

H. LUNDBECK A/S

**COMMENTS IN RESPONSE TO
THE COMMISSION'S PRELIMINARY
REPORT ON THE PHARMACEUTICAL
SECTOR**

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**COMMENTS OF H. LUNDBECK A/S
IN RESPONSE TO
THE PRELIMINARY REPORT ON THE INQUIRY INTO THE
PHARMACEUTICAL SECTOR**

CASE COMP/D2/39.514

I. INTRODUCTION AND EXECUTIVE SUMMARY

1. This response is provided on behalf of H. Lundbeck A/S and the affiliated group of companies of which H. Lundbeck A/S is the parent company (collectively referred to as "Lundbeck"). Lundbeck welcomes the opportunity to comment on the preliminary report ("Preliminary Report") in Case COMP/D2/39.514, *Inquiry into the Pharmaceutical Sector* ("Pharma Inquiry"), which was released by the European Commission ("Commission") on November 28, 2008.
2. Lundbeck fully supports the Commission's vision of ensuring that European citizens "*can increasingly benefit from a competitive industry that generates safe, innovative and accessible medicines*",¹ and hopes that the Commission will consider the points outlined in this submission as a means of furthering those objectives. In addition, Lundbeck requests that the Commission specifically address the matters discussed in Subsections A to G below in its final report on the Pharma Inquiry ("Final Report"), which Lundbeck understands is due to be released in the spring of 2009.
3. Lundbeck is aware that the Commission recognizes that pharmaceutical research and development ("R&D") is key to pharmaceutical innovation, and to improving the health and wellbeing of patients in Europe.² To state the obvious, patent rights, and in particular the right to exclude others from practicing a patented invention, are the main means by which the substantial investment in the development of new medicines are recouped. In Lundbeck's view, adoption of the Preliminary Report in its current form would have a chilling effect on R&D, to the detriment of European patients, for the reasons summarized below, and explained in more detail in Sections II to VII. Indeed, the societal costs of chilling research into new and better medicines could far outweigh any benefits from more aggressive antitrust enforcement.
4. In addition to the specific comments articulated in Sections II to VII, Lundbeck endorses the report submitted to the Commission by the European Federation of Pharmaceutical Industries and Associations ("EFPIA") on June 13, 2008 ("EFPIA June").

¹ *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Safe, Innovative and Accessible Medicines: A Renewed Vision for the Pharmaceutical Sector* (December 10, 2008), at page 4.

² *Ibid.*, at page 14.

2008 Report”) as well as EFPIA’s comments to be filed in response to the Commission’s Preliminary Report, and its identification of the many challenges facing innovator companies.³ In particular, Lundbeck is generally concerned regarding the Commission’s failure to establish adequately: (1) the actual existence of delays in generic entry following patent expiry in E.U. Member States; and (2) if such delays do exist, the reasons for the delays. The Commission has clearly acknowledged in the Preliminary Report that “*entry will not take place immediately on loss of exclusivity for every INN*”.⁴ However, the Commission does not attempt to articulate what it considers a realistic time period for entry, or how that may vary depending upon the circumstances of individual products. In Lundbeck’s view, the regulatory systems in many E.U. Member States during the period 2000-2007 would have made it unlikely that generics could enter the market until 7 to 12 months after the loss of exclusivity in any event. It follows that any “delays” in generic entry observed by the Commission were likely primarily the result of regulatory processes such as pricing and reimbursement systems (and perhaps also to some extent a result of decisions by generic companies regarding the precise timing of initiating litigation and opposition proceedings), rather than any conduct by innovator companies. In fact, in Lundbeck’s view, generic companies have been entering the market with increasing speed in recent years.⁵ Lundbeck therefore requests that the Commission include in the Final Report details of the average time to entry for molecules where patent protection expired in 2007, in order to provide a more accurate representation of the situation.⁶

5. While Lundbeck has attempted to address the points in this response in the order they appear in the Preliminary Report, some of the themes outlined below arise in several different places in the Preliminary Report. Lundbeck has cross-referenced these points in the response where relevant, in order to avoid duplication.

A. Lack Of A Clear Legal Framework For Analysis

6. The Preliminary Report is presented as a set of “factual findings”, and does not purport to reach any conclusions about whether particular conduct in the pharmaceutical sector is incompatible with EC competition law. The lack of guidelines as to when certain practices, which the Commission has labelled the “tool-box” of innovator companies, may infringe competition laws creates significant uncertainty for industry stakeholders.
7. Lundbeck considers that the Final Report should include a set of proposed guidelines as to the circumstances under which the Commission believes these types of conduct may be incompatible with EC competition law, and the legal basis for the principles that the Commission proposes to use to assess individual instances of such conduct. Indeed, Lundbeck considers that the scope of the proposed guidelines should extend to all technology-based sectors in which patents play an important role, because many of the

³ In order to avoid duplication, Lundbeck does not repeat herein all of the points made in the EFPIA submissions.

⁴ Preliminary Report, at para. 181.

⁵ EFPIA June 2008 Report, at para. 15.

⁶ This data was excluded from the Preliminary Report.

practices described in the Preliminary Report characterize all these sectors, not just the pharmaceutical sector.

8. Lundbeck further submits that any such guidelines should be subject to a further period of review by, and consultation with, stakeholders in the pharmaceutical and other sectors. Failure to do so is likely to result in lengthy and costly litigation to clarify the relevant principles. In the interim, pro-competitive, innovative conduct will be chilled by the legal uncertainty.

B. Recognition And Enforcement Of Intellectual Property Rights Lies Exclusively With Individual Member States

9. In Lundbeck's view, the Preliminary Report does not adequately address the fact that the existence and validity of patents remain the prerogative, and fall within the exclusive jurisdiction, of individual Member States. Comments in the Preliminary Report about matters that the Commission describes as "weak patents", "patent clusters" and "defensive patents" suggest that the Commission might unjustifiably seek to second-guess the legitimacy of intellectual property protection granted by individual Member States.
10. While the exercise of national intellectual property rights may fall within Articles 81 and/or 82 of the EC Treaty, simply applying for a patent cannot be considered an exercise of the rights derived from that patent and should not be considered unlawful, except in the case of patents found, on the basis of clear evidence, to have been obtained fraudulently (*i.e.*, obtained as the result of a false representation, made with the intent to deceive, on which the patent examiner relied).

C. Intellectual Property Rights Must Be Presumed Valid

11. The Preliminary Report refers to the requirements under Article 52(1) of the European Patent Convention ("EPC") that an invention must: (1) be new; (2) involve an inventive step; and (3) be susceptible to industrial application, before a patent will be granted for that invention.⁷ Notwithstanding those requirements, however, the Commission appears to accept the view of generic companies that some lawfully granted patents in the pharmaceutical industry, in their words, are nonetheless "weak" or "lack innovation". Moreover, the Commission appears to be prepared to treat the pharmaceutical industry differently than other industries, as there is no suggestion that this approach will be followed elsewhere.
12. Lundbeck submits that the Final Report should clearly acknowledge the established position that, for the purpose of applying EC competition law, intellectual property rights must be presumed to be valid.⁸ Further, it should acknowledge that once the requirements of the EPC have been met, innovator companies are entitled to enforce each of their patents on the basis that they are valid, valuable property rights, except if

⁷ Preliminary Report, at para. 218.

⁸ See, for example, *Microsoft v Commission*, Case T-201/04, [2007] ECR II-3601, at para. 695; *Windsurfing v Commission*, Case 193/83, [1986] ECR 611, at para. 30.

they have been obtained fraudulently, or if they are objectively and subjectively baseless. These basic principles do not change, regardless of the timing of patent applications, or whether an innovator company has a large number of patents, has patents that relate to an earlier patented product, or elects not to commercialize one or more of its patents. To suggest otherwise is to call into question the fundamental premise of the national patent systems.

D. Competition Law Must Not Deprive Companies Of Access To The Courts, Or Require Companies To License Intellectual Property Rights (Other Than In Exceptional Circumstances)

13. The Preliminary Report indicates that enforcement of patent rights against generic companies may be problematic in certain (unspecified) circumstances. In Lundbeck's view, the Final Report must clearly identify those circumstances. The Commission should not seek to depart from the principles set forth in the *ITT Promedia* judgment,⁹ namely, that there is a high burden to discharge in establishing that litigation is vexatious, and that access to the courts is a fundamental right that can only be circumscribed in exceptional circumstances.
14. Further, Lundbeck notes that the use of competition law to limit the ability of innovator companies to enforce their intellectual property rights in court would have the same effect as requiring companies to license their intellectual property rights to generic competitors. Yet it is well-established that a refusal to license intellectual property rights only violates Article 82 of the EC Treaty if that refusal prevents the emergence of a new product, or limits technological development more generally.¹⁰ These conditions do not exist here, as licensing the use of an innovator's patent to a generic company merely allows the production of copies of an existing product.¹¹ Accordingly, broader limits on innovators' ability to enforce their intellectual property rights against generic firms would conflict directly with well-established E.U. law regarding refusals to license.

E. Key Differences Between The Regulatory Framework In The United States And Europe Suggest That The U.S. Experience Is Not A Particularly Useful Benchmark

15. Lundbeck understands from the Preliminary Report that the Commission has discussed the issues raised in the Pharma Inquiry with competition enforcement agencies in the United States and, in particular, with the Federal Trade Commission ("FTC"). In Lundbeck's view there is significant value in transatlantic cooperation in this area. The

⁹ *ITT Promedia NV v Commission*, Case T-111/96, [1998] ECR II-2937, at paras. 60-61.

¹⁰ Moreover, in the narrow circumstances where mandatory licensing is required, the licensor is entitled to compensation. *Magill v Commission*, Joined cases C-241/91 and C-242/91, [1995] ECR I-00743, at para. 54; *IMS Health v Commission*, C-418/01, [2004] ECR I-05039, at para. 38; *Microsoft v Commission*, Case T-201/04, [2007] ECR II-3601, at paras 643-659.

¹¹ *Magill TV Guide* OJ [1989] L 78/43, at para. 27, confirmed in *Magill v Commission*, Joined cases C-241/91 and C-242/91, [1995] ECR I-00743, at para. 91; *Microsoft v Commission*, Case T-201/04, [2007] ECR II-3601, at paras. 808-810.

U.S. courts and antitrust agencies have a long record of considering similar issues in the pharmaceutical sector, and Europe can learn from those experiences. Indeed, in relation to some issues raised in the Preliminary Report, Lundbeck considers that the approach of the U.S. courts is a good starting point for the development of principles to govern conduct in Europe.

16. However, certain references in the Preliminary Report to the U.S. regulatory system and patent enforcement practices suggest that the Commission might benefit from further analysis of key aspects of the U.S. system, and these may have implications for the application of U.S. pharmaceutical industry antitrust law experience in the European regulatory context.
17. In particular, Lundbeck considers that the availability to an innovator company under the Drug Price Competition and Patent Term Restoration Act of 1984¹² (the “Hatch-Waxman Act”) of a 30-month mandatory injunction against the launch of a generic product by the “first filer” may encourage early litigation by innovator companies in the United States. Similarly, the 180-day exclusivity period for the first-filer may have traditionally encouraged settlement agreement provisions that “park” the marketing of the first generic product, and therefore avoid triggering the 180-day period, thereby barring the launch of other competing generics. While there have been amendments to this aspect of the Hatch-Waxman Act seeking to address this issue, Lundbeck notes that the only U.S. court of appeals case finding that such an agreement violated the U.S. antitrust laws arose in just such a fact pattern – where an agreement with a generic firm exploited this Hatch-Waxman Act loophole to keep *all* generic competitors off the market.¹³
18. Critically, neither of these aspects of the U.S. regulatory system are present in Europe, where the incentive for innovators to obtain what the Commission describes as “weak” patents is therefore significantly lower. Lundbeck therefore submits that the Commission should be cautious about concluding that enforcement priorities in the United States are equally applicable in Europe.

