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One reaction to the pharmaceuticals sector inquiry, particularly from the originator side of the industry, has been to question the need for the investigation. The European Federation of Pharmaceutical Industries and Associations ("EFPIA"), the trade association representing originators, has, for example, expressed "regret" at the implication that practices in the industry may be unlawful.[1] Others have even suggested that the Commission may use the process to "address" competition law concerns where none exist.[2]

What is certain is that the Commission has set itself a challenging task. It has chosen to investigate a number of competition law issues that are likely to pose substantial legal and evidential difficulties. However, the sector, and originators in particular, cannot afford to be complacent. Information already in the public domain suggests that the industry probably should not expect to be given a clean bill of health.

## I. THE CHALLENGES FACING THE COMMISSION

Early on, the Commission identified three key issues as the focus of the inquiry:

- the use of patent litigation to restrict market entry, particularly generic entry;

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[1]EFPIA submission to the European Commission in relation to the pharmaceutical sector inquiry, (June 13, 2008) *available at* http://www.efpia.org/Content/Default.asp?PageID=563.

[2]Kent S. Bernard, *The EC Sector Inquiry Regarding Pharmaceuticals: Some Thoughts from a US Perspective*, 2(1) GCP MAGAZINE (February 2008).

- originator patent strategies and other interventions before national regulatory authorities; and
- patent settlement agreements.

None of these issues is straightforward from a competition law perspective. Even by the standards of competition law, they raise difficult issues of fact and law in areas where there is little or no EU precedent.

Each of the first two issues—patent litigation and patent and other regulatory strategies—involve what is prima facie unilateral behavior. They are therefore likely to be pursued as abuse of dominance under Article 82 EC. If so, the Commission would be required to establish dominance on the part of the relevant undertaking before it could show a competition law issue. Particularly in markets like those in the pharmaceuticals sector where much competition is innovation driven, this is likely to be a challenge.

In addition, the Commission will need to show abuse. The leading case on abusive (or 'vexatious') litigation is *ITT Promedia*, in which the Commission makes it clear that litigation will be considered abusive only in "wholly exceptional circumstances" and sets a daunting two-part test of abuse.[3] According to that test, in order to establish an abuse, it must be shown that the litigation:

- is "manifestly unfounded," in the sense that it cannot reasonably be considered an attempt to establish the rights of the undertaking concerned; and
- was conceived as part of a plan to eliminate competition.

In effect, the litigation must be shown not only to be a sham, but a sham

[3]Case T-111/96 *ITT Promedia v. Commission* [1998] ECR II-2937.

perpetrated with the express purpose of eliminating competition. The fact that *ITT Promedia* has remained virtually the sole precedent in this area for more than 10 years perhaps underlines how difficult a standard this is to meet. Certainly there appears to have been no attempt to apply these principles to the complex field of pharmaceutical patent litigation.

In fact, the only existing case on abuse of dominance in the pharmaceuticals sector is *AstraZeneca*, which concerns abusive patent and regulatory strategies.[4] This case involved two separate abuses:

- a pattern of knowingly misleading representations to patent offices and others as part of a strategy to delay generic entry by obtaining supplementary protection certificates ("SCPs"); and
- deregistering marketing authorizations for the capsule form of the drug Losec (while introducing a tablet form) again as part of a strategy to delay generic entry.

The standard of evidence in relation to each of these abuses will be high. The first requires proof not only that representations made to the relevant authority were misleading, but also that they were knowingly misleading. Strong evidential support is generally required for allegations of bad faith of this kind. As for the second abuse, the Commission has acknowledged that such behavior "would not normally be regarded as an abuse," so we can assume that it will need to show that unusual circumstances apply.[5]

[4]Case COMP/37.507 *AstraZeneca*, OJ L 332, 2006, p. 24.

[5]*AstraZeneca*, supra, at para 793.

Further, the legislative loophole which permitted the particular strategy pursued by AstraZeneca (strategic deregistration of market authorizations) has now been closed.

The third area under investigation is patent settlements agreements. The particular focus here appears to be settlement agreements containing what are often referred to as "reverse payments"—i.e. payments made by a patent holder to the generic company challenging the patent as part of the settlement. This is a new area for EU competition law. The issue has however been a live one for some time now in the United States, where it has caused significant controversy.[6] The two main U.S. enforcement agencies, the Federal Trade Commission ("FTC") and the Department of Justice ("DOJ"), and the U.S. courts, have all taken different and conflicting positions on the appropriate legal analysis. The FTC has argued that, absent proof of some other explanation, a substantial reverse payment in a settlement should be treated as compensation offered by the patent holder for the generic company's agreement to, in effect, delay its entry into the market.[7] As a result, the FTC considers such payments to be almost per se unlawful. The DOJ has disagreed, arguing that the mere presence of a reverse payment is not sufficient to establish illegality and that an effects analysis involving an examination of the validity of the underlying patent is required.[8] In the U.S. courts, the FTC's view initially appeared to hold some sway.[9] However, more recent decisions, including one in October from the Court of Appeals for the Federal Circuit, have found that such payments fall outside the

[6]Karen A. Gibbs, *Generics: Hot Issues as Hatch-Waxman Approaches its 25th Year*, AHLA LIFE SCIENCES (September 2008).

