
COMMENTS OF MSD REGIONAL BUSINESS SUPPORT CENTER GMBH

**On The European Commission's Preliminary Report
In Case COMP/D2/39.514 *Pharmaceutical Sector Inquiry***

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TABLE OF CONTENT

I.	INTRODUCTION	1
II.	THE FINAL REPORT WOULD BENEFIT FROM A NUMBER OF METHODOLOGICAL IMPROVEMENTS	4
A.	The Final Report Should Acknowledge Case Law That Substantially Limits The Application Of EC Competition Law In The Areas Under Review.....	4
1.	Community case law establishes a presumption for the validity of patents	4
2.	Community case law confirms that a patent’s exclusion of copy products does not justify the concerns expressed in the Preliminary Report	5
3.	Other relevant case law.....	6
B.	The Final Report Should Not Rely On Criteria That Are Insufficient To Identify Potentially Problematic Conduct	6
1.	The Preliminary Report’s references to “delays” do not establish problematic conduct	6
2.	The Preliminary Report’s references to “legal uncertainty” do not establish problematic conduct.....	8
3.	In sum, the Final Report should exercise caution in its discussion of alleged delays and legal uncertainty	8
C.	The Final Report Should Recognize Limitations In The Referenced Evidence.....	8
1.	Arguments of generic companies are no substitute for objective evidence.....	9
2.	The referenced statistical data have limited relevance for EC competition law analysis.....	9
3.	Internal documents should be assessed by reference to their relevant context	10
D.	The Final Report Should Consider The Full Economic And Legal Context Of The Pharmaceutical Sector	10
1.	The Final Report should consider the effects of regulatory proceedings	11
2.	The Final Report should consider the impact of national monopsonists on competitive dynamics	12
3.	The Final Report should consider the implications for innovation of questioning patent-related conduct	13
4.	The Final Report should consider all dimensions of competition, including <i>intra</i> generic competition.....	13
III.	THE DISCUSSION OF INDIVIDUAL PRACTICES SHOULD RECOGNIZE LEGITIMATE CONDUCT	15
A.	Patent Filings, Including Multiple Filings For The Same Product, Are A Legitimate And Inherent Part Of The Patent System	15

1.	Patent filings are subject to independent review and decision by the competent public authorities.....	15
2.	Annulment rates do not provide a basis for concerns.....	16
3.	The Preliminary Report’s references to “ <i>intended effects</i> ” do not provide a basis for concerns	16
4.	The mere number of patents does not provide a basis for concerns.....	17
5.	Divisional patent filings are a legitimate measure specifically provided for by the patent system	17
B.	Patent Disputes And Litigation Represent The Means To Exercise The Fundamental Right To Judicial Protection	18
1.	Case law recognizes litigation as a fundamental right	18
2.	Patent litigation constitutes an exercise of the specific subject matter of intellectual property rights.....	18
3.	Patent actions of right holders are not offensive, but reactive in nature.....	19
4.	The referenced statistical data do not provide grounds for concerns	19
5.	If the discussion is meant to identify possible improvements to the patent system, the Final Report should state this more clearly without questioning company conduct	20
C.	Settlement Agreements Are A Legitimate Means To Resolve Disputes.....	21
D.	Regulatory Interventions and Litigation Are An Important Element Of The Regulatory Process	21
1.	Regulatory interventions and litigation represent the exercise of due process rights	22
2.	The matters raised in regulatory interventions and litigation do not provide grounds for competition concerns.	22
3.	Subjective “expectations” about duration of proceedings do not support claims about delays.....	23
E.	The Launch Of Follow-on Products Is An Inherent Part Of Competition	23
1.	Follow-on products do not prevent generic entry.....	23
2.	Questioning the legitimacy of follow-on products would undermine competition	24
3.	The circumstances described in the Preliminary Report do not provide grounds for concern	24
F.	The Combination Of Lawful Practices Does Not Render These Practices Questionable	25
IV.	IN CONCLUSION, THE PRELIMINARY REPORT DOES NOT IDENTIFY GROUNDS FOR EC COMPETITION LAW CONCERNS.....	26

I. INTRODUCTION

1. This submission provides comments of MSD Regional Business Support Center GmbH (“MSD”) on the preliminary report of the European Commission (the “Commission”) in Case COMP/D2/39.514 *Pharmaceutical Sector Inquiry* (the “Preliminary Report”). MSD is grateful for the opportunity to comment on the Preliminary Report. The Preliminary Report raises sensitive issues regarding the relationship between intellectual property rights and EC competition law that merit broader discussion and reflection.
2. MSD is part of a research-based group of companies whose ultimate parent is Merck Co., & Inc., Whitehouse Station, NJ, USA (“Merck”). Merck’s mission is to discover, develop, and deliver innovative medicines and vaccines for unmet medical needs. In the years 2006 and 2007 alone, Merck has obtained regulatory approval for seven new medical products. These include Gardasil®, a vaccine for the prevention of cervical cancer, the first cancer vaccine in the history of medical research. Gardasil® was awarded the Prix Galien in 2008, which is considered the pharmaceutical industry’s equivalent of the Nobel Prize. Merck also won the Prix Galien in 2007 with its diabetes medicine Januvia®, which is based on a novel mechanism that enables control of insulin levels in a more targeted and reliable manner. Merck has also been a pioneer in the research of medicines for the treatment of HIV. Merck scientists were the first to establish the role of HIV-1 protease, a key enzyme involved in the replication of HIV, and were among the first to discover and develop medicines for the treatment of HIV and AIDS, including the medicines Crixivan® and Stocrin®. In 2007, Merck received regulatory approval for a novel HIV medicine, Isentress®, which acts by suppressing integrase, an enzyme that is involved in the insertion of the HIV genome in the host DNA. The revolutionary mechanism of Isentress® increases the effectiveness of existing combination therapies and helps to address growing HIV resistance to existing therapies.
3. Merck also strongly believes in affordable access to innovative medicines across the world, including in developing countries. An example of Merck’s initiatives in this area is the African comprehensive HIV/AIDS partnership, which (in collaboration with the Bill and Melinda Gates Foundation) supports Botswana’s fight against HIV and AIDS. Another example is Merck’s donation program for Mectizan®, its medicine for the treatment of river blindness. The program is the largest disease specific donation program in history. It has reached more than 80 million people in Africa, Latin America, and the Middle East, with Merck donating more than 2.1 billion tablets.
4. Just as other innovators, Merck depends for its activities on a strong and effective patent system. A strong patent system is especially important for pharmaceutical companies, given the large investments, high risks, and long lead-times involved in pharmaceutical research and development.¹ Among other things, an effective patent system must allow innovators to trust the rules that govern the grant and enforcement of patents. Companies must have the legal certainty that they can seek and enforce patents under

¹ According to the Preliminary Report, research-based companies invest 17% of their turnover in R&D (Preliminary Report, ¶ 55, “*attrition rate [...] is very high*” (Preliminary Report, ¶ 138); and the development of a product from discovery to market launch can take numerous years (Preliminary Report, Figure 7).

these rules, without being potentially exposed *ex post* to regulatory intervention. In the absence of such legal certainty, the patent system is weakened and incentives to innovate are jeopardized.