F. There Are Significant Public Benefits In Settling Litigation

19. Just as access to the courts to determine disputes between parties is a fundamental right in the E.U., Lundbeck considers that the right of parties to settle such disputes on terms negotiated between themselves is equally important, particularly in light of the resulting potential cost savings.¹⁴ Such considerations are even more important here, as patent litigation occurs at the Member State level, and thus can involve multiple, duplicative litigation procedures. Lundbeck invites the Commission to provide clear guidance in

¹² Pub. L. No. 98-417, 98 Stat. 1585.

¹³ *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003).

¹⁴ The Commission has itself previously recognised the benefits of out-of-court settlement agreements – see, for example, the *White Paper on Damages Actions for Breach of the EC Antitrust Rules* (2008), stating that due consideration should be given to mechanisms fostering early resolution of cases, e.g., by settlements as this could significantly reduce or eliminate litigation costs for the parties and also the costs for the judicial system.

the Final Report as to the circumstances (if any) in which the Commission considers that patent settlement agreements may be anti-competitive, in order to avoid creating an increased incentive for innovator and generic companies to litigate all disputes until a final judgment is obtained rather than entering into settlement agreements which could delay generic entry. This will in turn result in valuable time and resources being tied up on litigation instead of being utilized for further R&D activities.

20. For example, Lundbeck notes the references in the Preliminary Report to settlement agreements which provide for the grant of a license to a generic company (particularly royalty-free licenses), and also to agreements that merely have the same effect as an interim injunction (but without the parties incurring the costs of litigation involved in proceedings for injunctive relief).¹⁵ Lundbeck considers that such agreements will rarely (if ever) have anti-competitive effects, and that there are significant public benefits that attach to these arrangements.

G. Innovators Compete With Generic Companies Through Innovation As Well As Price

21. The development of new and improved medicines is an ongoing process, and testing, trials and innovation do not cease once a product has been marketed. Indeed, innovators are best placed to identify potential improvements to their own products, so their efforts towards this end should come as no surprise. The Commission should be very careful to ensure that it does not chill the incentives of innovators to take the risks to develop and market such improvements. Doctors and national health authorities are well-placed to judge whether patients benefit from these improvements.
22. Even at, around, or after patent expiration, it is natural for innovators to compete with present or pending generic competition not only through price, but also through further innovation. Indeed, the invention of incremental improvements to an innovator's products is a legitimate, pro-competitive response to generic competition, which should be hailed for the significant benefits provided to patients. This is equally true whether investments yield incremental innovations in the product itself, or in the efficiency of the production processes. Thus, Lundbeck submits that proposed guidelines regarding such conduct (if any are deemed essential) should be clearly articulated in the Final Report.

¹⁵ See, for example, Box 1 on page 237 of the Preliminary Report, and Box 1 on page 235 of the Preliminary Report.

II. FRAMEWORK FOR ANALYSIS

A. Need For A Clear Legal Framework For Assessing Conduct in the Pharmaceutical Sector

1. No Legal Principles In The Preliminary Report

23. The Preliminary Report states that it does not seek to “*reach any conclusion as to whether certain practices described in the report infringe EC competition law*”, but instead “*provides the Commission with a factual basis for deciding whether further action is needed*”.¹⁶ The Commission also notes that the Preliminary Report is not intended to identify wrongdoing by individual companies.¹⁷
24. However, the Preliminary Report goes on to state that “[i]n the light of the findings set out in this and the final report, the Commission intends to take action where deemed appropriate”.¹⁸ The difficulty for industry stakeholders in responding to the Preliminary Report - and in assessing any action that the Commission may take on the basis of the Preliminary Report - is that the Commission’s factual findings are presented in a legal vacuum. The Preliminary Report contains no guidance as to when the practices that the Commission has labelled the “tool-box” of instruments constitute an acceptable exercise of legal rights, and when (if ever) they cross the line to become anti-competitive conduct.
25. Although Lundbeck agrees with the Commission’s position - noted in various places in the Preliminary Report – that it cannot reach a view on whether particular conduct is compatible or incompatible with EC competition law without an in-depth analysis of the individual conduct and the factual, economic and legal background,¹⁹ Lundbeck’s view is that the Final Report should nonetheless delineate the types of conduct that the Commission considers may be incompatible with EC competition law, the specific factual circumstances under which such types of conduct would be unlawful, and the legal principles that the Commission proposes to use to assess individual instances of such conduct.

2. No Existing EC Competition Law Precedent

26. The uncertainty created by the lack of a clearly articulated legal framework in the Preliminary Report is heightened by the fact that the practices discussed in the Preliminary Report have not been the subject of infringement decisions by the Commission or the Community courts.²⁰ This means there is no existing precedent

¹⁶ Preliminary Report, Executive Summary, at page 5.

¹⁷ Preliminary Report, Executive Summary, at page 5.

¹⁸ Preliminary Report, at para. 23.

¹⁹ See, for example, Preliminary Report, at para. 366 (in respect of the competitive relationship between innovators and generics), para. 574 (in respect of settlement agreements) and para. 663 (in respect of other agreements between innovators and generics).

²⁰ One notable exception is the *Astra-Zeneca* decision referred to in the Preliminary Report, but the outcome of this litigation is not yet known.

against which companies can measure their own behaviour, or assess the factual findings in the Preliminary Report.

3. Final Report Should Provide Guidance On Assessing The “Tool-Box” Practices

27. If, therefore, the Commission forms the view at the end of the Pharma Inquiry that some conduct in the pharmaceutical industry may be anti-competitive, Lundbeck considers that the Final Report should propose a clear legal framework in the form of guidelines for assessing such practices by reference to existing EC competition law. Further, Lundbeck considers that the scope of the proposed guidelines should extend to all technology-based sectors in which patents play an important role, because many of the practices described in the Preliminary Report characterize all these sectors, not just the pharmaceutical sector.
28. These guidelines would enable innovator companies to both analyze their past practices, and determine their future conduct, in accordance with the Commission’s proposed position. They would also form the basis for constructive, concrete discussion between the Commission and industry stakeholders about potential rules regarding these complex issues.

B. Need For Public Consultation On Proposed Legal Framework

29. Lundbeck further submits that any framework for analysis proposed by the Commission in the Final Report would need to be subject to significant public scrutiny and comment. The matters identified in the Preliminary Report are complex, and highlight the delicate relationship between intellectual property law and competition law, as well as the issues raised by the unique European regulatory environment. There is also a serious risk that over-enforcement will chill pro-competitive, life-saving innovations. Subjecting a potential analytical framework to public consultation, consideration and critique will inevitably result in a more coherent and legally sound set of guidelines, and one that is more likely to be accepted by industry stakeholders, the European courts, and other stakeholders, both inside and outside of the pharmaceutical industry.
30. If, contrary to the views expressed above, the Commission’s Final Report contains factual findings only, then the question of whether any of the “tool-box” practices infringe EC competition law is likely to take many years of litigation to be resolved. Lundbeck respectfully suggests that it would be a more efficient use of resources for the Commission to identify the relevant legal principles, and clarify the way the Commission sees them applying to the conduct of innovator companies, prior to the release of the Final Report.
31. This approach will help avoid the inevitable legal uncertainty that would result from the release of factual findings without an accompanying legal framework. Such uncertainty would place increased costs on pharmaceutical companies in attempting to identify and comply with their obligations under EC competition law, and is likely to have a corresponding chilling effect on innovation.

III. PATENT STRATEGIES OF INNOVATOR COMPANIES

32. The Preliminary Report rightly acknowledges the importance of patent protection in encouraging innovation in the field of prescription medicines for human use.²¹ However, the Preliminary Report also observes that “*originator companies seek to protect their market position using various means ranging from strategic patenting around the product to patent litigation and interventions before national regulatory authorities*”,²² and that “*in some cases originator companies might also have incentives to maintain and use patents for their effect of blocking or delaying the development [sic] generic product rather than for protecting an own invention*”.²³
33. In particular, the Preliminary Report raises concerns about situations where an innovator company files for a “*multitude of patent applications*” (on process, reformulation, etc.) in addition to the “*base patent*”, with the aim of creating several layers of defence against generic competition. The Preliminary Report refers to this approach as a “*patent cluster*”, and states that “*where generic companies might manage to invalidate the base patent before its regular expiry they still cannot enter the market, if the originator company has succeeded in creating multilayered defence or [sic] other patents surrounding the product*”.²⁴ The Commission considers 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 covered by the clusters.”*²⁵
34. Further, although the Commission acknowledges that an increase in “*secondary patents*” can be a sign of incremental innovation by the innovator companies,²⁶ the Commission also states that an increase can also reflect an “*increase of weak patents*”.²⁷
35. In Lundbeck’s view, the comments above are problematic for a number of reasons:
- The question of recognition and enforcement of intellectual property rights (including patents) lies exclusively with individual Member States, and the Commission does not have jurisdiction to determine which inventions (or how many) should be protected by intellectual property rights.
 - The comments suggest that the Commission has accepted the view of generic companies that, in their words, certain patents in the pharmaceutical industry are

²¹ Preliminary Report, at para. 4.

²² Preliminary Report, at para. 368.

²³ Preliminary Report, at para. 371.

²⁴ Preliminary Report, at para. 376.

²⁵ Preliminary Report, at para. 410.

²⁶ Preliminary Report, at para. 392.

²⁷ Preliminary Report, at para. 393.

“weak” or “lack innovation”. This is inconsistent with the tests under the EPC that innovator companies must satisfy before patents are granted.

- Notwithstanding the comments above, if the Commission concludes that innovator companies do regularly seek and obtain patents that should not be granted under existing intellectual property law principles, then a competition regulator is not well-placed to police this sort of conduct as the task is primarily an analysis of the underlying patents. Generic companies have the technical expertise, patent litigation experience, and financial incentives to monitor and oppose patents that should not have been granted. Thus, they already do so, and can be expected to continue to do so in the future.

Each of these points is discussed in more detail below.

A. Recognition And Enforcement Of Intellectual Property Rights Lies With Individual Member States

36. According to the consistent case law of the European Court of Justice (ECJ), as reflected, for example, in its judgment in *Magill*:

*“in the absence of Community standardization or harmonization of laws, determination of the conditions and procedures for granting protection of an intellectual property right is a matter for national rules.”*²⁸

37. In particular, the existence and validity of patents remains the prerogative, and falls within the exclusive jurisdiction, of individual E.U. Member States. As the ECJ has consistently determined, *“the national rules relating to the protection of industrial property have not yet been unified within the Community”* and *“the existence of patent rights is at present a matter solely of national law”*.²⁹

38. The Commission recognizes this position in the Preliminary Report, which states that:

“National courts therefore remain the ultimate arbiters of the validity of a patent in their territory. This means that any legal action needed to enforce or to

²⁸ Joined Cases C-241/91 P and C-242/91 P, [1995] ECR I-743, at para. 49. See also *Keurkoop BV v Nancy Kean Gifts BV*, Case 144/81, [1982] ECR 2853, at para. 18. In *Thetford Corporation v Fiamma SpA*, Case 35/87, [1988] ECR 3585, the plaintiff tried to distinguish *Keurkoop* on the basis that the relevant intellectual property rights at issue were patents, rather than designs (which had been the subject of the *Keurkoop* decision). The plaintiff argued that there was a higher degree of harmonization of national legislation in respect of patents. The Court did not accept this argument (at para. 14), as no harmonization of the patent legislation of Member States has yet been effected by virtue of measures of Community law.

²⁹ *Parke, Davies v Probel*, Case 24/67, [1968] ECR 55, at page 72, and most recently *Merck Genericos*, Case C-431/05, judgment of September 11, 2007 (not yet reported), where the ECJ stated that “[t]he fact is that the Community has not yet exercised its powers in the sphere of patents or that, at the very least, at internal level, that exercise has not to date been of sufficient importance to lead to the conclusion that, as matters now stand, that sphere falls within the scope of Community law” (at para. 46).

invalidate a patent or any action for a declaratory ruling of non-infringement, has to be brought before the national courts of each country concerned."³⁰

39. However, Lundbeck considers that comments in the Preliminary Report about matters that the Commission describes as "weak patents" and "patent clusters" are inconsistent with the principle that it is not for the Commission (or any other Community institution) to question the legitimacy of intellectual property protection lawfully granted by a Member State in any specific case.³¹ Provided that the requirements of the EPC referred to below are met, Member States are free to grant patents to innovator companies in respect of whichever inventions they wish, and can grant as many patents to a company as the relevant patent office considers satisfy the necessary tests. Lundbeck respectfully submits that any attempt by the Commission to place limits on this exclusive jurisdiction is inconsistent with EC law.

