FEBRUARY 2009, RELEASE TWO

GCP
THE ONLINE MAGAZINE FOR GLOBAL COMPETITION POLICY

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Quo Vadis, Commission?

Luc Gyselen*

In January 2008, the EC Commission started its Sector Inquiry ("SI") into the pharmaceutical sector because it had reached the tentative conclusion that competition in this sector was not working optimally. There were—according to the Commission—essentially two problems: not enough innovative medicines were being produced and market entry of cheaper generic medicines was often delayed.[1] In November 2008, the Commission issued its Preliminary Report ("Report") which provides it "with a factual basis for deciding whether further action is needed."[2]

As far as the "further action" is concerned, this sector inquiry—like all other sector inquiries—pursues a double-track agenda. On the one hand, it aims at preparing the ground for enforcing Art. 81 or Art. 82 EC Treaty against individual companies which may have engaged in unlawful market conduct. On the other hand, it seeks to identify shortcomings in—and advocate improvements of—the regulatory environment within which these companies operate on the market.

Pharmaceutical companies which have for many years invested—and continue to invest—heavily in innovative medicines take, by and large, the view that this Report is biased in at least two ways. First, it grossly understates the shortcomings of the regulatory

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[1]Cf. Commissioner Kroes' speech on January 16, 2008 (n° 08/18).

[2]Report, executive summary, p. 5.

environment. Second, while it contains a series of disclaimers stating the exact opposite, the Report seems to suggest that companies often engage in a myriad of unlawful practices aimed at stemming either competition on price (i.e. competition between originator and generic companies) or competition in innovation (i.e. competition between originator companies).[3]

This article will not deal with the limited competition advocacy findings in the Report. However, let us make three wishes for this report:

- We hope that DG Competition's final report will recognize less timidly that the regulatory environment is often a major cause of market entry delays for products developed either by incumbent originator companies or by their challengers (i.e. other originating companies or generic companies).
- Let us also hope that DG Enterprise will take due account of the final report's competition advocacy findings. This would be in line with the Commission's Communication that accompanied the "Verheugen package." In that Communication, we read that "future proposals of the Commission will also have to take into account the findings of the ongoing pharmaceutical sector inquiry."[4]
- Last but not least, we hope that the Commission will recognize that the regulatory shortcomings would raise a causality issue if and when it were to examine to what extent particular company conduct has delayed market entry of a potential (originator or generic) competitor. While the Commission has not squarely addressed this causality issue, certain statements in its Report or by Commissioner

[3]As far as these disclaimers are concerned, see e.g. ¶¶ 3, 366 and 931 of the Report.

[4]Commission communication to Council, European Parliament and Ecosoc Committee of December 10, 2008, COM (2008) 666 final, p. 3.

Kroes suggest that the regulatory shortcomings do *not* raise a causality issue once it has been demonstrated that company conduct has "contributed" to the entry problem.[5]

This article will focus on the Commission's antitrust enforcement agenda and examine two questions. First, why does the Report—in spite of repeated disclaimers that it does not contain any finding of wrongdoing—create the impression that the pharmaceutical companies engage in many practices that are unlawful (*infra* Section 1)? Second, which antitrust policy principles should guide the Commission in any future enforcement action under Art. 81 and Art. 82 EC (*infra* Section 2)?

I. WHY DOES THE REPORT CREATE THE IMPRESSION THAT CERTAIN PRACTICES ARE UNLAWFUL UNDER ART. 81 AND 82 EC?

In our view, the impression of bias to which we referred is not just—and not even primarily—due to the Report's overall hostile tone and the provocative terminology sometimes used therein ("deliberate strategy," "delaying tactics," "toolbox," etc.).[6] The more relevant—but, admittedly, more worrisome—explanation is that the Report only focuses on the so-called "foreclosure" potential of the various practices without examining whether these practices might be justified.

