Ex parte order to Bristol-Myers setback to Indian drug industry?

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Legal experts, health care activists question decision against Hetero; claim move violates Drugs and Cosmetics Act

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Mumbai / Delhi: A recent order by the Delhi high court in favour of US drug maker Bristol-Myers Squibb Co. (BMS) will effectively link India's drug regulatory process with its patent regime, throwing the country's huge and profitable generics or off-patent drugs industry into a tizzy.

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Legal experts and health care activists have raised questions on the so-called ex parte injunction—a court order that will remain in place until the actual hearing, in this case in March—that the court issued against Hyderabad-based generic drugs maker Hetero Drugs Ltd.

Apart from the wisdom of linking the process of granting regulatory approval to a drug with the status of its patent, the experts and activists claim the court's decision goes against India's Drugs and Cosmetics Act, which doesn't say marketing approval should be withheld because some other company holds a patent.

Although the US and a few other countries such as Chile and Singapore link regulatory approvals to the status of the patent, this isn't mandated by the World Trade Organization (WTO). This so-called TRIPS-plus (TRIPS stands for trade related intellectual property rights and is part of the WTO process) provision isn't recognized by any European country and experts say that even in the US, the capability of the drug regulatory authority to evaluate the validity of patents is suspect.

The injunction seeks to prevent Hetero from pursuing its last year's application with the drug controller general of India (DCGI), the country's drug regulator, for approval of a generic version of BMS' cancer drug Dasatinib. BMS has been selling the drug in India under patent protection since 2006 under the name Sprycel.

The court order, which has been reviewed by *Mint*, restrains the generics company from "manufacturing, selling, distributing advertising, exporting, offering for sale or in any manner dealing directly or indirectly in any product infringing the plaintiff's (Bristol Myers) patent…"

"It is expected that the DCGI, while performing statutory functions, will not allow any party to infringe any laws and if the drug for which approval has been sought by the defendants is in breach of the patent of the plaintiffs, the approval ought not be granted to the defendants," the injunction adds.

This so-called patent linkage necessarily means that DCGI, who is responsible for approving drugs in India after ensuring their safety and quality, will also have to look at the patent status of the drug before granting permission for marketing.

This, experts said, could potentially halt the approval process for generic drugs in cases where the original has a patent in India. The denial of approval could also potentially last through the entire life of the patent, which could be at least a decade in some cases.

Shamnad Basheer, a professor in IP Law at the National University of Juridical Sciences, Kolkata, said the drug application process is distinct from the patent process. “Given the Indian context, where the DCGI lacks any patent expertise and is understaffed and crunched for resources, the two should continue to remain separate. Presently, neither the court nor the drug controller has any authority to mandate drug patent linkage.”

Legal experts also pointed out that there are no grounds for the injunction as there is no patent infringement applicable yet.

“The stay order looks like an anticipatory bail, as the alleged patent infringement by Hetero is only expected and (has) not yet occurred,” said Lakshmi Kumaran V., a senior patent lawyer and partner at New Delhi-based law firm Lakshmi Kumaran and Sridharan. “Since one does not know whether Hetero’s actual plan is to launch the drug, muscling into an approval process looks strange.”

An 8 January *Mint* story quotes a Hetero executive as saying that the company is considering the next step ahead of a court hearing in March. He declined further details because the matter is before the court. This executive wasn’t identified because he isn’t authorized to speak to the media. The same story quoted Brian Henry, a top executive handling corporate communications at BMS as saying he could speak to *Mint* only after looking at specific information on the development.

The response of the pharmaceutical industry highlights the divide between Indian companies and multinationals.

Dilip G. Shah, secretary general of Indian Pharmaceutical Alliance (IPA), said there was no cause of action for the court even to hear the matter, because no infringing act had occurred. IPA represents top Indian drug makers such as Ranbaxy Laboratories Ltd, Dr Reddy’s Laboratories Ltd and Sun Pharmaceutical Industries Ltd.

However, the Organisation of Pharmaceutical Producers of India (OPPI), an industry lobby representing foreign drug makers in the country, argued that patent linkage is, in fact, critical to the law.

Tapan Ray, director general of OPPI, said: “The broad issue is how can the same government, which is granting a patent to the innovator, give marketing approval of a generic equivalent of the same patented molecule, paving the way for blatant patent infringement?”

The division within government of patent-related issues and marketing approval for a drug is irrelevant to the inventor, he said, adding that it is the government's responsibility to protect the patent. IPA's Shah, however, pointed out that the order, though not a directive to the drug regulator, ignores the Drugs and Cosmetics Act, which doesn't require DCGI to deny approval because of an existing patent.

A final court order along the same lines as the injunction could impact patients directly, potentially cutting off access to cheaper generic versions.

"Patented drugs are usually unaffordable, and in such cases the only option is compulsory licensing. If the DCGI cannot register generics until the patent expires, generic manufacturers will not be interested in seeking compulsory licences to produce affordable versions of essential medicines," said Leena Menghaney, the India project manager for the Campaign for Access to Essential Medicines from Medecins Sans Frontieres.

Sprycel currently costs about Rs18 lakh for an year's supply, a BMS executive told *Mint* on condition of anonymity. The company is also not engaged in any patient assistance programmes in India; under this, currently only in the US, the company provides free drugs on a temporary basis to patients who can't afford them.

Amar Lulla, managing director of Cipla Ltd, India's top generic drug company, said such an injunction would discourage domestic drug makers. "Importantly, there is no legal ground for such an ex parte injunction that effectively discourages generic industry from being prepared for developing cheaper alternatives for the poor," he said.

OPPI's Ray, though, took the opposite view, arguing such an order would actually incentivize domestic drug makers, since there will be protections in place when they launch their own patented drugs.

Sandeep Gupta, chairman and managing director, Eli Lilly India Ltd, the Indian arm of US biotech giant Eli Lilly and Co., also spoke of the need for patent linkage, saying not doing so provided a "backdoor entry" for generics. "On the broader issue of patent linkage, Lilly's stance has been consistent that it is critical to have this link if India has to honour its WTO commitments in letter and spirit," he said.

But Gopakumar Nair, an industry expert and a patent consultant, said the injunction seems to have been granted without the court being completely briefed about provisions for data exclusivity in India, which are currently non-existent. "Since it has only suggested the drug control department not to violate any law, it may not force the DCGI to stop the approval process."

Meanwhile, another controversial ex parte order of December by the Delhi high court, unlike in the Hetero case, had directly asked DCGI to reject a generic drug application filed a few months ago by Cipla. Cipla has sought the revocation of that decision, as reported in the *Economic Times* on Monday.

Cipla had sought approval for a generic version of German multinational Bayer AG's cancer drug Nexavar. Bayer holds a 2007 patent for this drug in India. The court order was on a writ petition filed by Bayer claiming patent violation. DCGI, as the first accused in the writ petition where Cipla is also a party, will be replying to the court in due course, and the case will come up for hearing on 19 January.

According to a lawyer, who asked not to be identified, since Bayer's move was premature and the charges in the writ petition had not yet occurred, the court may take an appropriate decision by hearing both the parties.

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