5. The Preliminary Report focuses on a number of practices of research-based companies in the area of patents and judicial remedies. These practices include patent applications, patent litigation, patent settlements, regulatory interventions, and the launch of follow-on products. The Preliminary Report describes these practices as a “*tool-box*” that research-based companies may use to delay generic entry (Preliminary Report, ¶¶ 365-925). The Report also suggests that some of these practices may serve to delay or impede entry of innovative medicines (Preliminary Report, ¶¶ 926-1081).
6. The practices discussed in the Preliminary Report represent the exercise of the essential function and specific subject matter of national patent systems and judicial remedies. As far as MSD is aware, none of the practices discussed in the Preliminary Report has been the subject of a finding of infringement under EC competition law.² Nor are these practices identified as potentially problematic in the Commission’s recently published Guidance Paper on Article 82 EC.³ This distinguishes the Pharmaceutical Sector Inquiry from previous sector inquiries where the focus typically was on conduct that had been the object of past case law and guidance notices.⁴
7. The absence of infringement findings in the area covered by the Preliminary Report suggests that particular caution should be exercised in formulating conclusions that could be understood as questioning the freedom of research-based companies to seek and enforce patent protection for their products. To the extent that elements of the patent system are considered to be subject to improvement, such improvements should be made through the legislative process, rather than competition proceedings.
8. Although the Preliminary Report generally recognizes that the practices at issue represent a legitimate exercise of patent rights, it includes at the same time qualifying statements that could be understood as suggesting that these practices may raise concerns in certain circumstances. The Preliminary Report, however, does not explain what these circumstances are, nor does it identify legal principles that could support such concerns. As a result, the positions expressed in the Preliminary Report risk contradicting the principles of the patent system and existing case law on the relationship between intellectual property rights and EC competition law.

² The Commission’s decision in Case COMP/37.507 *AstraZeneca*, which is mentioned in the Preliminary Report, concerns narrowly defined practices relating to the withdrawal of marketing authorizations and the submission of misleading information to patent offices. In contrast, the Preliminary Report (as noted) discusses much more general practices, such as patenting, litigation, settlements, or launch of follow-on products.

³ Guidance on the Commission’s Enforcement Priorities in Applying Article 82 EC Treaty to Abusive Exclusionary Conduct by Dominant Undertakings, December 3, 2008.

⁴ Such conduct included, for example, collusion among competitors (Banking Inquiry, Roaming Inquiry), long-term contracts (Insurance Inquiry, Energy Inquiry), tying (Banking Inquiry), abusive pricing (Local Loop Inquiry, Leased Line Inquiry, Roaming Inquiry) and refusal of access to essential facilities (Local Loop Inquiry, Leased Line Inquiry).

9. The Preliminary Report's repeated statements that it does not seek to identify individual infringements (Preliminary Report, ¶¶ 366, 574, 663, 931 and 1047) are not sufficient to resolve this issue, given the implied criticisms expressed in the Preliminary Report. MSD respectfully submits that the Commission's final report (the "Final Report") could help to avoid unwarranted conflicts with the patent system and existing case law by strengthening the clarity and rigor of the analysis that is currently presented in the Preliminary Report.
10. In the following sections, MSD describes a number of ways in which the Preliminary Report's analysis could be improved. Section II identifies improvements to the Preliminary Report's general methodological approach; Section III identifies improvements to the Preliminary Report's discussion of individual practices; and Section IV provides a brief conclusion.

II. THE FINAL REPORT WOULD BENEFIT FROM A NUMBER OF METHODOLOGICAL IMPROVEMENTS

A. The Final Report Should Acknowledge Case Law That Substantially Limits The Application Of EC Competition Law In The Areas Under Review

11. The relationship between intellectual property and EC competition law is the subject of a considerable body of existing case law that establishes high hurdles for EC competition law intervention in this area. Although that case law is directly relevant for the matters covered by the Preliminary Report, the Preliminary Report does not mention it.
12. This may be because the Preliminary Report declares that it only seeks to establish “*a factual basis for deciding whether further action is needed*”.⁵ Such an objective, however, does not justify silence on relevant case law. To the contrary, a factual analysis cannot be separated from the legal principles that govern that analysis. The manner in which facts are reviewed and presented must be guided by the legal principles that underpin that analysis. Without this, a factual analysis is unlikely to provide a reliable basis for meaningful conclusions.
13. To improve the rigor and transparency of the Commission’s analysis the Final Report should acknowledge the implications following from Community case law that are relevant to the matters raised in the Report and that substantially limit the application of EC competition law in the areas under review. In particular, the following considerations should be taken into account:
 1. **Community case law establishes a presumption for the validity of patents**
14. The case law of the Community Courts establishes that intellectual property rights (including patent rights) must be presumed to be innovative for the purpose of EC competition law assessment. In *Microsoft*, the Court of First Instance held that “*it is inherent in the fact that the undertaking concerned holds an intellectual property right that the subject-matter of that right is innovative or original. There can be no patent without an invention and no copyright without an original work.*”⁶ Similarly, in *Windsurfing*, the Court of Justice held that “*the scope of the German patent may be determined only on the basis of the wording of the patent claim accepted by the German patent office and the interpretative rulings hitherto given by the competent German courts and authorities*”.⁷
15. It follows that it is not for competition law to second-guess the validity or quality of patents. Nor should competition authorities question the conclusions of the authorities that are competent to decide on the grant of patents. Rather, the judgments in *Microsoft* and *Windsurfing* establish that EC competition law must respect the decisions rendered under the patent system. This also implies that right holders must be entitled to trust those decisions and rely on the validity of their granted patents. While it is inherent in

⁵ Preliminary Report, p.5.

⁶ Case T-201/04 *Microsoft* [2007] ECR II-3601, ¶ 695.

⁷ Case 193/83 *Windsurfing* [1986] ECR 611, ¶ 30.

the patent system that some patents may ultimately be found invalid, this cannot prevent right holders from relying on and enforcing granted patents, as long as the patents in question have not been revoked.

2. Community case law confirms that a patent's exclusion of copy products does not justify the concerns expressed in the Preliminary Report

16. Another key principle established by the Community Courts is that the application of EC competition law in the area of intellectual property can be envisaged only in narrow and limited situations. The Community Courts have expressly emphasized that “*it is only in exceptional circumstances that the exercise of the exclusive right by the owner of the intellectual property right may give rise*” to an abuse.⁸ More specifically, as regards obligations to grant access to intellectual property rights the Community Courts have made clear that such an obligation can only be envisaged if a number of strict conditions are cumulatively met.
17. One of these conditions is that access to the intellectual property in question must be indispensable for the emergence of a new product or for technological development more generally.⁹ As Advocate General Tizzano explained in *IMS*, the “new product” requirement arises from the need to strike a balance “*between the interest in protection of the intellectual property right and the economic freedom of its owner, on the one hand, and the interest in protection of free competition, on the other*”.¹⁰ The case law of the Community Courts thus specifically recognizes that the mere exclusion of a copy product, such as a generic medicine, by intellectual property rights does not represent a basis for EC competition law concerns. For the same reason, the mere possibility that a copy product may be offered at a lower price than the original does not justify intervention. Rather, intervention based on price competition considerations would conflict with the balance that national legislators have drawn between the exclusivity of intellectual property rights and price competition by copy products.
18. This has important implications for the areas under review by the Preliminary Report. A suggestion that research-based pharmaceutical companies should not enforce patents or should not file patents to protect their products from generics is equivalent to suggesting that they must allow generic companies to copy their products. Yet, generic products by definition do not constitute new products within the meaning of the case law, nor do they contribute to technological development within the meaning of Article 82(b) EC since they are mere copies.
19. Consequently, there is no duty under EC competition law for research-based pharmaceutical companies to abstain from patent filings or patent litigation merely because this may “delay” generic products. To hold differently would directly

⁸ Case T-201/04 *Microsoft* [2007] ECR II-3601, ¶ 331; Case C-418/01 *IMS Health* [2004] ECR I-05039, ¶ 35; Joined Cases C-241/91 and C-242/91 *Magill* [1995] ECR I-00743, ¶ 50.

⁹ Joined Cases C-241/91 and C-242/91 *Magill* [1995] ECR I-00743, ¶ 54; C-418/01 *IMS Health* [2004] ECR I-05039, ¶¶ 48-49; Case T-201/04 *Microsoft* [2007] ECR II-3601, ¶¶ 330, 332, 334, and 643-665. See too the Commission’s Guidance Paper on Article 82 EC, ¶ 86.

¹⁰ Case C-418/01 *IMS Health* [2004] ECR I-05039, Opinion of Advocate General Tizzano, ¶ 62.

contradict established case law on the refusal to license intellectual property rights and would disrupt the intellectual property balance drawn by national legislators.