It should be stressed that this focus on foreclosure is by no means unique to the pharmaceutical sector. It is in line with the Commission's two-tier approach under its

[5]Cf. Report, executive summary p. 6 and ¶ 782. *See also* Ms. Kroes speech on November 28, 2008 : "(…) originator companies have designed and implemented strategies aimed at hindering their competitors, and thereby ensuring continued revenue streams for their medicines. The Preliminary Report refers to such strategies as a "tool-box". The successful implementation of these strategies *contributes* to the delaying or blocking of generic entry" (emphasis added).

[6]For references to "deliberate strategy", *see e.g.* ¶¶ 707 and 740; for "delaying tactics, ¶¶ 232, 891; for "toolbox" ¶¶ 895 and 925.

analytical framework for assessing company conduct under Art. 81 and Art. 82 EC. The first step of this approach consists of examining the negative impact of the company's conduct on the competitive process while its second step consists of examining whether this conduct generates efficiency gains that outweigh the negative impact on the competitive process. However, in practice, the second step tends to carry less weight in the overall assessment.

Why is that so? The Commission explains this in two Communications which clarify the analytical framework for assessing company conduct under Art. 81 as well as under Art. 82 EC. The first Communication dates from April 2004 and contains guidelines on the application of Art. 81 (3) EC policy ("Art. 81 (3) Guidelines") while the second one dates from December 2008 and gives guidance on the Commission's enforcement priorities in applying Art. 82 EC to abusive exclusionary conduct by dominant undertakings ("Art. 82 Guidance Paper").[7] The latter builds on a Discussion Paper from December 2005.

Let us briefly revisit these policy documents because they shed light on the Commission's methodological thinking which—let us repeat it—is not flavored by any sector-specific biases. However, as we will explain, its thinking *is* based on a concept of competition that is bound to put companies (including patent holders) that hold—by the Commission's standards—a substantial degree of market power, in an awkward position.

On its website, DG Competition defines competition as a basic mechanism of the market economy that "encourages innovation, and pushes down prices" and "in order to

[7]For the Art. 81 (3) Guidelines, see O.J. C 101/97 of April 27, 2004 and for the Art. 82 Guidance Paper, see O.J. C 45/7 of February 24, 2009.

be effective, competition needs suppliers who are independent of each other, each subject to the competitive pressure exerted by the others." Whereas the first component of this definition focuses on result, i.e. consumer welfare in terms of better quality / lower prices, the second one zooms in on the process of rivalry between competitors—a process that needs to be preserved for consumer welfare to materialize (cf. "in order to be effective").

The analytical framework for assessing company conduct under Art. 81 or Art. 82 faithfully reflects this definition. The Commission will first identify the anticompetitive effects (in terms of negative impact on the competitive process) of a company's conduct and then examine whether the pro-competitive effects (in terms of positive impact on consumer welfare) of that conduct outweigh its anticompetitive effects.[8] This balancing of anti- and pro-competitive effects not only in an Art. 81 EC context but also when unilateral conduct of a dominant company is assessed, is—as such—to be welcomed. However, the question is *how* this balancing will be operated. The above quoted policy papers—and the Commission's enforcement track record in specific cases—contain anything but reassuring language.

To begin with, while even non-dominant companies usually manage to come up with a credible story about efficiencies (first condition of Art. 81 (3)), they will have a harder time convincing the Commission that the negative impact of their agreement on the process of rivalry is indispensable (third condition of Art. 81 (3)), i.e. that there is no

[8] Art. 81 (3) Guidelines, § 11 and Art. 82 Guidance Paper, §§ 6 and 30.

less restrictive alternative capable of achieving these efficiencies. The burden of proof is particularly high if the impact on the process of rivalry is significant.[9]

Furthermore, with regard to the requirement that the efficiencies must—at least in part—benefit consumers (second condition of Art. 81(3)), companies may even find it impossible to demonstrate that there is sufficient pass-on if their agreement leads to a substantial loss of rivalry in the competitive process (fourth condition of Art. 81 (3)). Or, as the Art. 81 (3) Guidelines formulate it:

> 101.(…) When the agreement causes a substantial reduction in the competitive constraint facing the parties, *extraordinarily large cost efficiencies* are normally required for sufficient pass-on to occur.

