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Directorate-General for Competition
Antitrust Registry
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By e-mail to: comp-sector-pharma@ec.europa.eu

January 29, 2009

Dear Sirs,

Pharmaceutical Sector Inquiry Preliminary Report (Ref 39514)

Introduction

These are the comments of the American Intellectual Property Law Association (AIPLA) in response to the European Commission's Pharmaceutical Sector Inquiry Preliminary Report.

AIPLA is a bar association of more than 16,000 members (including some practicing in Europe) constituted primarily of lawyers in private and corporate practice, in government service, and in the academic community. The AIPLA represents a wide and diverse spectrum of individuals, companies and institutions involved directly or indirectly in the practice of patent, trademark, copyright, unfair competition, and antitrust law, as well as other fields of law affecting intellectual property.

AIPLA's interest in providing these comments is its desire to assist the Commission in interpreting and understanding the patent laws, in particular as they apply to the pharmaceutical sector. AIPLA's members represent both owners and users of intellectual property, and our members from the pharmaceutical sector include both Originators and Generics. Many of AIPLA's members compete in Europe, and they patent inventions or work with or around patented inventions in Europe, as well as many other regions of the world. Thus, they are affected by interpretations of competition and patent laws in Europe.

Patents involve a calculated societal bargain which is especially important in the development of new pharmaceuticals. Originators disclose their inventions in exchange for an exclusive right for a limited period, after which those inventions can be used by anyone. The public benefits immediately from the new pharmaceuticals produced by Originators and, subsequently, from reduced prices for those pharmaceuticals produced by Generics.

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act) sought to achieve the delicate balance of providing Originators with the necessary incentives to innovate and produce new products, while allowing Generics to flourish in order to reduce prices once exclusive protection expires on existing products. AIPLA believes such a balance also should be sought in Europe, and believes it is important that the Commission consider both sides of this balance carefully.

The purpose of AIPLA's comments is to address those patent practices on which the Commission focused and not to deal with regulatory or other aspects. These comments respond to Section C.2 of the Report (Competition between Originator and Generic Companies). With these comments, AIPLA seeks to provide a better understanding of patent practices in the pharmaceutical industry, and their similarity to practices in other competitive industries.

Discussion

1. Patent Filing and Patent Enforcement Strategies (paras. 370-432)

The functions of patents are explained clearly in paras. 208-214 of the Report. Most importantly, a patent “grants its holder...the right to prevent third parties from making, using, offering for sale, selling or importing the product (including the product obtained directly by a patented process) without the patent holder’s prior consent”¹.

Thus a patent merely gives the right to prevent others from using the patented invention for a limited time. It does not grant the right or obligation to make the patented invention or use a process covered by the patent, although typically the patent holder will want to profit from its patent by marketing the patented invention or licensing others to do so. Where the patentee licenses others to manufacture or sell the invention, the patentee may choose not to practice the patented invention (just as a patentee would not normally practice every variation described in a single patent).

These functions of patents are not specific to the Pharmaceutical Sector. However, it is important that they are taken into consideration when analyzing patent filing and enforcement strategies in the Pharmaceutical Sector.

1.1 Divisional Patent Applications (paras. 398-409)

The reason for Divisional Patent Applications is explained briefly in para. 230 of the Report but it would be useful to supplement this.

In particular, the “principle of unity of invention” needs to be defined and explained. It derives from Article 82 of the European Patent Convention [EPC],² which states that:

The European patent application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.

The reason for the principle was discussed by the EPO Enlarged Board of Appeal in Case **G 0001/91** as follows:

4.1 Although unity of invention under Article 82 EPC is a material requirement, it is still merely an administrative regulation. It serves a number of administrative purposes, particularly in demarcating the respective responsibilities of the departments concerned with search, examination, opposition and further procedure. As is well known, the International Patent Classification is used in these departments for classifying documentation on the state of the art. However, the classification also serves as guidance to competitors keeping track of patent office publications. And the financial aspect prior and subsequent to grant of the patent - in other words, the amount of procedural and

¹ See, TRIPs Art. 28.1

² Art. 82 of both EPC (1973) and EPC (2000).

renewal fees both for patent applications and for the subsequent patents - is also important.

