



CRA Insights: Life Sciences

CRA Charles River
Associates

July 2010

Plaintiffs can't get no satisfaction: Reverse payment settlements resist being found anticompetitive

"I can't get no satisfaction, I can't get no satisfaction, 'cause I try and I try and I try and I try" – The Rolling Stones

The US appellate court recently affirmed a summary judgment ruling in the Cipro antitrust case that favored the defendants, Bayer and Barr, the branded and generic manufacturers of Cipro. As in other similar cases, the branded and generic manufacturers had settled their patent infringement litigation, which was proceeding under the Hatch-Waxman process for the introduction of generic drugs. Plaintiffs contend that the inclusion of cash payments totaling approximately \$400 million from Bayer to Barr as part of the settlement was anticompetitive; essentially alleging that the reverse payment was an inducement for the generic manufacturer to delay entry into the market (hence the term "pay for delay"). This recent ruling, however, also invited plaintiffs to petition for a rehearing to overturn the precedent upon which the Cipro decision is based. The FTC and other interested parties have filed amicus briefs in support of a rehearing and the overturning of the precedent case. Regardless of the outcome, reverse payment settlements will continue to be scrutinized.

While the FTC and other plaintiffs have argued that the presence of reverse payments show these arrangements to be anticompetitive on a prima facie basis, US courts have been reluctant to accept these arguments. First, US courts have affirmed pharmaceutical patent holders' rights to restrain competition within the scope of their patents. Second, the plaintiff's approach, which relies primarily on the presence of a reverse payment, has been rejected as insufficient to conclude that generic entry was delayed given the complexity of these settlements and the underlying business and legal setting.

An important lesson: reverse payment settlement cases are complex, and any assessment of the consequences must consider other factors besides the mere presence of a reverse payment.

The legality of reverse payment settlements remains a highly contentious area of antitrust law and involves significant economic issues. The FTC has continued to devote substantial resources to investigating these settlements. There have been proposals to Congress to ban such settlements as anticompetitive; one such proposal was recently approved by the US House of Representatives.

Three reverse payment cases: Tamoxifen, K-Dur, and Cipro¹

The Tamoxifen and K-Dur cases were among the first in which reverse payment settlements of patent infringement litigation under the Hatch-Waxman Act were challenged as antitrust violations. The rulings in these two cases illustrate certain central issues that the courts would consider when assessing other reverse payment antitrust cases, including Cipro.

The Tamoxifen, K-Dur, and Cipro cases have certain common elements: an unexpired patent covering the branded drug listed in the Orange Book, the generic applicant's claim of non-infringement, the branded manufacturer's responding claim of patent infringement, and a settlement that included a payment from the branded manufacturer to the generic manufacturer. The settlements in these cases share a similar structure but differ in the specific parameters. In Tamoxifen, entry occurs at expiration of the patent at issue; in Cipro, entry occurs six months prior to expiration; and in K-Dur, entry occurs five years prior to expiration. The amounts paid by the branded to the generic manufacturer vary: \$67 million in Tamoxifen; \$70 and \$15 million in K-Dur to Upsher and ESI, respectively; and \$398 million in Cipro. The K-Dur settlements include licenses to other products from the generic manufacturers, whereas the Tamoxifen and Cipro settlements both include a supply agreement.

Two themes have emerged in these cases. First, the courts are reluctant to impinge on the patent holder's legitimate rights to limit competition and on the rights of litigants to settle. In each of these cases, complex considerations were involved in assessing whether such settlements lie within the scope of a pharmaceutical patent holder's legitimate rights. Second, the courts have rejected the argument that the mere presence of a reverse payment proves that generic entry was delayed; details of these settlements have raised critical questions.

- When generic entry occurs before the patent expiration, it cannot be automatically assumed that entry is delayed as entry occurs earlier than it would if the litigation continued and the brand manufacturer prevailed. In K-Dur, "the court readily found that Schering's agreements with Upsher and ESI were, in fact, less exclusionary than the K-Dur 20 patent because they allowed [generic] entry...substantially before the patent's expiration."²
- When a side deal involving assets (product licenses) or services (raw material or product supply) from the generic to the brand is included, one must ask whether the payment from the brand manufacturer to the generic manufacturer is compensation for these other considerations?

Even accepting plaintiffs' framework in these cases, there can be other factors that need to be considered before finding an effect on generic entry due to a reverse payment settlement. Such other considerations include information asymmetries and litigation costs.

Conclusion

Throughout the history of reverse payment antitrust cases, the mere presence of a reverse payment has been insufficient to establish an antitrust violation. As has been remarked recently, "even if the tough legal issues are eventually resolved, [these] cases will still be complicated."³ The full version of this article discusses a few of the other factors that may need to be considered in order to understand whether patent settlements delay generic entry.

¹ CRA staff have served as expert witnesses in the K-Dur and Cipro cases.

² "Schering-Plough Corp. v. Federal Trade Commission: Eleventh Circuit Rejects the FTC's Position on "Reverse Payments" in Patent Suit Settlements," Antitrust and Competition Law Update, Wilmer Cutler Pickering Hale and Dorr LLP, March 22, 2005, pp. 1-4 at 3.

³ Kenneth Glazer and Jenée Desmond-Harris, "Reverse Payments: Hard Cases Even Under Good Law," Antitrust, Spring 2010, pp. 14-21 at 14.

To read the full version of this article, [click here](#).

About CRA's Life Sciences Practice

We provide life sciences companies, law firms, and regulatory agencies across the globe with the industry experience and analytical expertise needed to address the industry's toughest issues. We have developed a reputation for rigorous and innovative analysis, careful attention to detail, and the ability to work effectively as part of a wider team of advisers.

CRA has offices throughout the world, including European offices in London, Brussels, and Frankfurt; United States offices in Boston, Chicago, New York, Oakland, and Washington DC; and other international offices in Toronto, Bahrain, and Hong Kong.

Contact details

To learn more about the economics of reverse payment settlements in the US, please contact:

Dr. Peter Rankin
Vice President
+1-202-662-3935 tel
prankin@crai.com

www.crai.com/lifesciences



The conclusions set forth herein are based on independent research, and publicly available material. The views expressed herein do not purport to reflect or represent the views of Charles River Associates or any of the organizations with which the authors are affiliated. The authors and Charles River Associates accept no duty of care or liability of any kind whatsoever to any party, and no responsibility for damages, if any, suffered by any party as a result of decisions made, or not made, or actions taken, or not taken, based on this paper. If you have questions or require further information regarding this issue of *CRA Insights: Life Sciences*, please contact the contributor or editor at Charles River Associates. This material may be considered advertising. Detailed information about Charles River Associates, a registered trade name of CRA International, Inc., is available at <http://www.crai.com>.

Copyright 2010 Charles River Associates