

IP RIGHTS

More pharma firms trying to settle patent rows via talks

Move could give both generics makers and multinational firms respite from prolonged judicial process

By C.H. UNNIKRISHNAN
ch.unni@livemint.com

MUMBAI

Indian generics or copycat drug makers and multinational pharma companies are increasingly resorting to mediation to resolve patent fights.

The move could give both sides some respite from the prolonged judicial process involved in patent litigation. It could also make drugs costlier in countries such as India.

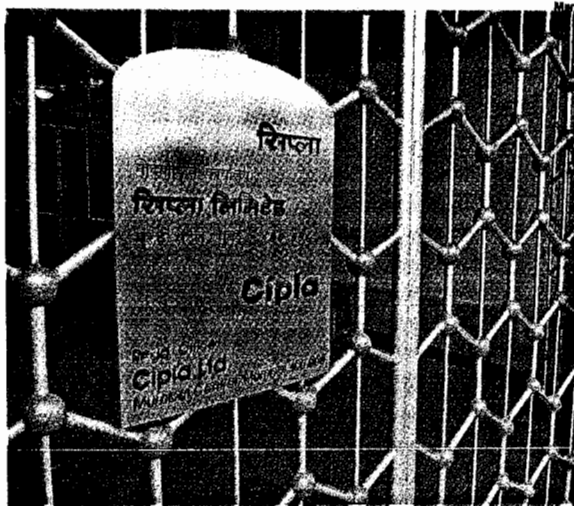
In April, Swiss drugmaker F. Hoffmann-La Roche Ltd and Cipla Ltd, a company that has emerged the global flag-bearer for generics manufacturers, sat down to mediate. The issue: the Tarceva patent infringement case that dates back to 2008.

In July, Merck & Co and Glenmark Pharmaceuticals Ltd decided to mediate their differences over their diabetes drug Sitagliptin.

And German firm Bayer AG may also end its two-year-long legal battle challenging India's decision to issue a compulsory licence on its kidney cancer drug Nexavar by mediating with the copy makers including licensee Natco Pharma Ltd for certain mutually agreeable terms, said two people familiar with the development who asked not to be identified.

However, in response to a Mint query, a Bayer India spokesperson, said the company will continue to defend its intellectual property rights and challenge the Bombay High Court's dismissal of the company's appeal of the Intellectual Property Appellate Board decision to allow Natco to sell a generic copy of Nexavar.

Patent mediation is new to India, which has witnessed



Mediation strategy: Cipla and F. Hoffmann-La Roche are in talks to settle the Tarceva patent infringement case that dates back to 2008.

hundreds of intellectual property rights (IPR) litigations in the pharmaceutical sector in the last nine years after it re-introduced product patent regime for drugs in 2005.

The patent mediation between Roche and Cipla over the lung cancer drug Tarceva came as a surprise: the firms had fought the case for the past six years and the Delhi High Court had already completed hearing the matter. Roche had filed the patent infringement case in 2008 when Cipla launched a copy version of its drug in India.

Talks are on—the outcome could set a precedent for similar patent infringement cases.

Roche did not respond to a query on the current status of the mediation. A Cipla spokesperson said the company had no comment to make.

Merck Sharp & Dohme Corp. (MSD), the international arm

of US drugmaker Merck and Co., and Glenmark agreed before the court, in July, to mediate and settle the patent infringement case filed by the former against the latter for launching generic copies of two diabetic drugs, Januvia and Janumet in the Indian market in 2013.

An MSD India spokesperson said: "We believe that our patents for Januvia and Janumet are valid and enforceable and we will continue to explore all options to defend them. We would also like to clarify that both parties have jointly decided to refer the matter for mediation."

Glenmark did not respond to a query on the status and the terms of the talks. The firms have to come up with a settlement by 25 September.

The move towards mediation is only to be expected, said a patent expert.

"Given that a number of

MNCs and domestic companies are now collaborating on a variety of fronts, it is expected that the number of pharma litigations and adversarial proceedings would anyway come down," said Shamnad Basheer, former IPR chair at National University of Juridical Sciences, Kolkata.

The mediation could be mutually beneficial, for Big Pharma and local companies, said a pharma industry consultant, who declined to be named.

"These settlement talks, which have been a trend in developed markets for sometime, are often on mutually agreeable commercial terms between the companies."

Some of the give-and-take terms could include royalties, maintaining product prices at mutually agreeable levels, protecting certain crucial markets without competition and terms that will allow entry of other products with mutual consensus, he added.

But patients could end up on the losing side, Basheer said.

"We all expect our generic majors to defend the public health turf and weed out undeserving pharma patents. If the generic majors are going to settle these privately, it presents a worrying trend. And the onus to challenge such undeserving patents falls on civil society and all of us," he said.

It isn't that Big Pharma has completely eschewed the legal option.

Some of the large MNCs now seem to have discovered it is easy to get Indian courts to give ex-parte (literally, one-sided) injunctions even while the case is being heard.

Merck, for instance, has secured ex-parte injunction from the Delhi High Court stopping eight other local drugmakers from launching its diabetic drugs.

Novartis, too, has stopped at least six Indian firms from launching copies of its anti-diabetic drug Galvus.

A spokesperson for Novartis declined to comment.

If patent disputes are settled privately, patients could end up on the losing side, according to experts

Patent