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The outcome of the EC pharmaceutical sector inquiry

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Abstract

On 8 July 2009, the European Commission’s released its long-awaited Final Report on its Pharmaceutical Sector Inquiry. The Final Report suggests that the shortcomings of the regulatory framework are a key explanatory factor for delayed generic entry and limited innovation. Meanwhile the Final Report nuances earlier, provisional, findings, that pharmaceutical companies’ conduct had blocked/limited generic entry and led to a decline in the number of new chemical entities reaching the market. The purpose of the present “Tendances” is to provide an overview of the Final Report and to discuss the Commission’s findings.

La Commission européenne vient d’adopter, le 8 juillet 2009, son rapport d’enquête final sur le secteur pharmaceutique. Ce rapport souligne que les retards observés dans la mise sur le marché des médicaments génériques et le recul apparent de l’innovation dans le secteur pharmaceutique découlent de manière significative du cadre réglementaire applicable. En outre, le rapport vient nuancer de précédentes constatations, qui stigmatisaient les pratiques des entreprises pharmaceutiques. L’objet du présent « Tendances » est de fournir un aperçu critique du rapport final de la Commission européenne.

* These are purely personal views. They do not represent the views of the firm or any of its clients.

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The outcome of the EC pharmaceutical sector inquiry

“Bark at the Moon?”

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1. On 8 July 2009, the European Commission (the “Commission”) adopted a much awaited Final Report (the “Report” or the “Final Report”) in the context of its sector inquiry into the pharmaceutical sector.[1] This Report formally closes a 18 months-long investigation which, in essence, sought to establish whether originator companies’ conduct delayed generics medicines entry and stifled innovation, thereby limiting both originator-generic competition as well as originator-originator competition.[2]

2. Since the early days of its inception, the Commission’s sector inquiry – which has subsequently been compared to a “*fishing expeditio(n) in disguise*” – has sparked a great deal of controversy.[3] First, by contrast to previous sector inquiries, the *scope* of the Commission’s investigation has been particularly wide with more than a hundred stakeholders requested to provide information (including 43 originators and 27 generic companies, as well as wholesalers, parallel traders, national health authorities, Member States’ marketing authorisation bodies and competition authorities).[4]

Second, the Commission has made full use of its *investigative powers* under Regulation 1/2003,[5] sending numerous requests for information (often under extremely tight deadlines), and conducting, for the first time in the context of a sector inquiry, on-the-spot inspections (dawn raids) on the premises of several pharmaceutical companies.[6]

1 *See* Communication from the Commission – Executive Summary of the Pharmaceutical Sector Inquiry Report. *See* also Commission Staff Working Document (Technical annex to the Commission Communication), Parts 1 and 2, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html. The scope of the sector inquiry has been circumscribed to human pharmaceutical products focusing predominantly on prescription medicines.

2 *See* Commission Decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector pursuant to Article 17 of Council Regulation 1/2003 (Case COMP/D2/39.514). The inquiry related “*to the introduction of innovative and generic medicines for human consumption on the market*”. *See* also MEMO/08/20 of 16 January 2008, Antitrust – sector inquiry into pharmaceuticals – frequently asked questions.

3 *See* H. Andersson and E. Legnerfält, “Dawn Raids in Sector Inquiries – Fishing Expeditions in Disguise?”, [2008] *ECLR*, 439. Whilst sector inquiries do not necessarily purport to lead to subsequent enforcement proceedings (amongst other things, their purpose is to allow the Commission to gain a better understanding of specific markets and/or commercial practices), the Commission seems increasingly to consider sector inquiries as a tool for uncovering infringements of EC competition law. This appeared particularly clearly in the aftermath of the energy sector inquiry, with the Commission launching two antitrust proceedings against E.ON.

4 *See* Communication from the Commission – Executive Summary of the Pharmaceutical Sector Inquiry Report, p. 4. The Commission’s requests for information covered all 27 EU Member States over the period 2000-2007. Several issues such as parallel were progressively set aside during the course of the sector inquiry.

5 *See* Council Regulation 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, OJ L 1, 4 January 2003, pp. 1–25 (Articles 18-20).

6 Before the adoption of the Final Report. On 16 January 2008, the Commission conducted unannounced inspections on the premises of a number of originator and generic companies in Europe, including (according to press reports) Pfizer, Merck, Sanofi-Aventis, GSK, Astra Zeneca, Novartis, Johnson & Johnson and Teva. *See* S. Creighton and S. Russell, “Comment on the EC’s Pharmaceutical Dawn Raids”, *Global Competition Policy Online*, Feb-08(1) & (2)

Third, the Commission's *substantive concerns* have been repeatedly challenged as misplaced, in particular following the adoption of its Preliminary Report on 28 November 2008.[7] In this Preliminary Report, the Commission reached the controversial, provisional, finding that there was a clear-cut competition problem in the market,[8] primarily due to the fact that originators conduct had "*contributed to generic delay as well as to the difficulties in innovation*".[9] Whilst conceding that several exogenous shortcomings of the regulatory framework might also have contributed to generic delays and limited innovation, officials from the Commission repeatedly stressed that the focus was on companies' behaviour,[10] and not on regulatory issues.[11] In this context, the Preliminary Report identified in a somewhat colourful, pejorative, language a "*tool-box*" of strategic instruments possibly designed and used by originators to delay and/or block generic entry: patent clusters or thickets, patent disputes and litigation, opposition and appeal procedures before the European Patent Office ("EPO"), patent settlements and other agreements, originators interventions before marketing authorities and pricing reimbursement authorities, and originators' launching of second generation and follow-on products.[12]

3. However, the public consultation process that followed the Preliminary Report unleashed a thorny policy discussion. Unexpectedly, most stakeholders including generic companies, instead of blaming originators, stigmatised the shortcomings of the regulatory framework (fragmentation of the patent court system, excessive duration of patent opposition procedures, award of weak patents, heavy burdens imposed by drug testing requirements, etc.) as a key explanatory factor for generic delay, hence marginalising the Preliminary Report's findings against originators. Moreover, in light of the controversial decisional precedent in *AstraZeneca*,[13] and of the Court of First Instance's judgment in *ITT Promedia*,[14] many doubts were raised as to whether Article 82 EC could constitute a solid legal basis to challenge originators' unilateral conduct.

4. The Commission's Final Report bears testimony of this debate. Unlike the Preliminary Report, the Final Report's semantics are far more neutral as regards originators' conduct. More importantly, whilst the Report contends that there are competition problems in the pharmaceutical industry and that originators may try (have tried) to delay the entry of generics medicines through a number of potentially problematic practices (and in particular, through settlement agreements which seem to fall squarely within the ambit of Article 81 EC, and which will be subject to "*focused monitoring*"),[15] it expressly endorses the view that the shortcomings of the regulatory framework also play a critical role in delaying generic entry and reducing innovation.[16] There is thus a noticeable contrast between the Commission's early muscular stance, and the more consensual tone of its Final Report.

