

**Divergence at Home:**

**Comments on the Differences between the Federal Antitrust Enforcement Agencies  
on How to Judge the Legality of Reverse Payments**

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We saw last year a rare public divergence on antitrust policy between the U.S. Department of Justice and the Federal Trade Commission. In separate filings with the U.S. Supreme Court they stated different approaches to the antitrust legality of “reverse payments” made as part of a settlement of patent infringement litigation. The Court has asked the United States for its views on another similar case. While the Commission has extensively explained the reasons for the approach it takes, the Department has only done so in summary fashion. This paper explores a possible explanation for the Department’s divergence from the FTC.

In doing so, I do not intend to repeat the fine work of other authors setting forth the background and history regarding “reverse payments” or “payments for exclusion.” Nor will I develop proposals for how to adjudicate antitrust challenges to patent settlements. Instead, my goal is more limited, namely, to comment on the possible doctrinal source of the disagreement. A better understanding of the disagreement helps appreciate the implications of the issue that has divided the agencies and provides a fuller basis to evaluate how the Department’s approach might evolve if it were adopted by the Supreme Court.

My thesis is that the Department, through the Antitrust Division, has developed a fundamental position regarding the importance of intellectual property that drives its tolerant position regarding reverse payments. The FTC, in contrast, has evolved a view on the importance of price competition between generic and branded pharmaceuticals that leads to more aggressive antitrust standards. The Department’s position suggests that the risks to investment in intellectual property from the FTC’s approach are too great, and the gains too little, to justify

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aggressive enforcement in this area. While the Department has not explained its views in detail, the FTC has addressed the point briefly and believes the risks are overstated.

### How Great Is the Divergence?

In some ways, I find it difficult to identify the precise boundaries of the gulf between the agencies because the Department has not had the opportunity to expand upon its brief statement of disagreement with the FTC. Nonetheless, a review of the agencies' public statements gives us the basic contours of where they disagree.

The FTC says that any payment by a branded drug manufacturer to a generic manufacturer to defer entry beyond when it otherwise would have entered is unlawful.<sup>2</sup> That does not tell us how we know whether the payment is intended to or did have that effect, of course. But, the FTC appears to take the position that the fact of a "substantial payment" gives rise to a mandatory, but rebuttable inference that the reason or effect of the payment is to delay entry which would otherwise have occurred sooner, absent the payment:

If, however, the patent holder makes a substantial payment to the challenger as part of the deal, absent proof of other offsetting consideration, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.<sup>3</sup>

The Commission does not advocate that such payments are *per se* illegal, but the difference between labeling the conclusion that such payments are *per se* illegal and the approach that the Commission has articulated is not clear.<sup>4</sup>

In some fundamental aspects, the Department agrees with the Commission. It recognizes the importance of the issues which the Commission has raised and that patent settlements may have anticompetitive consequences.<sup>5</sup> It parts ways with the Commission, however, when it comes to the nature of the evidence necessary to find an antitrust violation.

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<sup>2</sup> Prepared Statement of the Federal Trade Commission before the Special Committee on Aging of the United States Senate on Barriers to Generic Entry, (July 20, 2006), by Commissioner Jon Leibowitz ("Liebowitz, July 20, 2006") at 18, available at <http://www.ftc.gov/os/2006/07/P052103BarrierstoGenericEntryTestimonySenate07202006.pdf>.

<sup>3</sup> *FTC v. Schering-Plough Corp.*, No. 05-273, Petition for Writ of Certiorari at 18 (filed August 29, 2005), available at <http://www.ftc.gov/os/2005/08/050829scheringploughpet.pdf>.

<sup>4</sup> *Schering-Plough*, Reply Brief for the Petitioner at 5 (filed October 13, 2005), available at <http://www.ftc.gov/os/adjpro/d9297/051013certiorarireplybrief.pdf>.

<sup>5</sup> *Schering-Plough*, Brief for the United States as *Amicus Curiae*, at 1, 8 (filed May 17, 2006), available at <http://www.usdoj.gov/atr/cases/f216300/216358.pdf>.

The Department believes that an agency or court must first evaluate the relative likelihood of success of the patent challenge through a limited examination of the infringement suit before condemning any payment.<sup>6</sup> And, it states that it disagrees with the Commission in that the Department would examine objective evidence extrinsic to the settlement itself in deciding whether a payment is for delay, whereas the Commission relies on a subjective evaluation of the parties made at the time of settlement.<sup>7</sup>

The Department has not said too much about where this inquiry leads or how an agency or a court should conduct it, other than to observe that it need not constitute a full scale patent validity and infringement trial. For example, my sense is that the Department is saying that if a quick study shows the patent is likely valid and likely infringed, that no antitrust claim will lie. But, what if that is not the case? What if the quick hearing shows that there are serious question going to the validity of the patent or its infringement? Does that mean that any reverse payment is unlawful? Or would the Department allow the patent holder to mount a defense showing at a full trial, despite the preliminary conclusion, that it indeed would have won the patent infringement suit? Even if it cannot make that showing, must a plaintiff still prove relevant markets, market power, anticompetitive effects, or any of the other issues often presented in a full rule of reason case? May a defendant claim efficiencies?