B. Lawfully Granted Intellectual Property Rights Must Be Presumed Valid

40. As noted in the Preliminary Report, Article 52(1) of the EPC provides that a patent will be granted if: (1) the invention is new; (2) the invention involves an inventive step; and (3) the invention is susceptible to industrial application.³² In addition, pursuant to Article 83 of the EPC, a patent will be granted only if the application discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. It follows that the holder of a patent granted in accordance with the requirements of the EPC should be entitled to enforce that patent as it sees fit, on the basis that it is a valid property right.
41. Further, the underlying objective of all patent systems is to allow companies to prevent (or "exclude") identical copies of their products during the complete patent protected period. In doing so, patents reflect the public policy judgment that allowing a limited period of exclusivity in respect of the invention revealed in the patent balances the public benefits of innovation against the public benefits inherent in competition between parties commercializing the invention. In Lundbeck's view, terminology such as "solely to exclude competition"³³ only confuses the discussion. (Also, this public policy judgment is not unique to the pharmaceutical industry, so any policies that the Commission adopts that alter this balance will have broad repercussions on other industries in which intellectual property creates important incentives for investment.)
42. While it is true that the exercise of national intellectual property rights may in limited circumstances fall within Articles 81 and/or 82 of the EC Treaty, Lundbeck considers that simply applying for a patent in accordance with national patent requirements is not an exercise of the relevant intellectual property right and, in the absence of fraud, cannot be unlawful.

³⁰ Preliminary Report, at para. 241.

³¹ See, also, the ECJ decision in *Sirena v Eda*, Case 40-70 [1971] ECR 69, which has been consistently applied in EC case law.

³² Preliminary Report, at para. 218.

³³ See, for example, Preliminary Report, at paras. 371 and 394.

43. It must also follow that obtaining even a large number of patents (*i.e.*, a “patent cluster”) is not anti-competitive, because the EPC requirements must still be met in relation to each patent application. Indeed, filing patents claiming incremental innovations related to existing products is a common practice not only among innovators, but also among generic firms. Further, there are many companies in other industries that obtain significantly more patents than pharmaceutical companies do. Importantly, however, Lundbeck notes that it is not possible for one patent (or even a combination of many patents) to extend the protection period of an earlier patent, because no patent can issue for an invention that has already been patented and therefore constitutes part of the prior art.
44. In any event, it would not be feasible to articulate the point at which a series of patents becomes a “patent cluster” or “patent thicket”. Any attempt by the Commission to set a level at which a number of different patents becomes a “patent cluster” will necessarily be arbitrary, and is therefore unlikely to promote the Commission’s objective of supporting innovation in the pharmaceutical sector. Instead, it would inevitably chill the prospect of ongoing innovation by innovators, who are unlikely to undertake additional R&D activities on a particular product if they believe they will not be able to patent their discoveries and new inventions in the future.
45. Further, there is nothing in European patent law to suggest that some types of lawfully granted patents should be viewed, in the generic firms’ words, as inherently “weak” or somehow less valid than others. Patents do not fall on a legal spectrum; rather, they are subject to a binary test that finds them either valid or invalid (and infringed or not infringed) under applicable Member State law. In particular, innovator companies are equally entitled to apply for patents for new processes, formulations or other aspects of a particular molecule, as they are to seek a patent for a new molecule that they have discovered. In Lundbeck’s view, an innovator company that invents a number of different processes or formulations in respect of a new medicine should be entitled to patent each one of those, and to protect its invention from being copied by a third party during the period of exclusivity conferred by each patent. In some circumstances, a new process for producing an active ingredient may be almost as important to an innovator company as the invention of the ingredient itself, and if the patent is valid, there is no legal basis to consider it a second-rate innovation.
46. As regards the timing of patent applications, the existence of patent protection provides a strong incentive for companies to seek constant improvements to their products and, in particular, to their most valuable or “blockbuster” products. In Lundbeck’s view, the “*clear trend...for companies to file significant numbers of patent applications well after the first product launch, in particular immediately before or after the primary patent in the portfolio expires*”³⁴ is simply evidence that innovator companies continue to research, test, develop and improve their products well after they have been launched for the first time. This ultimately benefits patients, who obtain access to a wider and more effective range of treatment options.

³⁴ Preliminary Report, at para. 359.

47. Lundbeck also notes that the Community courts have taken the position that the active pursuit of patent portfolios - even extensive portfolios - is not unlawful.³⁵ In addition, the Court of First Instance (“CFI”) made it clear in the *Microsoft* judgment that for the purpose of applying competition law, intellectual property rights (including patent rights) must be presumed to be valid:

*“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.”*³⁶

48. If, contrary to the position outlined above, the Commission takes the view that obtaining (or seeking to obtain) particular types of patents, or a “patent cluster”, can be of itself anti-competitive, then the Commission will need to provide clear guidance for innovator companies on these issues. Lundbeck respectfully submits that any such position would not be sustainable.

C. Generics Are Competent Challengers Of Patents In The European Union

49. Notwithstanding the comments above, if, following the Pharma Inquiry, the Commission concludes that innovator companies do seek patents that are objectively baseless, or are solely intended for a purpose other than protecting a new innovation from being copied by an identical product, then Lundbeck’s respectful opinion is that the Commission (or any other competition regulator) is not best placed to monitor and assess such conduct.
50. There are numerous generic companies operating in Europe, each of which has a strong incentive to police patents alleged to be invalid, in light of the significant profits that can be made by marketing generic versions of branded products. Many of these generic companies are well-financed and experienced in litigation, patent law and the relevant technology. The significant turnover of certain generic companies is highlighted in Table 5 on page 40 in the Preliminary Report. In addition, as noted in the Preliminary Report, not only do larger generic companies have the financial resources for lengthy litigation, but in fact some of them reserve a significant part of their overall budget for litigation and damages.³⁷
51. The fact that generic companies are better placed than a competition regulator to identify and attack patents alleged to be invalid - and that they already perform this function efficiently and effectively today - is also evidenced by the number of

³⁵ See, for example, *Tetra Pak International SA v Commission*, Case T-83/91, [1994] ECR II-755, at para. 242.

³⁶ *Microsoft v Commission*, Case T-201/04, [2007] ECR II-3601, at para. 695. See, also, *Windsurfing v Commission*, Case 193/83, [1986] ECR 611, para. 30, where the ECJ held that the scope of the relevant patent must be determined only on the basis of the wording of the patent claim accepted by the patent office, and the interpretative rulings given by the courts and authorities of the relevant country.

³⁷ Preliminary Report, at para. 431.

opposition procedures by generic companies,³⁸ and the finding that there were, on average, at least two generic companies opposing the relevant patent in each of those procedures.³⁹

52. Finally, Lundbeck notes that if, as in the example posited by the Commission in paragraph 33 above, a generic company has managed to “*invalidate the base patent*” prior to its expiry, and it believes that the remaining “*secondary patents*” are also invalid or not infringed, then there is nothing in European patent law to stop the generic company from entering the market at risk. Conversely, if the generic company considers that there is a risk of infringing a valid secondary patent if it enters with a generic product, then that suggests the innovator company is entitled to rely on that patent (as the patent system permits it to do), even if the effect is to “delay generic entry” in respect of the patented product.

D. Potential Exception For Cases Of Fraud, Or Objectively And Subjectively Baseless Patents

53. Lundbeck notes that it is established law in the United States that the validity of a patent is generally not examined in assessing an antitrust claim, because a patent is presumed to be valid by statute. That presumption of validity applies except in extreme cases of fraud on the patent office.⁴⁰ For example, if an innovator were to obtain a patent by fraud and then enforce that patent, and in doing so maintain a monopoly over a relevant antitrust market, that conduct would likely be judged to violate the U.S. antitrust laws under the principles that the U.S. Supreme Court set forth in *Walker Process Equipment v. Food Machinery & Chemical Corporation*.⁴¹ To establish such a *Walker Process* claim, an antitrust plaintiff must prove as a threshold matter that the patent holder: (1) knowingly and willingly made a fraudulent omission or representation to the government during the patent prosecution; (2) the patent holder had the clear intent to deceive the examiner; and (3) the representation or omission was the proximate cause of the issuance of the patent.⁴²

³⁸ See, for example, Preliminary Report, at para. 563.

³⁹ Preliminary Report, at para. 563.

⁴⁰ See, for example, *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008).

⁴¹ 382 U.S. 172 (1965).

⁴² See *In re Remeron Antitrust Litig.*, 335 F.Supp.2d 522, 528 (D.N.J. 2004) (citing *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1364 (Fed. Cir. 1998)). The U.S. antitrust case law regarding the listing of patents in the so-called “Orange Book” should not be confused with the law governing patent applications as possible antitrust violations. U.S. patents obtained by innovators are subsequently notified to the U.S. Food and Drug Administration (“FDA”) for listing in the “Orange Book”. Contrary to the patent application process in both Europe and the United States, the government’s role in the Orange Book listing is more of a ministerial act, and thus the standard for antitrust liability is somewhat lower for Orange Book listings than for patent applications. Moreover, even Orange Book listings generally cannot give rise to antitrust liability, except where there is no reasonable basis for the listing. See, e.g., *Organon Inc. v. Mylan Pharmaceuticals*, 293 F. Supp. 2d 453, 459-60 (D.N.J. 2003); *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 376 (S.D.N.Y. 2002) (concluding that patent holder’s listing could be considered a “sham” because plaintiffs could demonstrate that the listing was objectively baseless).

54. Lundbeck accepts that it may be appropriate to apply principles similar to the U.S. “fraud on the patent office” principle in Europe, so that a company may be considered to have acted anti-competitively where it has obtained a patent by means of fraud, and has used that patent to exclude or restrict competition. As with any fraud case, there would need to be an extremely high burden of proof imposed on the party alleging the fraud, and there would also need to be a requirement that the relevant patent office relied in some way on the alleged fraud in granting the patent. Lundbeck expects that cases of this sort would be extremely rare in the European pharmaceutical industry.
55. If, however, the Commission also wishes to establish a test to determine whether strategic patenting may infringe competition laws even short of fraud, then Lundbeck considers that the appropriate test must take into account both the objective and subjective circumstances surrounding the patent application(s).
56. At a minimum, the standard should be that the patent application was a sham, the establishment of which would include two elements:
 - On an objective view, the innovator’s application was baseless (*i.e.*, a reasonable person would have known that it had no reasonable basis for filing the patent, which was clearly invalid); and
 - Subjectively, the innovator knew that its patent application was without any merit, but it filed the application nonetheless.
57. Lundbeck wishes to emphasise that, other than a purpose to deceive (or to knowingly file a patent without any merit), the purpose behind the innovator’s application should not be taken into account in any test for unlawful patenting. This is because an intention to obtain a patent for the purpose of “blocking generic entry” or “excluding competition” (in the Commission’s terminology) is equally consistent with obtaining a patent lawfully as with any anti-competitive conduct. To incorporate terminology of that sort into principles used to assess patenting strategies will cause unnecessary confusion and legal uncertainty, which will inevitably require significant amounts of litigation to resolve.

IV. PATENT LITIGATION AND ENFORCEMENT

58. Lundbeck fully agrees with the observations in the Preliminary Report that:

*“Patents are proprietary, exclusive rights and enforcing one’s patents against parties infringing them is a legitimate procedural dimension of the material right granted to the patent holder.”*⁴³

And that:

*“[E]nforcing patent rights as such is not objectionable. On the contrary, companies which benefit from patent protection are entitled to enforce their patent rights.”*⁴⁴

59. However, the Preliminary Report goes on to say that enforcing patent rights “*may be problematic under specific circumstances*”.⁴⁵

60. Lundbeck considers that the Commission’s concerns in this respect are misplaced, and that EC competition law should not attempt to regulate the enforcement of patents against generic competitors in any but the most exceptional circumstances. Lundbeck’s reasons for this are as follows.

