New Federal Initiatives Project

Reverse Payment Settlements and Upcoming Congressional Action

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In light of the recent political focus on healthcare, several Congressional bills propose to single out a class of contracts between pharmaceutical companies for closer antitrust scrutiny. Oftentimes, a pharmaceutical company will engineer a functionally identical substitute to a "brand name" drug with specific appeal to consumers. This substitute – with the chemical properties of the known drug but a different name – is known as a "generic drug," or simply a "generic." In an attempt to preserve the legal monopoly a patented brand-name enjoys, the branded drug's producer will sometimes offer the generic's producer a payment to delay entry into the market for a fixed amount of time. Known as a "reverse payment settlement" – or colloquially as "pay for delay" – these agreements are at the intersection of contemporary fears and debates about healthcare and a debate as old as the law of competition itself.

Bills Pending in Both House and Senate Seek to Make Reverse Payment Settlements *Per Se* Illegal

Senator Herbert Kohl introduced the "Preserve Access to Affordable Generics Act" (S. 369) on February 3, 2009.[1] The act bans reverse payments outright by forbidding "any person, in connection with the sale of a drug product, to directly or indirectly be a party to any agreement resolving a patent infringement claim in which (1) the [generic company] receives anything of value; and (2) the [generic company] agrees not to research, develop, manufacturer, market or sell the [generic] product for any period of time."[2] The bill's sponsors justify the imposition of such a sweeping rule by analogy to horizontal price-fixing arrangements: by delaying generic entry into a relevant product market, they allege, reverse payment agreements essentially reduce product quantities and inevitably raise prices for consumers.[3] Representative Bobby Rush of Illinois introduced the substantially similar "Protecting Consumer Access to Generic Drugs Act of 2009" on March 25, 2009.[4]

Both bills provide the equivalent of a regulatory "safety valve" to the proposed *per se* rule. Both Acts confer upon the Federal Trade Commission the power to exempt and authorize any reverse payment agreements which act "in furtherance of market competition and for the benefit of consumers."[5] In response, the Chairman of the Federal Trade Commission, Jon Leibowitz, recently praised Rep. Rush's bill as an effective method of controlling healthcare costs.[6] Leibowitz's logic echoes the supporters of both bills: by preventing entry into the relevant product market, pharmaceutical interests effectively increase prices to consumers, resulting in losses to consumer welfare.[7]

The Debate: *Per Se* or Rule of Reason Analysis?

While novel at first glance, support for both Sen. Kohl's and Rep. Rush's bills reflects a new manifestation of the applicability of a *per se* rule of illegality versus the more flexible (and lenient) rule of reason. Courts have been hesitant to apply the *per se* rule because of its unforgiving application: once so categorized, an agreement is almost unfailingly condemned and its progenitors subject to treble damages under the antitrust laws. Accordingly, courts apply the *per se* rule only where an agreement always or almost always reduces output to a product market and increases prices to consumers.[8] Some groups believe that reverse payment agreements fit this definition: the FTC, many state attorneys general, and numerous consumer protection groups suggest a *per se* approach is appropriate. Such advocates argue that "pay for delay" agreements inevitably reduce competition in the pharmaceutical industry, harming consumers with enough certainty to justify the stringent *per se* rule.

Many opponents of the bill, including several antitrust scholars, express hesitation due to the lack of empirical evidence supporting the *per se* approach.[9] They say the novelty of reverse payment arrangements alone militates against the application of the *per se* rule, as *per se* treatment is generally only rendered against agreements for which there is "considerable judicial experience" of anticompetitive effects.[10] Furthermore, they suggest that the little empirical research on the topic that exists undercuts the argument for *per se* illegality. Professor Dan Crane of the University of Michigan has argued that the existence of a reverse payment agreement in the brand name/generic drug context only weakly correlates

with a negative social cost.[11] At least two Circuit Courts of Appeals have similar hesitation in light of the absence of significant judicial experience. The Second and Eleventh Circuits have each explicitly rejected the proposition that reverse payment settlements are sufficiently facially anticompetitive to justify *per se* treatment. The Federal Circuit has shown similar division, rendering judgment for brand-name manufacturers in approximately half of patent infringement cases between 2004 and 2008.