4.2 However, the administrative purposes of unity are fulfilled in the main up to the time the patent is granted. *The purpose and intention of opposition proceedings is to give a competitor the opportunity of opposing unjustified protective rights. Since this serves the competitor's interests, he need not also be given the opportunity of contesting a patent on the ground of lack of unity. Lack of unity does not in fact rule out patent protection; it can only result in an application being divided to produce two or more patents. In view of the object and purpose of both unity and opposition, it seems neither necessary nor appropriate to continue to attach importance to any lack of unity at the opposition stage. Once the examination procedure has been concluded with the grant of a patent, the requirement of unity has fulfilled its administrative function.* [Emphasis added]

5.1 As long as unity is a requirement to be met under the patent law procedure, there must also be the possibility of establishing the required unity, either through partial surrender or division. Where division is no longer possible, lack of unity can have no further legal significance. The European patent law system does not provide for division once the patent has been granted. So even though Article 102(3) and Rule 61a EPC may leave some doubts as to the importance of unity at the opposition stage, the lack of the legal institution of division shows that unity can no longer have any importance for the opposition or in opposition proceedings.

In practice, it happens, not uncommonly, that more than one invention is disclosed in a single patent application. There are good reasons for this. For example:

- (a) The discovery of a new active ingredient will often have involved various particular inventions, but it is far more comprehensible to third parties to describe them in a single application rather than trying to file numerous separate applications which each tell a part of the story.
- (b) The patent applicant will rarely be aware of the full breadth of prior art which exists when the original application is filed. Therefore, in many cases, the extent to which inventions described in the original application are actually patentable will not become apparent to the patent applicant until the scope of the prior art is revealed during the prosecution of the application.
- (c) Commercial realities mean that a patent applicant will not want to incur the expense of filing numerous patent applications for inventions related to a new active ingredient at an early stage in development, when it is not clear whether any specific compounds might still fail in pre-clinical tests or clinical trials.

However, for the administrative reasons already described, a patent applicant can only pursue one independent or distinct invention in the original application. This does not mean that the other inventions disclosed in that application are unpatentable. Rather, the patent applicant must simply file Divisional Patent Applications including claims covering the other inventions.

Accordingly, the fact that an application is withdrawn or rejected is not generally relevant to whether a Divisional Patent Application will prove successful. The Divisional Application can cover a different invention (which may be a broader or narrower aspect of the invention

originally claimed). However, it is absolutely clear that Divisional Patent Applications can only extend to inventions that were properly disclosed in the original application. Art. 76(1) EPC (1973) and (2000) provides that:

A European divisional application shall be filed directly with the European Patent Office in accordance with the Implementing Regulations. It may be filed only in respect of subject-matter which does not extend beyond the content of the earlier application as filed; in so far as this requirement is complied with, the divisional application shall be deemed to have been filed on the date of filing of the earlier application and shall enjoy any right of priority.

Given that the original application is published within 18 months from filing, any third party is able to review it and assess the scope of the disclosure by the applicant and, hence, the likely scope of any possible Divisional Patent.

Equally, any Divisional Patent granted will expire on the same date as the original patent and so cannot extend the time of any protection. Third parties, therefore, again know from an early stage when any Divisional Patent will expire.

Divisional Patent Applications are used in all fields of technology and are not specific to the Pharmaceutical Sector. There is no suggestion in the Report that they are more prevalent in the Pharmaceutical Sector.

One other reason for apparently numerous patents is the impact of U.S. restriction practice. Even if inventions have a common inventive concept (and could thus be covered by a single patent in Europe under Article 82 EPC), the U.S. Patent and Trademark Office may require them to be restricted (protected by separate patents) because the inventions are considered to be “patentably distinct” for reasons unrelated to the common inventive concept. Where pharmaceuticals originate in the U.S. and the U.S. patents, as governed by U.S. restriction practice, serve as the basis for world-wide patent filings, there may as a result be more patents related to a particular product than would be otherwise necessary under strict European practice.

