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Patents/Foreign Offices

India Revokes Boehringer Lung Drug Patent On Opposition From Generic Maker Cipla

India's activist generic drug-maker Cipla Ltd. scored a victory in its ongoing opposition to patents on respiratory drugs when the Indian Patent Office March 4 revoked a patent held by German drug-maker Boehringer Ingelheim on its respiratory drug Spiriva.

Cipla had filed a post-grant opposition in 2013 against a patent involving the drug Spririva—an invention entitled ''crystalline tiotropium bromide monohydrate and process thereof'' in the patent application—and the assistant controller of patents and designs agreed with Cipla's contentions that the particular compound lacked an ''inventive step,'' the invention was ''obvious to a person skilled in the art'' and that the application had failed to provide data to prove that the invention resulted in ''enhanced therapeutic efficacy'' over existing drugs.

Spiriva is used in the treatment of chronic obstructive pulmonary disease.

Move to Respiratory Drugs. This is good news for Cipla, which had earlier this year suffered a setback when the Delhi High Court had issued an injunction against the company in a case involving another respiratory drug, Novartis AG's Indacaterol.

A single-judge bench had refused to accept Cipla's allegations that Novartis' inadequate working of the patent in India was thwarting overwhelming public need, and had asked Cipla to seek a compulsory license and stop selling copies of the drug in the meantime.

Cipla, India's fourth-largest drug-maker by sales, has a substantial HIV, cancer and respiratory drugs portfolio. It has been among the most prominent Indian generic drug-makers to challenge big multinational drug firms' patents, and has revolutionized HIV/AIDS treatment for poor patients in developing countries.

Company executives have spoken in the past about focusing more on its respiratory drugs business as margins on HIV drugs have been squeezed due to greater competition. At the same time, Cipla has stepped up patent challenges to respiratory drugs.

Leena Menghaney, access campaign director at the medical charity Medecins Sans Frontieres, told Bloomberg BNA that Cipla is seeking to do for respiratory drugs what it has done for HIV drugs. She said patent challenges anywhere in the world lead to greater scrutiny and increase chances of rejection or revocation, and hence recent revocations in India should not be seen as an anomaly.

However, in some instances of rejection or revocation, courts and tribunals have stepped in to order a re-examination or reconsideration of the decision, raising questions over the quality of patent examination in India (89 PTCJ 887, 2/6/15).

'Enhance Therapeutic Efficacy.' Most intellectual property rights experts and lawyers agree that the Patent Office needs more and better examiners, and the Patent Office is currently working on a plan to bring on more examiners as well as improve its overall infrastructure to speed up processing of applications and ensure quality examination.

Shukadev Khuraijam, Partner Designate at Remfry & Sagar, told Bloomberg BNA via e-mail March 11 that in pharmaceuticals cases, there have been a lot of refusals/revocations due to Section 3(d) of the Indian Patent Act—which mandates ''enhanced therapeutic efficacy'' as a prerequisite for grant of patent to a new form of an existing drug—and lack of clarity in the law. He said however that there has been a lack of consistency and uniformity in the applicability and interpretation of the law.

''Indian patent jurisprudence has certainly come a long way in the last 10 years,'' he said. ''The challenge is for applicants, practitioners, the Patent Office and the Courts alike to take this forward in a positive direction.''

Burden on Patent Office, Increased Litigation. Menghaney of Medecins Sans Frontieres said there is an ''abusive element'' in the way some companies file too many and frivolous application and overburden the Patent Office.

IP lawyers say, given the increasing number of patent applications filed by both Indian and foreign applicants, patent litigation will go up as well and the Patent Office must improve its processes.

J. Sai Deepak, Advocate at the Supreme Court of India and founder of IP blog ''The Demanding Mistress'', told Bloomberg BNA via e-mail March 11 that pre-grant oppositions have really proven their worth in the last few years, but the mechanism as it stands today is open to abuse that results in delays in patent grant.

''If this interstice could be addressed, it would help strengthen this vital mechanism's ability to weed out

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'bad patent applications' apart from reducing the delay caused to patent grant by disingenuous pre-grant oppositions,'' he said.

He said the upshot of increased IP litigation will be evolution of jurisprudence—as more and more patent applicants and patentees escalate matters to courts, the courts will have opportunities to lay down the law and interpret it.

Already, experts point out, case law has led to greater clarity in terms of interpretation of Section 3(d) and Section 8—which deals with supplying information to the Indian Patent Office on foreign patent applications and related proceedings.

Intellectual property attorney Ranjan Narula told Bloomberg BNA via e-mail March 12: ''Now this being settled law is being applied as such by the patent office, multinationals' PR machinery are of course perturbed and continue to drum the issue and equate this as an attempt to help generic industry. The law is evolving and until we see another case reaching the court where more elaborate guidelines on 'enhanced efficacy' are laid out both sides will hold their position.''

BY MADHUR SINGH

Full text of the order at http://pub.bna.com/ptcj/SpirivaOrder3415.pdf.

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