Scrutinizing Reverse-Payment Settlements

*Law360, New York (December 16, 2011, 3:09 PM ET)* -- Settlements of Hatch-Waxman litigation between branded and generic pharmaceutical companies that include a “reverse payment” by the branded firm to the generic have been the subject of significant antitrust litigation over the past several years.

Courts have not tended to use either a “per se” or “rule of reason” analysis, instead adopting a “scope of the patent” test to review such settlements.

This approach takes into account the particularized regulatory and patent enforcement framework under the Hatch-Waxman Act that governs both the relationship between branded and generic competitors, and generic competitors among themselves.

The three-step process in the “scope of the patent” test thus looks to the scope of the exclusionary potential of the patent, the extent to which the challenged agreement exceeds that scope, and any resulting anti-competitive effects.

Only if the settlement reaches beyond the reasonable scope of what is patented does the court engage in a balanced review of the reasons a settlement has been entered into, and whether the bargained-for consideration in such deals is driven by anti-competitive motives and has anti-competitive impact.

Recent legislative and Federal Trade Commission efforts aim to overturn this approach. In late October, for example, the FTC issued a press release concerning its new study detailing the number of reverse-payment settlements for fiscal year ended Sept. 30, 2011, compared to the prior year, concluding that reverse payments continue to be a problem that needs to be fixed.

The study catalogs patent settlements submitted to the FTC pursuant to the Hatch-Waxman Act, dividing them into categories involving generic “first filers” who challenge the branded company’s patents, settlements with compensation to the generic manufacturer and/or a restriction on the generic manufacturer’s ability to enter the market, whether the agreements also restrict the brand manufacturer from launching an authorized generic, and settlements with no restriction on entry.

The FTC claims that the category of settlements where a reverse payment is included costs consumers $3.5 billion per year, but the courts have not thus far accepted the FTC’s analysis.

Instead, the courts have recognized that the Hatch-Waxman Act artificially changed the competitive landscape of the market, finding that the act itself “explains the flow of settlement funds and their magnitude.”
Pursuant to the compromise reached in Congress in 1984, generic firms are shielded from patent lawsuits by a safe harbor while preparing their U.S. Food and Drug Administration filings, and can avoid the significant costs of research and development and clinical trials and the lead time associated therewith by following the procedures under the act.

In exchange, the branded companies obtained a potentially longer period of market exclusivity where the product is patent-protected in the form of patent-term extensions resulting from regulatory approval delay, certain data exclusivity for new chemical entities and clinical improvements, and a 30-month stay on generic entry if the patent is challenged and the branded company files suit promptly.

Some 27 years later, industry groups estimate that nearly 80 percent of all drug prescriptions are for generic products, compared to 15 percent at the time of passage. That is substantial progress for consumers.

One main feature of the act, intended to incentivize generic competitors to rush to the FDA for approval, was the promise that the first generic challenger would obtain 180 days of exclusivity before the launch of a competing generic product.

That would allow the first entrant the opportunity to gain a large market share while keeping the price relatively high until further generic competition entered after the end of the 180 days.

Until the act was amended in 2003, the 180 days was calculated from either the date of the first commercial marketing of the generic drug product by the first applicant who challenged the patent, or the date of a court decision declaring the patent invalid or not infringed by the first filer, whichever was earlier.

The existence of 180-day exclusivity led to a number of strategic responses in the first two decades of Hatch-Waxman, including the listing of multiple patents in order to invoke multiple 30-month stays, the possibility of multiple generics sharing 180-day exclusivity as a result of the multiple stays, the use of FDA citizen petitions to block generic approvals, the launch of “authorized generics” by the branded company or its licensee, and so-called “reverse payment” settlements, also sometimes called “pay for delay” settlements.

From the perspective of the generic firms, the authorized generic strategy was a fundamental violation of the spirit of what was intended in the originally brokered Hatch-Waxman compromise, because it allowed either the innovator or another generic to gain a large part of that critical market share in the first six months of generic life.

But the courts upheld the practice as a legitimate license of the branded companies’ FDA approval rights.

The reverse-payment settlement gained in popularity as a hedge by the generic firms in response to the reduced incentive occasioned by the possibility of unexpected authorized generic competition during 180-day exclusivity.

From an antitrust perspective, “reverse payment” settlements were troubling in their early days, in large measure, because the first generic to file a patent challenge could “park” its 180-day exclusivity by not coming on the market and not forcing a court decision, thus blocking the FDA from approving any other generic.[1]
One early federal court of appeals decision involving the drug Cardizem held such “parking,” along with other very specific conduct in that case, to be “per se” unlawful under the antitrust laws, but other circuits refused to follow that guidance or limited the case to its facts.[2]

The 2003 amendments to the Hatch-Waxman Act, under the Medicare Prescription Drug Improvement and Modernization Act (MMA), largely removed the potential for “parking” 180-day exclusivity, without making any changes to the potential for authorized generics.

The MMA did so in a number of ways, including, among other things, by removing the date of a court decision declaring the patent invalid or not infringed as a way to trigger the running of the 180 days, providing for just a single 30-month stay for a given product, permitting multiple “first filers” to obtain 180-day exclusivity by filing on the same day, and providing for forfeiture of 180-day exclusivity in certain circumstances.

