

## Generic drugs taking hold in the Asian marketplace

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Aging populations and rising healthcare costs across Asia — particularly in Japan — have created new market opportunities for generic drug makers operating in the region. For originator drug manufacturers, that means increased competitive pressures, and a new urgency to protect patents. Dr. Frederick Ch'en, an IP partner in Hogan Lovells' Tokyo office, explains the political and demographic changes fueling changes in Japan and throughout Asia, and the practical impact on pharmaceutical companies doing business in the region.

**Q: Broadly speaking, why are we seeing a trend towards generic drugs in Asia?**

"The Japanese pharmaceutical market is the world's second-largest (after the United States). Healthcare costs in the region have been spiraling, and the Japanese government has been encouraging the use of generic drugs with increased vigor over the past few years. That has created new incentive for generic companies to invest in Japan. And that creates new commercial problems for our originator clients."

**Q: What specific political pressures have spurred the proliferation of generics in Japan?**

"To encourage adoption of more generic products, the government has set a target that by the autumn of 2020, 80 percent of non-patented pharmaceutical products (i.e. the generic share of the market replaceable by generics) should be generic (from around 56 percent currently). That means that regulators may arguably be more lenient with certain types of authorizations... and in the last three or four years we've had the impression that they may be becoming a bit more relaxed in granting generic marketing authorizations. It may also be that regulators are increasingly feeling the need to 'do their part' to manage costs by increasing access to generic drugs."

**Q: What other challenges are originator companies facing?**

"One of the big trends we are seeing is that a lot of Japanese companies — and, to a greater extent, international pharmaceutical companies and their Japanese subsidiaries — are having their patents challenged. Generally speaking, Japanese companies don't like contentious litigation and prefer to settle. But we're still witnessing a huge increase in the number of preliminary injunctions and active litigation, especially in the life sciences sector."

**Q: How is defending a patent in Japan different than in the Western market?**

“If you are litigating patents in a Western country, one of the first priorities is to engage an expert. You’ll look for someone in the relevant technical field who can help advise and inform your legal arguments, and also be presentable in court, in the sense of having appropriate gravitas, skill in explaining complex concepts, and the ability to respond effectively to cross-examination and detailed questioning. In Japan, the practices are far more paper-based. One might engage an expert to help with legal arguments for the purpose of a written brief, but his or her role is much less weighted towards performance at the hearing, providing oral explanations or educating the court.”

**Q: Big picture, what should originator companies in Japan be thinking about?**

“There’s an interesting new tension (in Japan) right now because typically the population prefers branded products. They’ve learned to trust originator products, but now they’re getting more information on the generic side. Indeed, we’re even seeing a surge in TV commercials involving well-known personalities that encourage the use of generic drugs. Originator companies need to be prepared to navigate that shift. I’d encourage them to seek early advice from members of their legal team with expertise in the region. These new challenges require not only sound interpretation of the law and of changing trends, but the ability to interpret unique differences on a cultural level as well.”

Watch the video to learn more about patent trends in Asia and the legal issues facing the industry.

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