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Some Thoughts from a U.S. Perspective

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On January 16, 2008, the European Commission launched a sector inquiry by staging dawn raids on a number of pharmaceutical companies. When a major competition authority such as the Commission launches an "inquiry" into a sector of the economy, with no suggestion of specific wrongdoing but with a series of dawn raids on the affected parties, you have to wonder just what is going on. The stated reasons are puzzling, to put it nicely. There are many reasons for the lack of new drugs in the European Union—reimbursement levels and diversion/parallel trade come to mind. But it would be beyond odd if major manufacturers were getting together to cut their own throats, which is what it would amount to if there were any agreement to retard new product approvals and launches.

Further, the Commission already has a decision (now on appeal) against Astra-Zeneca concerning certain practices[1] and has brought an investigation against Boehringer alleging misuse of the patent system in order to exclude potential competition in the area of chronic obstructive pulmonary disease (COPD) drugs.[2] Interestingly, both of these

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* In January 2008, the author retired as Vice President and Assistant General Counsel of Pfizer, Inc. The opinions expressed herein are solely those of the author.

[1] Commission Decision 2006/857/EC, Re: AstraZeneca Plc, 2006 O.J. (L 332) 24.

[2] Case COMP/BE/39.246 – Boehringer (initiated Feb. 22, 2007).

cases are footnoted in the Commission's "Frequently Asked Questions" document issued as part of the current sector inquiry.

So what is really going on here? A couple of points are intriguing from a U.S lawyer's perspective.

DG Competition and the American Experience

For the past several years, DG Comp has been very interested in the activities in the United States with regard to patent litigation and settlements between innovator and generic companies. It is certainly an interesting topic, and one that has generated a lot of intellectual heat (if not always light). But the one key, immovable, irrefutable fact is that the U.S. laws that underlie and are responsible for that litigation are unique to the United States and have no analogue in the European Community. To extrapolate from the U.S. experience under its laws to anything in the European Community requires not simply a leap of faith, but the creation of an entirely new religion.

The Drug Price Competition and Patent Term Restoration Act of 1984[3] (referred to as "the Hatch-Waxman Act" after its legislative sponsors) fundamentally changed the legal and economic relationships between innovator and generic drugs. A full discussion of that law is well beyond the scope of this article. Relevant to this discussion though, are the two ways in which the Hatch-Waxman Act encouraged generic drug makers to challenge innovator patents.

First, it created an artificial act of infringement—filing an application for a specific type of approval that claimed either that the innovator patents were invalid or

[3] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 1984.

that they were not infringed. In traditional patent litigation, the potential infringer would have to run its clinical trials, get approval, manufacture, and launch; it would have risk. Under Hatch-Waxman, the risk no longer exists; filing for approval triggers the patent case. If that case is brought within time limits, then it triggers a 30-month stay on the U.S. Food & Drug Administration's (FDA) approval of the generic. The intent was that the case could be resolved before the generic company would be at risk by being allowed to market its product at all.[4]

But in addition to creating the riskless infringement, the U.S. Congress also created an incentive to bring that first challenge—make the first filing—which has made these cases very exciting. Under Hatch-Waxman, the first filer (if he wins) gets 180 days to sell without any other generic application being approved. So for 180 days, the generic could price at 85 percent to 90 percent of the innovator price and get *all* of the price sensitive business. And since many states (and private insurers) in the United States have mandatory generic substitution—well, you can see how the incentive becomes somewhat overwhelming.

But at the same time, the risk to the innovator ratchets up dramatically. Once the generic launches, the brand product is effectively dead. Even if he wins the case in the end, what he has is a claim for damages that may or may not be worth much (not many generic companies could respond to a billion dollar judgment, which is a real possibility when a major drug is challenged). So what you have is a huge incentive for the innovator

[4] This is vastly oversimplified, but for our purposes here it should be sufficient. For a fuller description of Hatch-Waxman, and the impact on litigation incentives, *see* Kent Bernard & Will Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 FED. CIR. B.J. 617 (2006).

to settle, in order to preserve at least some of its patent life (and the fruits of its research). While the U.S. Federal Trade Commission (FTC) and some commentators found this natural practice to be repugnant, most of the U.S. courts that have heard the challenges to the settlements have upheld the settlements.[5]

The lessons here are two-fold. First, the U.S. experience is grounded on U.S. laws and approval structures. The European Community has nothing like them. So the U.S. experience, while it may be interesting or instructive, cannot really be applied. Second, even if the U.S. experience could be applied, the cases before the U.S. courts have not always had the outcome the European Community seems to want. By and large, the U.S. courts have upheld the settlements as not violating the antitrust laws.

Some Machiavellian Speculation

So if the inquiry really is not about drug approvals, and if it really is not about innovator generic settlements (I am not aware of any trend towards such settlement in the European Union at all, although I will defer to others who may be closer to the ground on that), then what is it about? And why did it start with dawn raids?