Regardless of the answer to these questions, the Commission agrees that the Department and it disagree.<sup>8</sup> It simply would not look beyond the “contemporaneous acts of knowledgeable actors – particularly the generic firms’ refusal to defer entry absent substantial payments by the patent-holder. . . .”<sup>9</sup> The Commission might bolster the inference of intent to delay entry with other evidence, but would require the settling parties to rebut this *prima facie* case to avoid liability.<sup>10</sup> Essentially, the Commission invokes the quick look line of antitrust cases to support its approach.<sup>11</sup>

### Why Did The Department Express Its Disagreement Publicly?

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<sup>6</sup> *Id.* at 11 and n. 1.

<sup>7</sup> *Id.* at 12.

<sup>8</sup> *Federal Trade Commission v. Schering-Plough Corp.*, No. 05-273 (Sept. 12, 2006), Supplemental Brief for Petitioner in support of its petition for a writ of *certiorari*, at 3, available at <http://www.ftc.gov/os/adjpro/d9297/060612certiorarisupplementalbrief.pdf>. In addition to disagreeing with the approach that the Department suggested, the Commission also disagreed with whether the 11<sup>th</sup> Circuit’s decision in the *Schering-Plough* case would allow a “limited examination” of the patent merits. *Id.* The Commission believes that the appellate court’s ruling was more restrictive and would permit no challenge to a patent infringement settlement unless patent infringement claims were shown to be a sham. *Id.*

<sup>9</sup> *Id.* at 4.

<sup>10</sup> *Id.* at 5 n. 1.

<sup>11</sup> *Id.* at 5, citing *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 456 (1986); *California Dental Association v. FTC*, 526 U.S. 756, 781 (1999).

The actual point of divergence -- on the nature of the evidence and the relative burdens of proof -- seems at one level not to be the type of thing that would drive a public wedge between the agencies. That suggests there is something more at issue than a mere difference of opinion on a particular area of current enforcement activity.

While the event that prompted the divergence is the Supreme Court's request for the Solicitor General's views, I think that the setting would have driven consensus in most instances rather than prompt a disagreement. Admittedly the stakes are higher at the Supreme Court because of the broader impact of the decision, but the agencies have in the past submitted consensus briefs on controversial issues before the Court.<sup>12</sup> Absent some other consideration, the value of a consistent antitrust enforcement standard and message would likely have led to a consensus on the issue. Undoubtedly, the fact that the issues came before the Court brought to the surface the disagreement, but there needs to be something else going on besides the observation that thoughtful people at each of the agencies came up with differing solutions and refused to compromise when the case reached the high court.

The pharmaceutical context underscores this point. The FTC is the traditional and primary enforcer of the antitrust laws in the pharmaceutical industry.<sup>13</sup> It is common knowledge that the agencies have deferred to each other over which will enforce the antitrust laws in different industrial sectors to avoid duplicative investigations and confusion in enforcement signals. While in some sectors the agencies may not always agree on their relative expertise, the pharmaceutical industry is one in which the public has seen little or no disagreement between them -- the FTC is the cop on the pharmaceutical beat. In performing that job, the Commission has clearly built up substantial expertise about the markets in which pharmaceutical products compete.<sup>14</sup>

If for no other reason than to respect the principles that have made clearance work well in the pharmaceutical industry, the Department would be likely to defer to the FTC on industry-specific issues. In other sectors, antitrust enforcement has received criticism because of delay occasioned by the Department's and the FTC's inability to decide swiftly which will take the lead on an important and time-sensitive investigation. The agencies have recognized that such clearance disputes are a problem, and thus, all other things being equal, I would expect that they would not disrupt a clear line of enforcement responsibility, such as that regarding civil pharmaceutical enforcement, that has worked well. This point seems to have even greater force because the FTC's activity in this area is a high profile and deliberate policy. In a recent report

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<sup>12</sup> See, e.g., *California Dental Association v. Federal Trade Commission*, Case No. 97-1625, Brief for the Respondent (filed December 14, 1998), available at <http://www.usdoj.gov/osg/briefs/1998/3mer/2mer/97-1625.mer.pdf>.

<sup>13</sup> Statement of James M. Griffin, Deputy Assistant Attorney General, Antitrust Division, before the Committee on the Judiciary, United States Senate, Hearing on Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements at 4 (May 24, 2001) available at <http://www.usdoj.gov/atr/public/testimony/8327.pdf>.