- As outlined in the *ITT Promedia* judgment, access to the courts is a fundamental right that should be circumscribed in only exceptional circumstances.⁴⁶
- Thus, the test for establishing that litigation is “vexatious” or a “sham” is and should remain strict. To the extent that the Commission contemplates a lower threshold for unlawful patent litigation than the *ITT Promedia* test, Lundbeck submits that there is no logical point at which that threshold can be set, and any attempt to do so will operate as a significant restriction on innovators’ access to justice. Nor is there is any reason to treat the pharmaceutical sector differently to other industries in this respect.
- Limiting the ability of innovator companies to enforce their patent rights against generics would have the same effect as requiring those companies to license their rights to the generics to enable them to produce copies. It is well-established that Article 82 of the EC Treaty only applies to a refusal to license intellectual property rights if that refusal prevents the emergence of a new product, or limits technological development more generally. By definition, neither of those tests is met in the case of generic versions of a branded medicine.
- As noted in Section V, the Commission has stated - in the context of patent settlement agreements - that there are more similarities than differences in respect of

⁴³ Preliminary Report, at para. 422.

⁴⁴ Preliminary Report, at para. 433.

⁴⁵ Preliminary Report, at para. 433.

⁴⁶ *ITT Promedia NV v Commission*, Case T-111/96, [1998] ECR 11-2937, at paras. 60-61.

the U.S. regulatory regime and the framework in Europe. The Commission may therefore be aware of certain litigation tactics that, in conjunction with the regulatory regime in place in the United States, have been alleged to delay generic competition, and may be concerned that similar tactics could be used in the E.U. to do so as well. In Lundbeck's view, however, the key differences between the regulatory regimes in the United States and the E.U. make it difficult to draw meaningful comparisons regarding the alleged activities in these two jurisdictions.

Each of these issues is discussed in more detail below.

A. Access To The Courts Is A Fundamental Right

61. In the *ITT Promedia* judgment, the CFI made it clear that access to the courts is a fundamental right that can only be circumscribed in exceptional circumstances.⁴⁷ Following this case, the test for vexatious litigation giving rise to such an exception is well-established. Specifically, a claim in litigation is lawful unless it is made by a dominant company in a situation where: (1) it cannot reasonably be considered to be an attempt to assert the right of the undertaking concerned, and can therefore only serve to harass the opposing party; and (2) it is part of a plan to eliminate competition.⁴⁸ To constitute abuse, the litigation proceedings must be, on an objective view, "manifestly unfounded".
62. The threshold that must be met for a finding of vexatious litigation is rightly a high one, and Lundbeck considers that there is no justification for applying a lower standard in cases involving the pharmaceutical sector. Lundbeck notes, however, that the application of the second limb of the test in *ITT Promedia* presents certain difficulties in cases involving intellectual property rights (which *ITT Promedia* did not). This is because, as noted above, obtaining and enforcing intellectual property rights is always done for the purpose of excluding competition to the extent permitted by the particular intellectual property right. It follows that, by definition, litigation to enforce patent rights will always be part of a "plan to eliminate competition", within the scope of the patent.

B. Potential Exception For Cases Of Objectively and Subjectively Baseless Litigation

63. If the Commission therefore wishes to establish a test for assessing whether patent litigation by innovator companies is vexatious, Lundbeck's view is that the appropriate standard should be consistent with that described in paragraph 56 above in respect of patent strategies. Absent a showing that the patent was obtained through fraud, it should therefore be necessary to establish that:
 - On an objective view, the innovator's case was baseless (either because the relevant patent was clearly invalid, or the generic company's conduct clearly did not infringe the patent); and

⁴⁷ *ITT Promedia NV v Commission*, Case T-111/96, [1998] ECR II-2937, at para. 60.

⁴⁸ *Ibid*, at paras. 60-61.

- Subjectively, the innovator knew that its case was without any merit, but it pursued the proceedings nonetheless.

Again, for the reasons outlined in paragraph 62 above, Lundbeck considers that any intention by the innovator to exclude or restrict competition should not be included in the test for vexatious litigation. Such intention would be equally consistent with the lawful enforcement of valid patent rights as with anti-competitive conduct.

64. Lundbeck expects that this strict test for vexatious litigation will be satisfied in only exceptional circumstances. The complex nature of patent law – particularly in the pharmaceutical industry – means it will be a very rare case indeed where a company in the E.U. will bring proceedings to enforce a granted patent that are considered manifestly unfounded on an objective view of the circumstances. Short of these situations, Lundbeck respectfully submits that competition law should have little role to play in limiting access by pharmaceutical companies to the courts. Otherwise, the Commission will risk creating significant uncertainty about the value of patent rights, and would decrease the incentive for innovators to invest in the development of intellectual property rights that they may be unable to protect from exploitation by third parties.
65. In Lundbeck's view, even if the Commission contemplates a lower threshold for unlawful patent litigation than that set out above, it would be impossible to articulate what that threshold should be. An innovator company must surely be permitted to pursue litigation where it has a 50% chance or better of succeeding. Equally, however, there are many cases where the innovator has a realistic prospect of success, but that chance is somewhere less than 50%. Lundbeck considers that attempts to identify the appropriate threshold at which it becomes unlawful to bring such a case would be purely arbitrary, illogical and unfair. This would also have the effect of depriving innovator companies of access to the courts in many instances, because they would be too scared to litigate to defend their patent rights, even where they have a good chance of prevailing. This risk would be heightened by the fact that the outcome of litigation is often unpredictable, with the prospect of success in patent litigation being even more difficult to predict than in most proceedings because of the complex nature of the legal and factual issues involved.
66. Lundbeck also notes that, according to the Preliminary Report, 46% of patent litigation proceedings in the E.U. between 2000 and 2007 were initiated by generic companies.⁴⁹ It was stated in the *ITT Promedia* judgment that if Belgacom's actions were really part of a deliberate strategy to eliminate competition, it would not have waited for Promedia to institute proceedings before submitting a counterclaim.⁵⁰ Lundbeck considers that this analysis applies equally to the many proceedings where the innovator company has simply responded to a claim by a generic company. Innovator firms must be entitled to defend themselves and file appropriate counterclaims when sued.

⁴⁹ Preliminary Report, at para. 468.

⁵⁰ *ITT Promedia NV v Commission*, Case T-111/96, [1998] ECR II-2937, at para. 34.

67. Finally, Lundbeck observes that the position that access to the courts should not be curtailed other than in exceptional circumstances is consistent with the approach of the U.S. courts to this issue and, in particular, the need to identify what constitutes “baseless” litigation as opposed to strategically motivated and presumably not baseless litigation. The relevant U.S. case law on this issue is briefly summarized below for the Commission’s reference.
68. The U.S. Supreme Court has recognized the right, under the freedom of petition clause of the First Amendment to the U.S. Constitution, for parties to pursue legal redress in court, including through patent infringement litigation. This immunity is generally referred to as *Noerr-Pennington* immunity and is invoked as a defence to antitrust claims based on patent prosecution and infringement litigation.⁵¹
69. Though broad in conception, *Noerr-Pennington* immunity is not unlimited. In particular, where the litigation is a “sham”, there is no immunity. Sham litigation generally involves the assertion of patents known to be invalid (although not necessarily obtained by fraud) or not infringed. This can amount to an antitrust violation in the United States because, among other things, the mere initiation of such litigation may automatically stay FDA marketing approval (discussed in more detail below). Whether a particular patent infringement suit amounts to “sham” litigation depends on whether the initiating litigant could have reasonably expected success on the merits and whether the litigant subjectively filed the suit to harm its competitor (through use of the process of litigation – rather than through a genuine attempt to obtain the benefits of a successful outcome of the litigation).⁵²
70. Of course, actual success on the merits generally precludes a claim of “sham” litigation.⁵³ Favourable outcomes short of outright success likewise weigh against such a claim. For example, in *In re Terazosin Hydrochloride Antitrust Litigation*, the Southern District of Florida found that the patent holders’ voluntary dismissal of its patent prosecution did not support a finding of “sham” litigation where the opposing parties made reasonable concessions before the patent holder dismissed the suit.⁵⁴ In cases where the patent holder is unsuccessful, the court must still analyze whether the suit had any reasonable basis before finding that the litigation was a “sham”, and must “resist the understandable temptation to engage in post hoc reasoning by concluding” that an ultimately unsuccessful “action must have been unreasonable or without foundation”.⁵⁵ In analyzing whether litigation was a sham, the court will consider

⁵¹ This immunity is named after two cases, *Eastern Railroad Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127 (1961) and *United Mine Workers v. Pennington*, 381 U.S. 657 (1965).

⁵² *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49, 60 (1993).

⁵³ *Ibid.*, at page 61 n.5 (“A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham.”); see also *Andrx Pharms, Inc. v. Elan Corp. PLC*, 421 F.3d 1227, 1234 (11th Cir. 2005) (finding that because Andrx prevailed in two courts, its patent infringement suits could not have been “objectively baseless”).

⁵⁴ *In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1357-81 (S.D. Fla. 2004).

⁵⁵ *Professional Real Estate Investors*, 508 U.S. at 61 n.5 (internal citations omitted).

whether the claims survived summary judgment,⁵⁶ raised novel arguments,⁵⁷ or the litigant survived a motion for attorneys' fees or sanctions.⁵⁸

71. Despite these relatively high hurdles, Lundbeck notes that there are examples of sham litigation claims succeeding. For example, in *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.*, the District of Delaware allowed a sham litigation claim to go forward where an innovator's suit was disposed of by summary judgment motion and where the patent holder could not demonstrate that it had a reasonable expectation of success on the merits.⁵⁹ Similarly, "sham" litigation may be found where litigants unjustifiably use excessive procedural devices merely to delay (rather than to succeed on the merits) because such manoeuvres tend to bar competitors from a meaningful adjudicatory process.⁶⁰

C. Innovators Should Not Be Required By Default To License Their Intellectual Property Rights To Competitors

72. Lundbeck's view is that the use of EC competition law to regulate the ability of innovators to litigate patent rights would also be inconsistent with established precedent regarding compulsory licensing.
73. It is clear that Article 82 of the EC Treaty can only apply to a refusal to license intellectual property rights if that refusal prevents the emergence of a new product, or limits technological development more generally.⁶¹ Preventing an innovator company from enforcing its patent against a generic company during the exclusivity period would have the same effect as requiring that innovator to license its invention, notwithstanding the fact that the generic would neither be introducing a new product to the market nor furthering innovation. By definition, generic products are only copies of the original branded product. Moreover, in the narrow circumstances where mandatory licensing is required, the licensor is entitled to compensation.⁶²
74. Lundbeck is unable to see any justification for extending the law in relation to compulsory licensing to circumstances in which generic companies infringe the patent

⁵⁶ See, e.g., *Twin City Bakery Workers and Welfare Fund v. Astra Akeitbolag*, 207 F. Supp. 2d 221, 223-24 (S.D.N.Y. 2002); *Harris v. Custom Builders, Inc. v. Hoffmeyer*, 834 F. Supp. 256, 261-62 (N.D. Ill. 1993) (noting that by surviving summary judgment, a litigant could have reasonably concluded that it had "some chance of success on the merits").

⁵⁷ See, e.g., *Organon Inc. v. Mylan Pharms., Inc.*, 293 F. Supp. 2d 453, 461-62 (D. N.J. 2003).

⁵⁸ *In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1357-81 (S.D. Fla. 2004).

⁵⁹ 432 F. Supp. 2d 408, 426 (D. Del. 2006).

⁶⁰ See *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972).

⁶¹ *Magill v Commission*, Joined cases C-241/91 and C-242/91, [1995] ECR I-00743, at para 54; *IMS Health v Commission*, C-418/01, [2004] ECR I-05039, at para. 38; *Microsoft v Commission*, Case T-201/04, [2007] ECR II-3601, at paras. 643-659.