> 105. (…) Ultimately the protection of rivalry and the competitive process is given priority over potentially pro-competitive efficiency gains which could result from restrictive agreements. The last condition of Article 81(3) recognizes the fact that rivalry between undertakings is an essential driver of economic efficiency, including dynamic efficiencies in the shape of innovation. *In other words, the ultimate aim of Article 81 is to protect the competitive process.* When competition is eliminated the competitive process is brought to an end and short-term efficiency gains are outweighed by longer-term losses stemming inter alia from expenditures incurred by the incumbent to maintain its position (rent seeking), misallocation of resources, reduced innovation and higher prices. (emphasis added).

Since the Commission uses the same analytical framework for assessing a dominant company's unilateral conduct, it takes the same position in its Art. 82 Guidance Paper. While it accepts that dominant companies may also justify conduct that has a negative impact upon the process of rivalry, it observes:

> 30. (…) *Rivalry between undertakings is an essential driver of economic efficiency, including dynamic efficiencies in the form of innovation.* In its absence the dominant undertaking will lack adequate incentives to continue to create and pass on efficiency gains. Where there is no residual competition and no

[9] Art. 81 (3) Guidelines, § 79: "the more restrictive the restraint, the stricter the test under the third condition."

> foreseeable threat of entry, the protection of rivalry and the competitive process outweighs possible efficiency gains. In the Commission's view, exclusionary conduct which maintains, creates or strengthens a market position approaching that of a monopoly can normally not be justified on the grounds that it also creates efficiency gains. (emphasis added)

It is therefore not surprising—but no less regrettable—that the Report almost exclusively deals with the potential foreclosure effects of various types of company conduct without devoting much effort to exploring "the other side of the coin," i.e. the possible justifications for such conduct.

This is true for the Report's chapter (C2) concerning competition between originator and generic companies, i.e. the "price-driven" rivalry. For instance, the Commission stresses: that patent clusters or divisional patent applications create "uncertainty for generic companies;"[10] that originators "may consider litigation not so much on their merits but rather as a signal to deter generic entrants;" [11] or that "a toolbox of measures/instruments can be used throughout the product life cycles to maximize the revenue stream from existing pharmaceutical products by delaying or dampening the effect of generic entry" [12]—without addressing the question whether these strategies might perhaps fall within the subject matter of the patent rights held by the companies which have engaged in these practices. On the other hand, settlement agreements which have the virtue of *removing* the uncertainty inherent in patent litigation for potential generic entrants also seem to raise concern when they restrict the generic company's ability to enter the market and / or provide for a value transfer, especially when this

[10]Report, ¶412.

[11]Id. p. 166.

[12]Id. ¶ 887.

involves a so-called reverse payment to the generic company in return for its promise not to enter the market until a later point in time.[13] The Commission fails—it would seem—to see merit in such agreements, even when they enable parties with opposite interests to put an end to costly litigation with no benefit for consumers.

The Commission's fascination with practices that create foreclosure effects re-surfaces in the Report's chapter (C3) concerning competition between originator companies, i.e. the "innovation-driven" rivalry. Defensive patent strategies seem troublesome since they "might pursue the aim of patenting an invention that the patent holder has no interest in developing and bringing to the market, with the main purpose of keeping other originator companies from further developing a specific invention and bringing it to the market."[14] Putting on its *Microsoft* hat, the Commission also seems to be troubled by an originator company's refusal to grant a license to another originator company if the former's refusal forces the latter to abandon its research and development ("R&D") project.[15]

In sum, while the Commission has been careful enough not to float thoughts—at least not explicitly—about the possible unlawfulness of any of the practices covered by its Report, the analytical framework for assessing company conduct under Art. 81 or 82 EC explains why the focus is so much on the conduct's potential foreclosure effects and so little on its possible efficiencies and why, as a consequence, one inevitably gets the

[13]Id. ¶¶ 632 ff.

[14]Id. ¶ 963.

[15]Id. ¶ 998.

impression that the Commission has already jumped to conclusions regarding the lawfulness of some of these practices.

