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With pharmaceutical competition in Europe continuing to evolve, established companies and new market entrants alike need to understand how key patent litigation tools are shaping the competitive landscape.

Increasing competition within Europe’s pharmaceutical space makes knowing the market and understanding available patent protections more critical than ever for both well established and new market players. Andreas von Falck and Miriam Gundt, partners in Hogan Lovells’ Dusseldorf office, say that companies should consider five key factors influencing patent law across the European market.

1. Europe: a hotspot for patent litigation

Europe has seen a steady increase in patent litigation in recent years, a trend Gundt believes is being driven in part by the many litigation options available to patent holders. “Ten years ago, we saw much more patent litigation in the U.S., but now we’re seeing a sharp increase across all sectors in Europe,” she says. “Europe is a nice ground to litigate patents because companies can make use of the many different jurisdictions and procedural systems within the 27 member states.”

2. European courts are becoming more flexible regarding second medical use claims

“It used to be that second medical use patents, which protect a specific ‘use’ of a pharmaceutical product (e.g. a specific disease or group of patients), could only be infringed when the packaging of the product referred to the specific protected use,” says von Falck. “But many European courts are becoming a bit more flexible, claiming you must consider the overall context of the marketing for the product. This shift may ultimately benefit patentees in enforcing these types of patents. It also means that defendants and generic companies will ultimately need to do more to avoid patent infringement than simply excluding patent-protected information on their labels (also known as ‘skinny labeling”).”

3. The doctrine of equivalence creates additional opportunities and challenges for market players

Von Falck says that the doctrine of equivalence —which says that patent claims can capture
infringements beyond the “literal” meaning of a patent claim—continues to serve as a meaningful tool for patentees to achieve appropriate protection in litigation. Landmark cases, like 2017’s Actavis vs Eli Lilly are evidence that the doctrine continues to be relevant. “The pharmaceutical industry is one where the products are so valuable that parties will litigate these cases to the very end,” he says. “The [doctrine of equivalents] is an extra line of defense that can mean longer, more costly proceedings.”

4. Compulsory licenses ensure critical drugs stay on the market

Originally designed to allow generic drugs to enter markets where originators did not make product, compulsory licenses can also serve as a defense for originators. Where claims for injunctive relief are enforced against pharmaceuticals that are important from a public health perspective (such as for the treatment of HIV or cancer) European courts can grant permission for the maker of the pharmaceutical to continue marketing the product against payment of a royalty to be set by the court.

“The rate of compulsory licensing is a reflection of changing market behaviors,” says Gundt. “The temptation to remove a competitive product from the market continues to grow, and compulsory licensing ensures critical drugs stay on the market.”

5. Know the market and plan ahead

“Whether companies are looking to market new products, or they are trying to effectively protect their innovations as a patentee, planning ahead is crucial,” says Gundt. “What that means in practice is that pharmaceutical companies need to start preparing three to four years in advance of planned product launches by closely analyzing the competitive environment. The earlier they do that, the better prepared they’ll be to set up an effective (litigation) strategy that serves their interests. (If you wait until) you’re already being sued (as the defendant) or your patent is already being infringed, it’s definitely too late.”

For more insights from von Falck and Gundt on changing patent trends throughout Europe, watch the video above.

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