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Pharma is getting away with lots of patent ‘evergreening’ in India

By Ed Silverman @Pharmalot

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After a controversial court case five years ago in India, drug makers were put on notice that additional patents on medicines would have to demonstrate a degree of innovation. But a new analysis finds the vast majority of so-called secondary patents were granted for only marginal improvements, raising questions about the extent to which companies are adding value to their drugs.

Specifically, 72 percent of granted patents were found to offer little improvement and the findings suggest the Indian Patent Office is failing to guard against evergreening, a strategy for extending the market exclusivity of a prescription drug in order to delay the entry of generic versions, according to the analysis[1] by Accessibsa: Innovation & Access to Medicines in India, Brazil & South Africa.

Moreover, various types of secondary patents were deemed to violate distinct statutory exceptions to India law. Most of the questionable patents involved formulations: 78 percent, to be exact. And only 15 percent of the secondary patents that were granted were properly scrutinized and cited in final written orders, as required.

In reaching its conclusion, IBSA reviewed 2,293 patents that were granted between 2009 and 2016, and then analyzed the 249 secondary patents that were granted and subject to detailed scrutiny under Indian patent law. The nonprofit is funded by the Shuttleworth Foundation, which underwrites projects that seek social change.

Drug makers have long argued that patent modifications reflect substantive enhancements for methods of producing or manufacturing drugs, or developing new formulations or dosages. But the practice has prompted complaints that companies often make minor changes in order to thwart generic competition, which raises costs for governments and consumers.

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The issue gained notoriety in 2013 when the Indian Supreme Court rejected a bid by Novartis (NVS[4]) to obtain additional patents on its best-selling Gleevec cancer medicine. In a controversial move, the court ruled the additional patents were an example of evergreening, rather than genuine innovation that warranted extending patent protection.

Of course, the case pertained only to patents in India, but to patient advocates it became symbolic of a larger fight over the use of secondary patents to unfairly extend monopolies.

Even payers are joining the fray. Last month, a Dutch health insurer took the unusual move of filing a lawsuit[5] accusing AstraZeneca (AZN[6]) of creating an unfair monopoly for its Seroquel antipsychotic with a series of unwarranted patents that raised the cost of the medicine. The insurer, Menzis, claims more than $4.7 million in damages for having been forced to pay more for the drug instead of generics.

In the U.S., a study[9] published last year found that this approach to patents may be pervasive: At least 74 percent of medicines associated with new patents were already on the market. And of roughly 100 best-selling drugs, almost 80 percent extended patent protection at least once, with almost 50 percent winning added protection more than once.

One noted example involves Humira, the best-selling rheumatoid arthritis treatment. AbbVie (ABBV[10]) has allegedly used a so-called patent thicket[11], which includes dozens of secondary patents, to thwart biosimilar competition. Recently, the company settled patent litigation with several rivals, which will permit them to sell their versions in the U.S. in 2023.

Getting back to the IBSA analysis, the nonprofit identified 50 cases involving the requisite detailed scrutiny in which drug makers could have demonstrated improved therapeutic efficacy and other improvements to overcome objections. But IBSA found that no patent applicant submitted relevant clinical data to demonstrate therapeutic efficacy and, in fact, often bypassed stringent requirements.

The nonprofit recommended updating guidelines for examining pharmaceutical patents, providing patent examiners with a checklist of patents that might constitute evergreening, and amending the Indian patent law in order to exclude certain patents that might otherwise win approval.

About the Author

Ed Silverman[12]

Pharmalot Columnist, Senior Writer

Ed covers the pharmaceutical industry.

ed.silverman@statnews.com[13]
@Pharmalot[14]

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