[7]FTC Petition for certiorari, FTC v. Schering-Plough Corp., 126 S. Ct. 2929 (2006).

[8]Brief for Unites States as Amicus Curiae, FTC v. Schering-Plough Corp., supra.

[9]See, e.g. In re Cardizem CD Antitrust Litigation 332 F. 3d 896, 911 (6th cir. 2003), cert denied, 543 U.S. 939 (2004).

scope of U.S. antitrust law altogether (provided that generic entry is not delayed beyond the expiry of the relevant patent and the dispute is not a sham) since they fall within the "exclusionary zone" of the patent.[10]

So, given the substantial challenges for the Commission in terms of establishing that competition law concerns exist, is the pharmaceuticals sector inquiry destined to disappoint those, including generics, who believe that there are problems within the sector? Perhaps not, for despite these apparent difficulties there are also indications that the sort of issues identified by the Commission may, in fact, arise within the pharmaceuticals sector, in particular in relation to patent litigation and the strategic manipulation of patent and other regulatory processes.

## II. PATENT LITIGATION

As set out above, the standard that must be met in order to show that litigation constitutes a competition law infringement is a high one. However, it also seems to be the case that some pharmaceutical companies will push the boundaries of patent litigation right up to the boundaries of legitimacy. The dispute leading up to the U.K. Court of Appeal's judgment of May this year in *Servier v. Apotex* may serve as an example.[11]

The case concerned patents relating to Servier's drug Coversyl, a treatment for high blood pressure and heart failure. In the United Kingdom alone, annual sales of Coversyl are worth in the order of 70 million pounds.

Protection under the original patent covering the active substance in Coversyl,

[10]In re Ceproflexacin Hydrochloride Antitrust Litigation, F. 3d (Fed. Cir. 2008); see also Schering-Plough Corp. v. FTC, 402 F. 3d 1056 (11th Cir. 2005). cert. denied, 126 S. Ct. 2929 (2006) and In re Tamoxifen Citrate Antitrust Litigation, 466 F. 3d 187 (2nd Cir. 2006).

[11]Les Labaratoires Servier v. Apotex Inc. [2008] LWCA Cir. 445.

perindopril, expired in June 2003. Before its expiry, in July 2000 Servier obtained a further patent covering a particular crystalline form of a perindopril salt. And in 2006, in litigation based on that follow-on patent, Servier obtained an interim injunction preventing the generic company Apotex from launching a generic version of Coversyl. In July 2007, Apotex obtained a first instance judgment in the U.K. courts holding that Servier's follow-on patent was invalid for obviousness and lack of novelty. The judge in the case refused to maintain the injunction against Apotex pending an appeal by Servier on the grounds that the appeal had no real prospect of success.

Servier nonetheless appealed the first instance judgment to the U.K. Court of the Appeal. But, as predicted by the judge at first instance, the appeal did not go well. In a clear indication of its views as to the strength of the arguments, the Court of Appeal decided after hearing from counsel for Servier that it could proceed to judgment without hearing arguments from Apotex. It then issued a damning judgment upholding the first instance decision. The Court of Appeal described Servier's patent as a "try-on" and "the sort of patent which can give the patent system a bad name." It found that the judge at first instance had been right to hold, on the basis of the evidence of Servier's own expert witness, that the 'innovation' claimed by Servier was in fact obvious and to invalidate the patent on that basis. It further found that the crystalline form covered by the patent had in fact been disclosed in the original perindopril patent and that the 2000 patent was also therefore invalid for lack of novelty. In the words of the Court, the patent was not only invalid, it was "very plainly so." The Court went on to lament that competition law "thus

far has had nothing or virtually nothing to say about unmeritorious patents."

In the circumstances, there would appear to be at least an argument that the litigation based on the follow-on patent for perindopril was "manifestly unfounded" in the sense of the *ITT v. Promedia* test. Whether the second limb of that test—that the litigation was conceived as part of a plan to eliminate competition—was also fulfilled is necessarily more speculative, since there appears to have been no specific evidence in that regard before the U.K. courts. However, the Court of Appeal appeared to be in no doubt about the purpose of the litigation:

"The upshot of all this is that were the patent valid, Servier's monopoly in practice would last until 2020."

Moreover, as other commentators have pointed out, pharmaceutical companies often pursue Intellectual Property ("IP") strategies aimed at protecting their markets from generic competitors.[12] So establishing a plan to eliminate competition might not be unduly difficult.

Finally in this context, it is also worth noting that, as of shortly before the date of this article, the European patent at issue in *Servier v. Apotex* had only successfully been challenged in only one other EU state, the Netherlands. It seems that in other states it remains a barrier to generic entry.

## III. PATENT STRATEGIES AND INTERVENTIONS BEFORE NATIONAL AUTHORITIES

Although one mechanism for gaming the regulatory system for pharmaceuticals to

[12]David W. Hull, *The EC's Investigation into the Pharmaceutical Sector: Trouble Ahead at the IP/Competition Intersection?* 2(1) GCP MAGAZINE (Feb 08).

block generic entry was removed following *Astra Zeneca*, it seems that others may remain. This March, the BBC reported that it had received internal documents showing that executives at Reckitt Benckiser had developed plans to block the sale of generic versions of its Gaviscon product by manipulating regulatory processes in the United Kingdom.[13] According to press reports at the time, the facts of the case are as follows.