5. Overall, as a matter of *enforcement policy*, the outcome of the sector inquiry appears particularly slim. Whilst the Commission's inquiry has triggered a wide (and welcome) debate on the adequacy of the regulatory framework, it has only uncovered one case of potential infringement of Article 81 and/or 82 EC,[17] thereby indicating that anticompetitive practices in the pharmaceutical sector are not as pervasive as was initially suspected.[18] Of course, the finding that unlawful, anticompetitive, conduct is not widespread in the pharmaceutical sector should, in itself, be a cause of satisfaction. This notwithstanding, if an *ex post* input/output perspective is taken on the Commission's use of its limited administrative resources, one may beg the controversial question of whether the decision to open a sector inquiry was in the first place warranted (or whether the criterion enshrined in Article 17 of Regulation 1/2003 are sufficiently accurate).[19] This question is all the more relevant because the opening of a sector inquiry imposes heavy costs on companies (*e.g.*, disruption of ongoing business processes, investors'

7 *See* DG Competition Staff Working Paper, Pharmaceutical Sector Inquiry, Preliminary Report, 28 November 2008, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf.

8 *See* N. Kroes, Antitrust: preliminary report of sector inquiry into pharmaceuticals, Opening remarks at press conference, Brussels, 28th November 2008 ("*we find that competition in this industry does not work as well as it should*").

9 *See* the numerous pronouncements in that sense of the DG Competition Staff Working Paper, as well as Communication from the Commission – Executive Summary of the Pharmaceutical Sector Inquiry Report, p. 6.

10 *See* presentation of P. Gasparon at IEJE-FUSL Half-day Conference on the Commission's Pharmaceutical Sector Inquiry, 14 January 2009.

11 Another official of the Commission is reported to have explained that the focus of the Commission's inquiry was not on regulatory issues, on which the Commission has no authority to deal with. *See* Presentations and speeches, Public presentation of preliminary findings on 28 November 2008, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html

12 *See* DG Competition Staff Working Paper, Pharmaceutical Sector Inquiry, Preliminary Report, 28 November 2008, p.5. Those practices are not necessarily being used in isolation, but are allegedly also combined by originators to delay generic entry.

13 *See* Commission Decision of 15 June 2005, Case COMP/A. 37.507/F3 – *AstraZeneca*. *See*, on this, B. Bär-Bouyssière, "Patently dangerous – A faulty notion of "regulatory abuse" haunts the pharma sector inquiry", *Competition Law Insight*, 5 May 2009.

14 *See* Case T-111/96, *ITT Promedia NV v. Commission*, [1998] ECR II-2937.

15 *See* Communication from the Commission – Executive Summary of the Pharmaceutical Sector Inquiry Report, p. 27.

16 *Idem*. The Commission observes (i) that a Community patent and a unified specialised patent system would reduce administrative costs and uncertainty for companies; and (ii) that Member States should limit third parties submissions, accelerate approvals for generics medicines, take action if misleading information campaigns question the quality of generics medicines, and streamline trials that test the added value of novel medicines.

17 *See* MEMO/09/322 of 8 July 2009, Antitrust: Commission opens formal proceedings against Les Laboratoires Servier and a number of generic pharmaceutical companies. The Commission's press release attempts to disconnect formally this investigation from the sector inquiry, in expressly indicating that: "*The present investigation does not form part of the sector inquiry, but the knowledge acquired during the sector inquiry has allowed the Commission to draw conclusions on the areas where Commission action based on competition law could be appropriate and effective*". A plausible reason for this may be that the Commission seeks to preclude the parties from accessing to the entire sector inquiry file.

18 The Commission's inquiry has also uncovered many internal documents where employees of originator companies were expressing their intent to delay and/or block generic competition. Yet, evidence of anticompetitive intent is not, as such, sufficient to establish a competition law infringement.

19 In particular at a time where the Commission seems adamant to define optimal enforcement priorities. *See* in this context, Communication from the Commission – Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, 9 February 2009 – C(2009) 864 final.

defiance,[20] etc.)[21] as well as on the Commission itself (*e.g.*, the opportunity cost of not monitoring other sectors where competition law infringements may take place).[22]

6. Of course, this sector inquiry has indirect *competition advocacy* merits. In particular, the Commission has certainly promoted the degree of spontaneous compliance with the law, in increasing the awareness of pharmaceutical operators to risks of competition law exposure. This being said, however, because the Final Report is primarily factual in nature, it provides only little, if no, guidance on the boundaries between lawful and unlawful conduct. To maximise the return of its investigative effort, and help pharmaceutical firms comply with EC competition law, we thus believe that the Commission should build upon the factual findings of its Report to provide positive legal guidance to pharmaceutical firms.[23]

7. The purpose of the present "Tendances" is to provide an overview of, as well as a forum for debate on, the Final Report. The authors are distinguished competition law and intellectual property specialists who have closely followed the Commission's inquiry. Many thanks to all of them for having accepted to devote time and thinking to this fascinating issue. ■

20 Investors are generally reluctant to finance firms subject to potential competition law scrutiny. In the context of the current economic crisis, one cannot exclude that risks of future antitrust exposure might prompt investors to cut R&D spending, thereby hampering originators' investment into innovative drugs.

21 Paradoxically, whilst the Commission criticizes the costs imposed by the fragmented regulatory/litigation system in Europe on pharmaceutical companies, it does not question the costs imposed by its own sector inquiry on the same firms.

22 The Commission has established a "*Pharma Task Force*" to conduct the sector inquiry. The Task Force boasted approximately 40 case-handlers from DG Competition and was led by a senior official.

23 For instance through the adoption of soft law instruments (*e.g.*, guidelines) or through inapplicability decisions pursuant to Article 10 of Regulation 1/2003.

Proceed with caution across the IP/Competition intersection

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1. DG Competition's release of its long-awaited Final Report on its Pharmaceutical Sector Inquiry on 8 July 2009 was somewhat of a damp squib compared to the fireworks surrounding the publication of its Interim Report some eight months earlier. The release of the Interim Report in November 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.[24] The Interim Report elicited vociferous criticism from the pharmaceutical industry. Innovative pharmaceutical companies – or "*originator*" companies to use the Report's terminology – were concerned that practices that they deemed to be critical to the protection of their patents were being called into question. These concerns were set out in detail in the numerous submissions that were made to DG Competition after the publication of the Interim Report.[25]

2. In contrast, the release of the Final Report was a low-key affair, with just a routine press conference and relatively light press coverage. The reaction to the Final Report from both sides of the debate was muted, but generally positive. Both EFPIA – the trade association representing originator companies – and EGA – the generic companies' trade association – welcomed the Report's emphasis on the need for reform of the regulatory system.[26]

I. A more balanced, holistic approach

3. This positive reaction from both sides of the debate highlights the Final Report's more balanced and holistic approach when compared to the Interim Report. DG Competition clearly took on board many of the comments submitted in response to the Interim Report. First, it toned down the emotive rhetoric used in the Interim Report. It went out of its way to explain that the use of various terms that had attracted so much criticism in the Interim Report because they were viewed has having a pejorative connotation inconsistent with a Report that purported to be neutral – "*tool box*", "*patent clusters*", "*defensive*" patenting, "*secondary*" patents – were not intended to have such a connotation. For example, it explained that "*secondary*" patents "*should […] not be understood to mean that these patents are of a lower quality or value, but merely that – from a time perspective – they follow the primary patent.*"[27]

4. Second, the DG Competition recognized that practices by originator companies contribute to delays in generic entry, but that shortcomings in the regulatory framework are a major factor. In releasing the Final Report, Commissioner Kroes emphasized the need for less "*red tape*".[28] To this end, the Report puts forward a number of concrete proposals aimed at getting rid of this red tape:

→ The establishment of a single Community patent and a unified, specialized patent litigation system in Europe. These changes would reduce the costs and administrative burdens associated with multiple patent filings, eliminate parallel litigation between the same parties in different Member States, and enhance legal certainty through the avoidance of multiple rulings.

