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The release of DG Competition's Preliminary Report on its Pharmaceutical Sector Inquiry on November 28, 2008 was a Brussels media event, with press briefings, press releases, and an all-day public hearing that was covered by the Commission's live television channel.[1] Much of the discussion at the time of the Report's release and since has revolved around the European regime governing the recognition and enforcement of patents. Intellectual property experts are troubled by inaccuracies in the Report as well as by suggestions that practices that are common not just in the pharmaceutical sector, but all high-tech sectors, such as taking out numerous patents around an invention, are incompatible with the competition rules. Innovative pharmaceutical companies are concerned that practices that are critical to the protection of their patents and that are permissible under the intellectual property regime are being called into question. These concerns will undoubtedly be discussed in-depth in many of the submissions that were made to DG Competition at the end of January and that will be posted on its website.

Somewhat ironically, given that the Preliminary Report was issued by the competition directorate, it says virtually nothing about the assessment under EC

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[1]DG Competition's website has a specific section devoted to the sector inquiry, which includes the webcast of the remarks of various participants at the hearing and the press conference preceding the hearing.

competition law of the various practices described as comprising the nefarious "tool-box" of instruments used by innovative pharmaceutical companies to delay the entry of generics. Instead, DG Competition presents the Preliminary Report as a set of neutral findings that will form the "factual basis" for a decision on whether further action is needed.[2] It goes out of its way to disavow any intent to opine on the legality of the practices described in the Report, stating that "[i]t is not the purpose of this report to identify wrongdoing of individual companies or provide guidance on the compatibility of certain behavior with EC competition law."[3]

DG Competition's silence on the relevant competition analysis is troubling because a core issue raised by the Sector Inquiry is whether the competition rules may be used to place limits on the ability of pharmaceutical companies to exercise and defend their patent rights, which is one of the most complex and controversial areas of competition law. As discussed in this short comment, unless DG Competition breaks this silence and offers some guidance that will help innovative pharmaceuticals navigate the sometimes hazardous intersection of intellectual property and competition law, it will be fostering an unhealthy climate of legal uncertainty. DG Competition will also be creating more work for itself in the future as it attempts to clear out the litigation logjam caused by the lack of any clear guidance.

I. AN UNHEALTHY CLIMATE OF LEGAL UNCERTAINTY

The Preliminary Report's failure to provide guidance concerning the treatment of the various practices that it examines gives rise to a significant degree of uncertainty

[2]Preliminary Report, p. 5.

[3]Preliminary Report, ¶3.

because there is relatively little case law in this area and the issues are complex. To make matters worse, DG Competition has intimated that these practices are incompatible with the competition rules. Despite the supposed neutrality of the Report, its overall tone is critical of the practices of innovative companies, starting with its use of the pejorative tool-box metaphor to describe these practices. The following examples illustrate how the Preliminary Report—sometimes subtly, sometimes less so—suggests that a given practice is problematic under the competition rules.

Patent Strategies: The Preliminary Report recognizes the importance of patents in fostering innovation in the pharmaceutical industry,[4] but then suggests that the common practice of filing so-called "secondary" patents around the original patent could be anticompetitive. According to the Report,

> while an increase in secondary patents may be a sign for incremental innovation … a consequence flowing from the filing of numerous patent applications in order to create patent clusters around one product can also be an increase in weak patents.[5]

The Report also found that the creation of "patent clusters" around the original patent prevents or delays generic entry, which

> during the period of exclusivity, is generally in line with the underlying objectives of patent systems, it may in certain cases only be aimed at excluding competition and not at safeguarding a viable commercial development of own innovation covered by the clusters.[6]

Patent Litigation: The Preliminary Report never provides any guidance as to when patent litigation could give rise to competition concerns, but simply suggests by broad

[4]Preliminary Report, ¶4.

[5]Preliminary Report, ¶¶392-93.

[6]Preliminary Report, ¶410.

innuendo that innovative companies that pursue patent litigation against generics could be engaged in anticompetitive conduct. It recognizes that "companies which benefit from patent protection are entitled to enforce their patent rights," but then goes on to state that the enforcement of patent rights "may be problematic under specific circumstances."[7] It repeatedly notes that patent litigation can have a detrimental effect on generic entry. It also observes that innovators have lost the majority of cases, a statistic that, given the tone of the overall discussion, could be read as suggesting that innovators should not be able to bring cases unless they have a better than 50 percent chance of winning.[8]

Patent Settlements: The Preliminary Report recognizes that patent settlements are "a generally accepted way of ending disputes, opposition procedures and litigation."[9] However, it goes on to say that "it might be argued that settlements contain arrangements that could fall within the scope of the competition rules," giving the example of a settlement agreement that leads to a delay in generic entry in return for a payment by the innovative company to the generic company.[10]

In sum, for each practice, the Preliminary Report suggests that it may raise concerns under the competition rules in certain circumstances, but fails to given any guidance whatsoever as to what those circumstances may be. Statements made at the time of the Report's release simply reinforced the conclusion that DG Competition considers that many of the practices discussed in the Report are problematic. Commissioner Kroes

[7]Preliminary Report, ¶433.

[8]Preliminary Report, p. 199 ("The majority of court cases were initiated by originator companies. However, generic companies won a majority of cases in which a final judgment was given (62 percent).").

[9]Preliminary Report, ¶578.

[10]Preliminary Report, ¶579.

made it clear that, in light of the Report's findings, innovative companies should already be changing their behavior.[11] Another senior official referred to the "shocking facts" of the Report.[12]

The absence of any analysis of the practices comprising the tool-box of instruments and the suggestion that they are incompatible with the competition rules without any precise indication as to when this might be the case is very troubling for at least two reasons. First, and most importantly, the uncertainty created by DG Competition's approach means that, even in cases where a practice may be perfectly legal, an innovative pharmaceutical company may hesitate to engage in the practice. As most of these practices revolve around the recognition and protection of the innovator's patent rights, this uncertainty could have the effect of undermining the value of these rights. Ultimately, this uncertainty risks chilling the innovation that these rights are designed to foster and that even the DG Competition recognizes as being critical to the pharmaceutical industry.

