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I. INTRODUCTION

In the presentation of its Preliminary Report on the pharmaceutical sector inquiry,¹ the European Commission attempted to perform a delicate balancing of competition and International Property (“IP”) law. While the Commission went out of its way repeatedly to state that the value of IP rights in general, and patents in particular, are not in dispute in the sector inquiry, there are indications to the contrary. The Commission appears to be suggesting that certain patenting strategies are highly questionable under Article 82 EC. For a knowledge-based, Research & Development (“R&D”)-driven industry such as the pharmaceutical sector, this will be of great concern. At the same time, however, there remain a number of significant barriers that the Commission will need to overcome before it can successfully restrict pharmaceutical companies’ ability to obtain and defend their IP rights under EC competition rules.

The Preliminary Report suggests a clear tension between the monopoly rights granted by patents and the enforcement of competition law. EU competition law has long steered these waters by drawing a distinction between the existence of patents and their

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¹The Report is *available at* http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf.

exercise. In principle, EU competition law may not call into question the existence of patents, but can apply to, and limit, their exercise.² This principle should continue to govern the Commission's application of EU competition law to the conduct of pharmaceutical companies involving patents.

II. A "TOOLBOX" OF TACTICS UNDER SCRUTINY

The Report is careful not to show hostility to traditional IP rights, as such. However, the Report's treatment of "originator company"³ patenting strategies suggests that the Commission considers at least some of these strategies to be potentially problematic under Article 82 EC. Deputy Director General Herbert Ungerer went so far as to describe some of these strategies as "shocking." He appeared particularly to have in mind what the Report calls "defensive patents" and "patent clusters" or "patent thickets."

In the Report, the Commission seems to ascribe part of the alleged decline in innovation in the pharmaceutical sector to defensive patents, which are described as being solely or mainly aimed at limiting other originator companies' freedom of operation in areas of possible overlapping products or R&D poles. The Commission appears to believe there is an anticompetitive intent behind obtaining and maintaining these patents and that they have a corresponding negative effect on innovation. The problem is, however, that significant investment and innovation lies behind these patents, and originator companies may not know, when they apply for the patents, whether and

²The distinction between existence and exercise was first introduced by the ECJ in 1966 in *Consten and Grundig v Commission* Cases 56 and 58/64 [1966] ECR 299, [1966] CMLR 357, p. 375. The dichotomy was further elaborated in *Deutsche Grammophon Gesellschaft v Metro-SB-Grossmärkte GmbH* Case 78/70 [1971] ECR 487.

³The Report defines an "originator" as a novel drug that was under patent protection when launched onto the market, and defines an "originator company" as a company that sells originators.

how they will benefit from this innovation going forward.

The Report describes patent clusters or patent thickets as one of the tools used by originator companies to delay generic entry. At the Commission's public presentation of the Report, Dr. Ungerer reserved his greatest degree of “shock” for the fact that one originator company apparently has around 1,300 patents across Europe for one single blockbuster medicine.⁴ Another head of the task force immediately nuanced Dr. Ungerer's statement by explaining that patent clustering is not necessarily a problem in itself. The Commission's concern is not so much with the number of patents that an originator company may have for a particular international nonproprietary named pharmaceutical substance (“INN”). Rather, its concern is with the types of patents, the strength of those patents, their market effects, and the conduct and outcome of litigation involving them. The Commission seems suspicious that there is an anticompetitive intent behind patent clustering and a likely exclusionary effect on generic entry, both as a result of the existence of the patents and their enforcement through litigation.

But in what circumstances might the alleged exclusionary intent and exclusionary effects of these strategies be sufficient to give rise to an abuse of dominance and what additional elements might have to be present?

III. PATENT LITIGATION AS AN ABUSE OF DOMINANCE

In considering the appropriate legal standard to apply, it is helpful to consider the circumstances in which patent litigation has been found to constitute an abuse of dominance under Article 82 EC. In the EU's seminal case on this issue, *ITT Promedia*⁵,

⁴Note that this may correspond to only about 40 patents in each Member State.

⁵Case T-111/96, *ITT Promedia NV v. Commission*, [1998] E.C.R. II-2937.

the Commission rejected a complaint alleging that Belgacom, the Belgian telecoms incumbent, violated Article 82 EC by taking a business partner to court. The complainant appealed to the European Court of First Instance (“CFI”), but the Court upheld the Commission’s rejection of the complaint as being unfounded. According to the Court, the ability to assert rights through the courts is the expression of a general principle of law, common to the legal traditions of the Member States and laid down in the European Convention on Human Rights. The Court emphasized that only in “wholly exceptional circumstances”⁶ will the commencement of legal proceedings amount to an abuse of dominance.

When it rejected the complaint against Belgacom, the Commission took the position that two exceptional sets of circumstances needed to be present for a finding of an abuse of dominance. First, it had to be clear that the lawsuit is “manifestly unfounded,” in the sense that it could “not reasonably be considered as an attempt to establish the rights of the litigant” and could “only serve to harass the opponent.” In other words, it had to be both frivolous and vexatious. Second, the action had to be part of a plan whose goal was to eliminate competition.⁷

Because the criteria put forward by the Commission constitute an exception to the general principle of access to the courts, the Court stressed that a strict interpretation

⁶*Id.* at ¶160.