II. WHICH PRINCIPLES WILL GUIDE THE COMMISSION IN ANY FUTURE ENFORCEMENT ACTIVITY IN THE PHARMACEUTICAL SECTOR?

While the preservation of the competitive process seems to constitute the *alpha & omega* of the Commission's enforcement policy under the analytical framework set forth above, we take the view that this framework—especially as clarified in the Art. 82 Guidance Paper—enables the Commission to adopt a balanced approach.

Let us first remind ourselves that, in Art. 82 cases, the finding of dominance in a relevant market provides the starting point of any analysis. In its Guidance Paper, the Commission does not deal with market definition but it makes a couple of statements that seem highly relevant for the finding of dominance. Thus, it announces—albeit in general terms—that it will "take into account the specific regulatory environment in conducting its assessment" in regulated markets and—more specifically—that "even an undertaking with a high market share may not be able to act to an appreciable extent independently of customers with sufficient bargaining strength."[16] While the Commission explicitly states that it is not prepared to narrow down the concept of dominance to the capacity to profitably increase prices,[17] both statements imply that it is prepared to take into account the pervasive role of public authorities whose market authorization, price approval, and reimbursement decisions as well as any decisions to stimulate demand for alternative

[16]Guidance Paper, § 8 and § 18.

[17]*Id.* § 11: " (…) the expression "increase prices" (…) is used as shorthand for the various ways in which the parameters of competition (…) can be influenced".

(generic- or parallel-traded) medicines—in so far as all these decisions have an undeniable impact on any company's market power.[18]

Turning to the question under which circumstances a dominant company's conduct could be said to create anticompetitive foreclosure effects, we come across other helpful passages in the Guidance Paper.

A Detailed Plan. The Commission states that it will take account of "direct evidence of any exclusionary strategy," such as "internal documents" which reveal "a detailed plan to engage in certain conduct in order to exclude a rival, to prevent entry or to pre-empt the emergence of a market."[19] In our view, the "detailed plan" will only provide such cogent evidence in pharmaceutical cases if it confirms that it was the patent owner's *sole* purpose to exclude potential competition from generic companies or other originating companies. However, given the fact that a patent owner possesses the *lawful* power to exclude competition, the company's mere acquisition or exercise of this power, even when the company builds a bundle or "cluster" of patents, would not seem to amount to an *unlawful* "detailed plan" aimed at excluding competition. In our view, therefore, the Commission would have to adopt a "but for" approach, assessing only those types of practices that make no commercial sense for the dominant company but for its purpose to eliminate competition at the expense of consumer welfare.

Consumer Harm. This is probably the crux of the matter. The exclusionary strategy of a dominant company should only be qualified as abusive if there is cogent

[18]*Id.* § 18. The Commission specifies that "such countervailing buying power may result from the customers' size or their commercial significance for the dominant undertaking, and their ability to switch quickly to competing suppliers, to promote new entry (…)".

[19]Guidance Paper, § 20 in fine.

evidence that the dominant company harms consumers by harming its competitors. The Commission seems to agree since it talks about "anti-competitive foreclosure" in its Guidance Paper and describes it as foreclosure which has an "adverse impact on consumer welfare, whether in the form of higher price levels than would have otherwise prevailed or in some other form such as limiting quality or reducing consumer choice."[20]

The Commission adds that "the identification of likely consumer harm can rely on qualitative and, where possible and appropriate, quantitative evidence."[21] Looking at the Commission's enforcement track record in the pharmaceutical sector, it is fair to say that the Commission has so far exclusively focused on *price* competition (*cf.* e.g. its crusade in favor of parallel trade and—in a more recent past—its decision in *AstraZeneca* where generic competition was at stake). However, we note that the Report also focuses on competition between originating companies. This is—as such—to be welcomed since it shows that the Commission has understood that innovation is a crucial parameter of competition in the pharmaceutical sector. It remains to be seen, however, how the Commission will assess conduct that affects the process of rivalry between originating companies. If it remains convinced that "rivalry between undertakings is an essential driver of economic efficiency, including dynamic efficiencies in the form of innovation,"[22] there is a distinct risk that it will call into question the dominant company's capacity and willingness to innovate in the absence of external pressure from rival competitors. If so, a dominant company would be forced to identify substantial

[20] *Id.* § 19.

