Not only might this be difficult to provide such information, but it also forces patent holders and their licensees to potentially provide confidential business information to the government and public.

That the requirement to disclose this information annually is burdensome is quite simply not true. Most patentees will have this information readily because they need to inform their management and investors of earnings from each patent. Similarly on the point of disclosing confidential information, listed companies are anyway required to collect this information by securities regulators like the US Securities & Exchange Commission (SEC). (For example, see page 216 of this filing by Novartis with the SEC listing earnings by brand name of drugs.)

If the American SEC can force these companies to make such financial disclosures, India is well within its right to demand similar disclosures of information in exchange for granting monopoly rights under its patent law.

The proposed amendment concedes to the lobbying on Form 27 by proposing to amend the existing rule to require this information to be provided to the government only once in three years. While this rule change is not illegal since the Patents Act delegates the power to determine the filing schedule to the government, the amendment will make it tougher to collect information in order to demonstrate to the Patent Office that the patentee is selling the inventions at too high a price or that it is unable to meet the public requirements in



India.

This in turn will impede the filing of applications for compulsory licences. Similarly, academics will be impeded in understanding the impact of the Indian patent system on the Indian economy.

## A captured patent office

While the government must be receptive to business concerns, even if those concerns are raised by foreign businesses in India, one would expect the Indian bureaucracy to draw the line at safeguards meant to protect Indian public interest. The extent to which these proposed amendments respond to the specific concerns of American advocacy groups despite these amendments being against Indian public interest, should give us serious cause to worry.

This episode possibly signals that India's patent office is now firmly captured by special interest groups.

Prashant Reddy T is co-author of Create, Copy, Disrupt: India's Intellectual Property Dilemma (Oxford University Press: 2017).