Pharma

When Approaching The Patent Cliff, Must Companies Jump?

mypharma November 29, 2016

Some industry watchers call it the "patent cliff," while others call it LOE – "loss of exclusivity" – but regardless of its name, the expiration of patents and resultant appearance of generic drugs means a near-certain loss of income for drug makers. Patent expiration has hit in big waves starting in 2014 and is expected to accelerate in 2017 and continue through 2020.

Earlier in November, Valeant announced that their 2017 financials would drop due to loss of exclusivity. Branded drugs, which make up nearly half of the company's revenue, fell by 23% year-over-year. "Management expects 2017 to be even worse," reported one analyst.

Bristol-Myers Squibbs is reporting similar results. Revenues of Ability, an antipsychotic agent, fell 37% in the third quarter of 2016 after a loss of exclusivity. "Abilify is a high-profit product, so lower Ability sales had a negative impact on gross margin for 3Q16," reported another market watcher. Another stated that losses in the next 12-18 months could total $800 million.

With patent cliffs looming, do pharmas have an option other than jumping off?

Yes, say advisors, there are good options out there, and they apply to not only pharmas but to any company on the verge of losing patent exclusivity.

The first option may be a good old fire sale, says the Houston Chronicle: "If a company intends to continue producing a patented product that is about to pass into the public domain, it will probably have to reduce the price." That strategy could be paired with a preceding decrease in production so it's not left storing a product it can't sell as much of.

The flip side to that, however, is marketing. After all, if patients have come to know and love a drug by name, they might be willing to pay more for it, just as some shoppers pay more for premium brand tomato soup even if the store brand is next to it on the shelf. There is a certain amount of "brand equity" that companies can tap into.

"Sunsetting" the brand might be a consideration – here, the manufacturer would keep making the drug but suspect marketing and sales investments.

Researchers from the Sungkyunkwan University in Korea reported this year that there were legal options to protecting patents – pharma companies could pursue supplemental protection certificates (offered by the EU for a max of 5 years), apply for drug orphan status (7-10 years), create patent clusters (up to 20 years), seek pediatric exclusivity, or pursue patent settlement agreements with generic manufacturers to delay market entry.

"The most promising, but the most difficult strategy to implement, is the introduction of a follow-on product, which is either therapeutically or technologically innovative and permits better patient outcomes," the Korean authors wrote. "The underlying rationale behind this strategy is to transfer the brand reputation as well as the patient base to the follow-on product in order to make up for the losses of sales."

Then again, pharma companies could use an if-you-can't-beat-them strategy and simply launch their own generic – either in the form of a branded generic, an authorized generic, or a licensed generic. A similar route might be to create an over-the-counter formula – the downside is the cost of added trials and regulatory approval, though the upside is that it can expose the manufacturer to a broader audience and eliminate the headache of the reimbursement process.

Which strategy to take? Researchers from Rutgers studied three options (authorized generic, reformulation/combination, and pediatric exclusivity) and said their effectiveness was fairly similar. "Each strategy appeared to be similarly effective in mitigating revenue loss from patent expiration (average decrease in revenue of 29%) versus the potential decrease in revenue resulting from generic competition," the authors wrote.

Regardless of the choice, planning well in advance of expiration is critical, stressed researchers from the India Institute of Medical Sciences: "As patent expiries loom and product pipelines continue to remain thin, proactive planning for generic entry will be critical for pharma companies to drive growth and earnings in a sustainable manner."

"Planning should commence two years prior to the anticipated LOE date," reports Pharmaceutical Executive, which explained that LOE isn't something that just happens – it is a milestone everyone knows is coming and when.

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Tagged loss of exclusivity, patent cliff, trends in current licensing

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