Health Care Policy Reform Agenda Puts "Reverse Payment" Agreements Between Branded and Generic Drug Makers in the Spotlight: Proposals to Ban Payments Gaining Momentum

Dana S. Wood, Maggie C. Crosswy

August 12, 2009

This advisory addresses recent and upcoming developments regarding “reverse payment” pharmaceutical settlements, including: an unresolved circuit split, harmonization of Department of Justice (“DOJ”) and Federal Trade Commission (“FTC”) antitrust approaches, and a flurry of pending legislation. Proposals to ban reverse payments are gaining momentum, and have significant implications for companies that develop, produce, and market branded or generic drugs, and may affect the cost and availability of drug products.

Background

The regulatory backdrop for the reverse payment controversy is the complicated premarket clearance procedure upon which Food & Drug Administration (“FDA”) approval of generic drug products is based. The relevant standards and procedures are governed by the Hatch-Waxman amendments,[1] which were enacted in 1984 to provide incentives under the Federal Food Drug & Cosmetic Act (“FFDCA”) and patent laws that together would foster the development and early introduction of generic versions of “pioneer” or “branded” drug products in accordance with timetables governed by statute. Not surprisingly, passage of Hatch-Waxman amendments spurred the development of a new kind of patent infringement litigation in which manufacturers of patented, branded products challenged the rights of their would-be generic competitors to develop and introduce new generic versions of their branded drug products. Eventually, it became common for these lawsuits to be resolved by negotiated settlements between the parties which incorporated “reverse payments” (*i.e.*, a payment by the patent holder (pioneer) to the alleged infringer (generic) as a condition of the settlement).

In the context of the administration’s health care reform agenda, the implications reverse payments have for the purchasers and consumers of pharmaceutical products under current policies is receiving increased scrutiny. Critics of reverse payment settlements have questioned the consumer protection implications of reverse payments from both a competition and public health policy standpoint. For example, the FTC has questioned the effects of reverse payments on competition, in view of the amounts paid under settlements. In particular, FTC has suggested that the amounts paid

under reverse payment settlements cannot necessarily be justified by the legal merits of the underlying claim of patent infringement that is the subject of the settlement. Rather, FTC has suggested that these payments may amount to a *quid pro quo* in which the generic competitor is compensated for the opportunity costs associated with its agreement to delay market entry of its generic drug alternative to the branded product.[2]

In view of the difference in costs to consumers between branded and generic drug products, some stakeholders have argued that reverse payments have adverse economic and public health consequences, and present particular concerns for consumers with limited resources to cover the cost of medically necessary drug products.[3]

Are Reverse Payments Anticompetitive? The Circuit Courts are Split

The Supreme Court, for the second time in three years, recently declined to review the issue of whether a settlement incorporating reverse payments constitutes an unreasonable restraint of trade in violation of the antitrust laws. On June 22, the Court denied *certiorari* in *In re Ciprofloxacin Hydrochloride Antitrust Litigation* ("Cipro"),[4] a case in which the Federal Circuit held that a reverse payment settlement has no anticompetitive effect outside the lawful zone of exclusivity created by a patent, and therefore does not impermissibly restrain trade. In affirming the district court's application of a "rule of reason" analysis, the Federal Circuit emphasized the importance of respecting: (1) the powerful exclusivity conveyed under intellectual property rights, (2) the principle of freedom of contract, and (3) the preference for settlement over litigation.

As a result of the Supreme Court's failure to resolve the ongoing circuit split, reverse payment litigation is likely to continue in the lower courts. Currently, in the Second Circuit – except under limited circumstances – reverse payments are lawful.[5] However, the Department of Justice has challenged that standard, and it may be under reconsideration.[6] Both the Eleventh and Federal Circuits, after applying a rule of reason analysis, have likewise upheld settlements incorporating reverse payments.[7] The Sixth Circuit, however, has held them to be *per se* unlawful.[8] Consequently, in spite of a number of notable victories by proponents of reverse payments, brands and generics entering into reverse payment settlements can still expect those settlements to be challenged on antitrust grounds, both by government antitrust enforcers and private litigants.