Nonetheless, the Federal Trade Commission seeks favorable treatment of the *per se* theory so as to cause a "circuit split" on the issue and draw the attention of the Supreme Court. The Commission has recently filed an *amicus curiae* brief in the Second Circuit proposing that the Court view reverse payments as presumptively unlawful, requiring companies show a pro-competitive justification to avoid antitrust liability.[12] The Federal Circuit recently dismissed a substantially similar appeal; if the Second Circuit were to do so, it would effectively sustain the dismissal of the underlying antitrust suit and rebuff the Commission's approach again.[13] As these prospects dwindle, the FTC has turned its attention at least in part to the above-mentioned Congressional bills to legislatively impose the *per se* rule courts have thus far declined to find. Amongst other scholars, Professor Crane notes the likely result of the Commission's success: should reverse payment agreements remain economically productive, antitrust attorneys will devise new and myriad ways to enable brand-name manufacturers to preserve drug monopolies granted by patent.[14]

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[1] Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009), *available at* http://www.govtrack.us/congress/bill.xpd?bill=s111-369.
[2] G. Mark Edgarton & Eric J. Marandett, *Consequences of Banning Reverse Payments*, LAW360, April 9, 2009, at 1, *available at* http://www.choate.com/media/pnc/1/media.1961.pdf.
[3] S. 369, 111th Cong. § 2(a) (2009).
[4] Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009), *available at* http://www.govtrack.us/congress/bill.xpd?bill=h111-1706.
[5] S. 369, 111th Cong. §3 (2009); H.R. 1706, 111th Cong. §3 (2009).
[6] Press Release, Federal Trade Commission, FTC Chairman Praises House Subcommittee for Approving Protecting Consumer Access to Generic Drugs Act of 2009 (June 3, 2009), *available at* http://www.ftc.gov/opa/2009/06/genericdrugs.shtm.
[7] *Id*.
[8] Ken Letzler & Sonia Pfaffenroth, *Patent Settlement Legislation: Good Medicine or Wrong Prescription?*, 23 ANTITRUST 83, 84 (Spring 2009), *available at* http://www.arnoldporter.com/resources/documents/Arnold&PorterLLP_Antitrust_SPRING2009.pdf.
[9] Posting of Josh Wright to Truth on the Market, http://www.truthonthemarket.com/2009/03/30/crane-on-carriers-innovation-in-the-21st-century/ (Mar. 30, 2009, 00:39 EST).
[10] Letzler & Pfaffenroth, *supra* note 8, at 83.
[11] Posting of Dan Crane to Truth on the Market, http://www.truthonthemarket.com/2009/03/30/crane-on-carriers-innovation-in-the-21st-century/ (Mar. 30, 2009, 12:54 EST).
[12] Henson, Shannon, *'Reverse Payments' Presumptively Unlawful: DOJ*, LAW360, July 6, 2009, at 1, *available at* www.law360.com/articles/109839.
[13] *Id*.
[14] *See* Crane, *supra* note 11.

Related Links:

Preserve Access to Affordable Generics Act, S. 369, 111th Cong. (2009):
http://www.govtrack.us/congress/bill.xpd?bill=s111-369

Protecting Consumer Access to Generic Drugs Act of 2009, H.R. 1706, 111th Cong. (2009):
http://www.govtrack.us/congress/bill.xpd?bill=h111-1706

Press Release, Federal Trade Commission, FTC Chairman Praises House Subcommittee for Approving Protecting Consumer Access to Generic Drugs Act of 2009 (June 3, 2009):
http://www.ftc.gov/opa/2009/06/genericdrugs.shtm

"Patent Settlement Legislation: Good Medicine or Wrong Prescription?" by Ken Letzler & Sonia Pfaffenroth, 23 ANTITRUST 83, 84 (Spring 2009):
http://www.arnoldporter.com/resources/documents/Arnold&PorterLLP_Antitrust_SPRING2009.pdf

"Crane on Carrier's Innovation in the 21st Century," by Dan Crane, Truth on the Market,
http://www.truthonthemarket.com/2009/03/30/crane-on-carriers-innovation-in-the-21st-century/

"Consequences of Banning Reverse Payments," by G. Mark Edgarton & Eric J. Marandett, LAW360, April 9, 2009, at 1: http://www.choate.com/media/pnc/1/media.1961.pdf

The Obama Administration's Budget Proposal for Health and Human Services by Paula Stannard:
http://www.fed-soc.org/publications/pubid.1493/pub_detail.asp

"Antitrust Pricing War: Congress v. the Court" by Geoffrey A. Manne and Joshua D. Wright:
http://www.fed-soc.org/publications/pubid.1489/pub_detail.asp