[21] *Id.*

[22] Cf. *supra* § 29 *in fine*.

short-term efficiencies to dispel the Commission's concerns about its conduct's potential long-term negative impact on the competitive process. At worst, especially if the dominant company's position is "approaching that of a monopoly," it would seem that the dominant company will have virtually no chance to justify its allegedly exclusionary conduct.[23] Although the Court of First Instance upheld the Commission's decision in *Microsoft* and did so by diluting the "exceptional circumstances" under which—according to the *IMS* case law—a refusal to license intellectual property rights can be found abusive, we see no merit in transposing this case law to the pharmaceutical sector.[24] While the Commission—understandably—makes no attempt in its Guidance Paper to interpret the *Microsoft* judgment narrowly, it does acknowledge in its section concerning refusals to deal that it *also* has to take into account the "input owner's (…) incentives to invest and innovate," and not just *those* of its competitors.[25]

Capacity to Foreclose. Assuming there is evidence showing that a dominant pharmaceutical company has implemented a detailed plan aimed at excluding competition to consumers' detriment, the Commission should only intervene if there is evidence that the company has the capacity to foreclose. In this respect too, the Guidance Paper contains some interesting passages. While the Commission insists that it can intervene in cases where the potential foreclosure has not yet materialized, [26] it seems to

[23] *Id.*

[24] CFI judgment of September 17, 2007 case T-201/04 *Microsoft v. Commission*, ECR II-3601 and ECJ judgment of April 29, 2004, case C-418/01 *IMS Health*, ECR I-5039.

[25] *Id.* § 81.

[26] Guidance Paper, § 20: "(…) where (…) the allegedly abusive conduct is likely to lead to anticompetitive foreclosure."

be aware of the need to establish sufficient causality between the allegedly exclusionary conduct and allegedly anticompetitive foreclosure. There are at least two signs for this:

- First, the Commission recognizes the need to examine the so-called "counterfactual":

  > 21. (…) This assessment will usually be made by comparing the actual or likely future situation in the relevant market (with the dominant undertaking's conduct in place) with an appropriate counterfactual, such as the simple absence of the conduct in question or with another realistic alternative scenario, having regard to established business practices.

- Second, the Commission also recognizes the need to examine to what extent rival competitors "have realistic and effective counterstrategies at their disposal."[27] While the Commission makes this point in the context of assessing conditional rebates, the "counterstrategies" concept is no doubt valid for the assessment of just any type of allegedly abusive behavior.

Remedies. Any enforcement agency should ask itself how its intervention in the competitive process can enhance consumer welfare. Therefore, assuming—*arguendo*—that a company's conduct "ticks all the boxes" to be qualified as an abuse under Art. 82 EC, the Commission should not intervene if there is a regulatory remedy available for the "victimized" competitors. For instance, patent law may contain provisions that enable them to sanction "blocking patent" or "patent cluster" strategies (cf. e.g. Art. 5 (A) 2 of the Paris Convention for the protection of industrial property which provides for compulsory licensing in case the patent owner refrains from working his patented invention; Art. 31 (l) of the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS") which also provides for compulsory licensing where another company

[27] *Id.* § 43.

holds a so-called dependent patent covering an invention that presents an "important technical advance of considerable economic significance" but that cannot be exploited without infringing a pre-existing patent). Moreover, if such regulatory remedies would not be considered effective, the Commission could add this to the competition advocacy agenda of this Sector Inquiry.

III. CONCLUSION

It is still early days. The Commission has collected an unprecedented amount of information concerning just about every aspect of company conduct in the pharmaceutical sector. It is to be hoped that it will make constructive use of this information in the context of its efforts to create a more competition-friendly regulatory environment in Europe. On the enforcement side, the Commission will have to set its priorities. In our view, its Guidance Paper on Art. 82 contains a toolbox of sound antitrust policy concepts that should enable it to challenge only those types of practices that make no commercial sense for the dominant company except to eliminate competition at the expense of consumer welfare.