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A sector inquiry is never pleasant for the sector involved. It is much like going to the dentist for a checkup. The best possible result is that after all is said and done, nothing was wrong and life can go on. Well, this checkup began with a bang. On January 16, 2008, the European Commission launched a sector inquiry by staging a series of dawn raids on a number of pharmaceutical companies, with no suggestion of specific wrongdoing.[1]

The expressed reasons for the inquiry are puzzling. Commisioner Kroes stated that: "Individuals and governments want a strong pharmaceuticals sector that delivers better products and value for money. But if innovative products are not being produced, and cheaper generic alternatives to existing products are in some cases being delayed, then we need to find out why and, if necessary, take action."[2]

There are many reasons for the lack of new innovative drugs in the European Union—low reimbursement levels and insistent tolerance for diversion/parallel trade come quickly to mind.[3] But it would be very strange indeed if major manufacturers were

*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]See Commission Press Release IP/08/49 16 (January 2008).

[2]Id.

[3]The recent ECJ opinion in the GSK matter may have given us some guidance on the latter point; see Sot. Lelos kai Sia EE et.al. v. GlaxoSmithKline, Joined Cases C-468/06, ECJ September 16, 2008.

getting together to not innovate. There is no way for research-based drug companies to survive except by coming up with new drugs. If this is truly the target, then the inquiry is off base. Let's see what else could be going on.

The Commission already has a decision (now on appeal) against Astra-Zeneca ("AZ") concerning certain practices which, if the allegations are proven, could be viewed as fraud on the patent offices of several countries,[4] 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.[5] Interestingly, both of these cases are footnoted in the Commission's "Frequently Asked Questions" document issued as part of the current sector inquiry. Perhaps the inquiry is designed to flesh out these kinds of alleged cases—abusing the system by obtaining illegitimate patents, or by allegedly misusing legitimate Intellectual Property ("IP") (i.e. patent thickets)

But perhaps there is more at work here. The reference to generics being delayed suggests that there is some concern about generic/brand patent litigation and settlements. So we may have an inquiry that will find very little about why few new drugs have been released, but will focus on what may be viewed as "bad acts" by research-intensive drug companies attempting to preserve product sales and recoup their investments.

With the anticipated release of the preliminary findings from the Inquiry this fall, it seemed to be a good time to ask: (1) What prompted this; (2) What is it likely to conclude; and (3) What impact will it have?

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

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

I. WHAT PROMPTED THIS INQUIRY?

If we look at the AZ case on the allegations made, we see a company making arguably false statements to national patent authorities to get longer protection for its product than it otherwise would have had. And from what we can tell from the public record of the Boehringer case, the concern seems to be the practice of seeking multiple patents around a compound.

While no one would condone making false statements to government authorities, we do have to realize that seeking the broadest, deepest, and longest lasting patent protection for your inventions is not a bad thing. The ability to profit from inventions is critical in justifying investment.[6] If you can't make money, there is no reason to invest in the activity at issue.

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 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.

[6]I have written elsewhere about the need to allow research based pharmaceutical companies to enjoy the fruits of their success if we want them to continue to swallow the failures and still keep innovating: *see* Bernard, *Monopolization/Abuse of Dominance and the Research Based Pharmaceutical Industry – The Chilling Effect of Uncertain Rules of Enforcement* (forthcoming, Fordham Competition Law Institute 2008).

The Drug Price Competition and Patent Term Restoration Act of 1984[7] (referred to as "the Hatch-Waxman Act" after its legislative sponsors) fundamentally changed the legal and economic relationships between innovator and generic drugs in the United States. A full discussion of that law is well beyond the scope of this article. Indeed, to even look at the 2003 changes in the law will give you some idea of the way the various provisions form a unique legal structure.[8] 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 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.[9]

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

[8]*See, e.g.*, the write-up by the law firm Arendt Fox in December 2003, available at http://www.arentfox.com/publications/index.cfm?fa=legalUpdateDisp&content_id=1099

[9]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).

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 and led to most of the legal maneuvering. Under Hatch-Waxman, the first filer (if he wins) obtains 180 days to sell without any other generic application being approved. So for 180 days, the generic could sell its product 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 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 (especially before the law was amended—the original rule was that if the first filer did not launch, no later filer could launch at all; that has been changed, as is discussed later), most of the U.S. courts that have heard the challenges to the settlements have upheld the settlements.

The lessons here are two-fold. First, the U.S. experience is grounded on U.S. laws and approval structures. The European Community system is very different. 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 Commission seems to want. By and large, the U.S. courts have upheld the settlements as not violating the antitrust laws.[10]

Settlements of patent cases in the EU need to be viewed in the context of the EU laws, not the unique matrix of Hatch-Waxman. Traditionally, there has been broad discretion to settle patent cases across the spectrum. The reasoning has been that the parties are best positioned to evaluate the strength of their cases, and to negotiate an appropriate outcome.[11]

II. WHAT IS THE INQUIRY LIKELY TO CONCLUDE?

I have no crystal ball, nor any inside information from the Commission. But I think that we can get a sense of what is coming from the way the inquiry was positioned publicly and from the cases brought.

First, we are likely to be told that manufacturers are attempting to surround their products with "patent thickets," a wonderfully descriptive term that refers to the practice of getting as many patents as reasonably possible so that somebody doesn't slip in and

[10]The most recent decision is that of the Court of Appeals for the Federal Circuit in IN RE CIPROFLOXACIN HYDROCHLORIDE ANTITRUST LITIGATION (CAFC 2008-1097, October 15, 2008) holding that holding that any anti-competitive effects caused by the settlement agreements between Bayer and the generic defendants – including a "reverse payment" were within the exclusionary zone of the patent, and thus could not be redressed by federal antitrust law. *See also* 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.