Second, while the analysis of a given practice may ultimately depend on the specific facts of the case, many of the practices will only raise competition concerns in exceptional circumstances. By suggesting that these practices are more generally problematic, DG Competition is espousing a position that is inconsistent with existing law. Taking the three practices discussed above where the Preliminary Report indicates that they may raise competition concerns in certain circumstances, an analysis of these

[11] *See* Commissioner Kroes's statements at the press conference on the webcast found on DG Competition's website.

[12] *See* Mr. Ungerer's statements on the webcast of the public hearing found on DG Competition's website.

practices under existing competition rules shows that these circumstances are rare indeed.

Patent Strategies: The suggestion that the filing of secondary patents is anticompetitive raises concerns. First, it basically amounts to DG Competition second-guessing the patent system, something which it is not competent to do in either a legal or technical sense. Patent law is the domain of the Member States and, even if DG Competition had the power to rule on whether the grant of a secondary patent was appropriate, its officials do not possess the necessary technical expertise in this area. Second, the Preliminary Report's discussion of secondary patents is based on the false premise that such secondary patents are of lesser quality than the primary patents covering the original product. Inventions, whether break-through developments or incremental developments, must meet the same test for patentability. Absent fraud, applying for a patent is entirely legitimate and it should not matter whether a company applies for one or multiple patents. Indeed, any attempt to limit the number of patents for which a company may apply will necessarily result in arbitrary rules that are inconsistent with a company's rights under the patent system because there is no principled way to determine how many patents is too many.

Patent Litigation: Any extent to which the Preliminary Report is suggesting that patent litigation could constitute anticompetitive conduct in any but the most exceptional circumstances is contrary to established case law. If the company holds a dominant position, such litigation could be challenged as abusive under Article 82. In *ITT Promedia*[13]—the leading case on the abuse knows as "vexatious litigation"—both the

[13] *ITT Promedia NV v. Commission*, 1998 ECR II-2937.

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.[14] 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 the all Member States and that only in "wholly exceptional circumstances" will the commencement of legal proceedings be considered an abuse of a dominant position.[15] To apply these principles in the context of patent litigation brought by a dominant pharmaceutical company against a generic competitor; i.e., to establish that the litigation is "manifestly unfounded" would seem extremely difficult because these cases typically turn on difficult issues of fact (such as whether a generic is the biological equivalent of the patented drug).

Patent Settlements: Patent settlements can take a wide variety of forms, so each must be evaluated on its merits. As a general rule, however, patents must be presumed to be valid. Thus, as a general matter, settlements that do not impose restrictions on the generic company that run beyond the term of the patent should benefit from the same presumption. The suggestion that patent settlements, particularly those involving a reverse payment, are generally problematic under the competition rules is inconsistent

[14] *Id.* at ¶¶55-56.

[15] *Id.* at ¶60.

with this general principle. Moreover, there may be entirely legitimate reasons for payments. For instance, in many European countries, the innovative company will stand to lose financially even if it ultimately wins the patent litigation because it will not be able to recover adequate damages from the generic company to compensate it for lost sales during the period between the launch of the generic and the judgment. Thus, an innovative company may prefer to pay the generic to stay off the market until the final judgment is rendered.

II. A NEED FOR GUIDELINES

Unless DG Competition provides guidelines on the competition law analysis of the various practices reviewed in the course of the sector inquiry, innovative pharmaceutical companies will face an undesirable degree of legal uncertainty concerning practices that are not only common in the industry, but, in most cases, should not give rise to competition concerns. At present, the DG Competition does not appear to envision issuing such guidelines. Instead, its current plan seems to be to adopt a Final Report containing its factual findings, and then to pursue litigation against individual companies where it deems appropriate.[16]

Litigation is no substitute for guidelines in providing a coherent legal framework for assessing the various practices at issue. It could take years for an issue to wind its way through the administrative and judicial phases of the procedure. In the meantime, companies will be left guessing as to whether a given practice is acceptable, which, as noted, could chill innovation. More importantly, litigation is likely to result in an

[16]See Preliminary Report, ¶23.

incomplete and unbalanced legal framework erected on the basis of principles developed in a piecemeal, ad hoc fashion.

A better approach would be to develop a holistic set of guidelines. As case law develops, these guidelines could be amended to reflect the law's evolution, which is what DG Competition routinely does in other areas where it has issued guidelines. A proposal for guidelines could accompany the Final Report. As with other guidelines put out by DG Competition—most recently the Article 82 guidelines—there should be a broad public consultation on the draft, which would allow key players to bring their expertise to the table. Consultation with all stakeholders would seem to be particularly important here as such guidelines could implicate not only competition policy, but also intellectual property and health care policies. While the guidelines may need to address certain issues that are unique to the pharmaceutical industry, it would seem preferable for these guidelines not to be industry-specific as many of the issues cut across a range of high-technology sectors that depend heavily on intellectual property rights.

III. CONCLUSION

The pharmaceutical sector inquiry offers DG Competition a golden opportunity to develop, in consultation with all interested stakeholders, a coherent set of guiding principles to assess, under the competition rules, a wide range of practices that are common in the pharmaceutical industry. If it fails to take advantage of this opportunity and, instead, issues a Final Report that it limited to bare facts and attempts to develop the legal principles through litigation, it will be fostering a degree of legal uncertainty that

could undermine the patent rights that are the lifeblood of the industry and the drivers of innovation.