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Comments to the European Commission's interim findings in the pharmaceutical sector

<u>Subject</u>	<u>Business Perspective</u>	<u>AmCham EU Position</u>
<i>IP Innovation & Protection</i>	IP protection and legal certainty are an essential part of innovation.	The use of patent portfolios, active litigation to defend and enforce them, settling patent disputes, patenting and promoting second generation products are absolutely standard.
<i>IP Innovation & Protection</i>	An unwarranted overlay of competition law intervention would weaken IP protection and deter innovation for these incremental, but nonetheless important patentable advances.	Maintain the longstanding principle that EU competition law cannot call into question the existence of patents and can apply to limit their exercise only in exceptional circumstances.
<i>IP settlements</i>	Antitrust "second guessing" of settlements engenders damaging legal uncertainty.	In complex cases, a wide range of commercial concessions and restrictions on conduct will be necessary to ensure that a settlement encompasses the parties' differing needs and expectations.
<i>Second Generation Patented Products</i>	Condemning second generation patented products marketed at the end of the patent term of a first generation product is to invite economic stagnation.	There is no antitrust precedent that condemns second-generation products or their marketing.

The American Chamber of Commerce to the European Union (AmCham EU) wishes to comment on the European Commission's interim findings in the pharmaceutical sector, which were published on November 28th 2008.¹ AmCham EU is concerned that the interim report characterises as suspect a range of practices relating to patents, patent litigation, settlements and marketing of next generation technologies which are wholly standard in most high technology industries. Calling into doubt their validity would weaken intellectual property (IP) and stifle innovation. With the EU promising to launch fact finding studies into the use of IP as part of its *Industrial Property*

¹ *Pharmaceutical Sector Inquiry Preliminary Report*, DG Competition Staff Working Paper, November 2008 28th (available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf)

Rights Strategy for Europe,² the pharmaceutical inquiry has broader implications for other IP driven sectors.

- **The use of patent portfolios, active litigation to defend and enforce them, settling patent disputes, patenting and promoting second generation products are absolutely standard.** Though the press reports were that “Brussels condemns drug firms’ use of patents,”³ one of the most eminent European patent lawyers, and English Court of Appeal judge, Lord Justice Jacob, addressing a conference convened by the Commission on the release of the interim findings, robustly observed “there is absolutely nothing new in what the Commission are reporting about,” cautioning regulators to “keep a sense of perspective⁴”.
- **If these practices are to be the subject of antitrust scrutiny it must be made clear that this will only be in the most exceptional circumstances.** There is no legal analysis in the interim report, which subsequently creates legal uncertainty by raising doubts and threatening “cases against companies where there are indications that the antitrust rules may have been breached”. The case law and decisional practice under EC competition law as to patent portfolios, litigation and settlements, though limited, clearly favour the protection of an innovator’s intellectual property rights, finding that devaluation of those rights can be justified only in the most “exceptional circumstances.”⁵ If the practices raise antitrust concerns in exceptional circumstances, those circumstances must be articulated. The interim report offers no such guidance while threatening “cases against companies where there are indications that the antitrust rules may have been breached”.
- **Patent portfolios are an essential part of innovative competition.** The report finds that “webs”, “clusters” or “thickets” of patents may be expected to prevent generic copies entering the market. It also treats as suspicious examples of patents filed near to expiry of the “primary patent” protecting a product. The Commission’s suggestion appears to be that patenting late in a product’s lifecycle is evidence of an attempt to deter imitation products, rather than legitimate patenting of innovations related to a product that are discovered during its lifecycle. We would observe that in patent law there is no such thing as a ‘secondary’ patent. Patents are granted for true inventions of all types, following well-established and strict principles requiring novelty and inventiveness. But modern technologies rely upon extremely complex patented inventions that are updated and improved on an ongoing basis. Consumer electronics, semiconductors, computers and, indeed, pharmaceuticals have dozens, hundreds,

² *An Industrial Property Rights Strategy for Europe* COM(2008) 465/3 (Announcing studies of patent quality and the antitrust implications of IP and standard setting).