⁶² *Magill TV Guide* OJ [1989] L 78/43, at para. 27, confirmed in *Magill v Commission*, Joined cases C-241/91 and C-242/91, [1995] ECR I-00743, at para. 91; *Microsoft v Commission*, Case T-201/04, [2007] ECR II-3601, at paras. 808-810.

rights of innovators (particularly in light of the fact that those patent rights must be presumed to be valid – see Section III.B above).

D. Concerns Regarding Litigation By Innovators In The United States Have Limited Relevance For Europe

75. Regarding the U.S. regulatory system, the Preliminary Report states that “[c]ommentators have considered that the processes implemented through the Hatch-Waxman Act give specific incentives to generic companies to challenge originator companies’ patents with less risk. This incentive might well influence the dynamics of litigation”.⁶³ In Lundbeck’s view, it is more accurate to say that the U.S. Hatch-Waxman Act encourages early litigation to resolve questions about the validity of patents. As the European system is so different, the alleged incentives and resulting behaviour in the United States should not influence the Commission’s findings in respect of litigation by innovators.
76. Lundbeck submits, therefore, that it is important for the Commission to consider certain important differences between the drug regulatory regimes in the United States and the E.U., which are significant for competition policy in this area. As discussed in greater detail below, the U.S. regulatory regime includes special protections for innovators. The U.S. regulatory regime also elevates the first company that challenges an innovator’s patent(s) on a particular drug above later challenges. As will be seen, these features of the U.S. regulatory regime – wholly absent in Europe – create a structure that has been at the core of the FTC’s concerns and enforcement activities in the pharmaceutical industry.

1. Overview Of The U.S. Regulatory Regime

77. As the Commission is aware, the Hatch-Waxman Act provides a framework by which generic manufacturers can obtain U.S. FDA marketing approval for such drugs. The key elements of that process are outlined below.
78. The Hatch-Waxman Act created a new type of application for marketing approval called an Abbreviated New Drug Application (“ANDA”). Through the ANDA process, a generic manufacturer can obtain FDA marketing approval simply by demonstrating that the active ingredient of the generic drug is the bioequivalent of the approved drug.⁶⁴
79. To address concerns about innovators’ intellectual property, while at the same time allowing generic manufacturers to undertake development work without interference from patent infringement claims, the Hatch-Waxman Act includes procedures to identify and address such intellectual property. In particular, the Hatch-Waxman Act requires innovators to identify relevant patents for each branded drug and, as part of the

⁶³ Preliminary Report, Annex to Chapter C.2.4, at para. 5.

⁶⁴ Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study 4* (2002).

ANDA process, requires generic manufacturers to certify one of the following with respect to the drug at issue:⁶⁵

- I. That the innovator has not filed any patent information with respect to the drug.
 - II. That any patents that the innovator has identified as applicable to the drug have already expired.
 - III. That such identified patents have not yet expired, but will expire on a particular date and approval is sought for after that date.
 - IV. That such identified patents are invalid or will not be infringed by the manufacture, use, or sale of the drug for which the ANDA is submitted.
80. When a generic manufacturer submits an ANDA under Paragraph IV, the generic manufacturer is required to notify the innovator of the patents at issue, and explain why the generic manufacturer contends that the patents are invalid or not infringed.⁶⁶ If the innovator brings an infringement action within 45 days of receiving such notice, the FDA is precluded from granting final marketing approval until 30 months have passed from the date that the innovator received notice of the Paragraph IV certification (unless the patent expires or a court determines that it is invalid or not infringed).⁶⁷
81. In addition to precluding the FDA from issuing final marketing approval for a generic drug filed under a Paragraph IV certification, the Hatch-Waxman Act provides the first generic manufacturer to file an ANDA with a Paragraph IV certification for a particular drug with 180 days of “marketing exclusivity,” during which the FDA is precluded from granting approval to another generic manufacturer for the same drug. The purpose of this provision is to encourage generic companies to challenge innovators’ patents where appropriate.

2. Unique Competition Policy Issues Under the U.S. Regulatory Regime

82. Lundbeck does not agree with the comment in the Preliminary Report that “*it seems legitimate to conclude that there are more similarities than differences between the two systems*”.⁶⁸ In fact, the regulatory regime in the United States raises competition policy issues in respect of patent litigation, and also patent settlement agreements, that are unique to that regime and are not present in the E.U.

a. Automatic 30-Month Injunction For Innovators

83. The most significant feature of the U.S. regulatory scheme from a competition policy perspective is the Paragraph IV certification. Because U.S. law precludes the FDA

⁶⁵ 21 U.S.C. §355(j)(2)(A)(vii) (2004).

⁶⁶ Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study 7* (2002).

⁶⁷ 21 U.S.C. §355(j)(5)(B)(iii) (2004).

⁶⁸ Preliminary Report, at para. 661.

from granting final marketing approval to the generic product for 30 months from the time the innovator brings suit against a Paragraph IV generic (unless the suit is resolved sooner or the patent expires), an innovator has the ability, in effect, to obtain an *automatic* injunction against the generic product coming to market simply by filing a lawsuit. There are no comparable provisions in the E.U.

84. Given the value of an injunction against generic entry, innovators have the obvious incentive to bring patent infringement actions within the 45-day period. Not surprisingly, innovators have been accused of asserting patents without regard to their validity, enforceability, or applicability. Innovators have also been accused of seeking and obtaining patents of questionable merit to provide the grist for the 30-month injunction.
85. The lack of an automatic stay provision in the E.U. creates a very different environment. Without the prospect for an automatic injunction, innovators have little incentive to seek or enforce questionable patents. To the extent that an innovator tries to enforce such patents, the competitive consequences are likely to be nil. Rather than face an automatic injunction for 30 months as in the United States, a generic manufacturer that is the target of such an enforcement activity can simply ignore the patents and market the product. If the generic manufacturer is sued, it will be likely to prevail in litigation.

b. 180-Day Marketing Exclusivity For First Generic Filer

86. The other significant feature of the U.S. regulatory regime is the 180-day exclusivity period. As originally enacted, the first filer had complete control over that exclusivity, which would not begin to run until a final court order was issued or the generic came to market. Assuming no such order was issued, the first filer could prevent all generic entry by not coming to market (including as part of an agreement with an innovator). Later filers had no ability to obtain FDA marketing approval and enter in those circumstances.
87. Partially in response to the concerns raised by agreements between innovators and generic manufacturers, Congress included significant changes to the Hatch-Waxman regulatory scheme in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "2003 Medicare Act").⁶⁹ Those changes:
 - eliminated multiple 30-month stays for the same drug for later-issued patents;
 - gave generic manufacturers the right to file declaratory judgment actions against the patent holder⁷⁰ and to file a counterclaim to "de-list" a patent;

⁶⁹ Pub. L. No. 108-173, 117 Stat. 2066 (2003).

⁷⁰ To avoid such actions, innovators often declined to sue later-filing generics or even affirmatively committed not to sue. This led some U.S. courts to decline jurisdiction, concluding that there was no live controversy between the parties. Later decisions of the Supreme Court and the U.S. Court of Appeals for the Federal Circuit, however, have clarified that jurisdiction essentially always exists in these circumstances. See *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007); *Caraco Pharm. Labs.*,

- provided for the forfeiture of the 180-day exclusivity period at certain times, including the later of (a) the first filer’s failing to market its product within specified time periods after the approval of the ANDA, and (b) the date of a court finding of invalidity or non-infringement; and
 - required innovators and generic companies that enter into agreements regarding drugs for which the generic company submitted a Paragraph IV certification (and certain other agreements) to submit those agreements to the FTC and the Department of Justice (“DOJ”).
88. Even with those reforms, the FTC has argued that the 180-day exclusivity provision continues to allow the potential for a settlement between a brand-name company and a first generic filer to generate a bottleneck that prevents any generic competition, at least until such time as another generic company successfully challenges the innovator’s patents in court.⁷¹ The FTC maintains that further legislative changes are needed to address this issue.⁷²
89. In light of the differences in regulatory regimes, the Commission should not assume that the FTC’s views or enforcement actions in this area provide a useful guide to the Commission in assessing appropriate policies and priorities in the E.U. Even with the changes brought under the 2003 Medicare Act, the U.S. regulatory regime is said by some to encourage obtaining and enforcing invalid or inapplicable patents, with the automatic consequence – in the absence of rigorous antitrust enforcement – of delayed generic entry. No such regulatory incentives exist in the E.U.

Ltd. v. Forest Labs., Inc., 527 F.3d 1278 (Fed. Cir. 2008); *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330 (Fed. Cir. 2007). The Federal Circuit’s holding in *Caraco*, 527 F.2d at 1290-97, directly rejected the argument that an innovator could avoid a declaratory judgment action by refusing to bring a lawsuit against a later-filing generic.

⁷¹ See Prepared Statement of the Federal Trade Commission, before the Committee of the Judiciary of the United States Senate on *Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution* (Jan. 17, 2007), page 23.

⁷² *Ibid.*, at page 25 (recommending enactment of legislation to make innovator’s “submission of a covenant not to sue the generic applicant” and the “dismissal of a declaratory judgment action of non-infringement or invalidity for lack of a case or controversy, when brought by a generic application, ... forfeiture event[s] for the 180-day exclusivity period”) (available at http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf).

V. PATENT SETTLEMENT AGREEMENTS

90. As the Preliminary Report recognizes, “[patent settlement agreements] are...a generally accepted way of ending disputes, opposition procedures and litigation”, and “parties may prefer to discontinue the dispute or litigation because it proves to be costly and time-consuming, and might also be unpredictable in its outcome”.⁷³ Further, the Preliminary Report notes that “[p]harmaceutical companies in the EU see patent litigation cases as fact-intensive, legally complex, lengthy and costly”.⁷⁴
91. Just as access to the courts to determine disputes between parties is a fundamental right in the E.U. (see Section IV above), Lundbeck considers that the right of parties to settle or avoid such disputes on terms negotiated between themselves is equally important, particularly in light of the resulting potential cost-savings. It is often a commercially rational approach for companies to enter into patent settlement agreements, and there are important public policy reasons why the Commission should not use competition law to restrict such conduct. This is true whether litigation is ongoing or genuinely threatened. Requiring parties to litigate because of the risk that a settlement will be considered anti-competitive will waste money, time and other resources that would be better utilized for further R&D activities.
92. The U.S. Judge Richard Posner, a leading antitrust expert, recognised this risk in *Asahi Glass v Pentech Pharmaceuticals*, where he criticized the treatment of “reverse payment” settlements as *per se* illegal, stating that:
- “Whether it is a sound theory may be doubted, since if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent. A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger’s settlement options should he be sued for infringement, and so might well be thought anticompetitive.”*⁷⁵
93. Notwithstanding, if the Commission considers that patent settlement agreements can, in certain circumstances, be anticompetitive, then the Commission should outline a principled approach to assessing whether a particular agreement is incompatible with EC competition law. The key principles that, in Lundbeck’s view, would be most relevant to such assessment are discussed in Subsection A below. Lundbeck notes that some of these principles may differ from those the Commission uses to categorise settlement agreements in the Preliminary Report.⁷⁶
94. Further, regarding the discussion in the Preliminary Report (at paragraphs 650 to 661) of enforcement practice in the United States, Subsection B below provides information

⁷³ Preliminary Report, at para. 578.

⁷⁴ Preliminary Report, at para. 589.

⁷⁵ *Asahi Glass Co, Ltd v Pentech Pharmaceuticals, Inc.*, 289 F.Supp.2d 986, 994 (N.D.Ill.2003).

⁷⁶ In particular, Lundbeck refers to the categorisation of settlement agreements into Categories A, B.I and B.II, as outlined in Figure 98 on page 227 of the Preliminary Report.

on how reverse payment litigation, in which the FTC and private parties have almost uniformly failed to establish liability, has proceeded.

