Failure to launch

Joseph M O’Malley, Jr, Bruce M Wexler, Eric W Dittmann and Isaac S Ashkenazi explore generic at-risk launches in the US and their effects on pharmaceutical patent litigations

Patent protection is the life blood of any innovator pharmaceutical company, as it enables the innovator to manage product lifecycles, recoup its significant investment costs and fund future research and development efforts. As such, the potential for generic competition before patent expiration is of the utmost concern to the innovator.

Our study of, and involvement in, recent US pharmaceutical patent litigations has revealed an increase in the number of generic companies entering the market before patent expiration, even prior to any trial decision addressing validity or infringement. The emergence of these early generic entries – dubbed “at-risk launches” given the potential for large damage awards against the generic if the patents are eventually upheld – raises a number of important issues that innovators need to consider in connection with the patent protection of their important drug franchises.

Evolution of at-risk launches

Patent litigations in the US between innovator pharmaceutical companies and their generic competitors are governed by the Hatch-Waxman Act1. If the innovator brings an infringement action within a specified time after receiving notice of a generic patent challenge, the Act provides a 30-month stay2 of regulatory approval whereby the US Food and Drug Administration cannot, under most circumstances, grant final approval of the generic drug product during the stay period.

In the past, complicated patent litigations between innovators and generics often extended well beyond the 30-month stay without the launch of any generic product. In those days, generic companies were reluctant to launch their products until there was a favourable court decision on the merits. These rare early instances of at-risk launches were usually preceded by negative decisions from district courts (eg, on claim construction) that made it much more likely that the generic would ultimately prevail at trial. Generic challengers – led by the largest generic company, Teva Pharmaceuticals – appeared to have shifted their litigation and business strategies beginning around 2007, when the pharmaceutical industry witnessed several at-risk launches to some of the most successful branded drug products without any trial (or otherwise dispositive) decision.

As a result of this shift in tactics, and the severe consequences for innovator companies that typically follow at-risk launches, it is crucial for innovators to consider, plan for and, when possible, prevent such launches.

Importance of the 30-month stay

An innovator’s best tactic to prevent a generic at-risk launch is to obtain a favourable trial decision before the expiration of the 30-month stay, which results in the automatic issuance of a de facto permanent injunction for the
remaining life of the patents-in-suit. As such, the innovator should consider (in addition to, e.g., the pharmaceutical patent experience of the court and personal jurisdiction issues) the average time to trial before bringing suit in a particular jurisdiction. This is particularly important in light of the large variation in the average times to obtain a trial decision for various district courts. For example, the average time to a nonjury trial in the District of Connecticut is 28 months, whereas a trial is typically held within 20.5 months in the Eastern District of Pennsylvania. Reflecting the importance of the 30-month stay in these Hatch-Waxman litigations, at least one district court now requires the innovator to identify the exact date on which the 30-month stay will expire upon filing a complaint.

Preventing at-risk launches with preliminary injunctions

If a trial decision cannot be obtained within the 30-month stay, the innovator must plan for the possibility of an at-risk launch. Courts have the power to force a generic challenger to provide advance warning before it launches at risk; however, this practice varies depending on the jurisdiction and particular judge. For instance, it is not uncommon for the District of New Jersey to require, upon the innovator's request, 60 to 90 days' advanced notice of an at-risk launch, whereas the Southern District of New York recently held that there is no notice requirement. As such, innovators should be well versed with the particular court practices in the jurisdiction in which they bring suit.

As a practical matter, most generics planning an at-risk launch will voluntarily give the innovator some degree of notice specifically to trigger preliminary injunction proceedings, seeking the court's preliminary assessment of the merits to evaluate their risk. If, for example, the court grants an injunction based on its preliminary view that the innovator has a strong case, then the generic, while prevented from launching, has also avoided a potentially huge damage award that might have followed if it launched at risk and then found, only later, that it had misjudged the strength of its patent challenge. On the other hand, if the preliminary injunction decision casts serious doubt on the strength of the innovator's patent, the generics have, in the last few years, launched with some feeling of confidence that its eventual risk of liability after a decision on the merits is not so great. As discussed further, however, generics are beginning to discover that a preliminary injunction denial may well be a false indicator of risk because of the differing burdens applied in a preliminary injunction proceeding versus trial.