<sup>14</sup> See Liebowitz, July 20, 2006, *supra* at 4 for a partial description of the Commission's substantial expertise in this industry.

on its activities, the Commission listed protection of generic competition as the first item in the highlights of its activity.<sup>15</sup>

My point is not that the Department has no experience with the pharmaceutical industry. Quite to the contrary, it has both historical and current involvement with the industry. For example, in 1992, the Department indicted two generic pharmaceutical manufacturers for price fixing.<sup>16</sup> Similarly, the Department successfully broke up a major cartel of vitamin manufacturers.<sup>17</sup> It opined in a business review letter to the American Hospital Association that it had no intention to challenge the formation and operation of the Pharmaceutical Roundtable, a joint venture of the AHA and major pharmaceutical manufactures formed to sponsor and fund biomedical research.<sup>18</sup> The Division plays an important, ongoing role in advising the executive branch agencies regarding competition policy and antitrust enforcement in the pharmaceutical industry. For example, the Division provides competition expertise to the Drug Enforcement Administration.<sup>19</sup> And, the Attorney General is charged with the authority to grant an antitrust exemption to participants in the pharmaceutical industry to aid in the response to a pandemic or epidemic in appropriate circumstances.<sup>20</sup> But, these and other historical and current examples of the Department's antitrust role in the pharmaceutical industry are far too little to explain intrusion into the FTC's role as civil antitrust enforcer in the pharmaceutical industry. Fundamentally, because the FTC has developed such substantial expertise in the pharmaceutical industry, the Department would seem to lack the institutional experience to second guess the FTC's enforcement position on reverse payments as part of pharmaceutical patent settlement.

Thus, I doubt that the divergence occurred because the Department has simply disagreed with the FTC's conclusions regarding the importance of competition between generic and branded drugs. In fact, the Department has not stated any direct disagreement with the FTC on its conclusions regarding the dramatic impact of generic competition on the pricing of branded pharmaceuticals. Moreover, I doubt that the Department, even if it disagreed with those conclusions regarding the impact of generic competition, would have decided that the pharmaceutical industry was so large and important that it could not allow the FTC to err in an area viewed as belonging to the FTC. In short, the pharmaceutical context makes even more surprising that the Department would publicly undercut the FTC's enforcement position.

To explain the disagreement, I think we have to focus more closely for a moment on the benefits that the FTC asserts come from its enforcement efforts. The FTC's work in this area is

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<sup>15</sup> The FTC in 2007: A Champion for Consumers and Competition (Federal Trade Commission 2007) at 2, available at <http://www.ftc.gov/os/2007/04/ChairmansReport2007.pdf>.

<sup>16</sup> See Press Release at [http://www.usdoj.gov/atr/public/press\\_releases/1992/211320.htm](http://www.usdoj.gov/atr/public/press_releases/1992/211320.htm).

<sup>17</sup> Griffin, *supra* at 5.

<sup>18</sup> Letter from Joel I. Klein to David William Livingston (March 20, 1998), available at <http://www.usdoj.gov/atr/public/busreview/1608.htm>.

<sup>19</sup> See Federal Register, v. 67, no. 109 at 39041-46 (June 6, 2002).

<sup>20</sup> Pandemic and All-Hazards Preparedness Act, S. 3678, section 405(a)(4).

all about price competition.<sup>21</sup> The Commission acknowledges it has “aggressively protected competition” by generics with branded pharmaceuticals.<sup>22</sup> The point, as should become clearer in a moment from a look at the Department’s priorities, is that the Commission makes no claim that the competition it is protecting generates any innovation or intellectual property benefits. Instead, the Commission is seeking to foster immediate, short-term price reductions for consumers.

The Department, in contrast, has identified a potentially significant cost from this “aggressive enforcement” effort, namely, the impact on innovation and the costs of litigation. The Department asserts that legitimate settlements encourage innovation and avoid unnecessary litigation.<sup>23</sup> While one cannot logically quibble with the second of these – how can one challenge the proposition that “legitimate settlements . . . avoid unnecessary litigation” – I doubt that it has enough force or the Department enough expertise regarding the impact on the likelihood of patent settlements from strict antitrust enforcement to drive it to a public disagreement with the FTC over this issue. Instead, I think the root of the disagreement lies in the Department’s invocation of the potential impact on innovation.

The Department has a long and committed position on the value of innovation. That position has driven both aggressive enforcement and led to restraint in intervention in markets. For example, as early as 1993, the Department challenged a merger on the grounds that it would reduce innovation competition for the development of automatic transmissions for large trucks.<sup>24</sup> And, in explaining two merger challenges from the late 1990s, the Department emphasized the “particular relevanc[ce]” of antitrust enforcement to “high-technology and emerging growth industries”:

Antitrust enforcement in these industries is essential because of the importance of maintaining competition for innovation, the engine of our economic growth. Curtailing innovation through mergers may have serious anticompetitive consequences to consumers over the long run, and **may be even more damaging to them than a price increase or a quality decrease.** (Emphasis supplied.)<sup>25</sup>

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<sup>21</sup> See, e.g., Liebowitz, July 20, 2006 at 6.