→ The European Patent Office should continue with initiatives designed to maintain a high quality standard in granting patents and to accelerate procedures (such as limiting the time during which divisional patent applications may be filed).

24 DG Competition's website has a specific section devoted to the pharma sector inquiry, including webcasts of the remarks of vary participants at the hearing.

25 These submissions are on DG Competition's website.

26 *Pharmaceutical Sector Inquiry Highlights Regulatory Shortcomings and Need for Strong, Effective Patent System in Europe*, EFPIA Press Release, 8 July 2009; *European Commission Inquiry Recommends Systemic Improvements to Ensure Immediate Access for Patients to Affordable Generic Medicines upon Patent Expiry*, EGA Press Release, 8 July 2009.

27 Final Report, ¶ 20.

28 *Shortcomings in Pharmaceutical Sector Require Further Action*, European Commission Press Release, IP/09/1098 9 (8 July 2009).

→ Member States should ensure that market authorization approvals are not delayed by third party submissions, which should be kept to a minimum and made in a transparent way.

→ Member States should generally accelerate approval procedures for generics. In particular, generics should automatically receive pricing/reimbursement status where the originator company's product already has such status. Submissions by third parties should be kept to a minimum and not be allowed to delay the procedure.

5. The fact that a key set of conclusions in the Final Report focuses on regulatory reform as opposed to competition law issues highlights that, as an institutional matter, the sector inquiry evolved into an exercise that presented a significant challenge to DG Competition. The inquiry started out with a focus on commercial practices of companies leading to delays of generics onto the market and fewer new drugs coming to market.[29] The Interim Report reflected this focus. However, as the investigation progressed and DG Competition received additional input from industry in response to the Interim Report, it became apparent that the most significant problem was the regulatory system, not companies' commercial practices. Rather than limiting itself to narrow conclusions limited to the competition issues presented by commercial practices, DG Competition showed a laudable degree of institutional flexibility by interpreting its mandate in a broad manner. As a result, it was able to propose a broad set of policy recommendations the recognize the unusual complexity of the pharmaceutical sector.

II. A more cautious approach to issues at the IP/Competition intersection

6. In addition to adopting a more balanced approach, the Final Report takes a more cautious approach to issues arising at the IP/competition intersection that is more in line with existing case law. One of the main criticisms levied at the Interim Report was that it appeared to suggest that a whole range of practices used by originator companies to maximize the value of their intellectual property rights were problematic under the competition rules. It described these practices as belonging to a nefarious "*tool box*" of instruments used by originator companies to delay the entry of generics onto the market. Competition lawyers were concerned because, under established competition law principles, many of the practices would only give rise to issues in exceptional circumstances. Intellectual property experts were troubled by the suggestion that practices that are common, not just in the pharmaceutical sector, but in all high-tech sectors, such as taking out numerous patents around an invention, were incompatible with the competition rules. If DG Competition was suggesting that these practices were generally problematic, it was espousing a position that was not only inconsistent with existing law, but that risked chilling the innovation that intellectual property rights were designed to foster.

7. In the Final Report, DG Competition signals its intention to proceed cautiously at the IP/competition intersection. It starts out by emphasizing the crucial importance of innovation to the pharmaceutical sector and the key role of intellectual property rights in promoting innovation.[30] In discussing the application of competition law to practices involving intellectual property rights, it acknowledges that these practices would only give rise to infringements in "*exceptional circumstances*".[31] In its discussion of some of the main practices examined in the Report, it does not articulate clearly when competition concerns are likely to arise, but it generally adopts an approach that is much more cautious than that indicated in the Interim Report:

1. Patent strategies

8. The Interim Report suggested that the common practice of filing so-called "*secondary*" patents around the original patent could be anticompetitive. This position was heavily criticized. First, DG Competition was 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 were appropriate, its officials do not possess the necessary technical expertise in this area. Second, the Interim Report's discussion of secondary patents appeared to be based on the false premise that such secondary patents are of lesser quality that 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.

9. The Final Report indicates that filing for numerous patents on an invention is common practice and, taken alone, is not necessarily problematic. Competition concerns are most likely to arise when the originator company is filing for patents for the purpose of excluding competitors such as where it files for a patent, but does not use the patent and refuses requests to license the patent.[32] This more limited approach is much more in line with current law.

29 *See* Commission Decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector ("*There are indications of commercial practices by pharmaceutical suppliers […] which may not serve to protect innovation but to block innovative and/or generic competition, litigation. […] In order to establish the extent of the above-mentioned practices and to assess them fully in their proper factual and economic context, the use of formal investigative powers such as those granted to the Commission for sector inquiries is required.*")

30 Final Report, ¶¶ 9-10.

31 Final Report, ¶ 1568.

32 Final Report, ¶ 1571.

2. Patent litigation

10. The Interim Report suggested by broad innuendo that originator companies that pursue patent litigation against generics could be engaged in anti-competitive conduct. This suggestion gave rise to criticism because, under existing case law, patent litigation could only constitute anti-competitive conduct in the rarest of circumstances. If the company holds a dominant position, such litigation could be challenged as abusive under Article 82. In *ITT Promedia*[33] – 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.[34] 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.[35] Applying these principles in the context of patent litigation brought by a dominant pharmaceutical company against a generic competitor, it would seem extremely 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).

11. The Final Report appears to recognize that, as a general rule, a company is entitled to enforce its patent rights, even if this creates obstacles for generic companies. It notes that "*[e]nforcing patent rights is legitimate and constitutes a fundamental right guaranteed by the European Convention on Human Rights*".[36]

3. Patent settlements

12. The treatment of patent settlements is one area where the Final Report does not differ significantly from the Interim Report. The Final Report suggests that competition concerns are likely to arise with respect to agreements designed to keep competitors out of the market, in particular patent settlement agreements that limit generic entry and include a value transfer from the originator company to the generic company.[37]

13. As patent settlements can take a wide variety of forms, it is to be hoped that DG Competition will evaluate them on their merits, even those involving a reverse payment. As a general rule, 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 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 an amount of damages from the generic company adequate 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.

III. A need for guidelines

14. For many, the Final Report was a disappointment because DG Competition declined to provide any guidance on the competition law analysis of the various practices reviewed in the course of the sector inquiry, stating: "*It is important to underline that – whilst the report primarily analyses company behavior – it does not identify individual cases of wrongdoing or provide any guidance on the compatibility of the practices examined with the EC competition rules. It provides the Commission however with relevant context and a factual basis for deciding whether and what further action is needed, including enforcement action.*"[38]

15. Instead of providing general guidance, DG Competition has announced that it plans to pursue litigation against individual companies where it deems appropriate.[39]

16. The problem with this approach is that innovative pharmaceutical companies are left facing 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. 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 could chill innovation. More importantly, litigation is likely to result in an incomplete and unbalanced legal framework erected on the basis of principles developed in a piecemeal, ad hoc fashion.

17. 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. 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

33 *ITT Promedia NV v. Commission*, 1998 ECR II-2937.

34 *Id.* at ¶¶ 55-56.