[11]One would assume that the usual Article 81 standards would apply, and that the Commission could only break a settlement if it proved that the settlement had an anticompetitive object or effect. Resolving a dispute by settlement is not per se anticompetitive. And one should not assume that all patent challenger would have prevailed had the litigation gone to verdict.

patent the one formulation or isomer that you overlooked and then try to peddle that either to compel a royalty or to license for a competing product. Of course, even one patent can become 27 if it needs to be replicated in each member state, so you need to take total patent numbers with some skepticism.

But even assuming that people are going wild in filing patents, and assuming that there is a strategy behind the patenting (the expression ”strategic patenting” sounds evil, but no one patents randomly), a conscious attempt to obtain maximum protection for your invention is just what patents are meant to help you do. If there is a reasonable good faith basis for the applications, what is the problem with multiple patents? If the point of intellectual property is to protect inventions, and we want to encourage inventions (here, drug research and development) then we shouldn't complain if the increasing costs and risks of research lead people to seek increasing protection for the fruits of their work.[12]

Second, we are likely to be told of innovator/generic settlements that involved payments to the generic company. The question here should be—given that we are not in the original Hatch-Waxman context—why should this conduct in one industry be treated differently than it is in any other? In the U.S., the evil of paying the first challenger was that he could block any others, so that a single settlement could block all generic competition on a compound. The law has since changed on this point, and the bottleneck is no longer an issue. In any other field, no one particularly cared if someone settled one case, since another challenge could come along behind it. It was not viewed as a market

[12]Nothing here is meant to justify fraud on the patent office, or other misconduct in obtaining patents. But the mere fact of accumulating IP should not be deemed illegitimate, or even unexpected.

problem for antitrust to settle. And no one who has ever lived through a lawsuit as a client wants to force people to litigate more cases rather than to settle them.

Third, on the R&D slowdown, we can expect professions of concern and perhaps a suggestion that companies would rather buy off generic challenges to existing drugs than invest in finding new ones. That is a facially seductive argument, but is incorrect for a host of reasons that we can only touch on here. Just note for our purposes how short term such a strategy would be—once this generation of drugs goes off patent, the research based drug industry would die. That isn't a great business plan. And in fact you hope that the profits on a new drug, especially one that may be a medical breakthrough, would be greater than those from copying what is already on the market. If the profits won't be there, why invest in the research at all?

III. WHAT WILL THE IMPACT OF THE INQUIRY BE?

This is the key question and the one hardest to predict. Will the finding prompt new cases? Quite possibly. To have an agency gather that much information and then conclude that nothing violated any law or regulation, would be a delightful—and unlikely—surprise. New legislation may be sought, and almost surely some kind of advocacy paper or report will issue.

But the question remains, why did the inquiry take place at this time, and why did it start with Dawn Raids? While clearly if any "smoking guns" are found, some cases may be brought, the Commission may have a broader agenda. It may be looking to change law without the need (and risk) of bringing many cases, or seeking legislation.

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. And the recent opinion of the ECJ in the GSK matter[13] was clear on at least the point that dominant parties, including drug companies, have the right to protect themselves by reasonable measures. Settling patent litigation could well fall within that umbrella safe zone. Even the so-called "reverse payment" cases (where the innovator settles with a challenger by paying money and the challenger agrees to stay off the market until a later date) are only an issue if you assume that the patent was invalid (or that the challenger would have won). If the innovator would have won, then the agreement in fact gets competition to the market sooner than would otherwise have been the case. Every patent case has risks, and it is not irrational to settle a case even if you believe that you have a good chance of winning.[14] The Commission may have trouble getting favorable court decisions here.

Back in the late 1960s and early 1970s, in the United States the Antitrust Division of the U.S. Department of Justice ("DOJ") was not satisfied with the state of the law on patent licensing. 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

[13] *Supra*, note 3.

[14] This was a key argument of ours in Bernard & Tom, supra note 9. You cannot assume that every challenger wins, or that every patent is invalid.

became known as the "Nine No-Nos" speech—identifying nine practices that the speaker (at least) considered to be illegal.[15]

The DOJ repudiated the "No-Nos" in 1981,[16] but for a while they were considered to be "the law" even without cases supporting them. Will the Commission take a similar route here, perhaps backed up by one or two cases where it feels that it has the strongest chances?

The fact of the inquiry has had an impact; it has created some uncertainty. Companies need to be concerned that what should be considered as legitimate business conduct may be held up as a "bad act" at the end of the inquiry.

Perhaps the overall plan is to use whatever "bad acts" evidence is found to claim that research is being neglected because companies are focused on illicitly protecting their existing products.[17] This, coupled with one or two cases where the facts looked best for the Commission, would enable the Commission to declare a victory and go home. We shall see.

[15]Bruce P. Wilson, Remarks before the Michigan State Bar Antitrust Law Section (Sep. 21, 1972), *in* 5 Trade Reg. Rep. (CCH), at para. 50146.

[16]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. 1312.

[17]As noted above, such a strategy is essentially self-defeating—once this generation of drugs goes off patent, the industry would die. However, if the combined impact of price controls, reference pricing, and the inability to extract gains from markets where your innovation has given you and advantage, make innovation not worth pursuing at the margins (the higher risk projects), then it might be rational to focus on existing revenues. But then the short term focus is the symptom of a climate that is hostile to research investment; it is not the cause of the lack of investment.