<sup>22</sup> *Id.* at 4.

<sup>23</sup> DOJ *Amicus* brief at 8.

<sup>24</sup> *United States v. General Motors Corp.*, Civ. No. 93-530 (D. Del. filed Nov. 16, 1993), discussed in, The 1995 Antitrust Guidelines for the Licensing of Intellectual Property: New Signposts for the Intersection of Intellectual Property and the Antitrust Law, Richard J. Gilbert, Deputy Assistant Attorney General, Antitrust Division; ABA Section of Antitrust Law, Spring Meeting (Washington D.C. April 6, 1995), available at [www.usdoj.gov/atr/public/speeches/0167.htm](http://www.usdoj.gov/atr/public/speeches/0167.htm).

<sup>25</sup> Leap-Frog and Other Forms of Innovation: Protecting the Future for High-Tech and Emerging Industries Through Merger Enforcement, Constance K. Robinson, Director of Operations and Merger Enforcement, Antitrust Division, at 1-2, American Bar Association (Chicago, IL June 10, 1999) (emphasis supplied), available at [www.usdoj.gov/atr/public/speeches/2482](http://www.usdoj.gov/atr/public/speeches/2482).

The Division emphasized “the need to be vigilant to preserve innovation competition.”<sup>26</sup> Similarly, in explaining its antitrust challenge to the practices of the Microsoft Corporation, the Division lauded aggressive antitrust enforcement to protect competition to innovate.<sup>27</sup> Once again, the Division highlighted the greater benefits from innovation than from mere price competition:

In evaluating markets with relatively homogeneous products and a fixed or slowly-evolving technological base, the Antitrust Division often focuses on the price effects of potentially anticompetitive behavior. In dynamic network industries, however, technological change and innovation as well as price receive substantial attention. Innovation affects not so much the prices that consumers pay for given goods, **but more importantly** innovation affects the quality of products in the marketplace and especially whether dramatically new and better products will come into existence.<sup>28</sup> (Emphasis supplied.)

In short, the Division signaled and acted on the principle that it would normally not allow a lessening of competition where doing so would require it to accept “‘dynamic inefficiencies’ . . . in exchange for the current technology at an attractive price.”<sup>29</sup>

While used to explain aggressive intervention in some instances, the Division clearly did not, and does not, consider the underlying principles pointing only in that direction. Instead, the Division’s policy views when initially developed were described in more general terms: “In today’s economy, technology partnerships are essential to remain globally competitive and to market the products that knowledge assets help to create.”<sup>30</sup> The Division viewed investment in intellectual property as a key to the nation’s competitiveness in the world economy<sup>31</sup> and protecting that investment as an important component to our economic wellbeing: “There is a high correlation between the protection that a nation provides for owners of intellectual property and its success in creating economic prosperity.”<sup>32</sup> While the articulation of these principles has

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<sup>26</sup> *Id.* at 2.

<sup>27</sup> Competition, Innovation, and Antitrust Enforcement in Dynamic Network Industries, Daniel L. Rubinfeld, Deputy Assistant Attorney General, Antitrust Division, Software Publishers Association Spring Symposium (San Jose, CA March 24, 1998), available at [www.usdoj.gov/atr/public/speeches/1611.htm](http://www.usdoj.gov/atr/public/speeches/1611.htm).

<sup>28</sup> *Id.* at 1.

<sup>29</sup> Cross-Licensing and Antitrust Law, Joel I. Klein, Acting Assistant Attorney General, Antitrust Division at 6, American Intellectual Property Association (San Antonio, TX May 2, 1997), available at [www.usdoj.gov/atr/public/speeches/1118.htm](http://www.usdoj.gov/atr/public/speeches/1118.htm).

<sup>30</sup> Intellectual Property and the Antitrust Laws: Protecting Innovators and Innovation, Richard J. Gilbert, Deputy Assistant Attorney General, Antitrust Division, at 2, Annual Winter Meeting, Licensing Executives Society (Phoenix, AZ Feb. 17, 1995), available at [www.usdoj.gov/public/speeches/0130](http://www.usdoj.gov/public/speeches/0130).

<sup>31</sup> *Id.* (“The United States continues to lead the world in the creation and use of new technology.”)