35 *Id.* at ¶ 60.

36 Final Report, ¶ 548.

37 Final Report, ¶ 1573.

38 Final Report, ¶ 22.

39 See Final Report, ¶¶ 1571, 1575-76.

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.

IV. Conclusion

18. The Final Report is a marked improvement over the Interim Report. It is more balanced in its conclusions, recognizing that problems with the regulatory system are a key cause for delays of generic entry onto the market. While DG Competition found that the practices of originator companies also contribute to these delays, it acknowledged that these practices only raise competition concerns in exceptional circumstances.

19. Unfortunately, the Final Report fails to offer any useful guidance on what these circumstances are. 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. Unless DG Competition breaks this silence and offers some guidance, companies will be forced to operate in an unhealthy climate of legal uncertainty. They will be advised to proceed across the oftentimes hazardous intersection of intellectual property and competition law with extreme caution. ■

The elephant uncovered

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I. Introduction and summary of conclusions[40]

1. On 8 July 2009, the Competition Directorate of the European Commission ('DG COMP') published its Final Report on the pharmaceutical sector inquiry ('the Final Report').[41] Like the Preliminary Report published on 28 November 2008,[42] the Final Report concludes that the entry of generic medicines onto the market is being delayed (compared to the perfect competition scenario of generic entry immediately upon patent expiry) and that there has been a decline in the number of new chemical entities ('NCEs') reaching the market.[43]

2. While recognising that DG COMP's powers under Regulation 1/2003 are narrower than, for example, the UK Competition Commission, and focus almost solely on the conduct of undertakings,[44] we were critical of the fact that the Preliminary Report had missed a key part of the picture by failing to examine the crucial role played by the regulatory framework in the pharmaceutical industry. We suggested this was an undetected "elephant in the room."[45]

3. The Final Report goes a long way to remedying this omission – certainty as far as delayed generic entry is concerned. While the Final Report suggests that the conduct of R&D-based pharmaceutical companies ('originator companies'[46]) may be one of the causes of delayed generic entry and of the decline in NCEs reaching the market, it accepts that shortcomings in the regulatory framework may also explain and be a significant cause of these phenomena.

4. The question therefore arises as to how significant the regulatory impact is compared to the impact of conduct by originator companies. Or to pursue the elephant analogy: how big is the elephant is in the room? We explore this below.

First, we analyse the data and the findings in the Final Report as to the impact of regulation on generic entry. The Final Report now seems to recognise that the *primary* cause of the delays to generic entry identified by the sector inquiry is regulatory in nature and not practices of originator companies.

Second, we assess the reasons put forward by the Final Report for the decline in the number of NCEs. We note that the Final Report falls short of engaging in a full-blown analysis of all the regulatory factors that may explain this decline, with the result that DG COMP is unable to properly evaluate "*whether the behaviour of originator companies might be among the reasons for the difficulties to bring new medicines to the market.*"[47] It is therefore difficult to escape the conclusion that regulation may again be the primary reason for the decline in NCEs.

40 This article is adapted from a presentation given by James Killick on 14 January 2009 at the Conference on the Commission's Pharmaceutical Sector Inquiry and entitled "Regulatory Issues and the Pharma Sector Inquiry: is Regulation the Elephant in the Room?" available at http://www.droit.ulg.ac.be/ieje/fileadmin/IEJE/Pdf/Killick%20_Pharma_Sector_Inquiry_Conference.pdf.

41 Available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

42 Available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf.

43 Between 1995 and 1999, an average of 40 NCEs were launched while between 2000 and 2007 that number had dropped to an average of 27 NCEs according to DG COMP. See http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/09/321&format=HTML&aged=0&language=EN&guiLanguage=en.

44 See Powell & Innes-Stubb, "A Tale of Two Sector Inquiries: Comparing and Contrasting Experiences in the U.K. and EU," GCP Magazine, November 2008, http://www.globalcompetitionpolicy.org/index.php?&id=1798&action=600.

45 See footnote 1 above and Killick and Dawes, "The Undetected Elephant in the Room: An Analysis of DG Competition's Preliminary Report on the Pharmaceutical Sector Inquiry", GCP Magazine, February 2009, http://www.globalcompetitionpolicy.org/index.php?&id=1588&action=907.

46 Which DG COMP defines as companies that sell novel drugs that benefited from patent protection when launched onto the market.

47 ¶ 1082 of the Preliminary Report.

II. Why did DG COMP open a sector inquiry into the European pharmaceutical sector?

5. On 15 January 2008, DG COMP opened[48] a sector inquiry into the pharmaceutical industry by way of unannounced inspections – the first time that dawn raids have been used in a sector inquiry. At that time, DG COMP said it had started the inquiry to examine (a) delays to generic entry and (b) the reasons behind fewer new pharmaceutical products being brought to market, as the Competition Commissioner's words made clear: "*Individuals and governments want a strong pharmaceuticals sector that delivers better products and value for money. But if innovative products are not being produced, and cheaper generic alternatives to existing products are being delayed, then we need to find out why and, if necessary, take action.*"[49]

6. DG COMP was therefore interested in investigating causation when the sector inquiry was opened ("*we need to find out why*").

III. The 426-page Preliminary Report of 28 November 2008: What about the elephant?

7. The Preliminary Report claimed that originator companies had recourse to a "toolbox" of practices[50] in order to delay the entry of generic medicines onto the market and that these practices, where successful, "*may increase the likelihood of delays to generic entry*" and "*may significantly increase legal uncertainty to the detriment of generic entry and can cost public health budgets […] significant amounts of money.*"[51]

8. The Preliminary Report also claimed that originator companies applied defensive patenting strategies, primarily aimed at blocking other originator companies in the development of new medicines. In relation to the overlap between the patents of one company and patent/R&D programme of another, the Preliminary Report concluded that this "*creates significant potential for originator companies to find their research activities blocked, with detrimental effects on the innovation process.*"[52]

9. However, on the key issue of the effect of regulation, the Preliminary Report was almost entirely silent. Similarly, the Preliminary Report did not address the issue of causation. The quotes set out in the preceding two paragraphs were typical of the Preliminary Report as a whole: the use of "*may*" and "*creates significant potential*" rather than "*will*" or "*does*". The analysis was thus speculative and there was no finding that any of the practices by originator companies caused generic delay or a drop in innovation.

IV. An elephant which was the subject of much critical comment during the public consultation after the publication of the Preliminary Report

10. The failure to address the regulatory environment was the subject of much critical commentary by stakeholders during the public consultation following the publication of the Preliminary Report.[53] Many stakeholders pointed out that the failure to take this factor into account meant that no meaningful conclusions on causation could be drawn – in other words, there was no causal link between the practices by originator companies which the sector inquiry identifies and generic delays / reduction in innovation.

11. In relation to delays to generic entry, a number of stakeholders argued that national regulatory measures better explain the significant disparities as to the average time for generic entry amongst the different EU Member States than the "toolbox" – since there was no evidence that the elements of the "toolbox" were applied differently in different countries. In particular, it was said that the way in which Member States incentivise generic entry and the regulatory delays that generic producers incur during the process of bringing a product to market suggest that regulation was the major element at work.

12. Similarly, in relation to the lack of new innovative products reaching the market, a number of regulatory reasons were put forward to explain why there has been a drop in the number of NCEs. These included national pricing and reimbursement systems, cost-containment strategies, ever-higher requirements that need to be met in order to obtain a marketing authorisation and the increased costs of clinical trials.

