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I. Introduction

Efforts by innovative pharmaceutical companies to protect their markets against generic drugs have generated a wide-ranging debate over how to achieve the proper balance between these companies' legitimate interests in reaping the full rewards of their research and development (R&D) efforts and the public's interest in having access to cheaper drugs. In Europe, this debate has largely centered on issues relating to healthcare policy, national pricing, and reimbursement policies, and the overall pharmaceutical regulatory regime.

To date, competition law has not played a prominent role in this debate. With the notable exception of its decision in *AstraZeneca*[1]—in which the European Commission found that AstraZeneca had abused its dominant position by pursuing certain strategies aimed at keeping generics off the market—the Commission has not published any decisions dealing with the competition law implications of efforts by pharmaceutical companies to delay the entry of generics. The *AstraZeneca* decision signaled that such

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

efforts could give rise to competition concerns, but it provides limited guidance because the practices at issue were very specific to the facts of the case.

This situation changed overnight with the Commission's announcement on January 16, 2008 of a competition investigation into the pharmaceutical sector "relating to the introduction of innovative and generic medicines for human consumption on the market."[2] This sector-wide investigation moves competition law to the center of the generics debate. As discussed in this comment, it also raises thorny issues on the relationship between the competition rules and the intellectual property (IP) rules.

II. Practices Subject to Investigation

The Commission has announced that it intends to examine a range of practices, including filing patents or exercising patents in order to block the entry of generics, patent litigation brought by pharmaceutical companies against generic manufacturers, and patent settlements and other agreements between pharmaceutical companies and generic companies that delay the entry of generics onto the market. While a detailed analysis of these practices under the EC competition rules is beyond the scope of this short comment, even a cursory review of some of these practices and the competition principles applicable to them shows that all of these practices raise difficult and complex issues involving the intersection of competition and IP law.

A. *Patent Litigation*

Pharmaceutical companies frequently pursue patent litigation to protect their markets from generic entry. If the company holds a dominant position, such litigation

[2] Case COMP/D2/39.514, Commission Decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector, at art. 1.

could be challenged as abusive under Article 82 EC. In *ITT Promedia*[3]—the leading case on the abuse knows as "vexatious litigation"—both the Commission and the European Court of First Instance (CFI) made it clear that such a challenge will rarely be successful. In that case, the Commission advocated a strict test for determining whether the commencement of litigation is abusive: the claim must be "manifestly unfounded" and it must be brought with the aim of eliminating competition.[4] The Commission stated that litigation that may reasonably be considered as an attempt to assert rights against competitors is not abusive, even if it is part of a plan to eliminate competition. The CFI agreed with the Commission, stressing that the ability to assert one's rights through the courts is a basic principle of law, common to the constitutional traditions of all member states and that only in "wholly exceptional circumstances" will the commencement of legal proceedings be considered an abuse of a dominant position.[5] It also emphasized that, because the two criteria advanced by the Commission were an exception to the general principle of access to courts, they should be interpreted and applied strictly.[6]

When applying these principles in the context of patent litigation brought by a dominant pharmaceutical company against a generic competitor, it would seem difficult to establish that the litigation is "manifestly unfounded" because these cases typically turn on difficult issues of fact (such as whether a generic is the biological equivalent of the patented drug).

[3] Case T-111/96, ITT Promedia NV v. Commission, 1998 E.C.R. II-2937.

[4] *Id.* at ¶¶ 55-56.

[5] *Id.* at ¶ 60.

[6] *Id.* at ¶ 61.

Apart from the general concerns expressed by the CFI in *ITT Promedia* relating to a company's fundamental right of access to the courts to protect its rights, any attempt to challenge the right of pharmaceutical companies to pursue patent litigation on the basis of Article 82 would also raise more specific concerns relating to the IP rights at issue. If the competition rules are used to limit a pharmaceutical company's ability to protect its IP rights, then they could undermine the value of those rights and the incentives to innovate that they are designed to foster.

B. *Regulatory/Intellectual Property Strategy*

Pharmaceutical companies often pursue regulatory and IP strategies aimed at protecting their markets from generic competitors such as obtaining patents over different formulations of a drug so as to effectively extend existing patent protection. Such strategies could be challenged as abusive under Article 82. In *AstraZeneca*, the Commission found that AstraZeneca had abused its dominant position by taking advantage of the existing regulatory framework to delay generic entry and hinder parallel trade. While acknowledging that "single acts involving the launch, withdrawal or requests for deregistration of a pharmaceutical product would not normally be regarded as an abuse,"[7] the Commission determined that AstraZeneca had engaged in abusive conduct by pursuing a broad, coordinated strategy aimed at excluding generics and restricting parallel trade. More recently, the Commission initiated proceedings against Boehringer Ingelheim for possible "misuse of the patent system in order to exclude potential competition in the area of chronic obstructive pulmonary disease."[8]

[7] *AstraZeneca*, *supra* note 1, at ¶ 793.

[8] Case COMP/B2/39.246 – Boehringer (initiated Feb. 22, 2007).