<sup>32</sup> *Id.*

sharpened in the decade or so since first actively promoted, the fundamental point has not changed. The Division sees “intellectual property and antitrust law” as sharing “the common purpose of promoting dynamic competition and thereby enhancing consumer welfare. . . . More than ever before, the creation and dissemination of intellectual property is the engine driving economic growth and consumer satisfaction.”<sup>33</sup>

Naturally, these principles also counsel caution, where intervention might chill investment in intellectual property. For example, the Division has recently inveighed against government orders that amount to “regulatory second-guessing of private firms’ solutions to technological problems.”<sup>34</sup> The Division’s concern was that such intervention favored static efficiency over dynamic efficiency. The Division defined static efficiency in terms that match well the Commission’s efforts to protect price competition in the pharmaceutical industry through challenges to patent settlements: “[S]tatic efficiency . . . occurs when firms compete within an existing technology to streamline their methods, cut costs, and drive the price of product embodying that technology down to something close to the cost of production.”<sup>35</sup> The Division, as observed above, does not disagree with the Commission that the protection of such static efficiency is an important goal of antitrust enforcement; however, the Division clearly views the loss of “dynamic efficiencies” as easily swamping gains from price competition: “Static efficiency is a powerful force for increasing consumer welfare, but economists tell us that an even greater driver of consumer welfare is dynamic efficiency.”<sup>36</sup> And, the Division believes that government intervention, including antitrust enforcement, can encourage static competition at the expense of dynamic efficiency:

The same forces that yield the benefits of static competition – conditions that encourage rivals quickly to adopt a new business method and drive their production toward marginal cost – can discourage innovation (and thus dynamic efficiencies) if the drive toward marginal costs occurs at such an early stage that it makes innovation uneconomical. Where innovation requires substantial up-front research and development (R&D) costs, a rational firm will elect not to innovate if it anticipates a selling environment that too quickly resolves to marginal cost of production. This problem is sometimes described as the need to recoup R&D costs and

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<sup>33</sup> Joint DOJ-FTC Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, Charles A. James, Assistant Attorney General, Antitrust Division at 2 (Washington, D.C. Feb. 6, 2002), available at [www.usdoj.gov/atr/speeches/10162.htm](http://www.usdoj.gov/atr/speeches/10162.htm).

<sup>34</sup> Interoperability Between Antitrust and Intellectual Property, Thomas O. Barnett, Assistant Attorney General, Antitrust Division at 1, 8, George Mason University Law Symposium (Washington, D.C. Sept. 13, 2006), available at [www.usdoj.gov/atr/public/speeches/218316.htm](http://www.usdoj.gov/atr/public/speeches/218316.htm).

<sup>35</sup> *Id.* at 2.

<sup>36</sup> *Id.*

expected profit sufficient to induce firms to direct their capital to risky R&D ventures.<sup>37</sup>

Just as with the issue of whether patent settlements might violate the antitrust laws, the Department and the Commission do not necessarily disagree, in the abstract, on the relative value of dynamic efficiency and static efficiency and that it is not necessarily appropriate to trade off dynamic efficiency to promote static efficiency.<sup>38</sup> But, it bears repeating that there is no claim that the Commission's enforcement efforts against reverse payment settlements promote dynamic efficiency.<sup>39</sup> Instead, the Commission says that Congress already balanced these interests when it passed the Hatch-Waxman Act and that its enforcement position is limited to the unique circumstances of the Hatch-Waxman Act. My surmise is that the Division is not so sanguine about these points.

The Hatch-Waxman Act does not directly address or even implicitly address the standards that should apply to whether a reverse payment violates the antitrust laws. It seems a fair point, however, that Congress did say something about the balance between the trade-off of generic price competition against value of fostering investment in intellectual property when it made it easier for generic manufacturers to challenge those patents and offered them incentives to do so. But Congress was obviously silent on whether and under what circumstances the parties to patent litigation could settle such challenges. Indeed, the Commission recently made this point in supporting a bill to facilitate challenges to reverse payments.<sup>40</sup> Moreover, other than its generalized point about Hatch-Waxman, the Commission, in its formal statements, has not directly addressed the argument that the aggressive enforcement against reverse payments decreases the incentive to invest in intellectual property, other than, as mentioned, to assert that Hatch-Waxman sets the proper balance.<sup>41</sup>

The Division's concern that aggressive antitrust enforcement in this area may decrease the incentives for investment in innovation may have arisen for a number of reasons. First, any antitrust enforcement focused on patent infringement settlements, and in particular aggressive

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<sup>37</sup> *Id.*

<sup>38</sup> The FTC in 2007, *supra* at 6 (noting talking about pharmaceutical merger enforcement the importance of protecting intellectual property rights while "ensuring that consumers are able to reap the maximum benefit from generic competition. . . .")

<sup>39</sup> *Compare id.* at 6 (giving consideration to intellectual property rights in the pharmaceutical merger context) *to id.* at 10 (making no mention of such rights in the discussion of reverse payment settlements).