48 Commission Decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector pursuant to Article 17 of Council Regulation No 1/2003 OJ [2008] C 59/06.

49 Commission Press Release IP/08/49 of 16 January 2008, 'Antitrust: Commission launches sector inquiry into pharmaceuticals with unannounced inspections', available at http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/49&format=HTML&aged=0&language=EN&guiLanguage=en

50 According to ¶ 369 of the Preliminary Report, the "toolbox" was made up of the following elements: secondary patenting; disputes and contacts; patent litigation; patent settlements; interventions before regulatory bodies; other interventions; and life cycle strategies.

51 Preliminary Report, p. 322. The Preliminary Report stated that savings of EUR 14 billion had already occurred due to generic entry in the EU in 2000-2007 and that a further EUR 3 billion could have been saved assuming that generic entry had happened immediately i.e. on day one after patent expiry in 2000-2007 in the EU Member States for essentially all the medicines that went off patent in that period.

52 Preliminary Report, p. 350.

53 These comments are available at http://ec.europa.eu/competition/consultations/2009_pharma/index.html.

V. The 533-page Final Report of 8 July 2009 spots the elephant

13. These comments appear to have been taken on board by DG COMP in preparing its Final Report, which adopts a markedly different tone and emphasis to the Preliminary Report. While the "*primary focus*" remains "*on those practices which companies may use to block or delay generic competition as well as to block or delay the development of competing originator products*" (¶ 15), the Final Report accepts that "*as the industry is strongly regulated and the behaviour of the company needs to be assessed in the context of the existing regulatory framework, the sector inquiry also looked in broad terms at aspects of the regulatory framework*" (¶ 16).

1. Regulation and delays to generic entry

14. The Final Report now recognises that "*a number of regulatory variables play an important role*" (¶ 190) in relation to how generic entry takes place:

→ First, INN prescription by doctors and mandatory generic substitution by pharmacists. Where Member States encourage doctors to prescribe an active substance rather than a specific product and oblige pharmacists to dispense the cheapest generic available from those covered by a doctor's prescription, "*generic entry in the first year appears to be more prevalent*" (¶ 190) and "*the number of entrants tends to be higher*" (¶ 206);

→ Second, the imposition of mandatory discounts (in comparison to the pre-existing originator price) or price caps on generic products. In Member States which use such mechanisms, "*the speed of entry appears to be lower*" (¶ 197) as these measures "*may remove some of the advantage of first-movers into the market (the first generic entrant to enter the market has to give a mandatory discount, whereas otherwise it might be able to offer mild price reductions compared to the originator company until the point in time that other generic companies enter the market as well)*" (¶ 190). The number of entrants also "*appears to be lower*" (¶ 206).

15. These findings are not surprising as a 2006 report by Simeons and De Coster,[54] commissioned by the European Generics Association, had similarly found that generic entry depends, to a large extent, on the approach adopted by the Member States:

"*Penetration of generic medicines is more successful in countries that permit (relatively) free pricing of medicines (e.g. Germany, Netherlands, United Kingdom) than in countries that have pricing regulation (e.g. Austria, Belgium, France, Italy, Portugal, Spain). This is because countries that adhere to free market pricing generally have higher medicine prices, thereby facilitating market entry of generic medicines and a higher price difference between originator and generic medicines.*"

"*In Italy and Spain, the limited volume of generic medicines consumption in combination with low medicine prices due to certain supply-side measures has undermined the economic viability of the generic medicines market.*"

"*Countries that have promoted generic medicines for 10-15 years naturally have a more mature generic market than countries that have only recently implemented measures to stimulate generic medicines use.*"

16. The Final Report also acknowledges that the hurdles which generic producers face when getting through the regulatory process also contribute to delays:

→ First, marketing authorisation bottlenecks. The Final Report finds that bottlenecks – due to delays in procedures and accessibility of slots, with some agencies already "fully booked" until 2010 – "*may lead to delayed access for European patients to […] generic medicines*" (¶ 1372);

→ Second, national pricing and reimbursement systems. The Final Report calls for Member States to fully comply with the time-limits set out in the Transparency Directive (Directive 89/105) "*in order to avoid delays to the benefit* [detriment][55] *of patients and applicant companies*" (¶ 1432). It also invites all Member States "*to consider the introduction of national provisions granting automatic/immediate pricing and reimbursement status to generic products […] where the corresponding originator product already benefits from reimbursement based on a higher price*" as this would lead to "*faster access of generic products*" (¶ 1434).

17. These national regulatory factors do indeed appear to explain why generic entry may be delayed more in some countries than in others. They certainly explain the disparities in generic entry between different EU Member States much better than the original thesis, namely that practices of originator companies were to blame – a hypothesis that was suggested at the outset of the investigation but which was not confirmed in the Preliminary Report, as it never came to any conclusion on causation. The Final Report therefore sets the record straight and concludes that "*the Preliminary Report did not suggest that the observed delays were* exclusively *due to company behaviour, but emphasised that practices employed by originator companies* may *contribute to the delays*" (¶ 1512).

2. Regulation and the lack of new innovative products reaching the market

18. The Final Report also considers certain regulatory aspects which may explain the decline in the launch of new NCEs:

→ External reference pricing. The use by certain Member States of mechanisms whereby a price is set on the basis of the

54 "Sustaining Generic Medicines Markets in Europe", Leuven, April 2006, available at http://www.egagenerics.com/doc/simoens-report_2006-04.pdf.

55 The use of the word "benefit" appears to be a linguistic error.

prices in other Member States "*can lead to delays in market entry*" (¶ 1443) because new products will not be launched in lower-priced Member States until prices have been obtained in higher-priced Member States;

→ The fragmentation of national pricing and reimbursement systems. The fact that pricing and reimbursement decisions are increasingly taken at a regional/local or even hospital level also "*has an impact on the transaction costs to market the products*" (¶ 1445) and delays the launch of new products.

19. However, the Final Report falls short of engaging in a full-blown analysis of all the regulatory factors which may explain the decline in the number of innovative products reaching the market in recent years. For example, there is no consideration of the fact that regulatory requirements for the approval of NCEs are higher now than they were a decade ago.[56] If there is a higher regulatory failure rate, this in itself could explain part of the trend of lower numbers of NCEs reaching the market.

20. Similarly, the impact of the increased costs of clinical trials is also ignored by the Final Report. While originator R&D budgets continue to grow,[57] costs are also growing. Clinical trials have become more complex, due to increased difficulties in enrolling patients, because patients already have treatments for many diseases and because diseases are more complex.[58] The increased cost of clinical trials may also make certain research projects uneconomic, notably when viewed in combination with the impact of pricing and reimbursement and cost-containment strategies.