3. Other relevant case law

20. The Final Report should also acknowledge other case law that is relevant for the matters discussed in the Report. This includes case law that specifically recognizes the legitimacy of initiating litigation (*ITT Promedia*),¹¹ making representations to national authorities (*Albany* and *Arduino*)¹² and raising safety concerns (*Hilti*),¹³ which will be discussed in more detail in Section III.

B. The Final Report Should Not Rely On Criteria That Are Insufficient To Identify Potentially Problematic Conduct

21. Although the Preliminary Report does not identify a legal framework for its review, it seems to rely on two main criteria to describe potentially problematic conduct:
- delays in generic entry (Preliminary Report, ¶¶ 372, 388, 398, 410, 417, 423, 707, 832, 870, 872, 891, 899, 903, 1116, 1160)¹⁴ and
 - the creation of legal uncertainty (Preliminary Report, ¶¶ 232, 406, 412, 432, 505, 518, 553, 790, 897, 925, 1089, 1090, 1097 and 1113).
22. The Preliminary Report repeatedly contrasts conduct that is said to delay entry or create legal uncertainty with conduct that is said to be generally legitimate. This suggests that the Preliminary Report is based on the implicit premise that delay or legal uncertainty denotes potentially questionable conduct. A closer analysis, however, shows that neither of these two criteria is sufficient to identify problematic conduct for the reasons discussed in the following sections.

1. The Preliminary Report’s references to “delays” do not establish problematic conduct

23. The Preliminary Report’s references to delays in generic entry are not suited to identify potentially problematic conduct for three key reasons:
24. **Reliance on inherent characteristics of the patent system.** The very purpose of a patent is to provide a period of exclusivity that protects the covered invention. It is therefore inherent in the nature of a patent that it will “delay” copy products from entering the market in the sense that entry will be postponed compared to a situation where no patent exists. For this reason, the Preliminary Report’s key thesis that “*originator companies might also have incentives to maintain and use patents for their*

¹¹ Case T-111/96 *ITT Promedia* [1998] ECR II-2937.

¹² Case C-67/96 *Albany* [1999] ECR I-5751 and Case C-35/99 *Manuele Arduino*, [2002] ECR I-1529.

¹³ Case T-30/89 *Hilti* [1991] ECR II-01439.

¹⁴ See too the headline of the Commission’s press release announcing the Preliminary Report (“*preliminary report on pharmaceutical sector inquiry highlights cost of pharma companies’ delaying tactics*”), IP/08/1829; November, 28, 2008.

effect of blocking or delaying the development generic product rather than for protecting an own invention” is a *non sequitur* (Preliminary Report, ¶ 371). “Blocking” generics and “protecting own invention” are not opposing principles, but two sides of the same coin. The exclusivity of the patent that blocks generics is the means by which an invention is protected. Mere observations that patent-related conduct may block or delay generic entry therefore cannot serve to question the legitimacy of such conduct. Rather, such observations merely reflect the intended objectives and essential function of the patent system itself.

25. **No benchmark.** To the extent that the Preliminary Report implies that generic entry is delayed beyond what can be expected from a proper exercise of patent rights, this is not clearly articulated or substantiated. Crucially, the Preliminary Report does not identify a benchmark for establishing improper delays. The Preliminary Report appears to follow two different approaches in discussing delays, neither of which can offer a reliable basis to identify problematic conduct:
- In its general review of generic entry in Section B, the Preliminary Report calculates the average time between the date of patent expiration and the launch of generic products (Preliminary Report, ¶¶ 164-168), which suggests that a “delay” is considered to arise if entry is postponed beyond the date of patent expiration. However, since a patent by definition cannot prevent entry beyond the date of its validity, it is difficult to understand how patent-related conduct could be said to contribute to such delays.
 - In other instances, the Preliminary Report’s discussion of annulment statistics seems to imply that patent conduct may result in unjustified delays where the relevant patents are subsequently found to be invalid. Such a suggestion, however, amounts to *ex post* reasoning with the hindsight of concluded patent litigation. The circumstance that a patent is ultimately annulled does not imply that improper conduct took place *ex ante*. The grant of patents is subject to complex factual and legal conditions. Different people may legitimately have different views on whether these conditions are met in a particular case. Disputes on such issues must be resolved through the legal remedies that the patent system offers for this purpose. That a dispute may ultimately be decided in favor of the challenger does not imply bad faith or improper conduct on the part of the right holder. To the contrary, as seen above (¶¶ 14-15), right holders are entitled to trust in the validity of their patents, as long as they are not revoked.
26. **No evidence of causality.** The Preliminary Report does not establish causality between the “delays” discussed in Section B of the Report and the conduct reviewed in Section C. The Preliminary Report does not show that entry would have been quicker or would have evolved differently in the absence of the practices discussed in Section C. Indeed, as noted, it is hard to see how these practices could be said to have contributed to the “delays” described in Section B at all, given that Section B calculates delays from the date of patent expiration. In these circumstances, the considerations supporting the Preliminary Report’s suggestion that it “*highlights some of the possible causes*” for “*the decline of new chemical entities*” and “*delays of generic market entry*” (Preliminary Report, p.5 and 401) remain unclear.

2. The Preliminary Report’s references to “legal uncertainty” do not establish problematic conduct

27. The Preliminary Report’s references to legal uncertainty present the same issues as the references to alleged delays. Patents inevitably entail an element of uncertainty. Neither generics nor right holders can be certain that a patent will ultimately be upheld until a final judgment is rendered. There is no benchmark to define what would constitute undue legal uncertainty and there is no support to establish a causal link between alleged uncertainty and company conduct. Indeed, if anything, the references to legal uncertainty in the Preliminary Report are even less well defined than those concerning alleged delays. Complaining that originators increase legal uncertainty for generics by relying on patents would imply that generics act improperly by challenging patents since this creates legal uncertainty for originators. This merely confirms that “legal uncertainty” is not a proper criterion for assessing the legality of company conduct.

3. In sum, the Final Report should exercise caution in its discussion of alleged delays and legal uncertainty

28. For the reasons set out above, the Final Report should exercise caution in referring to alleged delays and legal uncertainty. In particular:
- The Final Report should not rely on general characteristics of the patent system to question individual company conduct that merely reflects the characteristics of that system.
 - The Final Report should not suggest the existence of undue delays or legal uncertainty in the absence of an objective and meaningful benchmark.
 - The Final Report should not attribute alleged delays and uncertainty to company conduct in the absence of evidence of any causal link.

C. The Final Report Should Recognize Limitations In The Referenced Evidence

29. According to consistent case law, evidence on which the Commission relies must be “*factually accurate, reliable and consistent*”, must contain “*all the information which must be taken into account in order to assess a complex situation*” and must be “*capable of substantiating the conclusions drawn from it*”.¹⁵
30. The Preliminary Report relies essentially on three types of evidentiary sources (1) statements from generic companies; (2) statistical data; and (3) isolated quotes from internal company documents. As discussed in the following sections, each of these sources has important limitations that the Final Report should recognize.

¹⁵ Case C-12/03 *Tetra Laval* [2005] ECR I-978, ¶ 39; Case C-525/04 *Lenzing* [2007] ECR I-9947, ¶ 57; Joined Cases T-44/02 et al. *Dresdner Bank* [2006] ECR II-3567, ¶ 67; Case C-413/06 *Bertelsman and Sony*, judgment of July 10, 2008, not yet published, ¶ 173.

1. Arguments of generic companies are no substitute for objective evidence

31. The Preliminary Report relies for a large part of its review on statements of generic companies. The Preliminary Report includes 107 references to such statements (including both direct quotes and paraphrased statements of generics). These statements are reproduced without verification or critical distance. Generic manufacturers are self-evidently interested parties. References to statements from generic manufacturers therefore require caution. The Final Report should make clear that such statements cannot substitute for objective evidence that the practices under review improperly restrict competition and harm consumers.