<sup>40</sup> Prepared Statement of the Federal Trade Commission before the Subcommittee on Commerce, Trade and Consumer Protection, Committee on Energy and Commerce, United States House of Representatives (May 2, 2007) ("Leibowitz, May 2, 2007") at 22, available at <http://www.ftc.gov/opa/2007/05/gendrugs.htm>

<sup>41</sup> Leibowitz, May 2, 2007 at 4. Senior Commission officials writing, however, in their individual capacity, have acknowledged this issue but dismissed it as subsumed within the patent law's general balancing of the amount of protection needed to encourage investment in intellectual property; they appear to argue that so long as the Commission has adopted the right standard for determining whether a reverse payment is merely a payment to exclude. Abbott and Michel, *The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 IDEA 1, 20-22 (2005).

enforcement, increases the uncertainty that a patent holder can protect its investment. My understanding is that a patent holder normally faces only the prospect of loss of profits from competitive entry, or any claims the alleged infringer may have for damages, when deciding whether to litigate or settle a patent infringement suit. When antitrust enforcement standards make the settlement a potential antitrust violation, the patent holder now faces a new source of substantial claims, namely treble-damage actions on behalf of the patent holder's and the alleged infringer's customers for claimed competitive benefits they would have received but for the settlement. From the perspective of a firm's investment decision into developing new products, the increased uncertainty and risk associated with patent infringement litigation would seem to decrease the likely payoff from investing in development of the new products.

Second, the magnitude of this decrease in incentive is increased by the likelihood that the Commission and the courts will err occasionally in deciding which patent settlements to challenge. That comment is not meant as a criticism of the Commission or the courts, but merely an observation that government agencies, despite their best faith efforts, probably make mistakes. Indeed, the Commission's "aggressive enforcement" standards suggest that it has decided to err on the side of over-enforcement because it has decided to foster price competition. The Commission has not asserted that it developed those standards while trying to balance the competing interest of fostering intellectual property investment. I suspect the Division would be challenged to accept this approach given its view that evaluation of intellectual property rights "is outside our core expertise as antitrust enforcers."<sup>42</sup> Because of that uncertainty (and the increased disincentive to invest mentioned above), the Division's solicitousness of intellectual property rights would lead it to favor a noninterventionist approach: "History shows us, both in the United States and elsewhere, that while markets may not be perfect, neither are government agencies."<sup>43</sup> Paraphrasing the language used to explain why the Division intervened to prevent mergers that threatened innovation competition, the Division might explain its divergence from the FTC in this way: "Curtailing innovation through [overly aggressive antitrust enforcement] may have serious anticompetitive consequences to consumers over the long run, and may be even more damaging to them than a price increase or a quality decrease."<sup>44</sup>

The Commission's other point on this issue of chilling innovation--that reverse payments are unique to the pharmaceutical industry--is relevant here because it suggests that the Division should defer to the Commission.<sup>45</sup> The Commission's point is a logical one that flows well from Hatch-Waxman's procedural and substantive provisions. The Act creates some unique incentives and opportunities for generic manufacturers to settle collusively. The absence of

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<sup>42</sup> Antitrust and Intellectual Property, R. Hewitt Pate, Acting Assistant Attorney General, Antitrust Division, American Intellectual Property Law Association (Marco Island, FL Jan. 24, 2003), available at [www.usdoj.gov/atr/pubil/speeches/200701.htm](http://www.usdoj.gov/atr/pubil/speeches/200701.htm).

<sup>43</sup> Antitrust Issues in Standard Setting, Hill B. Wellford, Counsel to the Assistant Attorney General, Antitrust Division at 4, 2d Annual Seminar on IT Standardization and Intellectual Property, China Electronics Standardization Institute (Beijing, China March 29, 2007).

<sup>44</sup> See n. 25, *supra* and accompanying text.

<sup>45</sup> *Id.* at 6.

“reverse payment” settlements or antitrust challenges to patent settlements in other areas underscores the logic of this argument.

The absence of precision, however, over how the Commission and the courts might interpret what constitutes a payment for exclusion undercuts the argument. If the principles on which the Commission relies are not limited to the pharmaceutical industry, then the Department’s concern over protection of the incentives to invest in intellectual property come more into play.<sup>46</sup>

The Department might fairly have been concerned that the *Schering* case would lead to establishment of legal principles applicable to patent settlements generally. While Hatch-Waxman creates some unique incentives to reach collusive settlements, other incentives are likely common to a broader range of patent infringement suits.<sup>47</sup> Moreover, the Commission’s legal arguments do not contain any principle that would have limited them to the pharmaceutical industry.<sup>48</sup> Even the idea that the Commission is only challenging the seemingly unique notion of a “reverse payment,” is not, on closer examination, easily limited. The Commission itself has tried to preserve flexibility in determining when a patent holder is providing compensation for exclusion -- “Other types of consideration, any early entry date or a royalty to the patent holder or compromising on a damages claim, do not generally involve sharing the benefits that come from eliminating potential competition.” (Emphasis supplied.)<sup>49</sup> The Commission has shown in *Schering-Plough* its willingness, moreover, to engage in inquiries to determine whether payments made in agreements that address more than just the settlement of the infringement claim might reflect some underlying consideration paid for exclusion. And, it recently made clear that reverse payment agreements include “agreements on a product other than the one at issue in the patent litigation” and “side deals” regarding rights to unrelated products or co-promotion of those products.<sup>50</sup>