Among the reasons for forfeiture include if the generic waits more than 75 days after it can otherwise launch or if there is a successful antitrust challenge by the FTC to a settlement. In addition, a subsequent filer can now bring a declaratory judgment action to trigger acceleration of a first filer’s exclusivity if the subsequent filer prevails in litigation.

While some commentators have argued there are still loopholes which may permit some form of parking after the MMA, none of the settlements thus far challenged in court have involved settlements involving post-MMA filed generic drug applications.

Legislative efforts to end reverse-payment settlements have not been successful to date. In the past four years, there have been efforts to completely ban the settlements, to add a presumption of illegality that could only be overcome by clear and convincing evidence, or to add other lesser restrictions.

Some of these efforts have been in self-contained proposals; others have been tacked on to various healthcare, tax or spending bills. None have passed.

In early November, some members of Congress proposed a still different set of rules, in the Fair and Immediate Release of Generic Drugs Act of 2011.[3]

Rather than making all reverse payments “per se” illegal, the FAIR Generics Act purports to “prevent parked exclusivities,” by granting the right to share exclusivity to any generic filer who wins a patent challenge in the district court, regardless of whether they are among the first to file; holding a settling generic company to the launch date agreed to in its settlement; and making invalid any acceleration clause if another generic enters the market while the subsequent filer who litigated the case to a successful resolution is free to launch at risk pending appeal.

Authorized generics are not addressed.

Passage seems unlikely; any legislative fix needs to look more closely at the evolution of how the original incentive embodied in 180-day exclusivity has been altered in practice by the advent of authorized generics. As one federal circuit court has recognized about the overall Hatch-Waxman scheme, “explains the flow of settlement funds and their magnitude.”[4]

Despite the reluctance of courts to interfere with settlements, it seems clear that both Congress and the FTC will continue to challenge them. Accordingly, firms entering into reverse-payment settlement agreements are wise to document their expectations about the potential litigation outcomes in order to put any consideration exchanged into proper perspective when the settlements are later scrutinized.
Some practical guidance can be gleaned from court decisions and FTC statements about how various settlement provisions will be viewed, and there are thus measures firms can take to reduce the possibility that their settlements will be challenged successfully.

Reverse-payment settlements can take several forms. They might or might not include, in addition to a payment, an agreement to delay entry, which may or may not be conditioned also on the branded company’s agreement not to launch or license an authorized generic.

One FTC commissioner, J. Thomas Rosch, has gone on record — while clarifying the remarks were his own and not those of the commission — as understanding that not all payments are nefarious: “Some settlements have no quid pro quo between the payment and the delay. In other cases, the quid pro quo may just reflect the parties’ reckoning of the patent strength.”[5]

Typically, there is a sliding scale between the amount of a payment and the agreed date of entry.

Nevertheless, the closer to patent expiration the agreed launch date is, the closer the scrutiny by the FTC will be, and is thus a factor parties should take into account in their agreements.

If each party documents its true expectations of its range of litigation outcomes as well as its other business concerns, even if not shared with each other, it will be that much harder to challenge the settlement as a sham.

Patent strength only tells part of the story why parties would agree to particular dollar amounts and dates of entry. Branded companies may be more risk-averse, given the relative size of their investment and the average likelihood of success in fully litigated Hatch-Waxman cases through appeal; on the other hand, generic companies may not be able to survive either the litigation or until the negotiated entry date and still be able to afford production of the drug without a payment.

Such alternative explanations should be documented by the parties at the time of agreement to insulate against an assumption that the payment represents an unlawful splitting of the market.

There can be situations where premature generic entry into a market can reduce output, since the branded company nearly always ceases promotional and detailing support that would have otherwise helped the product grow at the expense of competing products.

Similarly, the price premium enjoyed by the branded drug may be due to other factors besides the strength of the patent, such as the branded firm’s marketing prowess or favored position with benefit managers.

When marketing efforts cease as a result of generic entry, there can be a corresponding loss of market share to competing treatments. In a case where the branded product is relatively new and is in the process of overtaking older, less efficient or beneficial treatments, a premature generic entry could actually prop up the older product and prematurely stifle adoption of the new one.

Accordingly, the competitive landscape of the drug at issue within its product class should be well-documented by the parties if it is anticipated that there may be an antitrust challenge.

Because branded and generic firms are doing business with each other outside of the context of litigation much more frequently than when Hatch-Waxman was first enacted, so-called “side deals” have also become common place as part of the bargained-for consideration in Hatch-Waxman settlements.
Terms may include an array of services, such as manufacturing; supply; product development; licenses under the generic’s own intellectual property to improvements or even entirely different drugs, sometimes at royalty rates more favorable than would otherwise be available; marketing support, either related to the product being litigated or not; global settlements on the same drug in other countries; settlement of unrelated business or patent disputes; investment by the branded company into other drugs being developed by the generic firm; or even the injection of equity into generic firm, increasing the generic firm’s ability to survive in the long term.

Such terms are likely to raise regulatory scrutiny and court challenges because they can be viewed as efforts to mask overpayment for an extension of the brand’s monopoly beyond the scope of the patent.

Some of the legislative and FTC efforts aim to put the burden on the settling parties to show the side deal is at fair market value. Accordingly, firms entering into side deals as part of the consideration for settlements should create a record of the pro-competitive impact of such arrangements.

In sum, it is clear that reverse-payment settlements will continue to receive antitrust scrutiny, but industry participants can take away practical pointers from what has come before to try to avoid some of the earlier pitfalls.

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