FEBRUARY 2009, RELEASE TWO

GCP
THE ONLINE MAGAZINE FOR GLOBAL COMPETITION POLICY

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On January 16, 2008, the European Commission launched this sector inquiry by staging a series of dawn raids on a number of pharmaceutical companies, with no suggestion of specific wrongdoing.[1]Commissioner Kroes laid out the expressed reasons for the inquiry, stating 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]

The Commission's inquiry generated numerous follow up information requests, and led up to a full day hearing on November 28, 2008 where the Commission presented its preliminary findings and conclusions, as summarized in its Preliminary Report.[3]

You could posit several fairly obvious reasons for the perceived lack of new innovative drugs in the European Union: Low reimbursement levels for innovative

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[1]*See* Commission Press Release IP/08/49 16 (January 2008). The Press Release may be found at http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/49&format=HTML&aged=0&language=EN&guiLanguage=en

[2]*Id.*

[3]http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.html (Reference: IP/08/1829 Date: 28/11/2008). [hereinafter the *Preliminary Report*]. The Commission Press Release may be found at http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/1829&format=HTML&aged=0&language=EN&guiLanguage=en .

medicines and insistent tolerance for diversion/parallel would certainly be on the list.[4] And reference pricing often makes generics much more expensive in the EU than in the United States, while at the same time making research into new branded drugs less attractive. If you were making an investment decision, why would you invest in developing new products for which the risk of failure is high and for which the purchasers will not pay a price that justifies that risk?

But apart from all of these points, the Commission also seems deliberately to have ignored the elephant in the room. While it might have been politically delicate to look into the actions of Member States, it is unfortunate that the Commission excluded the effects of state regulation from the inquiry. Such regulation controls every aspect of competition in the prescription drug industry in Europe by way of restrictions on price, supply, and access. It has an overwhelming impact, yet the Sector Inquiry treats it as not being there at all.

Even on the Inquiry's own terms, it would be very strange indeed if major manufacturers were getting together to *not* innovate. There is no way for research-based drug companies to survive except by coming up with new drugs. Any other approach is to

[4]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. But it remains a fact of life that our EU colleagues continue the almost Sisyphean struggle to reconcile the ideas that you can encourage diversion of goods and yet still not risk counterfeit products entering the supply chain. But that is a discussion for another day.

For the sake of this discussion, we are not challenging the idea that there is a current lack of innovation concerning new drugs in Europe. However, a recent study by CRA International found that the evidence on the value of innovation suggests that the number of products seen as significant innovations is broadly staying constant over time; CRA International, *The Current State of Innovation in the Pharmaceutical Industry* (June 2008) at page 52. The full report may be found on the EFPIA website at http://www.efpia.org/Content/Default.asp?PageID=563 under the Annexes section to the EFPIA submission to the Commission with respect to the Sector Inquiry.

invite total destruction when the patents expire on the current generation of drugs. Few people would find that a sane business model.

For the past several years, DG Competition has been very interested in the activities in the United States with regard to patent litigation and settlements between innovator and generic companies. Indeed, one section of the Preliminary Report purports to summarize the state of U.S. law in this area.[5] 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.

The Drug Price Competition and Patent Term Restoration Act of 1984 (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. Two areas of the Act are worth noting here. Hatch-Waxman 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 do whatever testing was required, get approvals, manufacture, and launch. It would have risk. Under Hatch-Waxman, the risk no longer exists; filing for approval triggers the patent case.

[5]Preliminary Report, *supra* note 3, § 2.1.4.5 (¶ 647 et seq.). The Commission notes that people have said that the European context differs from that of the United States, so the Commission tried to identify areas of similarity between the two systems—seemingly to allow it to transplant what it likes out of the U.S experience. *See, e.g.*, Preliminary Report, supra note 3, ¶ 579. However, the Commission is not quite so keen on noting that the U.S. Courts have not agreed with many of the FTC enforcement attempts. *See infra* note 9.