³ Independent, November 29th 2008

⁴ English Court of Appeal judge, Lord Justice Jacob, addressing a conference convened by the Commission on the release of the interim findings

⁵ Case 238/87 *Volvo v Veng* [1989] 4 C.M.L.R. 122; Cases 241 & 242/91 *RTE & ITP v Commission* [1995] E.C.R. 743; Case C-7/97 *Oscar Bronner v Mediaprint* [1998] E.C.R. I-7791; Case T-504/93 *Tiercé Ladbroke SA v Commission* [1997] E.C.R. II 923; Case C-418/01 *IMS Health GmbH & Co OHG v NDC Health GmbH & Co KG* [2004] ECR 5039.

even thousands of patents applicable to them. In many of these industries, just as in the pharmaceuticals industry, advances are often made incrementally and the patent portfolio will grow over time with ongoing R&D. An unwarranted overlay of competition law intervention would weaken intellectual property protection and deter innovation for these incremental, but nonetheless important patentable advances. Moreover, any such overlay would need to take into account the longstanding principle that EU competition law cannot call into question the *existence* of patents and can apply to limit their *exercise* only in exceptional circumstances.

- **Patent litigation is the only means by which intangible intellectual property can be protected. Access to the courts is an inalienable right, protected by the Convention on Human rights, which is also applicable to intellectual property as a whole.⁶ Courts, not antitrust regulation, must decide patent validity.** The report finds innovators lost the majority of cases against generics (62% of 149 final judgements), though they won 51% of those they initiated. It suggests these statistics show that the patents asserted by innovators may be weak and granted too readily by the European Patent Office. Pharmaceutical patentees are no different to any other industry sector, with the patentee “win rate” ranging between 26% (UK) and 55% (France) across European jurisdictions.⁷ Since the vast majority of cases settle, only the most contentious and/or least predictable proceed to final judgment. In such cases, win/loss statistics of around 40-50% are entirely to be expected. Extrapolating from those cases to the vast majority of patents that are never litigated is not meaningful. Moreover, as the report notes, patent suits on the same invention are often brought in courts in multiple Member States; if a basis for invalidity – for example, invalidating prior art – is found in one jurisdiction, that information will typically be brought to bear in all jurisdictions, magnifying the “loss” rate in a biased manner.
- **Settlements are judicially encouraged and save wasteful litigation resources. In complex cases a wide range of commercial concessions and restrictions on conduct will be necessary to ensure that a settlement encompasses the parties’ differing needs and expectations. Antitrust “second guessing” of settlements engenders damaging legal uncertainty.** The allegation is that payments or benefits in kind transferred from innovators to generics as a *quid pro quo* for staying off the market are inherently suspicious. There is good reason to disagree with this analysis. Where a generic accepts an originator’s patent as valid, there is no “limitation” of that generic’s entry unless it is assumed that the patent-in-suit is in fact invalid. Given that approved patents are to be presumed valid, the better view of these patent settlements would be that articulated by the U.S. Courts in cases such as *Ciprofloxacin*,⁸ namely, that an agreement preventing

⁶ Case T-111/96 *ITT Promedia NV v Commission* [1998] ECR II-2937

⁷ *Global Patent Litigation – Win Rates and Strategies*, Michael Elmer, May 31st, 2007 (Based on an informal survey in the absence of authoritative data sources).

⁸ *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, No. 08-1097, 2008 WL 4570669 (Fed. Cir. October 15th, 2008).

generic entry only within the “exclusionary zone” of the patent-in-suit is not restrictive of competition. That is, if a patent excludes all competition, then any *bona fide* settlement agreement that imposes restrictions on generics going no further than the patent can have no illegitimate impact on competition. The complex, drawn out and costly nature of patent disputes and the parties’ differing expectations of the appropriate outcome, can lead to any number of good faith arrangements on which parties may seek to settle on commercially reasonable terms.