In any event, most innovators feel that, if they receive no assurance that a generic will not launch before a trial decision and cannot obtain a favourable trial decision before the 30-month stay expires, they have no choice but to bring a motion for a preliminary injunction. Preliminary injunctions, however, are "extraordinary remedies" that are not routinely granted. To obtain such an injunction, an innovator must establish:

- Likelihood of success on the merits;
- Irreparable harm in the absence of preliminary relief;
- That the balance of the equities tips in the innovator's favour; and
- That an injunction would be in the public interest.

With respect to likelihood of success on the merits, at trial the generic has to prove invalidity or unenforceability by clear and convincing evidence. On the other hand, because the innovator must demonstrate entitlement to a preliminary injunction, there is some modification of the generic's burden in the preliminary injunction context. Certain decisions of the Court of Appeals for the Federal Circuit, which reviews all US patent decisions, have addressed this issue by requiring the generic to show only that the patents-in-suit are "vulnerable" with respect to their validity or enforceability—a much lower standard than the high clear and convincing standard applied at trial. This standard has seemingly been applied by some courts to allow a generic company to avoid a preliminary injunction merely by showing that it has non-frivolous defences as to the alleged invalidity or unenforceability of the patents-in-suit. As discussed below, though, launching at risk after a mere showing of "vulnerability" has not proven to be a very effective hedge against eventual liability for damages.

Other Federal Circuit decisions have employed a standard requiring a showing of more than just vulnerability—namely, whether "the patentee is likely to succeed on the merits, upon application of the standards of proof that will prevail at trial." Regardless of the precise articulation of the standard, what is clear from the case law is that, far and away, the likelihood of success factor largely dictates whether injunctive relief is granted. As such, it is crucial for the innovator company to be prepared to present its case in a compelling fashion before the expiration of the 30-month stay.

A comparison of two recent pharmaceutical patent litigations relating to Lotrel® and Aricept® demonstrate the dominant importance of the likelihood of success factor in the preliminary injunction context. Both preliminary injunction motions were filed in the District Court of New Jersey and decided by the same judge, but only the innovator company in the Aricept® litigation, represented by the authors, succeeded in obtaining injunctive relief. Significantly, the innovators in both cases focused on very similar facts in arguing that they would be irreparably harmed by an at-risk launch, such as lost revenues, lost market share, irreversible price erosion, lost business prospects and lost research opportunities. The court, however, found that only the innovator company in the Aricept® litigation, who had demonstrated a strong likelihood of success, established irreparable harm.

Although the likelihood of success prong usually carries the day, it should be noted that an innovator still needs to make some demonstration that a generic launch will cause credible irreparable harm. Some courts have indicated that it may be harder to make such a showing when a generic product has already entered the marketplace. Indeed, only two preliminary injunctions have been granted after an at-risk launch, the first of which (obtained by the authors) related to Pfizer's Accupril® product. "Only two preliminary injunctions have been granted after an at-risk launch, the first of which (obtained by the authors) related to Pfizer's Accupril® product."

Softening the blow of an at-risk launch

If a generic product is launched at risk, the innovator often has a number of difficult decisions to make. If the branded company does nothing, they risk losing a substantial percentage of their drug market to the generic competitor until the case can be concluded through appeal. In certain situations, an innovator may determine that launching an "authorised" or "own" generic product to compete with the generic's product is the best course to attempt to mitigate some of
Traditionally, a patentee is permitted on the need to compete with the generic’s “authorised” generic would likely be sold based into account the full set of facts that typically accompany an at-risk launch. For example, the generic product would not be considered a noninfringing alternative, and should not limit such sales internally, the innovator may choose to try to mitigate its damages without destroying its entitlement to lost profits damages. As such, a strong argument can be made that the authorized generic sales should similarly not affect the innovator's entitlement to such damages.