Interestingly, the Preliminary Report makes much of the cost of litigation as a motivating factor for generics to settle:[6]

> For the vast majority of generic companies (75%), avoiding the costs related to litigation and also the impact on personnel costs (including monetary and personnel resources) are their major concerns. This is particularly the case when they receive either very limited or no revenues from the product during the court proceedings.

There is no comparable statistic for U.S. litigation, and the reason is likely that the U.S. system allows a court challenge before the generic actually sinks significant money into preparing to market the product. In Europe, the up-front costs are sunk, and so litigation delays the chance to recover them.

Second, 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 first generic can 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. And once that exclusivity period ends—if the product is a major one—the market price plummets as multiple generic companies enter.

But that same incentive also increases the economic risk to the innovator. Once the generic launches, the brand product is effectively dead. Even if he wins the case in the

[6]Preliminary Report, *supra* note 3, ¶ 609. Another factor impacting litigation is that in many countries other than the United States the loser of the litigation is responsible for paying the winner's legal fees. For a full discussion of this rule, and its economic impact, *see* Marie Gryphon, *Greater Justice, Lower Cost: How a "Loser Pays" Rule Would Improve the American Legal System*, Manhattan Institute for Policy Research, Civil Justice Report 11, December 2008, available at http://www.manhattan-institute.org/html/cjr_11.htm . The principle is not universal, however. A brief, unscientific survey of counsel in various European countries reveals a lovely diversity of actual approaches from country to country. Still, it seems fair to say that the principle of the loser paying the winner's costs of suit is the general rule, even if the actual amounts paid bear a distant relation to the actual costs.

end, what the innovator 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). We'll get back to this point when we look at some of the more interesting statements in the Preliminary Report about the timing of innovator generic settlements and the impact of market conditions.

In Europe, while there is no parallel incentive for the first filer, there is the lure of much higher profits on the generic side long-term, since many countries reimburse generics at a much higher price than that which prevails in the United States.[7] In effect, they squeeze the innovator and overpay the copier. It is hard to imagine a set of practices less encouraging for investment in new Research & Development ("R&D").

The EC seems to want to mirror the U.S. Federal Trade Commission ("FTC") approach to patent settlements.[8] But while the FTC and some commentators found the practice of settling drug patent cases to avoid the potential for catastrophic loss to be repugnant (especially before the law was amended—the original rule was that if the first

[7]Price competition among generics in the United States is vicious. Many large chains in the United States are now offering a 30 day supply of the most popular generic drugs for well under $10, and some at half that price or less. *See* the report of the National Conference of State Legislatures (January 2009) *available at* http://www.ncsl.org/PROGRAMS/HEALTH/generic$.htm. While some generics are expensive in the United States, namely the first generic approved under Hatch Waxman (who has 180 days to loot, pillage, and plunder under the statute), or the generic of a less popular drug (where the market size may act to limit the number of entrants, keeping the prices up), by and large if the Commission or the National Health Authorities in Europe wanted to explore saving money, they could profitably invest some time in exploring the workings of the generics markets.

According to the Preliminary Report, generic entry causes prices to drop on average between 20-25 percent; ¶ 180. This is a far cry from the cycling down of prices in the United States, and seems to reflect a tendency of governments to price higher for generics while keeping brand prices lower. The effect of such policies on the incentive to do research and development is worth exploring by the Commission.

