# Non-working of a patent cannot have a bearing on the rights of a patentee, says the Delhi High Court

Shrinkhala Jaiswal
Research Fellow, CIIPC · 12 June 2019

Recently, in an order passed by the Delhi High Court, Dr Reddy Laboratories (defendant) was injuncted from infringing patent No. 215528, owned by Arena Pharmaceuticals (plaintiff no. 2) and EISAI CO. LTD. (plaintiff no. 1) on *Lorcaserin* or any of its pharmaceutically acceptable salts including *Lorcaserin Hydrochloride* (hereinafter referred to as LH) and *Lorcaserin Hydrochloride Hemihydrate* (hereinafter referred to as LHH), a man-made molecule, used in treatment of obesity, sold by EISAI under the brand name BELVIQ.

Plaintiff no. 1 is the patentee and plaintiff no. 2 is the exclusive licensee of the patent in India. The plaintiffs have patent protection over Lorcaserin in 65 jurisdictions, none of which has been revoked. They have received marketing approval in 6 jurisdictions. In India, the plaintiffs applied for patent protection on 23rd September, 2004 in pursuance to which patent No.215528 was granted on 27th February, 2008 for the period of 20 years i.e. till 10th April, 2023. The application for attaining marketing approval in the India is pending before the regulatory authority. The Defendants were also planning to commercialize Lorcaserin in the Indian market and consequently applied for regulatory approval. The same was granted to the defendant by the regulatory body and hence the plaintiff filed this suit against the defendant. It is interesting to note that none of the parties have a product being supplied to the Indian market.

Plaintiffs have claimed that the defendant's product LHH infringes the plaintiffs patent as *Lorcaserin* forms the major portion of LH and LHH, which cannot be made without using *Lorcaserin.* Plaintiffs also relied on admissions made by the defendants on three occasions wherein the defendants have stated that their drug covers plaintiffs patent. The main arguments of the defendants were with respect to the non-working of the patent, LH and LHH not being within the scope of the plaintiff's patent and their admission of the same before the IPO and EPO and validity of the patent under section 3(d) of the patents Act, 1970. The defendants also invoked the public interest argument with respect to the non-working and unavailability of the patented drug to the public.

The Court after examining the arguments of both the parties, ruled in favour of grant of an injunction as the plaintiffs were able to establish that a prima facie case existed, balance of convenience lay in favour of the plaintiffs and that irreparable harm would incur if injunction was denied. The court agreed to the fact that plaintiffs' patent covers Lorcaserin and its pharmaceutically acceptable salts, including LHH. Moreover, the court also held that merely applying for a patent separately (as was the case with plaintiff) for a specific *species* of the genus would neither disentitle patent protection to the *species* patent nor exclude it from the coverage of the genus patent (i.e. the suit patent in the present case). While dealing with the contention of the non-working of the patent by the plaintiffs in India, the court opined that the defendants instead of acting on their own volition and securing marketing approval from the concerned

authorities, should have sought for the remedy available to them under section 83 and 84 of the Patents Act, 1970 for non-working of patents. The court relying on the division bench's judgment in *Cipla vs Novartis,* 017 (70) PTC 80 [DB], held that *"non-working of a patent particularly for a pharmaceutical product cannot have a bearing on the rights of a patentee under Section 48 of the Patents Act, 1970."*

The balance of convenience also lay in the favour of the plaintiffs as the defendants, even though being aware of a possible challenge to their product, went ahead with obtaining the marketing approval without either attempting to seek license for the patent or instituting revocation proceedings before the court. The Judge held that the defendants could have avoided these injunction proceedings if they had '*cleared the way*' before obtaining marketing approval. Lastly, the court was also convinced that the plaintiff would suffer irreparable harm if the injunction was not granted since the Defendants have not yet introduced the product in the market and if the same is allowed, pending trial, then the harm that the plaintiff would suffer cannot be compensated monetarily.

After the decision in e*bay vs MercExchange,* and the debate surrounding Non-Practicing Entities (NPEs) and whether they are entitled to injunctive relief, this decision hopefully establishes the view of the Indian Courts while dealing with cases where patentees are not practicing their patents. It has been observed that in infringement cases where non-working has been alleged by the defendants, Indian Courts have mostly considered this as a factor to deny injunctions*, The most recent one being *Bayer Intellectual Property Gmbh vs. Ajanta Pharma Ltd.*,(2016) wherein the court denied injunctive relief to the plaintiffs on the ground of non-use of the patent. Though the court accepted the argument of the plaintiffs that non-working cannot be used as a defence in a suit for infringement, but went ahead and considered the non-user principle as a ground under public interest and equity. However, as stated by the Court in *Cipla vs. Novartis and reiterated in this current single bench order,* non-working of a patent is a ground for grant of Compulsory License and not a factor to be considered while the patentee is asserting the rights granted to it under the Act. This decision is also unusual in the sense that even though the defendants have raised the argument of public interest with respect to non-working and unavailability of the patent to the public, the court has not addressed this particular issue in its findings. Unusual because Indian courts have mostly considered the non-working argument under the balance of convenience or the public interest factor while denying injunctions*.

This matter has now been listed before the regular bench on July 4, 2019.

* Based on the preliminary findings of an empirical study (ongoing) conducted by the author at the Centre for Innovation, Intellectual Property and Competition on its project on Practicing Patents in India.

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**Cite as (OSCOLA, 5th ed.):** Shrinkhala Jaiswal, 'Non-working of a patent cannot have a bearing on the rights of a patentee, says the Delhi High Court' (*The Innovation Brief*, 12 June 2019) <https://innovationbrief.nludelhi.ac.in/essays/non-working-of-a-patent-cannot-have-a-bearing-on-the-rights-of-a> accessed 18 November 2026.

The author is grateful to Mr. Yogesh Pai, Co-director, CIIPC, for his valuable comments. The author would also like to thank Mr. Karan Trehan, Student Fellow, CIIPC.

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Published by the Centre for Innovation, Intellectual Property and Competition, National Law University Delhi. Read online at https://innovationbrief.nludelhi.ac.in/essays/non-working-of-a-patent-cannot-have-a-bearing-on-the-rights-of-a.