21. These regulatory factors therefore also plausibly explain the decline in the number of NCEs reaching the market, yet, as the Final Report admits, they were not considered by DG COMP:

"*the sector inquiry did not analyse which other important factors – apart from company behaviour – could have contributed to a decline in innovation as measured by less novel medicines reaching the market. Reasons given by the industry include increased scientific complexities, high attrition rates in late state development due to regulatory risk aversion and uncertainty about financial awards.*"[59]

22. This gap in the analysis means that DG COMP is unable to reach any hard conclusions as to whether the conduct of originator companies has had any impact on the number of NCEs reaching the market. This is presumably why DG COMP has decided to focus only on relatively narrow conduct which – presumably – it views as being potentially anti-competitive: "*defensive patenting strategies that mainly focus on excluding competitors without pursuing innovative efforts and/or the refusal to grant a license on unused patents will remain under scrutiny in particular in situations where innovation was effectively blocked.*"[60] Given the relative rarity of defensive patenting,[61] and the consequent unlikelihood that defensive patenting could come close to explaining the considerable decline in NCEs identified by DG COMP, it is difficult to escape the conclusion that regulation may again be the primary factor in operation here.

VI. Conclusion

23. Regulation is one of the most relevant and important elements in the pharmaceutical sector. The Final Report gives this element the consideration it deserves. It concludes that regulation goes to the heart of the question of why generic entry is delayed, significantly in certain Member States. The Final Report does not, however, explicitly reach any conclusions on the impact of regulatory factors in relation to the decline in NCEs, but the implicit conclusion in the report is the same – regulatory factors are again at the heart of the issue.

24. DG COMP is to be congratulated for having taken the time between the Preliminary and Final Reports to undertake this analysis of the impact of regulation. Hopefully, the resulting focus on regulatory improvements will enable faster generic entry and greater innovation to the benefit of all patients in Europe. It is now time to give the elephant a bit more attention – and politely ask it to leave the room. ■

56 See the Response of the Association of the British Pharmaceutical Industry ('ABPI') to the Preliminary Report in the Pharmaceutical Sector Inquiry, paragraphs 8 to 10, available at http://ec.europa.eu/competition/consultations/2009_pharma/abpi.pdf.

57 For example, in its December 2008 Communication entitled 'Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector', COM(2008) 666 final, the Commission states that the European pharmaceutical sector accounts for more than 17% of the EU's annual R&D expenditure.

58 See the Response of the European Federation of Pharmaceutical Industries and Associations ('EFPIA') to the Preliminary Report in the Pharmaceutical Sector Inquiry, paragraph 120, available at http://ec.europa.eu/competition/consultations/2009_pharma/efpia.pdf.

59 ¶ 21 of the Final Report.

60 ¶ 1574 of the Final Report.

61 ¶¶ 1117-1114 of the Final Report. While the Report gives certain examples of defensive patenting strategies, it only finds "*a few cases [where] originator companies expressed concern about the patent strategies of a competitor*" (¶ 1336).

Un point de vue français

Geneviève Wibaux

Rapporteure permanente, Autorité de la Concurrence

1. Le rapport tant attendu de la Commission européenne qui clôt l'enquête dans le secteur pharmaceutique est paru le 8 juillet 2009. La Commission a respecté le calendrier qu'elle s'était fixé et qui avait débuté le 15 janvier 2008, par la décision d'ouvrir une enquête, immédiatement suivie par des inspections au sein de plusieurs laboratoires pharmaceutiques de l'Union européenne. L'envoi de questionnaires, aussi bien aux opérateurs du marché (100 laboratoires interrogés) qu'aux Autorités de santé ou de concurrence des différents États membres, a permis de compléter l'information de la Commission. Puis, le 28 novembre 2008, la Commission a publié un rapport préliminaire, proposant à tous les acteurs intéressés (industriels, représentants des consommateurs, assurance-maladie, office européen des brevets) de faire des commentaires, jusqu'au 31 janvier 2008. L'étape suivante est arrivée avec le rapport final.

2. La Commission avait justifié la nécessité d'une enquête dans le secteur pharmaceutique par le poids des dépenses de santé en Europe (en 2007, chaque Européen a dépensé en moyenne 430 euros pour des médicaments) et par les dysfonctionnements observés : retards dans la mise sur le marché des médicaments génériques et recul apparent de l'innovation, mesurée par le nombre de nouveaux médicaments mis sur le marché.

3. Les enquêtes sectorielles, prévues à l'article 17 du Règlement 1/2003, permettent à la Commission de recueillir toutes les informations nécessaires pour l'application future des articles 81 et 82 du traité. Au cas d'espèce, l'enquête a permis de rassembler à la fois un grand nombre de données factuelles sur le fonctionnement du secteur et des données statistiques, portant sur un échantillon de 219 principes actifs (soit 50 % du chiffre d'affaires total des médicaments délivrés sur ordonnance dans l'UE en 2007). Ces données chiffrées ont été collectées pour les produits sélectionnés, dans les 27 pays de l'Union, pour la période de 2000 à 2007 et ont servi de support à une analyse économétrique.

4. Le rapport, fruit d'un énorme travail accompli, contient à la fois une description du marché et du regard de la Commission sur son fonctionnement (structure et impact de la mise sur le marché des génériques) et sur les comportements des laboratoires. Toutefois, il ne contient, à ce stade, aucune orientation concernant la qualification des pratiques examinées avec les règles communautaires en matière de concurrence. Enfin, le rapport offre une conclusion qui lance des pistes à explorer pour l'avenir.

5. Est proposée une présentation synthétique du rapport qui suit le plan adopté par la Commission européenne, avant quelques commentaires relatifs à son intérêt par rapport à la situation française.

I. L'analyse du marché et des médicaments remboursables en Europe

1. Structure du marché

6. Le rapport indique que le secteur pharmaceutique est fortement réglementé et orienté vers la recherche et développement (R&D). Il précise cependant que les dépenses de R&D des laboratoires princeps sont moins importantes que celles de marketing (17 % contre 23 % du chiffre d'affaires réalisé avec les médicaments sur ordonnance). Parmi ces 17 % consacrés à la R&D, environ 1,5 % est consacré à la recherche fondamentale pour découvrir de nouveaux médicaments et 15,5 % sont consacrés au développement, c'est-à-dire aux essais pour vérifier que ces nouveaux médicaments sont suffisamment sûrs et efficaces pour être commercialisés. Quant aux coûts de fabrication, ils ont représenté, sur la période observée, 21 % du chiffre d'affaires total des laboratoires princeps. Le rapport indique que les laboratoires sont tributaires, dans une large mesure, de l'achat des composés auprès des tiers : en 2007, 35 % environ des molécules des laboratoires princeps qui étaient en attente d'une autorisation de mise sur le marché avaient été achetés ou produites sous licence. Certains de ces tiers sont des petites ou moyennes entreprises, présentes dans le secteur de la biotechnologie par exemple. En revanche, pour les fabricants de génériques, le plus gros poste de dépense est la fabrication (51 %), suivie du marketing (13 %) et des activités de R&D, ce qui montre bien que ces entreprises ont une structure de coût différente. Le rapport relève que les laboratoires princeps sont très dépendants des ventes de quelques médicaments "vedettes" dont les brevets sont sur le point d'expirer (ou ont expiré). Parmi les médicaments de l'échantillon, près de la moitié se sont trouvés confrontés à l'arrivée des génériques sur leur marché dès la première année qui a suivi l'expiration de leur brevet (Certificat complémentaire de protection compris).