[8]See Preliminary Report, *supra* note 3, ¶ 647 et seq.

filer did not launch, no later filer could launch at all; that has been changed to eliminate the potential bottleneck), most of the U.S. courts that have heard the challenges to the settlements have upheld the settlements. The FTC may not be happy about it, but the Courts are finding that even when settlements involve a payment from the innovator to the potential infringer, the settlements themselves (absent restraints outside of the patent scope) are not antitrust violations.[9]

Patent settlements aren't the whole subject matter of the Preliminary Report. 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,[10] 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.[11] Interestingly, both of these cases are footnoted in the Commission's "Frequently Asked Questions" document issued as part of the sector inquiry. Perhaps the inquiry was 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). And indeed the Preliminary Report identifies patent thickets as a problem.[12]

[9]Perhaps the most complete description of the U.S. law in this area, is the recent decision of The Court of Appeals for the Federal Circuit in *In Re* Cpirofloxacin Hydrochloride Antitrust Litigation (CAFC 2008-1097, October 15, 2008) holding that any anticompetitive 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. The case may be found at http://caselaw.lp.findlaw.com/data2/circs/fed/081097p.pdf .

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

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

[12]Preliminary Report, *supra* note 3, § 2.2.2 and ¶ 385.

Still, that having been said, the clear focus of the Preliminary Report seems to be on patent settlements, and what is said about them deserves our focused attention.

The Preliminary Report notes that it is not purporting to be a guidance document as to what practices in settlements are legal or not. That would require analysis of the individual facts of the settlements in question,[13] and no such analysis has been done.

But the Commission is not reluctant to throw statistics and charts at the reader that make it look as if something very bad is happening here, although we can't quite put our finger on what that is. In fact, once you get past the emotional buzzwords, it appears that the Commission has swept up a bunch of facts which it wants everyone to believe are bad, but when you take them apart really don't constitute any legal issue. We will examine some of the key points below.

Much is made over the statement in a document that companies have "toolkits" to protect themselves against generic erosion of their property.[14] That may be an unfortunate choice of words, but hardly makes the conduct illegal. One would hope that they also have "toolkits" to protect against people blowing up their plants, counterfeiting their products, or stealing their trade secrets. The fact that you pull together what you need to deal with an issue, is simply normal good planning.

The Commission has flagged what it considers to be three key points against the Research Based industry. And clearly there may be some actions that deserve condemnation under the law. But when you unpack the allegations and findings in the

[13]Preliminary Report, *supra* note 3, ¶ 574. It would, however, provide the kind of data necessary to justify the conclusions that the Preliminary Report would like to draw.

[14]*See, e.g.*, Preliminary Report, *supra* note 3, ¶¶ 369, 372.

Report, there is far less here than meets the eye. Indeed, some of what is condemned might more correctly be praised, or at least rephrased into more neutral language. For example, the Press Release accompanying the Preliminary Report states:

> The preliminary report shows that originator companies (that develop and sell new medicines) used a variety of methods with the objective of delaying or blocking market entry of generic companies (that sell medicines equivalent to original medicines once patents have expired) and other originator companies, and therefore maintain high income streams for the originator companies.[15]

So stated, it sounds evil. But it could just as easily be put something like this:

> Originator companies (that develop and sell new medicines) used a variety of methods with the objective of enforcing their intellectual property rights and protecting themselves against illegal market entry of generic companies (that sell medicines equivalent to original medicines once patents have expired) and other originator companies, and thereby protecting their investment in research and allowing them to fund research into the next generation of medicines.

The same type of unpacking the text can be applied to the allegations of "patent thickets."[16] 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. It justifies the investment in what is actually very risky R&D.

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 nefarious, 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

[15] Commission Press Release, *supra* note 3.

[16] Preliminary Report, *supra* note 3, ¶ 376-390.

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. The ability to profit from inventions is critical in justifying investment. If you can't make money, there is no reason to invest in the activity at issue.[17]

With that as prelude, let's look at the specific points that the Preliminary Report raises.

I. WHO BRINGS THE LITIGATION?

The Commission notes that the majority of infringement cases are initiated by originator companies.[18] This cannot be a shock or surprise. A generic company knows that if it simply launches there is a chance that the originator will not sue, and public sentiment favors generic launches "at risk" these days. And since the spread between innovator and generic price is state-controlled and relatively small compared to the United States market, there is not the risk of being bankrupted with damages if, in fact, the innovator eventually wins the patent case and gets an injunction (as opposed to royalty damages). A rational generic company seeking to minimize its costs might well elect not to start the legal process, but see whether the innovator—whose property is (perhaps) being stolen—will bring the case at all.