An innovator company may choose to avoid the uncertainty described above by launching an “own” generic product that is actually sold by the innovator (or one of its divisions). In addition to handling all aspects of such sales internally, the innovator may choose to employ a third party with experience selling authorised generic products as its sales agent. In the latter scenario, title in the goods never passes to the third party, who neither requires nor receives any express or implied licence under the patents-in-suit. Since the innovator is not providing any third party with a licence to sell the patented product, the “own” generic product would not be considered a noninfringing alternative, and should not limit the recovery of lost profits damages.

The innovators “strike back”
Taking advantage of the shifting burden of proof in the preliminary injunction context discussed, generic companies recorded a windfall of profits from 2007 to the present through numerous at-risk launches. Indeed, since 2007 there have been eight such launches against innovator products, having combined sales of over US$7 billion per year at the time of those launches. Only now are some of those decisions being closely scrutinised through the true burden of proof that accompanies a generic’s patent challenge at trial. An analysis of them shows that, after preliminary injunctions were denied, these cases are proceeding to trial and, perhaps much to the generic’s surprise, they are losing many of them.

For example, in 2007, two innovator companies sought a preliminary injunction to prevent at-risk launches of two generic Protonix® products. At the time, Protonix® had worldwide sales of roughly $2 billion per year. The generics opposed the preliminary injunction on the grounds that the patent covering Protonix® was allegedly invalid. Finding the patent-in-suit to be “vulnerable” to a validity attack, the district court denied the innovators’ request for a preliminary injunction. Following that denial, the generics launched their products and reaped substantial profits. But after a three-week trial in 2010, in which the innovator companies were represented by the authors and co-counsel, a jury (and later the court) found that the generics had not met their burden of proving invalidity by clear and convincing evidence. Now, the generics face a potential damage award that has been reported by analysts to be in the billions of dollars.

A generic was similarly successful in opposing a preliminary injunction in the Famvir® litigation in 2007, and subsequently launched its product at risk. In denying the injunction, the court went much further than finding vulnerability; indeed, the court stated that, based on its preliminary analysis, Teva provided “ample evidence” that the patent-in-suit was obvious. Nevertheless, following a full trial, a jury returned a verdict finding that the patent-in-suit was neither invalid nor unenforceable. After the verdict, which made the generic liable for potentially hundreds of millions of dollars in damages, the parties settled the case for an undisclosed lump sum and an ongoing royalty.

As these decisions make clear, the generics may have misjudged the degree to which a denial of a preliminary injunction can accurately predict their eventual chances at trial and the degree of risk involved in at-risk launches. But will the billions of dollars in potential damages resulting from such launches and subsequent trial losses impact their future at-risk strategy? Only time will tell.

Footnotes
1. See 21 USC § 355(i).
2. In certain cases involving NCE or NME exclusivity, the FDA will impose a stay of 42 months from the four-year anniversary of approval for that drug. See 21 USC § 355(j)(5)(B)(i).
5. See Delaware “Supplemental Information for Patent Cases Involving An Abbreviated New Drug Application (ANDA)” Form.
10. See Pfizer, Inc v Teva Pharmas. USA, Inc, 429 F.3d 1364 (Fed Cir 2005).
12. See Palf Corp v Micron Separations, Inc, 66 F.3d 1211, 1222-23 (Fed Cir 1995).
13. In absence of lost profit damages, however, the patentee is still entitled to (albeit lower) reasonable royalty damages.
17. See Novartis Pharm. Corp v Teva Pharmas. USA, Inc, No. 05-1887, D.I. 411 (DNJ Nov. 18, 2009).

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In the interests of full disclosure the authors of this article have represented the innovator companies in the Accupril®, Aricept® and Protonix® cases discussed in the article.