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<sup>46</sup> That is not to say that in theory the Department’s support of intellectual property investment would not be in play if this is purely a pharmaceutical industry issue. As discussed in the text, they would be and the Department might well disagree with the Commission’s approach. But, given the Commission’s expertise and hegemony over antitrust enforcement in that industry, the Department’s public divergence from the Commission becomes harder to explain. See nn. 13-20, *supra*, and accompanying text.

<sup>47</sup> Almost exactly 10 years ago, the Department expressed a concern that settlements of copyright and patent suits might lead to anticompetitive agreements: “But I remain convinced that the current situation means that, whenever there is even a more than trivial possibility of infringement, the costs of litigation skew the parties’ decisions, steering them away from a serious test of the bounds of the rights of the patentee or copyright holder and toward agreements that too often make teammates out of rivals.” *See Cross-Licensing and Antitrust Law*, Joel I. Klein, Acting Assistant Attorney General, Antitrust Division at 11 (American Intellectual Property Law Association, San Antonio, TX May 2, 1997). The Department’s suggested approach, however, was to intervene prospectively in highly circumscribed circumstances because it thought that the underlying settlement of the infringement suit would deprive it of the ability to intervene effectively.

<sup>48</sup> *See* Commission briefs cited a nn. 3, 4, 8, *supra*.

<sup>49</sup> Liebowitz, May 2, 2007 at 12.

<sup>50</sup> Liebowitz, May 2, 2007 at 17.

My point here is not that the Commission has some undisclosed agenda to broaden its inquiry into patent settlements beyond the pharmaceutical industry. Rather, the point is that legal principles, once established, are often difficult to limit. Thus, even if the Commission believed that it was addressing a problem unique to the pharmaceutical industry and would not itself have extended the underlying principles in a manner that applied its quick look approach to “reverse payments” into other fields, the Department could have a reasonable concern that private plaintiffs or state governments might take those principles and press antitrust claims where the Commission would not.

The principle reason supporting the Commission’s enforcement actions against pharmaceutical settlements, after all, would apply more broadly than the pharmaceutical industry. For example, I would expect to find many patented products with substantial margins and would not be surprised if entry of a matching product using the same technology would drive down the price of that product. Indeed, in those circumstances there would seem to be a healthy incentive for the patent holder and its competitor to agree not to compete. Of course, if actual infringement has occurred, it might be easier to mask the reverse payment in the form of a discount off the expected damages from infringement; but the point remains that in theory, the parties could be adjusting the economic benefits from the settlement to compensate the alleged infringer for deferral of entry beyond what it would have agreed to based on its probability of prevailing in the lawsuit.<sup>51</sup>

Antitrust scrutiny of that settlement, in the form of a treble damage action decided by a jury, might chill otherwise reasonable settlements, leading to the lessening of the incentive to invest in intellectual property that the Department has stated should be opposed. That chilling is particularly likely to occur if all that the plaintiff need show is that the patent settlement was somehow unreasonable and must have included a payment for exclusion to the infringer. Under the Commission’s quick look theory, the antitrust plaintiff need not say anything about the underlying merits of the patent lawsuit and the antitrust defendant cannot cite the strength of its patent claims as a defense. The plaintiff need not carry the traditional antitrust burdens of showing such things as market power. In short, antitrust litigation of patent settlements would rise or fall on juries’ *post hoc* review of the reasonableness of the settlement terms.

The Division, while it has not explained its comment in *Schering*, apparently believed for reasons such as those posited above or others, that the Commission’s position threatened to chill investment in innovation, and accordingly, demurred publicly. This is not a message that the Division saves for a domestic audience or its sister agency. Instead, it has actively and

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<sup>51</sup> See “What Constitutes a ‘Payment’ Can Be More Than Just Money,” testimony of C. Scott Hemphill, Associate Professor, Columbia Law School, House Committee on Energy and Commerce, Subcommittee on Commerce, Trade, and Consumer Protection, Hearing on H.R. 1902, Protecting Consumer Access to Generic Drugs Act of 2007 (May 2, 2007).

aggressively preached in Europe, South America and Asia the value of limited government intervention in the area of intellectual property rights in order to foster investment in them.<sup>52</sup>

I should explain that the Department's desire to preserve innovation incentives is really part of a much broader principle. That principle is that the over-enforcement of antitrust laws may chill many procompetitive activities.<sup>53</sup>