Antitrust Enforcement Policy Reforms are Emerging

Despite a number of litigation set-backs, FTC Chairman Jon Leibowitz continues to be a strong advocate for "reverse payment reform." Just one day after the Supreme Court denied *certiorari* on *Cipro*, Leibowitz delivered a speech identifying the elimination of reverse payments as one of the agency's "highest priorities," as doing so would save consumers an estimated $35 billion over the next ten years.[9] He also expressed concern that reverse payments undermine the role generic drugs could otherwise play in reducing health care costs and promoting the interests of consumers.[10]

While the FTC's position on reverse payments has remained constant, the Antitrust Division of the Department of Justice appears to have undergone a recent conversion. When the Supreme Court requested the views of United States in the 2006 *Schering-Plough* case, DOJ – then under Bush administration leadership – opined that reverse payments were a logical response to the incentives created by the Hatch-Waxman framework, and largely adopted the Eleventh Circuits favorable view of such settlements.[11] Three years later, and under new leadership, DOJ appears to have reversed course. When the Second Circuit requested the views of the United States on the same issue this

month, not only did DOJ argue that the court's existing reverse payment-favoring standard was erroneous, but that such settlements should be treated as presumptively unlawful.[12] Although DOJ's participation in both of these cases was as an advisory friend-of-the-court, rather than a litigating party, the change in position is nevertheless significant, as courts may be more inclined to defer to views of the expert antitrust agencies when they present a united front.

Pending Legislation Would Restrict Reverse Payments

Finally, since the start of the 111th Congress in January 2009, several bills have been introduced that propose to amend existing statutes in order to regulate the competitive relationships between brand and generic companies, including by banning reverse payments. Notably, several of these bills have been incorporated into broader health care reform legislation being considered by Congress.

On July 31st, the House Committee on Energy and Commerce favorably reported H.R. 3200, the "America's Affordable Health Choices Act." During the Committee markup, Representative Bobby Rush (D-IL) offered an amendment to prohibit reverse payment settlements. The amendment, which was approved by the Committee by voice vote, closely resembles H.R. 1706, the "Protecting Consumer Access to Generic Drugs Act," which was introduced by Rep. Rush earlier this year. The Senate companion to H.R. 1706 (S. 369, the "Preserve Access to Affordable Generics Act") was introduced by Senator Herb Kohl (D-WI) but related provisions have not to date been included in the Senate's health care reform legislation. If enacted, each proposal would prohibit reverse payments and cause the filer of an Abbreviated New Drug Application to forfeit exclusivity upon entering into any reverse payment agreement. H.R. 1706 and the Rush amendment to H.R. 3200 would do so by causing such action to be considered as an unfair and deceptive act or practice under Section 5 of the FTC Act. S. 369, in contrast, would amend the Clayton Act to prohibit such practices. Both proposals would provide the FTC with rulemaking authority to allow such reverse payment agreements if they are found to be beneficial to consumers.

The Energy and Commerce Committee also adopted an amendment to H.R. 3200 offered by Representatives Anna Eshoo (D-CA), Jay Inslee (D-WA), and Joe Barton (R-TX) which would amend the Public Health Service Act, as well as the patent laws, to establish a new regulatory framework authorizing FDA to approve generic versions of branded biologics (a.k.a. "generic biologics" or "biosimilars"). The amendment, which was adopted by a 47-11 vote, closely resembles H.R. 1548, the "Pathway for Biosimilars Act," which was introduced in March by Representatives Eshoo, Inslee, and Barton. The language adopted by the House Committee mirrors language adopted by the Senate Health, Education, Labor, and Pensions (HELP) Committee during its markup of the "Affordable Health Choices Act" (which was reported favorably by the Committee on July 15). The amendment was offered by Sens. Kay Hagan (D-NC), Mike Enzi (R-WY), and Orrin Hatch (R-UT). Both amendments provide twelve years of market exclusivity to pioneer biological products and, additionally, the amendment adopted by the House Committee provides for an additional six months for products used in pediatric populations.