My first reaction is to recall that there are a number of ways by which a competition agency can "make" case law. Obviously, it can bring specific cases, and the outcomes (along with court decisions) will shape future conduct. But sometimes an agency wants to change conduct without bringing cases, or seeking legislation, or trying any of the other traditional routes.

[5] *See* Bernard & Tom, op. cit. *See also* Phillip A. Proger, Testimony Regarding "H.R. 1902, Protecting Consumer Access to Generic Drugs Act of 2007", Before the United States House of Representatives Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy and Commerce (May 2, 2007), *available at* http://energycommerce.house.gov/cmte_mtgs/110-ctcp-hrg.050207.Proger-Testimony.pdf.

Back in the late 1960s and early 1970s, the United States went through another one of the periodic trips that the judicial pendulum makes through the antitrust & intellectual property (IP) interface. While the courts were taking a more restrictive view of what licensees could do, the Antitrust Division of the U.S. Department of Justice (DOJ) was not satisfied. So in addition to bringing cases, spokesmen went out and gave speeches and created what we referred to later in the U.S. antitrust bar as "luncheon law" (because the speeches typically followed a luncheon). Perhaps the most famous of these was a talk by then-Deputy Assistant Attorney General Bruce Wilson on patent licensing, which later became known as the "Nine No-Nos" speech—identifying nine practices that the speaker (at least) considered to be illegal.[6] The DOJ repudiated them in 1981,[7] but for a while they were considered to be "the law" even though few, if any, cases were brought to confirm that perception.

It is no secret that the Commission, and DG Competition specifically, has not always been happy with the outcomes of their attempts to block or outlaw specific conduct under Articles 81 and 82 EC. I want to make it clear that I am not suggesting that anyone in the Commission is trying to go outside the law. What I am suggesting is that one explanation for what has happened here, and the way that it has happened, is that people may want to try an approach at the Commission that has been tried in the past in other jurisdictions and that was outlined earlier—creating law without cases.

[6] Bruce P. Wilson, Remarks before the Michigan State Bar Antitrust Law Section (Sep. 21, 1972), *in* 5 TRADE REG. REP. (CCH), at para. 50146.

[7] Abbott B. Lipsky, Jr., Current Antitrust Division Views on Patent Licensing Practices, Remarks Before the American Bar Association Antitrust Section (Nov. 5, 1981), 4 TRADE REG. REP. (CCH), at para. 13129.

But how could this be done in the European Community? One possibility is Article 9 of Council Regulation 1/2003, which provides in relevant part:

> Where the Commission intends to adopt a decision requiring that an infringement be brought to an end and the undertakings concerned offer commitments to meet the concerns expressed to them by the Commission in its preliminary assessment, the Commission may by decision make those commitments binding on the undertakings. Such a decision may be adopted for a specified period and shall conclude that there are no longer grounds for action by the Commission.

Clearly this contemplates that a procedure has been brought. But does it require it, and who would like to risk finding out? What if the Commission came to one or more companies with something along the following lines: "We believe that you are doing X, your documents support us, and we also believe that X protects your income stream and can be put forth as something against the interests of consumers. If you agree to the following changes in your conduct regarding X, we will not seek any other relief." Isn't this almost exactly what happened in the recent Apple iTunes matter?[8] It was hard to find a competition law violation based on the merits there.

The mechanism for getting this done is a flexible view of Article 9. Just as every merger under U.S. law that involves a settlement technically requires that a complaint be filed and settled, so here the agreement would result in an agreed upon challenge being set out, and settled, such that the Commission shall conclude that there are no longer grounds for action.

Another reaction is that this makes the Article 9 process a sham. I am not sure that it does, any more than the need to have a complaint and order makes the FTC settlement

[8] *See* Press Release, European Commission IP/08/22, European Commission welcomes Apple's announcement to equalise prices for music downloads from iTunes in Europe (Jan. 9, 2008), *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/22&format=HTML&aged=0&language=EN&guiLanguage=en.

of merger cases a sham. But I defer to my EU colleagues as to what is, or is not, valid interpretation in Brussels.

Conclusion

What this interpretation does is harmonize some of the odder elements in what the Commission has done. The dawn raid, for example, is hard to justify on the grounds that the documents sought are more likely to be destroyed than any other documents. Since the Commission admits that it has no evidence of specific illegal activity, why the big splash? If you are sending a message about your ability to use publicity to deter anticompetitive behavior, even in the absence of specific allegations, then it makes some sense. And, if we take it in the context of a preliminary report in 2008, and a final one in 2009 (the proposed schedule), then you have the time to find whatever "bad" facts you can, put together your proposals, and take them to the companies to try to get the conduct changes before you have to make any final recommendations.

It is just speculation. But to an old antitrust hand, government action for which there is no obvious explanation invites speculation—and concern.