1.2 *Patent Clusters (paras. 382-397)*

The Report uses “Primary” or “Base” patents to mean patents which cover new active ingredients, and “Secondary” patents to mean all other patents, such as new uses for existing active ingredients, new formulations or new production processes (for instance, see para. 216 and footnote 223). However, it is important to bear in mind that labeling patents as “Primary” or “Secondary” is not in itself indicative of the scientific, commercial, economic or even moral value of the patents. Nor should expiry of the “Primary” patent be regarded as a proxy for the “loss of exclusivity” for the medicinal product which is actually being sold (for instance, as suggested in Figure 52 on page 154 of the Report). As discussed further below, and as indicated in the definition on page 19 of the Report, exclusivity for the product is only lost when all patent, SPC³ and data exclusivity protection expires.

³ An SPC is a Supplementary Protection Certificate, which is a form of additional protection for pharmaceutical products for up to five years after patent expiry. It was introduced to compensate for the length of time it takes between a patent application for that product and the time when that product can for the first time be effectively marketed in the European Economic Area (EEA).

Just as patents are indicative of innovation, Secondary Patents are typically indicative of incremental innovation, as indicated in para. 392 of the Report.⁴ Moreover, such innovation is not restricted to Originators. As noted in para. 364 of the Report, Generics are free to, and do, file Secondary Patents on pharmaceutical substances (INNs⁵) discovered by Originators. More broadly, the practice of seeking Secondary Patents to cover developments, improvements and variants of the original invention, leading to what is described in the Report as “Patent Clusters”, is a feature of the patent system which is not unique to the Pharmaceutical Sector.

Secondary Patents are required to involve an inventive step over the disclosure in the original application (and all other prior art). If not, the claimed invention is not patentable and should be rejected during prosecution or, if granted, during Opposition or revocation.

Para. 393 of the Report draws the conclusion that, because the majority of litigated Secondary Patents are revoked, the EPO is setting too low a burden for inventive step for such patents. This is not a sustainable inference, as will be discussed further below.

It should also be noted that, when considering whether an Opposition is successful, the relevant question is not whether the patent as granted is amended, but whether it is amended sufficiently to give the Opponent freedom to operate. Often an Opposition will lead to minor amendments which tidy up the patent but do not significantly affect its scope. In other words, the patent as amended during the Opposition will still allow the patent holder to prevent the Opponent from producing the relevant product or using the relevant process. Therefore, the suggestion in the Report that all amendments should be regarded as successes for the Generics is overstated.

The Report suggests in para. 349 that there can be as many as 1300 patents and patent applications per INN. However, this counts identical patents granted in different countries separately (as explained in para. 340). It would be useful if the final Report could indicate how many patents and applications with different scope of claims are granted per INN, as this is the more relevant figure for considered policy-making.

In any event, the more important question for Generics is whether it is necessary to use all or indeed any of these Secondary Patents.

If the Generic simply wants to produce and market the product as covered by the Primary patent(s), the Generic will normally be unconcerned by Secondary Patents. Once the Primary patents expire (or are revoked) there is nothing to prevent the Generics from doing anything which was obvious in the light of the Primary patents. If Secondary Patents have been granted which claim inventions that are obvious, then the Generic can seek to have those Secondary Patents revoked while awaiting the expiry of the Originator's term of data exclusivity.

In some cases, however, the route from making the core invention of the active ingredient to obtaining Marketing Authorization for a marketable product is not clear. In such cases, the

⁴ See also Albert Wertheimer, Richard Levy and Thomas O'Connor, “Too Many Drugs? The Clinical and Economic Value of Incremental Innovations” 14 *Investing in Health: The Social and Economic Benefits of Health Care Innovation*, 77-118 (2001).

⁵ An INN is the International Non-proprietary Name or “generic” name for a pharmaceutical substance (as opposed to the proprietary brand name under which that substance is marketed by the Originator, which may vary from country to country).

Originator may create developments or improvements along the way which can be validly patented with Secondary Patents. In such cases, there can be more than one patent term to expire before the product becomes "patent free" and available for the generic market. However, that is only the case if the Generics want to use the Originator's route. The Generics remain free to research and develop alternative routes. Indeed, the Generics are free to discover and patent any alternative routes as soon as the original patent application is published. Given that Europe operates a "first to file" system, not a "first to invent" system, this situation can act as a serious disincentive to Originators to delaying the filing of any such Secondary Patents.