2. The referenced statistical data have limited relevance for EC competition law analysis

32. The Preliminary Report references a variety of statistical data. While these data may have some general interest, their legal significance for an EC competition law analysis is limited. The following considerations are relevant in this respect:

- **Risk of distortions in the data.** Most of the data referenced in the Preliminary Report have been compiled from responses to Commission information requests. These requests often relied on complex and ambiguous terminology, creating the potential for inconsistencies in the collected data. Moreover, some of the parameters used in the questions have likely increased the potential for inconsistencies. For example, the Preliminary Report's reliance on court reference numbers (Preliminary Report, Fn.247), means that litigation involving multiple parties or patents may be counted as a single case or multiple cases depending on how reference numbers were allocated in a particular matter. Given that sample sizes are relatively small, it cannot be excluded that such phenomena have led to distortions in the data.
- **Risk of distortions in the presentation.** The manner in which data are calculated and presented should also be approached with caution. At various points, the Preliminary Report presents statistical data in a manner that may give an inaccurate impression of the underlying facts. For example, the Preliminary Reports quotes success rates of generics in annulling patents for the proposition that the EPO grants patents "*too easily*" (Preliminary Report, ¶ 393). But the Preliminary Report calculates annulment rates as a percentage of *litigated* patents, rather than as a percentage of *granted* patents. As a result, the data give the impression that a significant proportion of patents are annulled, even though in reality this is only the case for a small fraction of all granted patents.¹⁶ More generally, the Preliminary Report does not seem to give sufficient consideration to the broader context of the referenced figures. For example, data are often aggregated across 27 different national patent systems and an eight-year period, which inflates referenced figures. Taking into account the aggregated nature of the data, the data suggest that patent related activities are rather moderate in the pharmaceutical sector.

¹⁶ The data presented in the Preliminary Report indicate that the 219 INNs covered by the Commission's sector inquiry were the subject of 26,630 granted patents, of which less than 100 patents were annulled or revoked, amounting to a combined annulment and revocation rate of substantially less than 1%.

- **Unclear relevance.** There is little or no explanation in the Preliminary Report on how referenced figures should be judged or assessed. In particular, the Preliminary Report does not identify an objective benchmark for assessing referenced data, nor does it compare the data with other research-intensive industries. Further, the relevance of the referenced data within the context of any established principles of competition law is unclear. Accordingly, it is difficult to see what conclusions, if any, can be drawn from these figures.

3. Internal documents should be assessed by reference to their relevant context

33. At some instances, the Preliminary Report also relies on quotes from internal documents of individual employees of originator companies. These quotes, however, are cited without a description of their full context or an explanation of their broader significance. It is, moreover, not clear how the referenced quotes can serve as a basis for general conclusions for the purpose of the Preliminary Report, given that they represent isolated statements of a few individuals.
34. More generally, it is settled case law that an abuse under Article 82 EC “*is an objective concept relating to the behavior of an undertaking in a dominant position*”.¹⁷ Mere subjective statements therefore cannot provide a basis for EC competition law concerns in the absence of conduct that is objectively distinguishable from legitimate behavior. This applies *a fortiori* in the area of patent-related conduct, which is governed by a specific body of law that regulates such conduct independently of subjective motives or views. In these circumstances, the application of EC competition law requires conduct that objectively goes beyond the exercise of the essential function and specific subject matter of the patent system.

D. The Final Report Should Consider The Full Economic And Legal Context Of The Pharmaceutical Sector

35. It is well established that the review of company conduct under EC competition law must take account of the full legal and economic context of that conduct.¹⁸ The pharmaceutical industry is probably one of the industries with the most complex legal and economic characteristics. In particular:
 - The pharmaceutical industry is subject to a high degree of regulation that governs virtually every aspect of market conduct, including market access, pricing and reimbursement, distribution and production, and marketing.

¹⁷ Case 85/76 *Hoffmann La Roche* [1979] ECR 461, ¶ 91; Case T-31/80 *L’Oréal* [1980] ECR 3775, ¶ 27; Case T-51/89 *Tetra Pak* [1990] ECR II-309, ¶ 64; Case T-111/96 *ITT Promedia* [1998] ECR II-2937, ¶ 138; Case T-65/98 *Van den Bergh* [2003] ECR II-4653, ¶ 157; Case T-201/04 *Microsoft* [2007] ECR II-3601, ¶ 398.

¹⁸ Case C-234/89 *Delimitis* [1991] ECR I-935, ¶ 31; Case C-399/93 *Oude Luttikhuis* [1995] ECR I-4515, ¶ 10; Case C-214/99 *Neste* [2000] ECR I-11121, ¶ 25; Joined Cases T-374/94 et al. *European Night Services* [1998] ECR II-3141 ¶ 134; Case T-77/94 *VGB* [1997] ECR II-758, ¶ 140.

- Member States not only regulate the pharmaceutical industry, but actively participate in the market as *de facto* monopsonist buyers through their health insurance systems.
 - Competition involves companies with fundamentally different business models and takes place across multiple dimensions (innovators vs. innovators, innovators vs. generics, and generics vs. generics).
 - Research-based pharmaceutical companies are dependent on strong and effective patent protection. Without such protection the viability of future innovation is critically undermined.
36. All these aspects are relevant for the matters under review by the Preliminary Report, but are not fully addressed in the Report. The following sections discuss relevant considerations in more detail.

1. The Final Report should consider the effects of regulatory proceedings

37. The Preliminary Report declares that “*the Commission services are fully aware that the pharmaceutical sector is highly regulated. From research to marketing, the existing regulations have a major impact on competitive conditions*”, but goes on to note that “*this did not, however, change the focus of the inquiry, namely, on the extent to which company practices affect market entry*” (Preliminary Report, ¶ 7). As a result, the Preliminary Report includes only a cursory discussion of the regulatory system, which is limited essentially to summarizing views expressed by industry participants. Crucially, the Preliminary Report does not include its own assessment of the regulatory impact on the entry of pharmaceutical products. For example, even though the Commission’s questionnaires requested data on the timing of pricing and reimbursement approvals,¹⁹ the Preliminary Report does not discuss these data.
38. This is inconsistent with the Community Courts’ case law requiring that full account be taken of the economic and legal context of the conduct under review. Regulatory provisions that have “*a major impact on competitive conditions*” cannot be ignored in an assessment of company conduct, particularly in the case of a sector inquiry, whose very purpose is to provide a better understanding of the broader competitive situation in an industry.
39. The impact of regulatory systems on market entry is directly relevant to the Preliminary Report’s subject matter. It is hard to see how a review of “*the extent to which company practices affect market entry*” could take place without consideration for the impact that regulatory proceedings have on such entry. A review of data on the duration of regulatory proceedings illustrates this point. For example, Directive 89/105/EEC allows a six-month period for pricing and reimbursement proceedings. Data on such proceedings suggest that national authorities often significantly exceed these periods.²⁰

¹⁹ Question 25 of the Commission’s information request of March 28, 2009.

²⁰ For example, EFPIA WAIT data indicate that the average time between marketing authorization and reimbursement approval amounts to more than 10 months in several Member States. While these data relate to approval proceedings for innovative medicines, they suggest systemic failures that are likely to affect generics as well.

Moreover, several Member States only update their reimbursement lists at infrequent intervals (e.g., every three or six months). As a result, even if pricing and reimbursement approvals are granted within the deadlines foreseen by Directive 89/105/EEC (by no means a certainty), it may take several additional months until the product becomes available on the market. Comparing the time required to obtain pricing and reimbursement approval alone with the average time to entry of 6.6 months identified by the Preliminary Report (Preliminary Report, ¶ 164) therefore strongly suggests that regulatory proceedings, rather than any company conduct, are largely responsible for observed entry times.