Any attempt to use Article 82 to limit a pharmaceutical company's ability to pursue a regulatory strategy under the applicable intellectual property and pharmaceutical rules aimed at protecting its markets will raise issues similar to those raised by attempts to limit its ability to pursue patent litigation. First, there is the broader issue of whether the competition rules may be used to limit the ability of companies—even dominant ones—to assert their legal rights. Just as a company has a fundamental right to protect its interests through litigation, it is arguably entirely legitimate for a company to work within the existing regulatory and intellectual property framework to advance its interests.

Second, there are issues relating to the relationship between the competition rules and the intellectual property and related pharmaceutical regulatory rules. The intellectual property rules give patent owners exclusivity for a specified period to reward them for their inventions. The pharmaceutical rules—specifically, those on data exclusivity—give patent owners an additional period of exclusivity beyond the expiry of their patent rights. This extra protection is aimed at ensuring that pharmaceutical companies receive adequate rewards for their innovative efforts in light of the unusually high costs of R&D and the lengthy approval process for drugs. If the competition rules are used to prevent pharmaceutical companies from obtaining the full period of exclusivity to which they are entitled, then they could undermine the policies underlying the IP and pharmaceutical rules.

C. *Patent Settlements*

Patent settlements can clearly give rise to issues under Article 81 because, at the very least, the innovative pharmaceutical company and the generic company are potential

competitors. The key question is whether any restriction of competition is outweighed by pro-competitive benefits such as allowing the generic product to enter the market sooner than it otherwise could have entered. In the United States, the question of how such settlements should be analyzed has given rise to a heated debate. In fact, the two main antitrust enforcement agencies—the U.S. Department of Justice and the FTC—disagree about precisely how these settlements should be analyzed. The EC debate is likely to be equally intense.

III. Comment

The core issue that will confront the Commission as it proceeds with its investigation into the practices discussed in this paper is determining whether the competition rules may be used to place limits on the ability of pharmaceutical companies to exercise and defend their IP rights. The principle that should guide the Commission in resolving this issue is that the competition rules should be allowed to override the intellectual property rules only in exceptional circumstances. Otherwise, the incentives to innovate that the IP rules are designed to promote will be undermined. This deference to IP rights is reflected in a well-established line of cases dealing with compulsory licensing of IP rights, culminating in the recent *Microsoft* judgment. In these cases, the European courts in Luxembourg have held that a dominant firm may only be required to license its IP rights in exceptional circumstances, although questions remain concerning precisely what those circumstances are.

While the competition rules should rarely be allowed to impinge on IP rights as a general policy matter, this is all the more true in the case of IP rights covering

pharmaceutical products. Patents are the lifeblood of the pharmaceutical industry. As the Commission specifically acknowledged when it launched its sector-wide investigation, "the pharmaceutical industry is knowledge-based." Unless pharmaceutical companies are able to rely on their patents, they will not be able to make the massive investments in R&D necessary to discover and develop new products. Today, a fundamental problem facing the pharmaceutical companies is how to keep their product pipelines from running dry. This problem will only be exacerbated if pharmaceutical companies are restricted in their ability to fully exploit the commercial potential of their existing products.

As the CFI made clear in the GlaxoSmithKline Spanish dual-pricing case,[9] the specific challenges faced by the pharmaceutical industry may not be ignored when applying the competition rules. While restrictions on parallel trade may be incompatible with the competition rules in the majority of cases, restrictions imposed by pharmaceutical companies may be justified by the specific circumstances surrounding parallel trade in pharmaceutical products and by the need to ensure the availability of funds for R&D. Likewise, in considering the application of competition rules to attempts by pharmaceutical companies to rely on their IP rights to protect their markets against generic entrants, the particular importance of IP rights to these companies must be taken into account.

The Commission has sought to assuage concerns that its investigation will encroach on IP rights that are so critical to the ongoing success of pharmaceutical

[9] Case T-168/01, GlaxoSmithKline v. Commission, CFI judgment of 27 Sep. 2006 (not yet reported).

companies. In the press release accompanying its announcement of its investigation of the pharmaceutical industry, the Commission stated:

> Innovation in the pharmaceutical sector is driven by patents and other intellectual property rights, and the inquiry will be conducted taking into account those existing rights. The Commission's action will therefore complement, not challenge, intellectual property law, as both systems share the objectives of fostering innovation, and increasing consumer welfare.[10]

Judging from past cases in which the Commission has grappled with issues at the intersection of IP and competition law, pharmaceutical companies should not take too much comfort from this statement. In the line of cases dealing with the compulsory licensing of IP rights, the Commission has shown a tendency to gradually expand the circumstances in which it will use the competition rules to override the rights of IP owners. The CFI's judgment in *Microsoft* could encourage this tendency as the CFI gave short shrift to arguments that the remedy imposed by the Commission undermined Microsoft's IP rights.

In contrast to individual cases, a sector-wide investigation offers the Commission an opportunity to take the time needed to analyze the key policy issues in a thorough manner that allows all interested stakeholders to express their views. It is hoped that the Commission will take advantage of this opportunity in the case of its current investigation. Competition law cannot be applied in a vacuum and it is critical that the policies underlying the IP rules and pharmaceutical regulatory rules that are at the heart of the generics debate not be undermined.

[10] Press Release IP/08/49, European Commission, Commission launches sector inquiry into pharmaceuticals with unannounced inspections (Jan. 16, 2008), *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/49&format=HTML&aged=0&language=EN&guiLanguage=en.