While the regulatory framework that would be established under the pending legislation to authorize generic biologics is similar to the Hatch-Waxman framework governing generic drugs, none of the pending bills contain provisions that would ban or regulate reverse payments for generic biologics. The above referenced bills that would ban reverse payments would apply only to drug products, but the scope and nature of the policies that are developed to address reverse payments can be expected to continue to evolve in the current legislative and regulatory environment.

Leaders in the House and Senate have pledged to vote on comprehensive health care reform

legislation this Fall. That said, both Chambers continue to finalize their respective bills and the ultimate inclusion of the provisions outlined above remains unclear.

Kelley Drye and Warren LLP

Kelley Drye is recognized as a premier antitrust and competition firm. Our national reputation stems from our proven track record of successfully representing clients in complex competition issues arising under federal and state antitrust laws. Our professionals include officials from the ABA Antitrust Section, and former officials of the United States Department of Justice Antitrust Division and the FTC. Our firm is also supported by Georgetown Economic Services, an economic consulting firm.

Kelley Drye's team of Food and Drug lawyers strives to integrate our clients' business strategies with FDA compliance and to help resolve regulatory enforcement matters when they arise. Working side-by-side with business development and marketing professionals, we provide comprehensive regulatory counseling and assist in developing products, labels, and promotional materials that achieve our clients' goals without running afoul of regulatory requirements. With close knowledge of FDA's enforcement priorities and deep experience with the FTC's regulation of advertising, our team can provide comprehensive legal advice with an eye towards giving clients a competitive edge.

Kelley Drye's Government Relations & Public Policy practice helps clients interpret and shape governing laws, enabling them to achieve and maintain market leadership. The Government Relations practice includes attorneys who are both litigators and legislative advocates, as well as non-lawyer legislative professionals who have experience with the legislative and executive branches and the federal agencies. We work closely with the full range of Kelley Drye's regulatory practice groups, including, but not limited to, antitrust, advertising, consumer product safety, environmental, food and drug, healthcare, international trade, tax and telecommunications and e-commerce.

For more information about this Client Advisory, please contact one of the members of our multidisciplinary team for assistance:

Dana Wood
(202) 342-8608
dwood@kelleydrye.com

[1] *See* Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. No. 98-417)(Sept. 24, 1984) (amending § 505 of the Federal Food Drug & Cosmetic Act, and other laws, to authorize FDA approval of generic drug alternatives to brand name pioneer drugs under abbreviated new drug application requirements, grant patent term extension for pioneer drugs approved under full new drug application requirements, and authorize a 180-day period of market exclusivity to the first successful generic drug applicant under specified conditions).

[2] Jon Leibowitz, Chairman, Fed. Trade Comm'n, "Pay-for-Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform (The $35 Billion Solution), at the Center for American Progress (June 23, 2009).

[3] *See, e.g.*, Diane Bartz, *FEATURE-US trade agency wants to end deals delaying generics*, REUTERS, May 6, 2008 available at http://www.reuters.com/article/sphereNews/idCAN2933425920080506?sp=true&view=sphere. (John Rother of AARP has pointed out, the brand/generic price differential

could also limit access, as seniors that “need medication and . . . can't get a generic drug, they’re probably not going to be able to afford it”).

[4]544 F.3d 1232 (Fed. Cir. 2008).

[5]*In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006).

[6]On July 6, 2009, upon request from the Second Circuit, the Department of Justice filed a brief stating that reverse payments are presumptively a restraint of trade under the Sherman Act and that drug companies should offer justifications to avoid liability. The brief recommends that the Second Circuit should adopt a rebuttable presumption of anticompetitive conduct when hearing a reverse payment case.

[7]*Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

[8]*In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003).

[9]*See* Leibowitz, *supra* note 2.

[10]*Id.* [11]Brief for the United States as Amicus Curiae, FTC v. Schering-Plough Corp., 402 F.3d 1056 (11th Cir. 2005) (No. 05-273).

[12]Brief for the United States In Response to the Court’s Invitation, In Re Ciprofloaxin Hydrochloride Antitrust Litigation. (No. 05-2851-cv(L)) (2d. Cir. July 6, 2009).