40. This is further confirmed by the Preliminary Report's country-by-country data on the average time to entry post patent expiration. Figure 14 of the Preliminary Report shows that average entry times vary widely across Member States, with Spain and Greece – two countries that historically have had well-known weaknesses in patent enforcement mechanisms – accounting for the longest time to entry. Such a pattern is inconsistent with a suggestion that patent-related conduct is responsible for delays, but rather suggests that the observed entry times are due to differences in national regulatory systems and local market conditions. As the Commission has found in a different context, “*different systems lead to disparities in pricing, time-to-market delays and access inequalities*”.²¹

2. The Final Report should consider the impact of national monopsonists on competitive dynamics

41. Member States not only subject the pharmaceutical industry to extensive regulation, they also actively participate in the market as *de facto* monopsonists through their national health insurance systems. The effect of national health insurance systems on demand and supply of pharmaceuticals has two main implications that the Final Report should take into account.
42. First, the presence of state bodies that not only hold extensive regulatory powers, but also control to a large extent demand for pharmaceuticals is relevant for assessing competitive dynamics and market power. In particular, it raises the question under what circumstances pharmaceutical companies could be qualified as dominant under Article 82 EC. Given the extensive control of health insurance bodies over demand and supply of pharmaceuticals, it seems difficult to see how pharmaceutical companies could be said to have “*the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of the consumers*” as required by case law.²² Since most of the practices discussed in the Preliminary Report constitute unilateral conduct, which from the outset cannot raise EC competition law concerns in the absence of dominance, the impact of health insurance bodies on competitive dynamics is directly relevant for the matters under review.
43. Second, given that national health insurance bodies largely control pharmaceutical demand, it seems reasonable to assume that the design of national reimbursement and health insurance systems may have a considerable impact on the timing and extent of

²¹ Commission Communication, “Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector”, December 10, 2008, p.5.

²² Case 85/76 *Hoffmann-La Roche* [1979] ECR 461, ¶ 38.

both generic and innovator entry. As a result, a comprehensive assessment of the matters under review needs to consider the effects of national health insurance systems on demand and supply of pharmaceuticals.

3. The Final Report should consider the implications for innovation of questioning patent-related conduct

44. The Preliminary Report focuses on reviewing the implications of patent-related conduct for static price competition from generics, without considering the dynamic component of competition through innovation in the pharmaceutical sector. In particular, the Preliminary Report does not recognize the potential adverse consequences that a weakening of the patent system may have on dynamic competition through innovation. The Preliminary Report acknowledges that “*adequate and efficient patent protection is an essential prerequisite for future innovation*” (Preliminary Report, ¶ 4) and observes that “*the pharmaceutical sector relies very heavily on patents to protect inventions*” (Preliminary Report, ¶ 210). It also notes that “*a few blockbuster medicines [...] account for a substantial part of the sales and profits of large originator companies*” (Preliminary Report, p.7). But the Preliminary Report does not draw the proper conclusion from these circumstances.
45. The dependence of innovator companies on a few successful medicines implies that questioning the legitimacy of protecting these medicines under the patent system threatens the ability and incentives of pharmaceutical companies to support future innovation. Revenues from successful medicines represent the means by which innovators finance current and future research and development. Without the ability to trust the protection granted by the patent system to these medicines, the basis for future innovation is compromised.
46. A comprehensive and balanced discussion of the relationship between IP rights and competition therefore cannot only focus on the impact of patents on static price competition, but must consider the pro-competitive effects that patents create for dynamic competition through the stimulation of innovation. Any measures (whether in the form of legislative changes or competition law intervention) that would make it more difficult to file or enforce patents would likely have significant adverse consequences for innovation and, in the end, improved patient healthcare. It is important to consider such dynamic effects to avoid the risk of sacrificing long-run innovation incentives for the sake of short-run price effects.

4. The Final Report should consider all dimensions of competition, including *intra* generic competition

47. The Preliminary Report reviews competition between innovators and generics without considering competition among generic companies. In particular, it does not examine to what extent distortions in regulatory systems or arrangements among generic companies restrict *intra* generic competition. The issue of *intra* generic competition, however, cannot be separated from a review of generic vs. innovator competition. To understand how competition in the pharmaceutical industry works and what factors affect such competition all dimensions of competition need to be taken into account.

48. For example, it is well known that prices of generic products in the United States are considerably cheaper than in Europe.²³ Such differences in competitive patterns suggest that observed generic market conduct (including entry and pricing) are the result of differences in national regulatory regimes and market conditions that affect *intra* generic competition, rather than the consequence of any conduct by innovators. This illustrates that the factors that govern competition among generics are relevant for understanding competition between generics and innovators. A comprehensive and balanced assessment requires that account be taken of all these factors.

²³ According to a 2004 study of the US Department of Commerce, European prices of generic medicines amounted to more than 130% of US prices. The Commission requested extensive US data for both generics and innovators as part of its inquiry (Questionnaire of May 29, 2008), but these data are not referenced in the Preliminary Report.

III. THE DISCUSSION OF INDIVIDUAL PRACTICES SHOULD RECOGNIZE LEGITIMATE CONDUCT

49. In Section C, the Preliminary Report discusses a number of practices related to patents and judicial remedies, which it describes as a “*tool-box*” of instruments that innovators may use to delay generic entry or hinder entry of new medicines (Preliminary Report, ¶¶ 9, 143, 369, 372, 665, 707, 771, 870, 873, 887, 890, 895, 897, 900, 905, 912, 925). While the Preliminary Report generally recognizes the legitimacy of the described practices, it systematically qualifies that recognition through ambiguous language. However, on closer review, it is evident that the circumstances identified in the Preliminary Report do not provide an objective basis for possible concerns. To preserve legal certainty and protect the integrity of the patent system, the Final Report should therefore avoid language that could be misunderstood as a criticism of practices that are not only lawful and legitimate, but the specific object of the patent system itself. The following sections discuss the various practices identified in the Preliminary Report and show that they should not give rise to concerns.

A. Patent Filings, Including Multiple Filings For The Same Product, Are A Legitimate And Inherent Part Of The Patent System

50. The Preliminary Report claims that “*patent strategies can form part of a company’s tool-box, which are used in order to protect continuous revenue streams from pharmaceutical products by preventing or delaying generic entry*” (Preliminary Report, ¶ 372). The Preliminary Report refers to “*patent clusters*” and divisional patent filings as examples of possible measures that “*prevent or delay generic entry*” (Preliminary Report, ¶¶ 382-409). However, the Preliminary Report does not indicate a clear basis for any concerns regarding patent filings. Once the legal context of the patent system is taken into account, it is apparent that the elements discussed in the Preliminary Report cannot serve to question the legitimacy of patent filings, including multiple filings relating to the same product. The following considerations are relevant in this respect:

1. Patent filings are subject to independent review and decision by the competent public authorities

51. Patent filings are mere applications to the patent authorities. Whether a patent will be granted or not is subject to the independent decision of these authorities. The exclusivity that is associated with a patent results therefore from the authorities’ decision to grant the patent, rather than from the patent application as such. In these circumstances, it is difficult to see how the mere filing of a patent application could give rise to concerns.

52. As Advocate General Jacobs held in *Albany*, “*mere efforts on the part of undertakings to convince public authorities*” are not caught by EC competition rules, *inter alia* because any possible resulting restriction “*is a consequence of subsequent State action*”, rather than company conduct.²⁴ This principle must apply *a fortiori* where the

²⁴ Case C-67/96 *Albany* [1999] ECR I-5751, Opinion of Advocate General Jacobs, ¶¶ 291-293 (see too Case C-35/99 *Manuele Arduino*, [2002] ECR I-1529, Opinion of Advocate General Léger ¶ 74). Although the Opinion was rendered on the application of Article 81 EC to joint lobbying, its rationale applies in the same way in the present context.

legal system expressly provides for the right to make applications and establishes a special procedure to review these applications.

53. Given that the patent system establishes a specific framework for the filing of patent applications, EC competition law cannot require companies to abstain from making such applications. Instead, it is for the procedures established under the patent system to determine whether a particular application has merit.