2. Impacts de la mise sur le marché des génériques

7. Selon le rapport, il faut plus de sept mois, en moyenne pondérée, pour qu'un médicament générique apparaisse sur le marché, lorsque le princeps a perdu son exclusivité. Pour les médicaments les plus vendus, ce délai est plus court – quatre mois en moyenne. Il existe de grands écarts d'un pays à l'autre. Les retards à l'entrée des génériques sur le marché ont des conséquences importantes en termes d'économies pour les systèmes de santé, car les prix de vente des génériques sont en moyenne 25 % inférieurs aux prix des princeps avant la perte de leur exclusivité. Deux ans après leur entrée, les prix des génériques étaient en moyenne 40 % inférieurs au prix du princeps. Les prix des princeps semblent aussi baisser après la mise sur le marché d'un médicament générique. La part de marché, en volume, des fabricants de génériques s'élevait à 30 % à la fin de la première année, et à 45 % au bout de deux ans. Pour l'échantillon de médicaments analysés, pendant la période 2000-2007, le rapport estime que les économies réalisées grâce à la mise sur le marché de médicaments génériques auraient pu être de 20 % supérieures à ce qu'elles ont effectivement été – soit 3 milliards d'euros –, si cette mise sur le marché avait été réalisée dès l'expiration du brevet.

II. L'analyse des comportements des laboratoires pharmaceutiques

8. S'agissant des comportements des laboratoires sur le marché, le rapport distingue entre ceux mis en œuvre par les entreprises princeps vis-à-vis des fabricants de génériques et ceux adoptés par les laboratoires princeps vis-à-vis d'autres laboratoires princeps. Il souligne au préalable la multiplication des brevets entre 2000 et 2007, et ajoute que ces brevets ont essentiellement été déposés à la fin de la période de protection.

1. La concurrence entre laboratoire princeps et fabricants de génériques

1.1. Les stratégies de dépôts des brevets

9. Le rapport commence par indiquer que le dépôt de nouveaux brevets un peu avant la fin du brevet originel est devenu un véritable outil pour les laboratoires pharmaceutiques afin d'étendre la portée et la durée de la protection fournies par les brevets. Il estime que le dépôt de nombreuses demandes de brevet pour le même médicament, formant ce que l'on appelle des grappes de brevets ("*patents clusters*") ou maquis de brevets ("*patents thickets*"), est devenu une pratique courante qui gêne le développement des génériques qui sont obligés d'aller en justice pour invalider ces brevets. Il considère que même si la majorité de ces procès sont favorables aux fabricants de génériques, ils retardent leur entrée sur le marché. Se développent aussi, selon le rapport, les demandes de brevet "*divisionnaire*". Ce type de demande, prévu par le droit des brevets, permet de scinder une demande initiale. Elle n'a pas pour effet d'élargir le contenu de la demande initiale, ni d'étendre la période de protection, mais peut prolonger le délai dont dispose l'office des brevets pour examiner la demande, ce qui a également pour effet d'accroître l'incertitude juridique pour les fabricants de génériques[62]. Enfin, le rapport expose que les laboratoires déposent des brevets pour des produits de seconde génération qui sont en réalité les mêmes produits avec une amélioration mineure. Le rapport observe que ces différentes actions sont considérées comme des moyens très efficaces pour créer des obstacles à l'entrée des génériques, notamment commercialisés par des sociétés de petite taille. Le rapport indique aussi que le procès en contrefaçon contre un fabricant de générique est utilisé comme un signal vis-à-vis des autres fabricants de génériques. L'arme du procès a de plus en plus été utilisée à partir de 2000. Le rapport dénombre 698 différends relatifs à des brevets pour toute l'Union européenne, engagés majoritairement par des laboratoires pharmaceutiques. Sur ces 698 affaires, 223 ont fait l'objet d'un règlement amiable et 326 se sont poursuivies devant les tribunaux, qui ont statué définitivement sur 149 de ces affaires, et dans 62 % des cas dans un sens favorable aux fabricants de génériques. Le rapport note à cet égard que si dans la phase précontentieuse, les laboratoires princeps invoquaient les brevets principaux, pendant l'action en justice, c'étaient les brevets secondaires qui étaient en cause.

1.2. Les oppositions et recours

10. L'enquête indique que le taux d'opposition devant l'office européen des brevets (OEB) est constamment plus élevé dans le secteur pharmaceutique que dans d'autres secteurs, et que ces oppositions, de la part des fabricants de générique, ont concerné presque exclusivement des brevets secondaires, et enfin que près de 60 % des décisions finales leur ont été favorables.

1.3. Les règlements amiables et autres arrangements entre laboratoires et fabricants de génériques

11. Le rapport dénombre 200 accords conclus entre 2000 et juin 2008[63], concernant 49 molécules dont 63 % étaient des "*best-sellers*" qui devaient perdre leur protection entre 2000 et 2007. Il note que la probabilité de conclure un accord pour un laboratoire dépend de l'évaluation de ses chances de gagner ou non un procès contre un fabricant de génériques. Il ajoute que la moitié des accords limitent la possibilité d'entrée du générique sur le marché et qu'une proportion non négligeable de ces accords, non seulement limitent cette entrée, mais prévoient des compensations à verser au fabricant de générique, soit sous la forme d'un paiement direct, soit d'une licence, d'un accord de distribution ou d'un accord accessoire ("*side-deal*"). Les paiements directs sont intervenus dans plus de 20 règlements amiables et le montant total de ces transferts a été supérieur à 200 millions d'euros[64]. Le rapport note également qu'un tiers des accords conclus entre princeps et fabricants de génériques concernaient des produits encore sous exclusivité.

62 Le 25 mars 2009, l'OEB a pris des mesures qui limitent les possibilités de dépôt volontaire d'une demande de brevet divisionnaire et les délais dans lesquels une telle demande peut être présentée.

63 En 2004 et 2005 le nombre d'accords conclus a été plus important en Europe qu'aux États-Unis.

64 Ce type d'accords est très contrôlé par les autorités antitrust aux États-Unis.

1.4. Les autres types de pratiques

12. Le rapport signale que les interventions auprès des pouvoirs publics ont été vérifiées dans un grand nombre de cas. Les laboratoires feraient du lobbying auprès des organismes délivrant les autorisations de mise sur le marché (AMM) pour savoir quand vont sortir les génériques et pour lier la délivrance de l'AMM du générique à la vérification de l'expiration des droits de propriété intellectuelle du princeps ("*patent linkage*") ou encore font de la rétention de données empêchant les génériques de copier le produit. Ils dénigreraient aussi l'efficacité ou la sécurité des génériques vis-à-vis de ces organismes. Le rapport note encore la multiplication des procès, qui peuvent même être intentés contre les autorités réglementaires, et qui, même s'ils sont perdus dans la plupart des cas par les laboratoires, ont pour effet de retarder l'entrée des génériques sur le marché. Des pratiques commerciales sont aussi utilisées notamment des actions de promotion intensives auprès des médecins ou des pharmaciens : le rapport note à cet égard que le développement de la vente directe qui peut gêner la pénétration des génériques, et enfin les accords d'exclusivité avec les fournisseurs de principe actif.