Finally, the Report suggests that the filing of Secondary Patents is a new phenomenon (para. 383, picked up in the Summary on p166). This does not accord with the experience of AIPLA's members, and the evidentiary basis provided in the Report for this is very thin. Patent applicants in all sectors, including pharmaceuticals, have always sought to obtain as broad and lengthy protection for their products as possible.

2. *Patent-Related Exchanges and Litigation (paras. 433-536)*

According to the Report, there were 1337 contacts and disputes between Originators and Generics between 2000 and 2007 which have not resulted in litigation (para. 438), of which 457 could be classified as "disputes" (para. 447).

The disputes involved 187 patents (para. 452) and concerned 80 INNs (para. 440). Therefore, on average just over 2 patents were asserted per INN in disputes which have not led to litigation.

In addition, there were 698 patent litigation cases initiated in the EU between 2000 and 2007 (para. 468). These concerned a total of 478 patents (para. 488) and 68 INNs (para. 482). Therefore, on average just over 7 patents were asserted per INN in litigation.

Patents in the Pharmaceutical Sector are immensely valuable assets and, accordingly, it is not surprising for the Originator to police such assets actively. The main challenge faced by Generics is that a European Patent may designate up to 27 Member States in the European Community and, once granted, it becomes a separate patent in each of the designated States. "Clearing the path" of these patents can involve extensive and uncertain pan-European litigation. More generally, the extent to which statistics result from such duplication across Member States should be analyzed carefully.

This is the same for all sectors, not just pharmaceuticals. Only a Community Patent and/or European Patent Litigation System will change that (as discussed at various points in the Report: see, for instance, paras. 446, 505 and 518). It is important that policy-making in the competition field, as opposed to reform of the patent system, is not influenced by the increased number of cases which result from the lack of such a system. With this in mind, the figures above for patents per INN includes counterparts of the same patent in different countries (as explained in para. 340). For instance, 80% of the cases concerned 20 INNs which were each litigated in at least three Member States (paras. 482 and 485). Putting to one side the impact of the territorial system of patent grant and enforcement, the number of different patents actually asserted per INN was even lower than 2 (disputes) and 7 (litigation).

2.1 *Outcome of the Main Action on the Merits (paras. 499-519)*

The statistics in the Report indicate that Originators primarily are obtaining valid patents.

The Report rightly focuses on the question of whether the Originator or the Generic is successful in litigation. However, it is also important to consider as a separate question whether the patent is being revoked in these cases, in order to determine the extent to which invalid patents are being granted and asserted (whether knowingly or not).

Of the 698 litigation cases started, 320 were launched by Generics and 76% of those (243) sought revocation of the patent. In addition, Counterclaims were brought by Generics in 86 cases launched by Originators. Although the number of those Counterclaims seeking revocation is not given, this is likely to be a significant proportion.

Only 149 of the 698 litigation cases were reported to have led to final judgment on the merits (para. 500). In those judgments, the patent was revoked 28.8% of the time (43 cases) and was upheld 23% of the time (34 cases), giving a 56/44 split (para 502).

The remaining 48.2% of judgments (72 cases) did not consider validity of the patent. In some cases (such as litigation in Germany) validity will not have been considered, because the question could not be before the court dealing with infringement. In other cases the Generic will have chosen not to challenge the validity of the patent. Without the full statistical breakdown, it is impossible to determine which case is which. However, it appears overall that pharmaceutical patents remain in force more often than not after litigation.

In judgments in litigation brought by Generics (84 cases), the patent was revoked 40% of the time (34 cases) and upheld 25% of the time (21 cases), giving a 62/38 split, and was not considered 35% of the time (31 cases). In litigation brought by Originators (65 cases), the patent was revoked 13.5% of the time (9 cases) and upheld 20% of the time (13 cases), giving a 41/59 split, and was not considered the remaining 76.5% of the time (43 cases). (paras. 503-504)

Where Primary Patents were litigated through to judgment they were upheld 27.5% of the time, revoked 15.5% of the time and not considered 57% of the time (para. 507). Where Secondary Patents were litigated through to judgment, they were upheld 21% of the time, revoked 38% of the time and not considered 41% of the time (para. 508).

A similar analysis could and should be carried out on the different types of patents (paras. 510-513).