2. Annulment rates do not provide a basis for concerns

54. At ¶ 393, the Preliminary Report argues that the EPO grants patents “*too easily*” because “*the majority of litigated patents were revoked*”. The annulment rates quoted in the Preliminary Report, however, do not provide grounds for concerns. First, as noted above (¶ 32), annulment rates of *litigated* patents do not represent a meaningful metric. In reality, only a small fraction of all granted patents (*i.e.*, less than 1%) gets annulled. Second, as also discussed above (¶ 25), reliance on annulment rates represents an argument based on hindsight that cannot serve to assess company conduct.
55. That some patents may be annulled does not imply that right-holders act improperly in applying for patents. Rather, it shows that the system works as intended. The patent system is based on a dialectic process where research-based companies will file patents that they hope will protect their innovations and generic companies will challenge patents that they believe are vulnerable. Within this system, companies must be free to make patent filings without fear of being entangled in antitrust proceedings. To hold differently, would undermine the patent system and risk chilling incentives to innovate.

3. The Preliminary Report’s references to “intended effects” do not provide a basis for concerns

56. The Preliminary Report claims that the “*intended effects*” of patent clusters and divisional filings are “*to prevent or delay generic entry*” and states that “*while this during the period of exclusivity, is generally in line with the underlying objectives of patent systems, it may in certain cases only be aimed at excluding competition and not at safeguarding a viable commercial development of own innovation*” (Preliminary Report, ¶ 410). This reasoning is difficult to follow.
57. First, patents by definition cannot prevent or delay generics beyond “*the period of exclusivity*”, during which the delay is legitimate, as the Preliminary Report itself recognizes. It is therefore unclear under what circumstances the Preliminary Report’s referenced concern could arise.
58. Second, the argument suffers from its reliance on elements that are inherent in the patent system. As discussed, “*excluding competition*” and “*safeguarding [...] own innovation*” are not opposing principles, but intrinsically connected. In circumstances where the objective effect of a lawful measure is to exclude copy products, subjective “*intended effects*” cannot serve to distinguish problematic conduct.
59. Third, national (and international) patent authorities are the competent bodies to decide whether a patent application serves to protect “*own innovation*”. No patent will be granted, if the authorities find that the application does not cover an innovation. If, on

the other hand, they decide that the conditions for the grant of a patent are met, the applicant must be able to trust that decision and must be free to rely on the patent.

4. The mere number of patents does not provide a basis for concerns

60. The Preliminary Report's discussion of patent clusters centers on the number or "*multitude of patents*" (Preliminary Report, ¶¶ 376, 377, 382, 384, 385) that are filed for the same product. However, there is no legal basis for suggesting that the mere number of patents filed for a product could denote a potential concern. Products will often be characterized by multiple innovations that companies must be allowed to protect. It is difficult to see what meaningful benchmark could exist for deciding at what point the permissible number of patents is exceeded. It is for the competent patent offices and courts to determine which aspects of a product are sufficiently innovative to warrant a patent.

5. Divisional patent filings are a legitimate measure specifically provided for by the patent system

61. The Preliminary Report refers to complaints from generic companies who characterize divisional filings "*as a potential instrument to prevent or delay generic entry*" (Preliminary Report, ¶ 398). Beyond these unsubstantiated claims from competitors, the Preliminary Report contains nothing that could provide a basis for possible concerns. Divisional patent filings represent a legitimate instrument that is necessary to address some of the formalistic aspects of the patent system and that is specifically foreseen in Article 76 EPC. In particular, the following points are worth noting:
 62. First, divisional patents have the same lifetime as the parent patent and cannot exceed the scope of the parent. As a result, it is difficult to see how such patents could be said to delay generic entry beyond the life of the parent in the first place.
 63. Second, there are many legitimate reasons for making divisional filings, including the following:
 - **Need to meet the requirement of unity of invention.** Patent law requires that only one invention can form the subject matter of a patent. Where the patent authorities conclude that the patent covers multiple inventions, the applicant needs to split up the application through divisional filings.
 - **Interest in speeding up the grant of claims.** During discussions with the patent authorities, it may become apparent that the authorities are prepared to accept certain claims immediately, but require additional data to show that the conditions for patenting other claims are met. In such circumstances, the applicant may opt to split those claims that can be granted right away from those that require further data to ensure that the claims without further data requirement can be granted quickly. Rather, than delaying the grant process, divisional filings can therefore serve to speed up that process.
 - **Protection of claims against formalistic errors.** Given the highly formalistic nature of the patent system, it is possible that a patent may be annulled in opposition or appeal proceedings for formal reasons, even though the patent's underlying substance is valid. In such cases (depending on the procedural status of

the proceedings), it may no longer be possible to rectify the formal errors, unless a divisional patent covering the same subject matter is pending before the authorities. In these circumstances, divisional applications simply ensure the survival of valid claims that protect the innovation in question.

64. Third, contrary to what the Preliminary Report seems to suggest, there is therefore nothing problematic if a company “*insist[s] in pursuing the grant procedure for divisional patents, even if the parent patent application was subsequently withdrawn*” (Preliminary Report, ¶ 401). Rather, the filing and prosecution of divisional patents is not only legitimate, but good and prudent practice for a diligent research-based company.

B. Patent Disputes And Litigation Represent The Means To Exercise The Fundamental Right To Judicial Protection

65. The Preliminary Report recognizes that “*enforcing patent rights as such is not objectionable*”, but qualifies this observation by stating that “*this may be problematic under specific circumstances*” (Preliminary Report, ¶ 433). The Preliminary Report, however, does not appear to identify “*circumstances*” where patent litigation by originator companies could be said to be “*problematic*”. The following sections discuss the various circumstances described in the Preliminary Report in more detail and set them in context with the inherent characteristics of patent litigation.

1. Case law recognizes litigation as a fundamental right

66. In *ITT Promedia*, the Court of First Instance specifically held that Article 82 EC can apply to litigation only “*in wholly exceptional circumstances*”.²⁵ The Court stressed in that case that “*access to the Court is a fundamental right and a general principle ensuring the rule of law*”.²⁶ The Commission itself suggested in that case that the application of Article 82 EC could only be contemplated in circumstances where litigation “*cannot reasonably be considered as an attempt to establish the rights of the undertaking concerned*” and “*is conceived in the framework of a plan whose goal is to eliminate competition*”.²⁷ The Court left open whether or not these were sufficient criteria for applying Article 82 EC, but emphasized that any such criteria must in any event “*be applied and interpreted restrictively in a manner, which does not frustrate the general rule of access to the courts*”.²⁸ In these circumstances, the Final Report should acknowledge the clear limitations in applying EC competition law to litigation.

2. Patent litigation constitutes an exercise of the specific subject matter of intellectual property rights

67. Patent actions brought by right holders are not only covered by the fundamental right to judicial protection that applies generally to litigation, they moreover represent the

²⁵ Case T-111/96 *ITT Promedia* [1998] ECR II-2937, ¶ 60.

²⁶ *Ibid.* See too Case 222/84 *Johnston v Chief Constable of the Royal Ulster Constabulary* [1986] ECR 1651, ¶¶ 17-18.

²⁷ Case T-111/96 *ITT Promedia* [1998] ECR II-2937, ¶ 1.

²⁸ Case T-111/96 *ITT Promedia* [1998] ECR II-2937, summary and ¶ 61 with cross reference to Case T-105/95 *WWF UK* [1997] ECR II-313, ¶ 56.

exercise of the specific subject matter of intellectual property rights. As discussed above, any suggestion that right holders are under an obligation to abstain from enforcing their granted patents would be equivalent to imposing a duty to grant access to these patents. Such a duty is from the outset excluded in the case of mere generic products.