[17]For a more detailed exposition of 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).

[18]Preliminary Report, *supra* note 3, ¶ 468.

II. WHO WINS THE CASES?

The Commission makes much of the point that generics prevailed in some 62 percent of the cases that actually were litigated to a judgment.[19] This statistic may or may not be meaningful. It all depends on what happens to the cases that were not litigated to conclusion. In the United States, when the FTC was aggressively going after settlements (before the courts rejected the attack), the percentage of cases won by the innovators actually *increased*.[20] What that suggests is that innovators are risk averse, and are settling some cases that could be won. Indeed, the Commission notes this in quoting from one innovator company's response.[21] The ramifications of this litigation risk aversion, and settlement of cases that ultimately could have been won, are enormous and worthy of far more attention than they have been given.

If innovators are settling cases that they ultimately could have won, then in fact there has been *greater* and *faster* generic entry when settlements were allowed, than when settlements were barred. Far from being anticompetitive, settlements in this context lead to exactly what the Commission wants—more and faster generic entry. And that leads us to point three.

III. HOW DO THE SETTLEMENTS WORK?

The Commission headline here is that in 48 percent of the settlements, the generic's ability to market its product was restricted.[22] This is a tricky point to

[19]Preliminary Report, *supra* note 3, ¶ 502.

[20]*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) at 627 and note 56.

[21]Preliminary Report, *supra* note 3, ¶ 598.

[22]Preliminary Report, *supra* note 3, ¶ 628; see also Figure 98 (227).

deconstruct, since it sounds as if it means one thing but may in fact mean something quite different. The Preliminary Report defines "restricted" as anything other than a complete and total victory for the generic, allowing it to launch when it pleases regardless of the patent status of the drug.[23]

But this definition contains a hidden assumption—namely that in each case the generic had a right to market its product freely and this right was diminished by the settlement.

Interestingly, in some 64 percent of the settlements where there was no "limitation" on the generic, not only had the defendant generic already entered the market, but one or more other generics had entered as well.[24] Furthermore, the clear majority of the settlement agreements in such "category A" cases were concluded after or just around the time when the originator company's product effectively lost market exclusivity.[25] Given that an injunction was impossible (or unlikely) under those facts, it is hard to see what kind of "limitation" on the generic even the most creative innovator could have imposed in those cases.

But let's look at the settlements earlier on the time line; the ones that happened while there was patent life left for the innovator and where "limitations" were imposed. The Commission assumption seems to be that that such limitations were bad, that they diminished an existing right of the generic. For only on that assumption can you come up

[23]See Preliminary Report, *supra* note 3, ¶ 616. One could argue that such an outcome isn't properly described as a settlement at all, but rather as an abdication by the innovator

[24]Preliminary Report, *supra* note 3, ¶ 618.

[25]Preliminary Report, *supra* note 3, ¶ 619.

with estimates of the "harm" caused by the conduct at issue[26] (without examining the details of every case and patent, which the Commission did not do, and which would be a monstrous task involving opinions as to patent strength and projected litigation outcomes).

But what if, in fact, the generic had no right to be on the market? Let's examine that counterfactual for a moment. For every case that the innovator would have won, any settlement which let the generic on market at all before the last-to-expire of the relevant patents gave the generic something beyond what the law entitled it to have. And for every case that the generic would have won, the settlement kept it off the market longer than it would have if the litigation was pursued.[27] The essence of settlement is compromise.

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[26]This assumption is inherent both in the very definition of "limitation" that the Commission uses, and in the assumptions of the Press Release accompanying the publishing of the Preliminary Report, *supra* note 3 where it was stated:

> The sector inquiry confirms that generic entry often occurs later than expected. On average it took about seven months for generic products to enter the market on a weighted average basis and even the top-selling medicines faced an average delay of four months. Given the strong impact of generic entry, this amounted to lost savings of about € 3 billion for the health systems during 2000 to 2007 for the chosen sample of medicines facing patent expiry in 17 Member States.

