OUTSIDE PERSPECTIVES

Should We Settle? Considerations For Generic Companies Before Settling Hatch-Waxman Litigation

IT CAN BE LUCRATIVE TO BE THE FIRST-to-file generic company that successfully challenges patents listed in the Orange Book: a 180-day exclusivity period can be worth an average of $60 million per drug. But what if you are not a first filer? When the average patent litigation costs approximately $5 million, and the overall success rate for the generic company in cases that go to trial is under 50% over the last decade, settling a Paragraph IV litigation can be a more profitable option for a generic company than litigating the case to its end.

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Although not as prevalent as in patent suits generally, settlement of pharmaceutical patent litigation under the Hatch-Waxman Act is not uncommon. The Federal Trade Commission ("FTC") reported that there were 113 "final resolutions of patent disputes" in the Hatch-Waxman context in the 2010 fiscal year (October 1, 2009 to September 30, 2010)—more than double the number of settlements reported in any previous year. This is not surprising given the increasing cost of litigation, clogged judicial dockets that result in litigations lasting considerably longer than the 30-month stay period, and the rising number of cases with multiple filers. Settlement provides certainty for the generic company (and its shareholders), and makes budgeting for things like the launch of the generic product more predictable.

Whether settlement is the best option depends on numerous factors, such as the strength of the case and the expected timing of approval of the Abbreviate New Drug Application ("ANDA"). Pursuing settlement is a decision that must be made on a case-by-case basis. We discuss below some things to consider when thinking about settling a Hatch-Waxman litigation.

Authorized Generics

An authorized generic is the brand company's product packaged and marketed as a generic by a subsidiary of the brand company or by a third party. An authorized generic can be marketed at any time, including during the first-filer's 180-day exclusivity period. Authorized generics can impact settlement considerations in a number of ways.

A generic company can agree to become the authorized generic distributor as part of the settlement agreement. Approximately 96 authorized generics were launched by independent generic companies in the period spanning the years 2000-2009. While becoming an authorized generic can be an attractive option despite the small margins, authorized generics also devalue the 180-day exclusivity period and thus are disfavored by many members of Congress as well as the Generic Pharmaceutical Association.

If an authorized generic will be launched during the 180-day exclusivity period, there may be more financial incentive for a later-filer to settle. When an authorized generic competes with just one generic during the 180-day exclusivity period, the FTC reports that revenues for the generic during those 180 days decline an average of 50%. Due to the smaller market share and the greatly-reduced revenue that would be available to a later-filer (and thus later entrant), it may make financial sense to forego litigation costs and enter into a settlement with the brand company.

In fiscal years 2004-2008, about one-quarter of settlement agreements reviewed by the FTC included provisions relating to authorized generics. Even if a generic company is not agreeing to become the authorized generic, it is important to take the possibility and/or existence of an authorized generic into account when determining the terms of a settlement.

Pay-For-Delay

In pay-for-delay agreements, also known as reverse payment settlements, a brand company pays the generic company to delay entry of its generic drug into the market. Brand companies may also offer other incentives to delay generic market entry, such

as allowing the generic company to market its generic drug in some markets without legal challenge.

Pay-for-delay settlement agreements are controversial. Opponents of pay-for-delay agreements, including the FTC, argue that such agreements are nothing but payments not to compete that violate the antitrust laws and are contradictory to the goals of the Hatch-Waxman Act. This argument seems to at least partly depend on the idea that the generic company would prevail in litigation. Advocates of pay-for-delay agreements, on the other hand, contend that patents necessarily delay competition and that all settlements involve consideration to avoid risk.

The FTC recently described its efforts to stop pay-for-delay agreements as its "top competition priority," and it continues to support legislation that would end the practice altogether. The Supreme Court has so far refused to take on any legal challenges against pay-for-delay agreements, but with a potentially growing split in authority among the circuits, it is possible that the Supreme Court will eventually step in.

Nevertheless, approximately 27% of the 113 patent settlement agreements submitted to the FTC in the 2010 fiscal year included potential pay-for-delay provisions. Due to the increased antitrust scrutiny given to pay-for-delay settlements, a generic company considering entering into such an agreement should carefully consider the possible legal consequences as well as the potential financial benefits to the company.

Parked Exclusivity

The first-filer can settle with the brand company and still maintain its 180-day exclusivity period. As a result, the exclusivity is effectively "parked" until the first-filer launches, unless another generic company prevails in litigation with the brand company and thus triggers the running of the exclusivity period.

The first-filer's settlement—and its parked exclusivity—can impact a later-filer's decision to settle in a number ways. If the first-filer's date of entry is far in the future, and the later-filer has a very strong case, litigating the case in an attempt to trigger the first-filer's exclusivity may be the preferable option. Alternatively, if the first-filer's launch date is likely to occur before the later-filer's ANDA is likely to be approvable, settlement may be the more attractive option. The effect of parked exclusivity on the date of entry a later-filer can secure should be considered before entering into settlement negotiations.

Conclusion

In some circumstances, settling a Hatch-Waxman litigation is the best option for a generic company. Before making that decision, the generic company should carefully consider its options, and their consequences.

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