68. Moreover, the legitimate nature of patent litigation extends to both litigation on the substance and applications for interim measures. Indeed, the very purpose of interim measures is to safeguard the substance of the intellectual property right where that substance would be prejudiced in the absence of such measures.²⁹ While the Preliminary Report suggests that interim injunctions may have a “*very serious effect*” on generic companies (Preliminary Report, ¶ 466), it does not identify objective support for this suggestion. Nor does it consider the “*very serious effect*” that premature generic entry has on innovator companies. Entry of generic products in violation of patent rights results in changes to the market structure that are very difficult or impossible to undo even if right holders ultimately prevail on the substance. In the context of Community law litigation, such changes in market structure have been specifically recognized as grounds for the grant of interim injunction.³⁰

3. Patent actions of right holders are not offensive, but reactive in nature

69. It is also worth noting that a theory of improper harassment through litigation presupposes some form of offensive conduct. Patent actions of right holders, however are by definition reactive, rather than offensive in nature. Such litigation is triggered as a reaction to premature entry by generic companies prior to patent expiration. Clearly, if a generic company decides to enter a market prior to patent expiration, it must be prepared to bear the consequences of that decision. The Preliminary Report does not identify objective evidence to support the suggestion that generic companies may be unduly deterred by litigation (Preliminary Report, ¶¶ 430-431, 458, 466). Generic companies are sophisticated and resourceful companies that are capable of assessing the risks and rewards of their strategies. Moreover, the patent and judicial system provides generic companies with a range of instruments to minimize litigation risks, including through opposition proceedings, annulment actions, and requests for bond payments for interim measures. Indeed, the ability of generics “to clear the path” through annulment actions is one of the reasons why, in the UK, courts typically grant interim injunctions, if generics have failed to do so prior to entry. These considerations confirm that there is no basis for believing that patent litigation may be “*problematic*”.

4. The referenced statistical data do not provide grounds for concerns

70. To a large extent, the Preliminary Report’s discussion of patent litigation is limited to the presentation of a series of statistical data, such as the number, type, duration, and success rate of litigation. None of these data support a suggestion that the initiation of litigation by originators could be “*problematic*”. On the contrary, if anything, the

²⁹ For interim measures before the Community Courts, see, e.g., Case C-180/01 P-R *NALOO* [2001] ECR I-5737, ¶ 52: “*the purpose of the procedure for interim relief is to guarantee the full effectiveness of the definitive future decision, in order to ensure that there is no lacuna in the legal protection provided*”.

³⁰ See, e.g., Case T-31/07 R *Du Pont* [2007] ECR II-2767.

figures quoted in the Report indicate that there are no grounds for concern. Thus, the Preliminary Report finds that 46% of all identified patent litigations were initiated by generic companies (Preliminary Report, ¶ 468). Given that litigations are, on average, initiated almost as often by generic companies as by originators, there is no reason to assume that generic companies are “*dissuaded*” or deterred by the possibility of litigation as the Preliminary Report appears to suggest (Preliminary Report, ¶¶ 430-431, 458, 466).

71. More specifically, the following considerations are worth noting with respect to the referenced data:

- As with patent filings, the mere number of litigations cannot denote “*problematic*” actions, particularly since patent litigations are the result of challenges brought by generic companies against patents either directly through annulment suits or indirectly by entry prior to patent expiration. EC competition law does not require right-holders to remain passive *vis-à-vis* such challenges, regardless of their number.
- The success rate of litigation does not indicate “*problematic*” actions either. As with annulment rates, a reference to success rates represents an argument based on hindsight. The Preliminary Report’s observation that some actions “*can be judged ex post to be unfounded*” (Preliminary Report, ¶ 917) is a *non sequitur*. The uncertainties of litigation render it inevitable that some actions will turn out to be “*unfounded*”, but the fact that litigation may ultimately be lost, does not denote improper conduct *ex ante*.
- This is true, irrespective of the *ex ante* expectations about the probability of success. The Preliminary Report’s suggestion that the filing of an appeal with a “*low*” expected chance of success demonstrates that “*originator companies seem to engage in litigations as a deliberate strategy to delay generics*” (Preliminary Report, ¶¶ 740, 893) is unfounded. Setting aside that estimations of chances of success are subjective and subject to differing views, even a “*low*” chance of success represents a chance to be right. Seeking to realize that chance does not imply a “*deliberate strategy to delay generics*”, but constitutes simply the exercise of a company’s fundamental right of “*access to the courts*”. There is no legal basis for suggesting that companies should be deprived of their right to realize their chance of succeeding in judicial proceedings, irrespective of how high or low that chance might be.

5. If the discussion is meant to identify possible improvements to the patent system, the Final Report should state this more clearly without questioning company conduct

72. The Preliminary Report’s discussion of patent litigation includes several references to the possible introduction of a Community patent (Preliminary Report, ¶¶ 505, 518, 523). This suggests that the Preliminary Report’s discussion may be intended to support proposals for regulatory changes. MSD welcomes suggestions for improving the efficiency and effectiveness of the process for obtaining and enforcing patents. Such suggestions can be made through the appropriate legislative proceedings that allow for a full debate of all relevant considerations. To the extent that areas of possible improvement are identified, the Final Report should therefore make clear that

this concerns the legislative design of the patent system, rather than the legitimacy of individual company conduct. In particular, the Final Report should avoid language that could be understood as suggesting (contrary to established case law) that it may be “*problematic*” for companies to enforce their patent rights through litigation.

C. Settlement Agreements Are A Legitimate Means To Resolve Disputes

73. Settlement agreements are a necessary and legitimate means to resolve disputes through compromise. While the Preliminary Report distinguishes between different categories of patent settlements (Preliminary Report, ¶¶ 611, 615, 628, 632, 635 and 636), it is not entirely clear from the discussion, which categories, if any, may potentially raise concerns or under what circumstances such concerns may arise.
74. During the presentation of the Preliminary Report on November 28, 2008, Commission officials stated that no concerns should arise from settlements that do not restrict generic entry or restrict such entry until patent expiration, but do not involve a value transfer from the originator to the generic in consideration for the settlement. MSD welcomes this clarification and would hope that it will be reflected in the Final Report as an example of unproblematic settlement agreements, without excluding the possibility of other types of legitimate settlements.
75. The Preliminary Report also briefly discusses other types of agreements with generic companies. It states that the launch of an authorized or licensed generic product “*may be part of the tool-box used by originator companies to maximize revenue streams from existing products and to anticipate generic competition*” (Preliminary Report, ¶ 665). It is unclear whether this formulation intends to suggest that such agreements might raise concerns. It would, moreover, be difficult to see what the legal basis for such concerns could be. The conclusion of a license or distribution agreement prior to patent expiration is pro-competitive since it creates a second independent source of supply for the product in question. Moreover, the conclusion of such agreements represents the exercise of the essential subject matter of the underlying patent rights, which falls outside the scope of EC competition law.³¹

D. Regulatory Interventions and Litigation Are An Important Element Of The Regulatory Process

76. At ¶¶ 700-772, the Preliminary Report discusses interventions and litigation regarding regulatory decisions of marketing authorization and pricing and reimbursement bodies. The Preliminary Report suggests that such measures may be “*a deliberate strategy pursued by some originator companies to delay generic entry*” (Preliminary Report, ¶ 707). The Preliminary Report, however, does not identify grounds for possible concerns in this respect.

³¹ See Opinion of Advocate General Reischl in Case 262/81 *Coditel II* [1982] ECR 3381 at pp.3409 and 3412 holding that “*the application of Article 85 is excluded from the outset where the issue is one of safeguarding rights which form the specific subject-matter of an industrial or other property right*” and noting that the specific-subject matter of an intellectual property rights “*comprises not only the right to exclude unauthorized third parties from its exploitation but also, where appropriate, the right to have it exploited by a single person, whether it be the owner of the right himself or an exclusive licensee to whom the right is assigned for valuable consideration*”.

1. Regulatory interventions and litigation represent the exercise of due process rights

77. Regulatory interventions and litigations represent the means for interested third parties to raise matters in administrative proceedings that are of direct concern to them. The possibility to make such interventions therefore follows from the right to due process and judicial protection, which is protected as a fundamental right as recognized by the Court of First Instance in *ITT Promedia*.³² Moreover, as regards interventions *vis-à-vis* public authorities more specifically, the opinion of Advocate General Jacobs in *Albany* (as discussed above at ¶ 52) makes clear that such interventions fall outside the scope of EC competition law.

2. The matters raised in regulatory interventions and litigation do not provide grounds for competition concerns.

78. According to the Preliminary Report the matters typically raised in regulatory interventions relate to (1) safety and quality concerns; (2) data exclusivity; and (3) possible conflicts with patents. None of these matters represent grounds for possible EC competition law concerns.