⁷These tests are similar to those under the case-law in the United States on the circumstances in which starting litigation may violate Sherman Act Section 2. Under the *Professional Real Estate Investors* case, the lawsuit would need to be “objectively baseless” and the fact of the lawsuit would have to create a deterrent to entry. See *Professional Real Estate Investors, Inc., et al. v. Columbia Pictures Industries, Inc. et al.*, 508 U.S. 49.

should apply.⁸ On appeal, the CFI did not decide whether the Commission's test was correct, but did nothing to cast doubt, either on the concept of frivolous and vexatious litigation as an abuse, or on the Commission's particular tests for lack of merit and vexatiousness. As such, even though the Commission's criteria have not been blessed by the Community Courts, they nevertheless do provide a good indication of the types of circumstances in which the Commission would consider that patent litigation is "wholly exceptional" and as giving rise to a possible abuse of dominance.

As regards the second prong of the Commission's test, the Report claims that the Commission has found numerous documents that could be read as describing intent to delay generic entry. So the second prong of the test may not be so hard to establish. As a result, the key issue would likely be whether the litigation could reasonably be considered an attempt to establish legitimate rights or whether it only serves another, anticompetitive purpose and is thus "manifestly unfounded." Answering this question is particularly difficult in relation to the patent litigation under scrutiny in this sector inquiry, given the often complex and technical nature of the underlying facts. Moreover, up until today, *ITT/Promedia* has remained the only precedent on unmeritorious and vexatious litigation, which illustrates the high level at which the Commission has set the significant evidentiary standard. Finally, even though the Commission questions a number of originator company litigation strategies, the general view is that enforcing patent rights in court is a legitimate way of protecting them.

⁸Case T-111/96, *ITT Promedia NV v. Commission*, [1998] E.C.R. II-2937 at ¶61.

IV. TRANSPOSING THE ITT PROMEDIA CRITERIA TO PATENTING STRATEGIES

It might be possible to build a claim of abuse of dominance based on the notion that defensive patenting or patent clustering: first, could “not reasonably be considered” an attempt to obtain patent protection for innovation and could only serve to deter innovation or generic entry; and second, forms part of an anticompetitive strategy. Another way of phrasing the first part of this test would be to ask whether the exercise of defensive patents or patents in clusters could not reasonably be considered an assertion of the rights inherent in the patent.

But that raises the question of how the reasonableness of the attempt to obtain patent protection or the reasonableness of the assertion of rights should be determined in an antitrust context. One issue in this regard is whether the answer hinges on the strength or the weakness of the patents in question. The Commission seems to suggest that the weaker the patents the greater the likelihood of an abuse. But who would be the arbiter of that issue? Officials at the Commission's Directorate General for Competition are much less expert in these matters than patent specialists.

V. COMPETITION AND IP LAW ON THE SCALES

A fundamental issue is at stake: Does the Commission intend to attempt to modify the balance between competition law and intellectual property rights? If that is the intention, it raises the follow-on question of whether any new approach would be consistent with the rationale and the objectives of both competition and IP law.

There are really only two possible ways to look at the patenting strategies of pharmaceutical companies. Either the Commission intends to prevent such strategies from the outset; or it plans to penalize pharmaceutical companies if and when they use them, that is, when they exercise their patent rights. It remains unclear from the Preliminary Report what the Commission's position really is.

A number of issues arise from these options. First, if the Commission considers that it should prevent those strategies, it would have to ensure that pharmaceutical companies are not in a position to be granted or to maintain patents for allegedly abusive purposes. The Report seems to suggest that it is the defensive patent's existence that limits the freedom of operation of other originator companies, because it establishes prior art. In the case of "patent thickets," it is also the fact of the existence of the multiple patents that make the "thicket" so difficult for generic companies to find their way through to entry. But if it's the existence of the patents that creates the barrier to entry, wouldn't the application of EU competition law to defensive patenting and patent clustering be calling into question the very existence of the patents concerned? Given the longstanding principle that EU competition law applies only to the exercise of patents—and cannot be applied in a way that questions their existence, the Commission would have to challenge a fundamental tenet of EU law if it wanted to use Article 82 EC to attack the mere fact of obtaining and maintaining defensive patents or the mere fact of obtaining and maintaining clusters of patents.

By contrast, if the originator company exercises its patent rights in any way, the

Commission would be competent to assess whether that exercise is consistent with European competition law. But a finding of abuse would presumably have to be based on wholly exceptional circumstances. It would have to be based on the notion, first, that the exercise of the patent rights could “not reasonably be considered” an attempt to assert rights inherent in the patent, but must instead be viewed as being aimed solely at preventing innovation or deterring generic entry. Where patent litigation and other conduct around the exercise of patents is aimed at protecting granted patents against challenge or erosion, this first prong of the test would seem a very high threshold indeed. Second, there would need to be evidence that the patenting strategy is part of an anticompetitive, exclusionary plan.

VI. CONCLUSION

The Preliminary Report of the Commission’s pharmaceutical sector inquiry has exposed—but not addressed—a number of prickly issues regarding the complex interplay of competition and IP law. Pharmaceutical companies, whose core business is dependent on IP rights, will be anxiously awaiting the release of the Commission’s Final Report in the spring of this year. If competition rules are skewed to limit the ability of originator companies to obtain and protect their patents, the Commission may unintentionally reduce patent value and undermine the very incentives to innovate that the Report intends to encourage. In principle, competition law should be allowed to interfere with IP protection only in “exceptional circumstances,” but the exact practical impact of this phrase remains unclear. The sector inquiry is a major Commission initiative, and its final

findings could well have a significant influence on how pharmaceutical companies manage patent application and enforcement strategies going forward.