2. La concurrence entre laboratoires princeps

2.1. Les stratégies développées avec le dépôt des brevets

13. Le rapport note que le choix de la zone géographique où seront déposés les brevets est important. Le dépôt d'un brevet a d'abord pour objet de protéger le laboratoire contre les suiveurs en créant un droit objectif dont l'efficacité sera renforcée par des publications qui donneront une antériorité et empêcheront d'autres laboratoires d'invoquer la nouveauté lorsqu'ils demanderont un brevet. La stratégie de "division" des brevets est aussi utilisée pour créer des barrières à la R&D des autres laboratoires et notamment au dépôt de brevets secondaires. Le rapport recense 1 100 cas de litiges potentiels liés à des chevauchements de brevets détenus par des laboratoires princeps, ce qui pourrait bloquer l'innovation. Toutefois dans de nombreux cas, les laboratoires de princeps ont réussi à prévenir les litiges potentiels, par exemple grâce à des accords de licences. Cependant, dans 20 % des 99 cas répertoriés, la licence a été refusée par le détenteur du brevet. Le rapport dénombre 66 actions en justice (concernant 18 médicaments) engagées par les laboratoires princeps à l'encontre d'autres laboratoires princeps. Il observe que dans 64 % des cas, les procès se sont conclus par un accord amiable. Il relève que le nombre de procès achevés a été faible et que les propriétaires des brevets ont perdu dans 77 % des cas. Il signale aussi que dans la période 2000 à 2007, pour les procès relatifs aux brevets secondaires, les laboratoires s'opposant à ces brevets ont majoritairement gagné (89 % des cas).

65 Décision du 30 mars 2001, de l'OFT, disponible sur le site www.oft.gouv.uk/shared_oft/ca_public_registrer/decisions/napp.pdf.

2.2. Opposition et recours

14. Entre 2000 et 2007, sur la base de l'échantillon de médicaments, les laboratoires princeps se sont principalement opposés aux brevets secondaires d'autres laboratoires princeps. Les premiers ont très souvent obtenu gain de cause. Leur position a prévalu dans près de 70 % des décisions rendues par l'OEB (chambres de recours incluses). En outre, dans 19 autres cas sur 100, la portée des brevets a été réduite.

2.3. Accords amiables et autres accords entre laboratoires princeps

15. Le rapport recense 27 accords amiables pour résoudre des conflits pour la période étudiée et précise que 67 % de ces accords concernaient des accords de licence. Mais il relève que 1 450 autres accords ont été conclus pendant la même période, concernant majoritairement la phase de commercialisation des produits plutôt que la R&D. Pour 80 % de ces accords – dont la part de marché cumulée des entreprises contractante était supérieure à 20 % – existaient des dispositions prévoyant un type de relation d'exclusivité entre les entreprises, soit une obligation de fourniture ou d'approvisionnement exclusif, de licence exclusive ou toute autre sorte d'exclusivité et/ou une obligation de non-concurrence. La durée moyenne de ces accords comportant une obligation d'exclusivité était de huit ans.

3. Quelles pistes pour l'avenir ?

16. Avant de formuler plusieurs recommandations qui visent plutôt le cadre réglementaire, la Commission indique qu'elle fera pleinement usage des pouvoirs qui lui sont conférés par les articles 81, 82 et 86 du Traité CE mais aussi par les règles du contrôle des concentrations et des aides d'État.

17. La Commission indique qu'elle n'hésitera pas à sanctionner les pratiques de laboratoires qui auront pu avoir pour objet ou pour effet de porter atteinte au libre jeu de la concurrence. Elle signale qu'entre 2000 et 2007, les Autorités de concurrence des États membres et la Commission ont déjà pris des mesures et/ou sanctionné des laboratoires. Elle cite le cas *Napp*[65], le cas *Schering Plough*[66] ; le cas *GSK*[67] et l'affaire *Astra Zeneca*[68] dans laquelle ont été sanctionnés deux abus d'un laboratoire en position dominante, ayant retardé l'entrée des génériques sur le marché.

18. Pour réduire le risque que des règlements amiables ne soient conclus au détriment des consommateurs, la Commission indique envisager, dans le contexte juridique en vigueur, un contrôle plus approfondi de ces arrangements, qui sont susceptibles de léser les consommateurs européens.

66 Décision 07-MC-06, disponible sur le site www.autoritedelaconcurrence.fr.

67 Décision du 8 février 2006, disponible sur le site www.agcm.it/.

68 Décision du 15 juin 2005, affaire COMP/A.37.507/F3.

19. Quant aux recommandations, elles concernent en premier lieu le brevet européen : la Commission approuve les efforts de l’office européen des brevets pour raccourcir la durée des procédures d’opposition et d’appel. Elle appelle de ses vœux la création d’un brevet communautaire unique et la mise en place, en Europe d’un système de Règlement des litiges unifié et spécialisé dans les brevets.

En deuxième lieu, la Commission demande que les procédures de délivrance d’autorisation de mise sur le marché et de fixation des prix par les Autorités nationales soient plus transparentes et plus rapides. La Commission estime que les progrès engendrés par la création de l’agence européenne du médicament (EMEA) qui permet la délivrance d’une autorisation unique de mise sur le marché d’un médicament ont été un grand pas dans l’unification des procédures, mais que ces progrès peuvent être réduits à néant si les États membres ne sont pas vigilants et n’appliquent pas strictement les règles de reconnaissance mutuelle prévues dans la directive 2001/83/CE. Elle rappelle que le “*patent linkage*”, qui consiste à lier la délivrance d’une AMM par une Autorité de santé d’un État membre à la vérification que les droits de propriété intellectuelle sont expirés, est interdit. En matière de fixation de prix et de taux de remboursement, la Commission exprime les mêmes préoccupations et précise qu’elle va vérifier que chaque Etat Membre respecte les règles fixées par la directive 89/105/CE, à savoir un délai maximum de 90 jours laissé à l’autorité réglementaire pour déterminer le prix et le taux de remboursement, une fois accordée l’autorisation de mise sur le marché.

III. Conclusion

20. Le rapport final terminant l’enquête réalisée par la Commission a le grand mérite donner une vision complète du secteur. Mais son principal intérêt est d’avoir été centré sur la question des relations entre le droit des brevets et le droit de la concurrence, qui est le cœur de la problématique actuelle du secteur pharmaceutique puisque l’innovation est nécessaire, et doit être encouragée, sans que le prix à payer par la collectivité par le biais de l’exclusivité temporaire n’excède le gain qu’elle retire de l’innovation. Cette question est particulièrement cruciale dans un pays comme la France, qui continue à occuper la première place des pays européens en termes de dépense moyenne par habitant en médicaments remboursables, et où la lecture des statistiques de l’assurance-maladie montre le poids des médicaments “nouveaux” dans la croissance des dépenses en 2007 : 85 % de la hausse enregistrée en 2007 provenaient de produits mis sur le marché depuis moins de 3 ans. Or, selon l’assurance-maladie, les médicaments “nouveaux” ne sont pas toujours des médicaments innovants : dans la mesure où 45 % des dépenses supplémentaires relatives aux médicaments nouveaux concernaient des molécules qui ne présentaient pas ou peu d’amélioration du service médical rendu par rapport à l’arsenal thérapeutique préexistant. On peut noter, par ailleurs, que même si la France a atteint un niveau de pénétration très élevé des génériques de 81,7 %, comparable à ses voisins européens, il subsiste encore une proportion importante de prescriptions réalisées en dehors du répertoire des génériques[69] alors que la croissance des médicaments génériques contribue à financer la croissance des médicaments réellement innovants. ■

69 À titre d’exemple, les Espagnols consomment près de 85 % de médicaments antiulcéreux (IPP) génériqués (83 % pour les Allemands et 51 % pour les Français).

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