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Two new weapons for defending Hatch-Waxman litigation

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Mark Remus of Brinks Gilson & Lione discusses two patent-related challenges for generic pharmaceutical companies and how they might be overcome.

The generic pharmaceutical market is as competitive today as ever. Generic companies compete with innovator companies to clear the legal pathway and they compete with each other to create, maintain or destroy exclusivity. They seek to accomplish all of these objectives with minimal legal spend. The following discussion addresses two particular challenges and potential ways to overcome them.

New life to an old defence

Induced infringement arises most often in the context of method of treatment claims. Induced infringement requires the patent owner to prove that the accused infringer will do something that causes others to infringe the patent-in-suit. Generic companies have long argued that they do

nothing to encourage others to infringe the innovators' patents because they do not administer medication to patients and neither, typically, do they market or advertise their products.

As a result, the sole hook for innovators is the product labelling associated with the generic medication. By law, and with limited exceptions, the product labelling must be identical to the brand product labelling. That labelling includes instructions that tell doctors and patients why, when, and how the medication should be administered to patients. Thus, the innovators argue, the generic labelling encourages patients to practise the claimed method.

The Federal Circuit and district courts have long held that the product labelling associated with a generic medication can be sufficient evidence that a generic manufacture will cause others to infringe the patent-in-suit. *See, eg, Sanofi v Watson Labs* 875 F.3d 636, 646 (Fed. Cir. 2017); and *AstraZeneca v Apotex*, 633 F.3d 1042, 100 (Fed. Cir. 2010). In these cases, the courts found induced infringement without any evidence that the generic labelling would actually cause others to practise the claimed methods or that physicians or patients even read the generic labeling.

However, in a decision dated March 28, 2018, Judge Stark of the District of Delaware held that the patent owner, GSK, failed to present sufficient evidence that Teva induced infringement of GSK's patent directed to methods of using carvedilol to treat congestive heart failure. *GlaxoSmithKline v Teva Pharms*, 2018 US Dist. LEXIS 51169 (D. Del. March 28, 2018) (emphasis in the original).

Judge Stark held that GSK was required to prove by a preponderance of the evidence that "Teva's alleged inducement, **as opposed to other factors**, actually caused the physicians to directly infringe." *Id.* at *13 (emphasis in the original).

The court found that factors other than Teva's actions caused doctors to infringe GSK's patent. For example, the court found that doctors deciding to prescribe carvedilol relied on various sources other than Teva's label, including industry guidelines, research studies published in medical journals, the label for GSK's carvedilol product and GSK's extensive promotional activity that included sending doctors to hospitals, giving seminars, and detailing, marketing, and advertising carvedilol. *Id*. at *22.

Even GSK's expert admitted that he had not read Teva's generic label prior to writing prescriptions for carvedilol. For this reason, Judge Stark found that factors other than Teva's label caused others to infringe GSK's patent.

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GSK has appealed Judge Stark's decision to the Federal Circuit, where it has already attracted substantial interest. Two industry organisations that represent innovator companies' interests have already filed *amicus* briefs in favour of GSK. A decision from the Federal Circuit is expected in 2019.

In the interim, this case gives new hope to generic companies seeking to argue that their actions will not encourage others to infringe an innovator's patent-in-suit. The facts in the carvedilol case are not unique and will likely apply to many other drug products.

Attorneys' fees aren't just for plaintiffs

Innovator companies have made effective use of their large, sophisticated patent portfolios to delay generic competition, or at least make the required Hatch-Waxman litigation much more expensive. Historically, it has been extremely difficult to recover attorneys' fees from innovator companies that file or maintain lawsuits in bad faith. The standard for recovering fees under 35 USC §285 was lowered for all patent cases in *Octane Fitness v ICON Health & Fitness*, 134 S. Ct. 1749 (2014). While *Octane Fitness* initially had relatively little impact on Hatch-Waxman cases, over the past year there has been increased use of fee awards in Hatch-Waxman cases to punish innovator companies who litigate in bad faith.

In *Roxane Labs v Camber Pharms*, No. 14-CV-04042 (March 26, 2018 D.N.J), the District of New Jersey awarded fees to the defendants because "Roxane pursued an infringement claim for which it lacked any legal or factual support". In particular, Judge Chesler singled out Roxane's claim construction arguments, which lacked any support in the intrinsic evidence.

The District of New Jersey again awarded fees to the defendant in *Par Pharm v Luitpold Pharms*, No. 14-CV-1650 (D.N.J. April 24, 2017). The court held that Par's suit was "completely unsupported by case law". Par admitted that Luitpold's Abbreviated New Drug Application did not infringe, but argued that Luitpold may later change its formulation so that it did infringe.

The court disagreed, finding the suit "meritless" and holding that Par's "unjustified maintenance of this suit and attempts to use discovery to police defendants' future conduct makes an award of fees appropriate".

Most recently, the Southern District of New York awarded fees to the defendant in *Regeneron Pharmaceuticals v Merus,* No. 14-cv-1650 (KBF) (S.D.N.Y. Jun. 25, 2018), after finding the patent-insuit unenforceable due to inequitable conduct. In awarding fees, the court held that while the finding of inequitable conduct alone warranted an award of attorneys' fees, the court did not need to rely on that ground because the plaintiff's "mischief was so vast". In particular, the plaintiff improperly withheld "a massive amount of information" including documents the court previously ordered plaintiff to produce.

These three cases highlight the value of attorneys' fees under section 285 to a Hatch-Waxman defendant. It is hoped that the threat of fees will minimise egregious conduct by innovators, but if it does not, Hatch-Waxman defendants have an excellent chance of recovering their fees and being compensated for the harm caused by the misconduct.

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