A. Principles For Assessing Patent Settlement Agreements

1. Presumed Validity Of Patent

95. Patent settlement agreements in the pharmaceutical sector must be assessed in the context of a presumptively valid patent which permits an innovator company to exclude generics from marketing identical versions of a product for the period of exclusivity granted by the patent.
96. Lundbeck respectfully suggests, therefore, that great care should be taken before condemning as anti-competitive any settlement agreement that does not maintain the exclusivity of the branded product beyond the expiry of the relevant patent. In any event, any apparent restriction on competition arising from such an agreement must be measured relative to the preclusive effect of the patent itself on entry. The relevant question, in Lundbeck's view and in accordance with the large majority of U.S. courts that have considered the issue, as outlined in Subsection B below, is whether the alleged exclusionary effects of the agreement exceed the scope of the patent's protection.
97. For example, the Preliminary Report notes that a settlement agreement may contain a clause stating that the generic company recognizes the validity of the innovator company's patent(s), and agrees to refrain from entering the market until the patent(s) have expired.⁷⁷ The Preliminary Report categorizes such agreements as limiting generic entry. Lundbeck agrees that the effect of such a provision is to prevent the generic company from entering the relevant markets but submits that, of itself, such provision cannot be considered anticompetitive because it does no more than recognize the rights that the innovator company has under the patents in any event. The outcome does not differ from that which would have resulted if the companies had gone to trial and the innovator had won.
98. In Lundbeck's view, the appropriate principle for the Commission to apply in this area is that an agreement that settles existing or genuinely threatened patent litigation is not unlawful, provided that:
 - the underlying litigation was not vexatious (under the test outlined in paragraph 63 above); and
 - the settlement agreement does not exclude or restrict competition to a greater extent than would be possible under the relevant patents, in the event that the innovator company was successful at trial.
99. It follows that a fact-specific analysis of the merits of the underlying patent is necessary before antitrust liability should be considered regarding particular so-called reverse payment agreements. Unless there was little or no prospect that the innovator would

⁷⁷ Preliminary Report, Box: Categorisation criteria – patent settlement agreements, at page 226.

have prevailed in the proceedings that gave rise to the settlement agreement, a reverse payment agreement that does not extend the scope of the patent should not be challenged. Lundbeck expects that such fact patterns will emerge only in very rare cases, which is appropriate as the validity of intellectual property rights lawfully granted by E.U. Member States is being called into question.

2. Nature Of Apparent Restriction

100. Lundbeck considers that any principles used to assess the compatibility of patent settlement agreements with EC competition law must address the question of what types of “restrictions” on the conduct of generic companies may be anti-competitive.
101. In particular, the Preliminary Report appears to adopt the position that a settlement agreement under which the innovator company grants a license to the generic company could constitute a limit on generic entry.⁷⁸ Lundbeck respectfully disagrees with this position, and requests that the Commission clearly identify the circumstances in which granting a license to a generic company can ever operate as a restriction on that company’s freedom to enter the market.
102. In light of the fact that a patent presumptively permits an innovator company to prevent generic copies of its product or process for the duration of the patent, Lundbeck considers that in general licenses have a pro-competitive effect. A license permits a generic company to enter a market in circumstances where it would not otherwise have been permitted to do so, or where there would at least be a risk in doing so. In effect, this expands the generic company’s freedom to enter, rather than restricting it (assuming that there is no agreement by the generic not to enter other than through the license). This is the case notwithstanding the fact that a license will inevitably contain certain limits that are inherent to any contractual right – all licenses must be limited in scope in some way, whether it be by reference to countries, products or time periods.
103. By way of example, Box 1 on page 237 of the Preliminary Report concerns a settlement agreement under which the innovator company grants the generic a royalty-free license to its products, effective from a certain date. On the basis that the innovator company would have the right to take steps to prevent the generic company from using the patent(s) in the relevant countries in any event, the license actually permits the generic to market products in circumstances where it would not otherwise have been able to do so, and it is therefore an expansion – rather than a restriction – of the generic company’s rights.
104. The fact that the license in the above example is royalty-free further enhances the ability of the generic company to enter the market, because it decreases the costs of entry faced by the generic. Lundbeck believes that the grant of a royalty-free license to a generic company cannot be considered incompatible with EC competition law. Further, royalty-free licenses that are non-exclusive are even more pro-competitive, because they leave open the possibility of additional competition in the relevant market in the future.

⁷⁸ Preliminary Report, Box: Categorisation criteria – patent settlement agreements, at page 226.

105. Another type of “restriction” on generic conduct discussed in the Preliminary Report is the settlement agreements that provide for the generic company to become a distributor of the innovator’s products, or to source its supplies of the relevant active ingredient from the innovator company. For the reasons outlined above, Lundbeck considers that such agreements are also pro-competitive. They enable generic companies to enter the market, and provide patients with an alternative source of the relevant product, and may facilitate entry at an earlier stage than the generic firm would otherwise have achieved.

3. Duration Of Apparent Restriction

106. Lundbeck considers that a relevant factor in assessing the compatibility of patent settlement agreements with EC competition law is the duration of any alleged restriction on generic competition, and the rationale for the duration that is agreed between the parties. In Lundbeck’s view, the shorter the term of the agreement, the less likely it is to give rise to any competitive concerns.
107. In particular, the Preliminary Report includes examples of settlement agreements that maintain the *status quo* in a particular market or markets until issues of patent infringement and/or invalidity between the parties can be resolved by the courts. In Box 1 on page 235 of the Preliminary Report, the Commission refers to a settlement agreement under which the generic company agreed not to market its product in a Member State until judgment had been obtained in the infringement litigation between the parties. In exchange, the innovator company paid the generic a lump sum.
108. Lundbeck considers that agreements of this type are an efficient and commercially rational use of resources. In effect, the parties have chosen to enter into a mutually beneficial agreement with a certain outcome, rather than consume time and money pursuing interim injunction proceedings in court – in addition to the substantive infringement proceedings – whose outcome would be uncertain and result in inevitable risks for both parties. When considering that duplicative patent litigation often must proceed independently in multiple Member States’ courts, the efficiency of this approach is even clearer. As noted above, Judge Posner has observed that a generic firm would have less incentive to launch its products if it did not have such settlement options available, instead of being subject to duplicative interim injunction actions, as well as possible damage claims.
109. If the Commission were to adopt the view that settlement agreements of this sort (*i.e.*, short-term agreements to maintain the *status quo* in lieu of injunctive relief) are anti-competitive, that would have the effect of forcing innovator companies to pursue injunctive relief rather than concluding interim settlement agreements in the circumstances outlined above. In light of the Commission’s apparent concerns about the volume of patent litigation in the E.U.,⁷⁹ and the potential delays in obtaining final outcomes in litigation proceedings, Lundbeck would be surprised if the Commission intends this result.

⁷⁹ See, for example, Preliminary Report, at para. 471, where the Commission observed that patent litigation in the E.U. increased nearly fourfold between 2000 and 2007.

110. Lundbeck considers that the same considerations apply to settlement agreements where the parties agree to maintain the *status quo* pending the outcome of patent litigation between the innovator and a third party generic company, assuming that such litigation raises similar questions of infringement or invalidity as those between the parties to the agreement. Such agreements also have the effect of avoiding duplication of litigation and wasted litigation costs, as well as the risk of inconsistent outcomes in litigation (which the Commission has raised as a concern in the Preliminary Report⁸⁰). Again, this is particularly true where each generic firm may litigate with the innovator in several jurisdictions. Consolidating litigation in a single jurisdiction, and with a single generic firm, should increase incentives for generic entry, reduce litigation costs, and thus be beneficial to European patients.

4. Value Transfer To Generic Company

111. The transfer of value to the generic firm should not create a presumption that the agreement is anticompetitive. In Lundbeck's view, if the "restriction" on the generic company's conduct under a settlement agreement is not of itself anticompetitive, then the fact that an innovator company has transferred value in some form to the generic company does not change this position. The very nature of any contract is an exchange of value between two parties.

112. More particularly, a short-term agreement to obtain interim relief until the substantive issues can be addressed by the court avoids the risk to the innovator company that a later damages award will fail to compensate for the true harm caused by generic entry in violation of the innovator's lawful patent or patents.

113. Indeed, a payment to the generic firm under certain circumstances may merely reflect the strong bargaining leverage that a generic firm holds even if the innovator is very likely to prevail in the patent litigation. As a U.S. appellate court put it: "*Due to the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.*"⁸¹ Quite simply, during the brief period when litigation is occurring over injunctions, a generic firm may be able to inflict much more financial pain upon an innovator (whether it wins or loses) than it risks suffering itself during the same period. This creates a "hold-up" problem that may result in a transfer of value to the generic firm. This occurs as a result of the combination of several factors:

- First, reflecting the value of the originator's intellectual property, which is itself created through R&D investments, margins of innovators before generic entry are higher than margins of generic firms after generic entry. Thus, the loss of profits an innovator suffers per unit sold are higher than that of the generic.
- Second, even shortly after generic entry, the unit volume of sales may still be higher for the innovator for some period of time, which can further increase this disparity.

⁸⁰ See, for example, Preliminary Report, at paras. 535-536.

⁸¹ *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003).

- Third, one of the risks peculiar to innovator companies in the E.U. pharmaceutical sector is that entry by a generic company onto the market may trigger mandatory price reductions under the national rules of Member States on generic pricing. In most cases, when this occurs it is often very difficult or even impossible for the innovator company to restore the price to previous levels, even if it ultimately succeeds at trial and the generic competitor is removed from the market.⁸² When combined with the inevitable loss of market share that occurs upon generic entry, this can give rise to significant losses to the innovator that are often unquantifiable in the event that the innovator company ultimately prevails at trial on the issue of infringement. Thus, the length of time over which the innovator will suffer losses is longer than is the case for the generic firm.
- Fourth, in the case of thinly capitalized generic firms, it might be more difficult for an innovator to collect a judgment if it prevails than it would be for the generic firm to collect a judgment from an innovator firm. For a poorly capitalized generic firm, even a “long shot” generic entry (*i.e.*, low probability of success in litigation) can be economically rational if the assets it stands to lose are limited, thereby avoiding the risk of having to pay for the full damage it causes.

In sum, litigation can present greater risks to the innovator than to the generic firm. As a result, a settlement resulting in a payment to a generic firm can be economically rational for the innovator, even if the innovator believes it has a strong chance of prevailing in the litigation. In light of this distinct possibility, there is no basis for any sort of presumption against settlements in the “B.II.” category of the Preliminary Report.

114. There may also be other strong commercial reasons – that are not anticompetitive – why a particular transfer of value is required under a settlement agreement. For example, if an innovator and a generic company have entered into a short-term settlement agreement in lieu of an interim injunction, then the innovator may also agree to pay a sum of money to the generic company on the understanding that this sum will be full compensation for any loss incurred as a result of the agreement, in the event that the generic ultimately prevails in the substantive proceedings. This is no different than an undertaking to pay damages if unsuccessful in an interim injunction action.
115. Similarly, an innovator company may agree to acquire stock of the relevant product held by the generic company at the time of the agreement. This may simply be a practical safeguard for the innovator company to ensure compliance with the agreement, or may be required to compensate the generic firm in light of the potential expiration of its product.

⁸² For example, in France and Spain, the state may require that generic products entering the market do so at a specific discount to the formerly patented drug. This can be a single price cut for the first entrant or cumulative price cuts as later entrants also come to the market. See, for example, *Report for the DG Competition: Surveying, Assessing and Analyzing the Pharmaceutical Sector in the 25 EU Member States*, Österreichisches Bundesinstitut für Gesundheitswesen, July 2006, pp. 239-240 (France); *Factors Affecting Generic Entry in Europe*, CRA International, June 2008, Table 9 at p. 40 (Spain).

116. Lundbeck respectfully submits that the Commission must be careful to consider all potential rationales for provisions in patent settlement agreements before concluding that a value transfer to a generic company is somehow indicative of anti-competitive conduct. Otherwise, the Commission risks stifling benign and even pro-competitive behaviour going forward.