The Division urges foreign nations to adopt "a system of sound competition laws," which relies on an effects-based analysis that "avoids rigid rules in favor of a focus on the ultimate question of whether a practice harms competition."<sup>54</sup> The Division believes that application of this effects-based analysis strikes "the right balance between antitrust enforcement and permitting the robust exercise of intellectual property rights."<sup>55</sup> While the Division was not talking directly about reverse payment settlements in these international fora, its statements in those settings may well reflect the underlying rationale for its public divergence from the Commission and a criticism it may be implicitly leveling at the FTC's quick look condemnation of reverse payment settlements:

Our analysis is effects-based, which is a concept best understood in contrast to its alternative, which would be a form-based or rule-based approach. A form-based method of analysis would prohibit a broad group of practices or would establish a series of checklists and thresholds that, if met, would lead automatically to antitrust liability. . . .For the ultimate liability decision, we use an effects-based test: we ask, what is the short- and long-term effect of the challenged conduct on competition and efficiency? . . . Finally, the Department of Justice employs the enforcement model of antitrust, as opposed to the regulatory model. A regulatory approach is one in which a government agency identifies specific ways that a business should act, and then orders the business to do those particular things or penalizes it, after the fact, if the business does not adhere to those rules.<sup>56</sup>

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<sup>52</sup> See, *inter alia*, Intellectual Property and Competition: Four Principles for Encouraging Innovation, Gerald F. Masoudi, Deputy Assistant Attorney General, Antitrust Division, Digital Americas 2006 Meeting (Sao Paolo, Brazil April 11, 2006), available at [www.usdoj.gov/atr/public/speeches/215645.htm](http://www.usdoj.gov/atr/public/speeches/215645.htm); Efficiency in Analysis of Antitrust, Standard Setting, and Intellectual Property, Gerald F. Masoudi, Deputy Assistant Attorney General, Antitrust Division, High-Level Workshop on Standardization, IP Licensing, and Antitrust (Brussels, Belgium Jan. 18, 2007), available at [www.usdoj.gov/atr/public/speeches/220972.htm](http://www.usdoj.gov/atr/public/speeches/220972.htm); Contemporary Issues at the Intersection of Intellectual Property and Antitrust, Makan Delrahim, Deputy Assistant Attorney General, Antitrust Division, The Fair Competition & Market Economy, 2004 Shanghai International Forum (Shanghai, China Nov. 10, 2004), available at [www.usdoj.gov/atr/public/speeches/206607.htm](http://www.usdoj.gov/atr/public/speeches/206607.htm).

<sup>53</sup> Delrahim, Nov. 10, 2004 at 2.

<sup>54</sup> Masoudi, April 11, 2006 at 6.

<sup>55</sup> Delrahim, Nov. 10, 2004 at 3.

<sup>56</sup> Wellford, March 29, 2007 at 3.

One of the Department's goals in speaking on antitrust and intellectual property law in foreign settings is to achieve a convergence of standards. In doing so, the Department has pursued public splits with foreign enforcement agencies on how they viewed important issues, describing this approach as "constructive divergence."<sup>57</sup> Perhaps that is the best way to view the schism between the Department and the Commission on how to treat reverse payments, as an opportunity to air differences on an important issue with the goal that the public dialogue will lead ultimately to a consensus: "By recognizing our differences, paying close attention to the economic consequences of our respective enforcement decisions over time, and using those observations to test the assumptions that underlie our analyses, we might be able to come together and achieve even greater levels of convergence in the future."<sup>58</sup> Certainly the thoughtful expositions by the Commission of its views on reverse payment settlements, in part in response to the Department's divergence from it, have sharpened the understanding of this important issue.

Perhaps it will be the case as the debate continues that the Commission will persuade the Department and the courts that its laudable goal of fostering price competition and the attendant direct benefits to consumers should drive the antitrust standards applicable to antitrust mergers. Or, the Commission's position might evolve and become one clearly limited to settlements arising in the Hatch-Waxman context.

Alternatively, should the Division's suggested approach prevail, a public explanation for why that approach is a sound one would allow a better understanding of what should be the fuller parameters of the approach. Is the Division recommending a threshold inquiry into the patent merits before employing a version of the FTC's quick look test? Or, does its effects based analysis augur something more like a full-blown rule of reason inquiry, with the patent inquiry serving as screening step along the way?

In either event, we can have greater confidence that the right result was reached where the debate over the issue is a public one, rather than a dialogue pursued between the agencies privately.

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<sup>57</sup> The Long and Winding Road: Convergence in the Application of Antitrust to Intellectual Property, Makan Delrahim, Deputy Assistant Attorney General, Antitrust Division, George Mason Law Review Symposium (Washington, D.C. Oct. 6, 2004), available at [www.usdoj.gov/atr/speeches/205712.htm](http://www.usdoj.gov/atr/speeches/205712.htm).

<sup>58</sup> *Id.* at 6-7.