- As regards safety and quality concerns, originator companies must be in a position to raise *bona fide* concerns about the safety and quality of generic products. Indeed, in *Hilti*, the Court of First Instance specifically held that the proper way to deal with possible safety issues of competing products is to bring such issues to the attention of the competent regulatory authorities.³³ Originators are particularly well placed to identify safety or quality issues of generics at an early stage, given their experience with the products concerned. It is therefore in the public interest that originators can raise such concerns free from the fear of being drawn into competition law proceedings. Moreover, safety or quality issues of generic products may have adverse consequences for the reputation of the original product since the general public may attribute such problems to the original product as well. Originators must therefore be able to defend themselves against such an eventuality.
- As regards data exclusivity, the protection of such exclusivity is specifically foreseen by the EC law provisions governing the grant of marketing authorizations.³⁴ Accordingly, right holders must have the right to invoke such exclusivity through the remedies provided for this purpose.
- As regards patent-based arguments, the Preliminary Report suggests that it is incompatible with applicable EC directives for regulatory bodies to consider such arguments (Preliminary Report, ¶¶ 715, 758). The wording of the relevant

³² Case T-111/96 *ITT Promedia* [1998] ECR II-2937.

³³ Case T-30/89 *Hilti* [1991] ECR II-01439, ¶¶ 115-117, stressing that “if *Hilti* had made use of the possibilities available to it under the relevant United Kingdom legislation” to raise safety concerns “the legitimate rights of the interveners would in no way have been impaired had the United Kingdom authorities acceded to *Hilti*’s request for a ban on the use in its tools of nails produced by the interveners”.

³⁴ Article 10 of Directive 2001/83 and Article 14(11) of Regulation 726/2004.

directives, however, does not seem to support that position.³⁵ Moreover the application of directives is in any event an issue of Member States compliance, rather than an issue of company conduct since directives have no direct effect against private persons.³⁶

3 Subjective “expectations” about duration of proceedings do not support claims about delays

79. Moreover, there appear to be no objective reasons for assuming that regulatory interventions unduly delay proceedings. The Preliminary Report’s claims about delays in regulatory proceedings seem to be essentially based on a comparison between the date of the grant of regulatory approval and the date “*when the generic company had initially expected to receive approval*” (Preliminary Report, ¶ 741). It is manifest that such an approach cannot provide a sound basis for a suggestion that regulatory interventions and litigations cause “*delays*”. Declarations of generic companies about what they “*expected*” concerning the timing of regulatory proceedings are evidently subjective and colored by their own interests.

E. The Launch Of Follow-on Products Is An Inherent Part Of Competition

80. In its review of follow-on products, the Preliminary Report states that “*the circumstances typically associated with the introduction of follow-on products to the market suggest that the latter often form part of originator companies’ broader life cycle strategy attempting to delay or prevent generic erosion*” (Preliminary Report, ¶ 832). However, as with the other practices described in the Preliminary Report, the “*circumstances*” discussed in the Report do not appear to provide grounds for possible concerns. The following considerations are worth noting:

1. Follow-on products do not prevent generic entry

81. The development of follow-on products does not prevent a generic company from launching a copy of the first generation product once patents on that product have expired. Whether the generic product will be successful on the market depends on the choices that doctors and patients make in deciding between the generic product and any follow-on product. There is no apparent basis for suggesting that the exercise of such choice could give rise to possible competition concerns.

³⁵ While Article 126 of Directive 2001/83 provides that marketing authorizations can only be refused for the reasons listed in the Directive, Article 10(1) of Directive 2001/83 states that the grant of an authorization to a generic is “*without prejudice to the law relating to the protection of industrial and commercial property*”, which suggests that patent considerations can be taken into account. As regards pricing and reimbursement proceedings, Directive 89/105/EEC merely requires such proceedings to be based on verifiable and objective criteria, which does not exclude patent considerations, particularly where the right-holder’s own product is concerned. If governments wish to reward innovation, Directive 89/105/EEC does not preclude them from doing so.

³⁶ Article 249 EC. While private persons can invoke directives against public bodies and in certain limited circumstances against other private persons, directives cannot be invoked by public bodies against private persons (see, *e.g.*, Case 80/86 *Nijmegen* [1987] ECR 3969, ¶ 14).

2. **Questioning the legitimacy of follow-on products would undermine competition**

82. The development and launch of new products represents normal and desirable competitive conduct. Companies in many industries develop new products to distinguish themselves from their competition and to offer benefits beyond those offered by their competitors, including generic competitors. In pharmaceuticals, new product versions can offer improvements in a number of different ways, including by reducing side effects, increasing efficacy, facilitating compliance, reducing the burden of dosage regimes, and expanding the scope of indications. This is not anti-competitive, but the essence of competition on the merits. Generic companies that argue against follow-on products in effect seek protection from the R&D dimension of competition, on which they do not want to compete. Accepting the arguments of generic companies by suggesting that the launch of new products could raise concerns would therefore have the effect of shielding special interest groups from competition, rather than promoting competition.

3. **The circumstances described in the Preliminary Report do not provide grounds for concern**

83. The circumstances described in the Preliminary Report do not provide grounds for concerns with regard to the launch of follow-on products. The Preliminary Report discusses three main factors that may be associated with the launch of follow-on products: (1) a launch “*shortly before loss of exclusivity of the first generation product*” (Preliminary Report, ¶ 827; (2) “*patenting of originator incremental innovation*” (Preliminary Report, ¶ 845); and (3) “*intensive marketing efforts*” (Preliminary Report, ¶ 827). None of these circumstances suggests problematic conduct.
- **Timing of launch.** Given the long lead times in pharmaceutical R&D, it does not seem particularly surprising that new products may be launched close to patent expiration of the first generation product. More importantly, there is no legal basis for a suggestion that companies should abstain from launching new products during a particular time window.
 - **Patenting of follow-on innovations.** The patenting of follow-on innovations is qualitatively no different from the patenting of other innovations. The same considerations discussed above for patent filings more generally therefore apply here as well.
 - **Marketing.** It is both normal and legitimate for companies to market products, in particular newly launched products. In the pharmaceutical industry, marketing has a particularly important two-way function: it provides doctors with information about the characteristics and the proper use of a medicine and, at the same time, provides the innovator company with feed-back from doctors about their experience with the medicine, which in turn can serve as a basis for further improvements and product developments. There is no apparent legal basis for a suggestion that companies could be under an obligation to refrain from such marketing activities as a result of EC competition law.

F. The Combination Of Lawful Practices Does Not Render These Practices Questionable

84. At ¶¶ 887-925, the Preliminary Report discusses the combination of several of the practices described in the Report. The Report states that such a “*cumulative use [...] will normally render generic entry more difficult than if only a single tool is used*” (Preliminary Report, ¶ 888). It is unclear whether the Preliminary Report considers that the combination of different practices may in itself create possible concerns. While the Preliminary Report seems not to exclude this, there is no apparent factual and legal basis for such a suggestion.
85. The Preliminary Report’s discussion of both follow-on products and what it calls “*bridging strategies*” (Preliminary Report, ¶¶ 866, 872) does not go beyond describing a combination of different lawful patent-related practices. Given that the described practices constitute a lawful exercise of patent rights, their combination cannot render these practices questionable. A suggestion that the combination of different lawful measures would create grounds for concerns would conflict with basic principles of legal certainty and the rule of law.

IV. IN CONCLUSION, THE PRELIMINARY REPORT DOES NOT IDENTIFY GROUNDS FOR EC COMPETITION LAW CONCERNS

86. For the reasons set out above, the circumstances identified in the Preliminary Report do not provide grounds for EC competition law concerns. The Preliminary Report subjects the right of research-based companies to file and enforce patents and to pursue other legitimate commercial interests to vague criticism without a clear legal basis or objective factual support. As a result, such criticism does not provide a solid basis for general policy recommendations or individual follow-on action. A proper and balanced discussion of the matters raised in the Preliminary Report requires that account be taken of the limitations established by Community case law for EC competition law intervention in the area of intellectual property law and to consider the full legal and economic context of the practices under review.

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