B. Litigation Regarding Reverse Payment Agreements In The United States

117. The Preliminary Report contains a brief summary of the enforcement action by the FTC, which has taken the view that some settlement agreements involve potentially anticompetitive arrangements. The Preliminary Report describes the FTC's "general policy line" as being that "*payments made by the originator company to the generic company are unlawful if they are combined with a restriction on the generic company from entering the market with its own product*".⁸³ Box 1 on page 243 of the Preliminary Report summarizes the FTC's allegations in the *Cephalon* case. The Report notes the FTC's failure to prevail in court in the *Schering-Plough* case.
118. The Preliminary Report also states that the DOJ "*supports the general view that patent settlements can amount to a violation of USA antitrust law*", although the DOJ considers that "*the mere presence of a payment from an originator company to the generic company is not sufficient to establish that the settlement is unlawful*".⁸⁴
119. The Commission is correct to identify the significant divergence of views among the two U.S. antitrust agencies under the Bush administration, and the failure of the FTC's litigation efforts in *Schering-Plough*.
120. In addition, Lundbeck submits that it is important to recognize that the FTC has not generally taken the position that reverse payment agreements amount to a *per se* violation of the U.S. antitrust laws. Although some private plaintiffs have sought to advance that argument, appellate courts in the United States have for the most part rejected it. Rather, with one exception, U.S. appellate courts have held that such arrangements do not violate the U.S. antitrust laws, except possibly in circumstances where they extend exclusivity beyond the scope of the patent. In addition, one U.S. appellate court has recently affirmed that, even if afforded *per se* treatment, such an agreement would not violate the U.S. antitrust laws unless it actually can be shown to have caused a delay in generic entry. The one U.S. court of appeals that did find that a reverse payment agreement is subject to *per se* illegality relied at least in part on the fact that the generic manufacturer at issue controlled the 180-day exclusivity period and had agreed not to transfer it to another generic manufacturer, thereby precluding the possibility of competition *by other generic firms as well* and, in effect, extending the exclusivity beyond the scope of the patent. As discussed in Subsection IV.D above, there is no comparable exclusivity provision in European regulatory regimes.

⁸³ Preliminary Report, at para. 652.

⁸⁴ Preliminary Report, at para. 653.

121. As to the cases that the FTC has litigated, the *Cephalon* case is in its infancy and there have been no substantive court rulings as to the merits of the FTC's position. But, as the Commission notes, the FTC lost its challenge to a reverse payment agreement in the factually similar *Schering-Plough* case.⁸⁵ In *Schering-Plough*, the FTC argued that the agreement violated the antitrust laws under the rule of reason. On appeal, the U.S. Court of Appeals for the Eleventh Circuit held that neither a *per se* nor a traditional rule of reason analysis was appropriate because a patent, by its nature, excludes competition and is therefore anticompetitive in the antitrust sense. The court instead held that "proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects". The court held that the agreement at issue, by potentially allowing entry before the expiration of the patent, did not exceed the patents' scope and that it therefore did not violate the U.S. antitrust laws.⁸⁶ In doing so, the court sharply criticized the argument that reverse payment settlement agreements are always or nearly always illegal:

*"We have said before, and we say it again, that the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the asymmetries [sic] of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement. An exception cannot lie, as the Commission might think, when the issue turns on validity ... as opposed to infringement. The effect is the same: a generic's entry into the market is delayed. What we must focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection. Here, we find that the agreements fell well within the protections of the... patent, and were therefore not illegal."*⁸⁷

122. The FTC sought to appeal the Eleventh Circuit's decision to the U.S. Supreme Court, and, in an extremely unusual turn of events, the Antitrust Division of the DOJ and the U.S. Solicitor General recommended that the Supreme Court decline to hear the appeal. The Court acceded to those recommendations and did not hear the appeal.
123. The Eleventh Circuit in *Schering-Plough* relied on an earlier decision of the same court in a case involving private parties called *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*⁸⁸ In *Valley Drug*, patent holder Abbott negotiated separate agreements with two generic companies, whereby both companies promised, among other things, not to sell any product containing the active ingredient of the patented medicine, until the patent expired, was found to be invalid, or until another company introduced a generic version of the drug. The Eleventh Circuit reversed the lower court's holding that the

⁸⁵ *Schering-Plough v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

⁸⁶ *Ibid*, at 1076.

⁸⁷ *Ibid*, at 1076-77 (citations and internal quotation marks omitted).

⁸⁸ 344 F.3d 1294 (11th Cir. 2003).

agreements were *per se* illegal under the U.S. antitrust laws, citing the exclusionary nature of the patent grant.⁸⁹

124. Similarly, the Second Circuit in *In re Tamoxifen Citrate Antitrust Litigation*,⁹⁰ also evaluated antitrust claims arising out of a reverse payment settlement agreement by considering the scope of exclusivity granted by the patent. During the patent infringement trial, the district court found Zeneca's patent to be invalid. On appeal, Zeneca and the generic company, Barr, reached a settlement whereby Barr received a \$21 million payment and received rights to market Zeneca-manufactured Tamoxifen. In accordance with the settlement agreement, Zeneca and Barr filed a joint motion to vacate the district court's judgment that the patent was invalid. Plaintiffs claimed that this settlement violated the antitrust laws. The Second Circuit found that an agreement that finally settles patent litigation is not illegal *per se* as long as the litigation is "neither a sham nor otherwise baseless". The court held that the antitrust analysis of reverse settlements should focus on whether the exclusionary effects of the agreement exceed the scope of the patent's protection.
125. The Federal Circuit, the U.S. court of appeal with special nationwide jurisdiction over appeals in patent cases, affirmatively upheld the legality of a reverse payment settlement in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*.⁹¹ In that case, patent holder Bayer and generic challenger Barr settled a Paragraph IV patent infringement suit. The settlement provided that Bayer would make a cash payment to Barr and that Barr would not challenge Bayer's patent on Cipro or market its generic version of the drug until six months before the patent expired. Purchasers of Cipro and certain advocacy groups filed antitrust actions challenging the settlement agreements.
126. In rejecting the antitrust claims, the Federal Circuit held that a patent holder is entitled to settle an infringement claim even though the settlement precludes the alleged infringer from challenging the validity of the patent and therefore has the potential to diminish competition. Echoing the Eleventh Circuit's holdings in *Schering-Plough and Valley Drug*, and the Second Circuit's holding in *Tamoxifen*, the court reasoned that because a patent is inherently anticompetitive in the sense that it excludes others from the patented invention, a settlement that does not restrain competition beyond the facial scope of the patent is not *per se* illegal under the antitrust laws. Instead, the Federal

⁸⁹ On remand, the trial court concluded that, notwithstanding the Eleventh Circuit's prior decision, the aspects of the agreements that prevented entry "exceed[ed] the exclusionary scope of the patent," and thus could be subjected to *per se* treatment. See *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1310-20 (S.D. Fla. 2005). Most of the parties then settled, leaving one case to be tried in its originating district, the Central District of California. There the trial court employed a *per se* analysis but rejected the claim as a result of the jury's finding that the agreement did not, in fact, delay generic entry. On appeal, the Ninth Circuit Court of Appeals affirmed the district court's dismissal of the claim and as a result did not need to address the issue of whether *per se* or rule-of-reason treatment was appropriate. *Kaiser Foundation Health Plan Inc. v. Abbott Laboratories, Inc.*, ___ F.3d ___, Nos. 06-55687, 06-55748 (9th Cir. Jan. 13, 2009) (available at <http://www.ca9.uscourts.gov/datastore/opinions/2009/01/12/0655687.pdf>).

⁹⁰ 466 F.3d 187 (2d Cir. 2006).

⁹¹ 544 F.3d 1323 (Fed. Cir. 2008).

Circuit found that rule of reason analysis was proper and upheld the district court's determination that the agreement was not illegal under the rule of reason, particularly as the plaintiffs could not show that the agreements created a "bottleneck" to challenging the patent at issue, or that the conduct at issue had an actual adverse effect on competition in the relevant market. The court noted that reverse payments do not deter other generic companies from challenging the innovator company's patent.

127. The only appellate case holding that a reverse payment scheme could be a *per se* violation of U.S. antitrust laws is *In re Cardizem CD Antitrust Litigation*.⁹² In that case, the Sixth Circuit held that an agreement whereby the branded manufacturer Hoechst agreed to pay the generic manufacturer Andrx \$10 million per quarter while patent litigation between them was ongoing in exchange for Andrx's commitment not to launch its product and not to relinquish its 180-day exclusivity right to another generic manufacturer was a *per se* violation of the U.S. antitrust laws.
128. The agreement in *Cardizem* differed from the reverse payment settlement agreements that were at issue in most of the other cases.⁹³ In particular, in addition to not resolving the litigation, the agreement in *Cardizem* prevented *all* competition in the drug, not just the entry of Andrx. The court emphasized this feature of the agreement, citing the fact that the agreement "*also delayed the entry of other generic competitors, who could not enter until the expiration of Andrx's 180-day period of marketing exclusivity, which Andrx had agreed not to relinquish*".⁹⁴ The court concluded that the agreement thereby not only enforced Hoechst's patent rights, it also "*bolster[ed] the patent's effectiveness in inhibiting competition by paying the only potential competitor \$40 million per year to stay out of the market.*"⁹⁵ The Federal Circuit in *Ciprofloxacin* cited this issue in distinguishing *Cardizem* and upholding the agreement at issue there.⁹⁶
129. In summary, therefore, although some in the United States, including the FTC, have been sharply critical of reverse payment settlements, U.S. appellate courts have not endorsed that view. Rather, except in cases where the agreement affords exclusivity beyond the scope of the patent, U.S. courts generally have upheld the legality of such agreements. Moreover, even the FTC's concerns seem motivated by features of the U.S. regulatory regime, particularly the automatic 30-month stay and the 180-day exclusivity period, that are not present in the E.U.
130. Finally, Lundbeck notes that significant differences in how pharmaceutical products are priced in the United States and the E.U. mean that reverse payment settlement

⁹² 332 F.3d 896 (6th Cir. 2003).

⁹³ The agreements at issue in *Valley Drug* also involved interim payments.

⁹⁴ 332 F.3d 896 (6th Cir. 2003), at page 907.

⁹⁵ *Ibid*, at page 908 (emphasis added).

⁹⁶ *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, at page 1335. In *Andrx Pharms. Inc. v. Biovail Corp*, 256 F.3d 799 (D.C. Cir. 2001), the D.C. Circuit analyzed the same agreement in the context of a lawsuit between Andrx and a competing generic manufacturer, Biovail. The court suggested that the agreement might give rise to an antitrust claim, but did not address the question of whether the agreement would be subject to *per se* illegality or should be evaluated under the rule of reason.

agreements are less likely to be a concern in the E.U. The economic incentives to settle on potentially anticompetitive terms are not the same in the E.U. as they are in the United States. In the United States, the generic version of a drug sells at a significant discount, often 50% to 80% below the price of the branded drug. In the United States, the profits that the generic manufacturer anticipates from sales of its own product are therefore significantly less than the profits the innovator would lose from its product if there were generic entry. As a result, the FTC has argued that in the United States, even when the generic is perceived by all to be highly likely to succeed in litigation, it can be more profitable for both parties to enter into a settlement providing for a later generic entry date and instead share (via a reverse payment settlement) the innovator's "monopoly" profits on continued sales of the branded drug. In the E.U., where the price difference between branded and generic drugs is not as pronounced (as noted in the Preliminary Report, the Commission found that on average prices dropped by almost 20% in the first year following generic entry, and about 25% after two years⁹⁷), the incentives are not the same.

131. This feature of the U.S. pharmaceutical products markets helps explain why the sheer magnitude of value of reverse payment settlement agreements seen in the United States is simply not observed in Europe. In the United States, the Ciprofloxacin settlement agreement alone represented \$398 million.⁹⁸ Similarly, a single generic company received payments of \$40 million *per year* under the *Cardizem* settlement agreement, and an innovator company paid approximately \$48 million under the agreement in the *Valley Drug* proceedings. By contrast, the Preliminary Report states that innovators paid a total of only around €200 million to generics in 23 settlements over a 7 ½ year period.⁹⁹ All but two of these European settlements involved direct payments of less than €20 million total.¹⁰⁰ Further, with payments so low, the Commission should be even more cautious. Even the FTC has recognized that a transfer of value from the innovator to the generic should not be challenged if it can be linked to avoiding litigation costs, though the Court in *Schering-Plough* considered the FTC's approach on this point arbitrary as it placed a \$2 million cap on this safe harbour.¹⁰¹ In sum, the issue perceived by the FTC in the United States simply does not exist on a similar scale in Europe, and much of the limited value that has been transferred likely represents the legitimate avoidance of litigation costs.