This assumes that settlements and other conduct delayed entry that was otherwise justified. That assumption is not supported, and may well be unjustified.

[27]We are assuming here that the litigation was brought in good faith and was not a sham simply to delay launch. We also are not dealing with the question of the time that the litigation could take. Assuming that the suit is brought in good faith, the time that it takes to resolve is simply a price that we pay for the enforcement of intellectual property rights. There is no solution to this issue, short of doing away with all legal rights, which seems a bit extreme. Note also that absent an injunction, the generic in Europe can try to launch at risk without waiting for the litigation to conclude. At least in some countries, health and pricing approval is not blocked or delayed by patent litigation. Indeed, the Preliminary Report states at ¶ 594:

> Originator companies also assess the chances of obtaining an interim injunction. Some originator companies—according to their submissions—settle cases in which it has been impossible to obtain an interim injunction against the generic company, whereas some generic companies stated that they had no interest in concluding a settlement if a court refused to grant an interim injunction to the originator company, since they can continue to be present on the market. An originator company commented as follows:
>
> > We often settle not because we think that we had a weak case, but because it would have been impossible to obtain an interim injunction against a generic company. Thus,

Each side feels that it could win the case, and each evaluates its chances internally. If those estimates violently disagree (e.g. each side feels that it has a 100 percent chance of winning), there is no settlement. If the estimates are less extreme, even if they still disagree, there is the possibility of settlement. So an innovator that felt that it had a strong case might still cut a deal letting in a generic a year before patent expiry, and a generic might well take that deal rather than risk being shut out entirely.[28] The 48 percent figure sounds impressive, but it is really empty without a context of fact and patent strength. The U.S. Courts seem to have accepted the idea that parties should be allowed to settle disputes so long as the settlement does not go beyond the scope of the patents at issue. That may be the only practical result, since otherwise every settlement invites a full inquiry into the merits of the patent case itself, which undercuts the idea of settlement.

This is the bedrock point that Courts seem to recognize but that the Commissions (whether European or U.S. Federal Trade) don't want to admit: patents are presumed to be valid. Under existing law you can't start with a presumption that all originator pharmaceutical patents are invalid and that any outcome that is less than a complete victory for the generic (for example, a settlement) is anticompetitive. That would turn established patent law on its head (and certainly would deal a crushing blow to R&D investment). But if we presume that patents are valid until proven otherwise, many of the

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there is no longer any significant commercial benefit in continuing litigation, in particular after the entry of other generic companies.

[28]It is impossible to know whether such a result is "good" or "bad" in terms of its impact on the public, without actually forcing everyone to litigate each case to the death. Predicting patent litigation outcomes is only for the strong of heart and stomach. In my personal experience I have seen my clients win cases that I thought that we would lose, lose cases that I thought that we would win, and settle cases that I thought that we would win but that we could not risk losing. No doubt most lawyers who have been around long enough have had similar experiences

so-called "restrictive" settlements in fact are simply rational compromises, and may well let generics reach the market earlier than if each party was somehow required to litigate to the death.[29]

If the European Commission truly wants to see why R&D is less than it would like, and generics are not competing harder with one another, it will have to broaden its focus and look at the actions of the member states in terms of price, access, and supply (all issues with no U.S. counterparts). As much as the Commission may want to look to the U.S. FTC position as a model, there may be no simple U.S. law type of solution to what is, in the end, a very European problem.

[29] If the Commission feels that invalid patents are being allowed by the various patent offices, it should deal with that transparently rather than cobbling up competition law issues. Just because you have a hammer doesn't mean that everything out there is a nail. Using competition law to "correct" the patent system has all sorts of potential for mischief.