- **Condemning second generation patented products marketed at the end of the patent term of a first generation product is to invite economic stagnation. After all, making the innovations that lead to a second generation product, introducing that product, and promoting it are inherently pro-competitive activities. Moreover, secondary patents on the innovations that create the second generation product encourage that innovation, which benefits consumers and cannot fairly be considered anticompetitive.** It is clear that any patents applied for after the launch of a drug cannot prevent generic copies of that drug being introduced when the originator’s initial patent (or SPC) protection expires. There is, therefore, rightly no antitrust precedent which condemns second generation products or their marketing. U.S. law on this subject suggests that competitive harm can flow not from the introduction and promotion of second generation products, but on rare occasion, from a monopolist’s withdrawal of an older product which is interoperable or complementary to rivals’ products. Even then, however, there are many valid reasons to withdraw old products, such as avoiding consumer confusion, capturing cost savings, simplifying product lines, or building a brand, and so the introduction of a new product and withdrawal of an old should be condemned only when the new product offers no improvement whatsoever but is designed solely to harm rivals.
- **In a long R&D cycle, no innovator can tell which of his inventions will ultimately be commercially viable and he is under no antitrust obligation to hand his research to rivals.** The report identified 1,100 instances across 27 Member States where patents of one company may be infringed by the products, R&D programmes and/or patents of another pharmaceutical company and that in some cases innovators obtained “defensive patents” solely to block competitors. This is scarcely a structural problem and the definition of “defensive patents” is simplistic. In a long research cycle, an innovator will have little idea as to which of the many compounds it patents will ultimately prove technically or commercially viable. It will not want to hand research over to competitors while it is still possible the invention might be useful. To suggest that multiple patent filings or unworked patents are suspect blocks for rivals is hugely damaging. By implication it would require an innovator to choose definitively at a very early stage which of its inventions is viable and to hand the rest to rivals. We suggest this conclusion has no legal basis under EC competition law which permits

intrusion into IP only in exceptional circumstances⁹ recognising the immense harm to innovation from compulsory licensing claims.¹⁰

In its response to the Commission’s public consultation on the review of Regulation 1/2003 last November 2008¹¹, AmCham EU has already expressed its concerns about the due process issues that the sector inquiry has raised. AmCham EU would urge the Commission to use the instrument of sector inquiry with restraint and moderation and hopes that the Final Report expected in the summer will be a more balanced review that does not create further legal uncertainty.

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The American Chamber of Commerce to the European Union (AmCham EU) is the voice of companies of American parentage committed to Europe towards the institutions and governments of the European Union. It aims to ensure an optimum business and investment climate in Europe. AmCham EU facilitates the resolution of EU – US issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Total US investment in Europe amounts to €702 billion, and currently supports over 4.1 million jobs.

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⁹ Case 238/87 *Volvo v Veng* [1989] 4 C.M.L.R. 122; Cases 241 & 242/91 *RTE & ITP v Commission* [1995] E.C.R. 743; Case C-7/97 *Oscar Bronner v Mediaprint* [1998] E.C.R. I-7791; Case T-504/93 *Tiercé Ladbroke SA v Commission* [1997] E.C.R. II 923; Case C-418/01 *IMS Health GmbH & Co OHG v NDC Health GmbH & Co KG* [2004] ECR 5039.

¹⁰ Guidance on the Commission's Enforcement Priorities in Applying Article 82 EC Treaty to Abusive Exclusionary Conduct by Dominant Undertakings, 3 December 2008, paras. 88-89

¹¹ AmCham EU response to the Public Consultation on Regulation 1/2003, November 7th 2008, Please see the website : http://www.amchameu.be/Pops/2008/Comp_AmCham%20EU%20response%20to%20the%20Public%20Consultation%20on%20Regulation%201-2003%2007112008.pdf