⁹⁷ Preliminary Report, at para. 180.

⁹⁸ *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323, 1329 n.5 (Fed. Cir. 2008).

⁹⁹ Preliminary Report, at para. 637.

¹⁰⁰ *Ibid*, at figure 104.

¹⁰¹ *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1062 (11th Cir. 2005)).

VI. LIFE CYCLE STRATEGIES FOR FOLLOW-ON PRODUCTS

132. The Preliminary Report notes that generic companies have criticized the use of what they term “second generation products” or “evergreening” on the basis that “*some of the new products show little if any innovation and limited if any additional benefits, and that they serve primarily to retain the revenue streams of the first generation product*”.¹⁰²
133. In Lundbeck’s view, there are two fundamental points that demonstrate why the concerns of the generic companies are unfounded, and that the conduct of innovator companies in launching new products does not infringe EC competition law.
- First, it is implicit in the concerns about “evergreening” that the innovator company has obtained a patent for its “second generation product”.¹⁰³ (Otherwise, the new product would be susceptible to generic competition at the outset.) Any suggestion that “second generation products” are not sufficiently innovative does not fall within the Commission’s jurisdiction to consider, because it is the domain of the individual Member States (*see* Section III.A above).
 - Second, if the new product does not in fact offer benefits beyond that of the original product (or provides only limited benefits), then generic producers of the original product should not have any difficulty in competing with the innovator’s new product. Generic companies can simply offer copies of the original product to market as an equivalent product to the “second generation product”, but at a significantly lower price. Doctors and national health authorities are well-placed to make judgments regarding whether or not there are legitimate benefits to the new product.
 - Conversely, if generic companies find themselves unable to compete effectively with the “second generation product” in this way, that suggests that the new product does in fact have advantages over the original product. Patients, doctors, and payers should therefore be entitled to choose the new product to obtain those advantages if they wish to do so.
134. In addition to the points above, Lundbeck emphasizes that the development of new medicines is an ongoing process, and testing, trials and innovation do not cease once a product has been marketed. Innovator companies should be encouraged to invent new, improved versions of patented products, because this ultimately benefits patients through a wider and more effective range of treatment options. Equally, innovators must be permitted to market actively any such new products. There is no basis in EC competition law for suggesting that companies could be under an obligation to refrain from marketing activities in respect of new products they have developed.
135. In Lundbeck’s view, the desire of an innovator company to invent incremental improvements to its products is a positive response to competition from generic

¹⁰² Preliminary Report, at para. 830.

¹⁰³ *See*, for example, Preliminary Report, at para. 845.

companies. Around the time of patent expiry, it should be expected that competition between innovators and generics will increase in relation to innovation as well as price, and this should be encouraged.

136. In many cases, the fact that the new product is launched shortly before (or after) the original product patent expires may simply reflect the length of time it takes to develop the improved version – or the heightened sense of urgency that an innovator feels as generic competition marches closer to the original product (in other words, generic competition manifesting itself in an increased incentive for the innovator to innovate).
137. Finally, Lundbeck notes the reference in the Preliminary Report to the *Astra-Zeneca* decision.¹⁰⁴ Lundbeck considers that the Final Report should acknowledge the subsequent changes to the relevant legislation - namely, adoption of Directive 2004/27/EC - under which, as of 30 October 2005, it is no longer possible for an innovator company to prevent generic entry by withdrawing the marketing authorization for a reference product. It follows that the issue raised by the specific facts of the *Astra-Zeneca* case is no longer of concern today.
138. Notwithstanding the comments above, if the Commission considers that the launch of “second generation products” by innovator companies may infringe EC competition laws in certain circumstances, Lundbeck suggests that the position adopted by the U.S. courts would be a good starting point for this analysis.
139. U.S. courts have evaluated claims of “evergreening” or “product hopping” by focusing on whether both the original and new formulations remain available to the patient, and whether the consumer is able to choose between the products. In such cases, the design change is generally assumed not to harm competition. On the other hand, where the original product is no longer available to the public and patients are forced to purchase the reformulated product, the court typically takes a closer look at whether the design change as a whole was pro-competitive. In that circumstance, the court analyzes whether the benefits of the new design outweighs anticompetitive harm (rather than assuming a *per se* infringement of competition laws).
140. For example, in *Abbott Laboratories v. Teva Pharmaceuticals*, Abbott, the patent holder for the capsule form of its drug TriCor, initiated patent infringement suit against Teva, a generic manufacture of the drug.¹⁰⁵ While that suit and the resulting 30-month stay were pending, the FDA approved Abbott’s New Drug Application for a tablet form of TriCor. Following FDA approval, Abbott stopped selling TriCor in capsule form and bought back the old supply of capsules, removing them from the market.¹⁰⁶ Abbott then listed the National Drug Data File (“NDDF”) code for the capsule form of TriCor as “obsolete”.¹⁰⁷ This “obsolete” designation caused the TriCor capsule to be removed from the NDDF, which had the effect of preventing pharmacies from dispensing the

¹⁰⁴ Preliminary Report, at para. 870.

¹⁰⁵ 432 F. Supp. 2d 408, 415 (D. Del 2006).

¹⁰⁶ *Ibid*, at page 416.

¹⁰⁷ *Ibid*.

generic capsule formulation when TriCor was prescribed.¹⁰⁸ The plaintiffs claimed that Abbott's changes to TriCor's formulation violated Section 2 of the Sherman Act because Abbott made the changes not to improve the product but to prevent generics from becoming substitutes for TriCor.¹⁰⁹

141. The District of Delaware denied Abbott's motion to dismiss and found that, when the introduction of the new product "prevents consumer choice", the court must analyze the benefits of the product change.¹¹⁰ If the actual benefit of the product reformulation outweighs anticompetitive harm, there is no antitrust liability. The court noted that where the initiation of a new product enhances consumer choice, by adding products to the market, the court would defer to the design changes.¹¹¹ The court went on to conclude that Teva need not prove that it was foreclosed from all avenues of competition to survive a motion to dismiss. Rather, it was sufficient that Teva was barred "from the cost-efficient" avenues of competition.¹¹²
142. In contrast, in *Walgreen Co. v. AstraZeneca Pharmaceuticals L.P.*, AstraZeneca held a patent to a drug called Prilosec.¹¹³ About eight months before the expiration of that patent, AstraZeneca began marketing Nexium, a substitute drug for Prilosec.¹¹⁴ AstraZeneca did not remove Prilosec from the market, however, but did engage in a marketing effort to promote Nexium.¹¹⁵ The court found that AstraZeneca added to consumer choices by selling both Nexium and Prilosec. Therefore, the court examined AstraZeneca's decision with deference to the company's design choice.¹¹⁶ The court concluded that marketing one drug more vigorously than another does not amount to an antitrust violation and accordingly granted AstraZeneca's motion to dismiss.¹¹⁷

¹⁰⁸ Ibid.

¹⁰⁹ Ibid, at page 415.

¹¹⁰ Ibid, at page 421.

¹¹¹ Ibid, at pages 421-22.

¹¹² Ibid, at page 423 (quoting *United States v. Microsoft Corp.*, 253 F.3d 34, 61 (DC Cir. 2001)).

¹¹³ *Walgreen Co. v. AstraZeneca Pharms. L.P.*, 534 F. Supp. 2d 146, 148 (D. D.C. 2008).

¹¹⁴ Ibid, at pages 148-49.

¹¹⁵ Ibid, at page 152.

¹¹⁶ Ibid, at page 151 ("[AstraZeneca] introduced a new drug to compete with already-established drugs - both its own and others' - and with the generic substitutes for at least one of the established drugs.").

¹¹⁷ Ibid, at page 152.

VII. COMPETITION BETWEEN INNOVATOR COMPANIES

143. The Commission has raised concerns about innovator companies filing “defensive patents” to block the development of new and competing medicines by other innovators. The Preliminary Report states that:

“From society’s viewpoint...restriction of another company’s freedom to operate may be problematic where the originator company maintains and uses patents to block the development of a new, competing product rather than for protecting an invention of its own. This is sometimes referred to as “defensive patenting”....[D]efensive patent applications usually refer to inventions which the applying company considers to have little or no prospect of being developed and/or commercialised and/or which, once granted, the company holds primarily to protect itself against actual or potential competition.”¹¹⁸

144. In Lundbeck’s view, if an innovator company ultimately chooses not to market a particular product for which it has obtained a patent, or to delay marketing that product for a period of time, it should have the right to do so. There may be many valid and commercially sound reasons why an innovator would want to do this, none of which are of themselves anti-competitive. For example, an innovator has to prioritize the use of funds in its R&D and/or marketing budgets. It may therefore decide that another patented product is likely to be more profitable when marketed, or perhaps would allow the innovator to move into new fields of treatment, and therefore should be exploited first.
145. It is rational economic behaviour for innovator companies to keep as many avenues of future research and product development open as possible. Many new inventions ultimately turn out to be unsuccessful, or not commercially viable, but an innovator company cannot know this at the outset and must therefore patent the invention to protect its R&D efforts wherever possible. Similarly, the fact that an innovator company does not currently intend to commercialize one of its patents (whether or not that intention is objectively discernible) does not mean that in 5 or 10 years’ time the innovator’s view will not change. Patent holders are entitled to enforce their intellectual rights in a flexible manner.
146. Indeed, Lundbeck believes that even if a patent holder has no intention of commercializing an invention – and holds a patent merely to block others – interfering with the intellectual property rights granted under Member State law would be unsound as a matter of competition policy. There may well be cases where making and patenting multiple inventions is necessary to provide the incentives to invest in commercializing an actual product. An inventor may view such investments as too risky without “purely defensive” patents. If others desire to compete against the inventor through subsequent inventions, they should invent the alternatives before the original inventor does. (Indeed, generic firms frequently file process and other patents related to products launched by innovators, so there is an active competition to innovate with respect to incremental improvements on existing products.) In any event, where a

¹¹⁸ Preliminary Report, at paras. 958-959.

patent is valid, it would simply not be feasible to try to sort out cases of “purely defensive” patents from cases where an inventor merely did not know whether it might one day commercialize an invention.

147. In Lundbeck’s view, competition law has no role to play in regulating the investment and product development decisions of innovator companies, save for exceptional circumstances such as those identified in the compulsory licensing decisions referred to in Section IV.C above.
148. Moreover, Lundbeck considers that the term “defensive patents” is a clear example of a pejorative term used in the Preliminary Report to describe a lawful intellectual property right. The Commission’s use of “loaded” terminology when discussing its findings in the Preliminary Report does not assist with obtaining clarity on the relevant issues. It unfairly suggests wrongdoing on the part of innovator companies, when in fact the conduct at issue is lawful. A similar example of this is the concept of “blocking” or “delaying” the market entry of generics by filing a number of patents (as discussed in Section III above).
149. Lundbeck submits that, in assessing the application of patent rights in the pharmaceutical industry (or indeed in any industry), the Commission should avoid viewing patents as falling on a spectrum, with “good” or “strong” patents at one end, and “weak” or “purely defensive” patents on the other. The reality is that every company that lawfully obtains a patent has the right to rely on, and enforce, that patent as a valid intellectual property right unless and until it is the subject of successful invalidity proceedings. This position is the same, regardless of whether the company decides to commercialize the product covered by the patent immediately, or to delay commercialization until a later date.

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150. In conclusion, Lundbeck greatly appreciates the opportunity to comment on the Preliminary Report. As noted, Lundbeck would also welcome the opportunity for public comment – from the pharmaceutical industry and other industries – on a set of detailed guidelines that appropriately balance the many important issues described above. In formulating such guidelines, Lundbeck urges the Commission to give due regard to the universal public policy judgment of the Member States that robust intellectual property protections provide critical incentives for investment in innovative medicines that save or improve the lives of millions of European patients.