Gaviscon, a treatment for acid indigestion, represents 88 percent of the alginic acid compounds supplied by the U.K.'s National Health Service ("NHS"). Reckitt documents describe the product as a "power brand." Annual sales of Gaviscon to the NHS are of the order of UK 21 million pounds.

In 1999, Gaviscon came off patent. In 2000, Reckitt objected to the issuing of an official title for the drug by the British National Formulary ("BNF"). In the United Kingdom, a drug must have a BNF name before a doctor can prescribe a generic version. The basis for Reckitt's objection was that, as a compound of three separate chemicals, Gaviscon was so unusual that the BNF had no right to issue a name. Once this objection had been rejected in 2003, further blocking tactics were again employed in 2005 and 2006. During this period, a Reckitt marketing manager wrote the following email:

"If we were to change the formulation … with the rationale that we are doing it for health and safety reasons … we could withdraw Gaviscon liquid from sale within the NHS and replace it with the new formulation … We could potentially apply for a new patent on this formulation and effectively protect all our Gaviscon liquid business within the NHS for another 20 years."

[13]Meirion Jones, *Gaviscon maker 'cheated NHS',* BBC Newsnight (March 7, 2008).

In 2005, it seems that Reckitt restricted low cost supplies of Gaviscon to the NHS and its sales force sought to persuade doctors to switch patients onto Gaviscon Advance, a slightly reformulated product, which was not covered by the generic specifications for Gaviscon liquid. Some of the high-pressure tactics used by at least one individual in Gaviscon's sales force during this period were formally condemned by the industry watchdog.

The whistleblower who provided the documents to the BBC, a former Reckitt senior executive, described the company as having "cheated the NHS." Reckitt has denied wrongdoing and says the memos provided to the BBC were "inappropriate" and did not reflect its actual actions. The BBC has now handed the document file to the U.K. competition enforcement agency, the Office of Fair Trading ("OFT"), following a request from the OFT.

## IV. REVERSE PAYMENTS

In the case of reverse payments, it is more difficult to argue that there is an issue that merits investigation by the Commission. Certainly, it is difficult to point to individual examples of settlements that might merit investigation by the Commission. This may be due to the confidentially obligations that generally form part of such agreements in the European Union. However, it may also be due to differences in the incentives created by U.S. and EU law in relation to patent settlements.

In the United States, the Drug Price Competition and Patent Term restoration Act of 1984[14] (better know as the "Hatch-Waxman" Act) permits generic companies to

[14] 21 U.S.C. § 355 (2000).

challenge pharmaceutical patents by filing an abbreviated new drug application ("ANDA") with the US Food and Drug Administration ("FDA") certifying that the relevant patent(s) are invalid or not infringed, then notifying the patent holder of the application. Upon receiving notice of the ANDA, the patent holder has forty-five days to file a patent infringement law suit against the ANDA filer. Ideally, the mechanism allows the generic company to test the patent(s) at issue without first incurring much of the expense of bringing a product to the market.

Additionally, the Act provides that, if successful, the first ANDA filer obtains a 180-day exclusivity period during which it has the right to offer the only generic alternative to the patented product. This 180-day period is not triggered until the first filer enters the market, which must occur within seventy-five days of approval of the ANDA by the FDA. It has been observed that the mechanism provided by the Hatch-Waxman Act has yielded considerable litigation between originator and generic companies. It has also been observed that such litigation creates an incentive, in many cases, to settle with the first filer (and potentially even to pay to do so) since this may postpone not only entry by the first filer but also entry by other generics who are locked out of the market by the exclusivity period.[15]

There is no legislative equivalent to the Hatch-Waxman Act in the European Union. The incentives to enter into litigation and settlement in relation to pharmaceutical patents in the European Union are therefore very different from those in the United States. It may be that, as a result, settlements involving reverse payments simply do not

[15]Herbert Hovenkamp, Mark Janis, & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L REV. 1719 (2003).

arise in the European Union, or at least not in any significant number.

Against that, it should be noted that the dawn raids carried out by the Commission at the launch of the inquiry covered generic companies as well as originators. The only issue under investigation likely to involve active participation by generics is patent settlements. And, despite its public statements, it seems unlikely that the Commission would act without at least some evidence against at least some companies.

However, whatever the position as regards the existence of reverse payment settlements in the European Union as a matter of fact, the complexity of the legal issues surrounding them may limit the extent to which the Commission will feel able to take action against them.

## V. CONCLUSIONS

The competition law issues the Commission has chosen to investigate as part of the pharmaceutical inquiry are likely to pose substantial legal and evidential challenges. However, this does not mean that those who question the need for the inquiry are right. Even the public record suggests that there are issues within the sector that merit attention. The precise scope and magnitude of those issue remains to be seen. The Commission's interim report to be published on November 28 may go some way to providing answers to those questions.