In addition, in the 549 litigation cases which did not result in a final judgment the outcome is that the patent remains registered. It is typically only the "marginal" cases that go to trial. For instance, of the 243 cases brought by Generics seeking revocation of the patent, the patent has only actually been revoked in 34 cases (14%).

Given the complexity and judgment involved in the patent examination process, it is not reasonable to expect all granted patents to be valid in all respects if the cost of the EPO system is to remain economically efficient and allow SMEs⁶ to participate. Slower, more extensive and more costly review by national courts of the cases which merit it will

⁶ Small and Medium Sized Enterprises.

inevitably lead to some patents being revoked, because the claimed inventions are not novel or do not incorporate an inventive step (of course, national courts will not consider patents which have been rejected by the EPO, even if they were wrongly rejected). However, the fact that patents were upheld in 44% of the cases where challenged, and were not challenged in many other cases, indicates that Originators are predominantly obtaining valid patents.

2.2 *Interim injunctions (paras. 520-530)*

As correctly identified in the Report, other than urgency and an arguable claim, the main ground for obtaining an interim injunction is that there is a risk of irreparable harm to the patentee if such an injunction is not granted (para. 520).

Once generic medicines come onto the market, the consequent price depression is generally accepted to be irreversible. Consequently, if a Generic is permitted to market pending trial and the patent is subsequently upheld and found infringed, the successful Originator (28% according to the Report) will be unable to restore the price to that at which the medicine was previously sold. The Originator will often have no ongoing effective recourse against the unsuccessful Generic challenger, who may not have sufficient funds to compensate the Originator for the loss.

Consequently, it is not surprising that interim injunctions are granted in a high proportion of cases (44%).

The obvious way to reduce the impact of interim injunctions would be to reduce the duration of litigation to final judgment. However, the average duration is not disproportionately long, given the complexities of many pharmaceutical patent cases.

In terms of the duration of litigation, all EC Member States are signatories to the WTO and its provisions on intellectual property in TRIPS. TRIPS Art. 32 provides for the right for judicial review of a decision to revoke a patent.

As a consequence, most litigation where invalidity of a patent is alleged is likely to go through two instances: trial (or administrative decision) and appeal. An average duration of 2.8 years is not disproportionately long in such circumstances. Statistically, it is likely to mirror the average time to resolve other commercial disputes of comparable complexity.

The sure way to avoid the risk of an interim injunction is for the Generic to "clear the path" before bringing the generic product onto the market, by applying to revoke the patent and/or obtain a declaration of non-infringement. The Generic can do so while awaiting the expiration of the Originator's term of data exclusivity.

In any event, even if a Generic fails to "clear the path", under Article 9(7) of the Enforcement Directive⁷ the Generic can obtain compensation from the Originator if the patent is ultimately held to be invalid or not infringed:

9(7) Where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, upon request of the defendant,

⁷ Directive 2004/48/EC of 29 April 2004 which was generally implemented in all Member States before or during 2007.

to provide the defendant appropriate compensation for any injury caused by those measures.

3. *Oppositions and Appeals (paras. 537-572)*

Of the 52 final decisions reported, only three concerned Primary Patents and the remainder concerned Secondary Patents (para. 570). Here the Report is dealing with Secondary Patents. This indicates that Generics do not typically oppose the original Primary Patents on the active ingredient. This is not surprising, as such patents are generally only open to Opposition at a stage where it is not known whether the compound will emerge as a marketable/successful medicine.

The Report indicates that Generics were successful in 75% of their Oppositions against Originator patents, covering cases where the patent was revoked or amended (paras. 569-570). For Secondary Patents, the figure was slightly lower at 73% (36 out of 49) (para. 570). The Report also indicates that, more generally, 62% of all patent Oppositions result in patents being revoked or amended (para. 234). The latter statistic needs to be considered and should be mentioned when drawing conclusions such as that “generic companies are very successful in opposing originator company secondary patents”.

In addition, as indicated above, the suggestion in the Report that all amendments should be regarded as successes for the Generics is overstated.

The average duration to achieve a final decision on an Opposition (including any Appeal) is said to be approximately 3.6 years (para. 554). This is slightly longer than the average period for a court decision of 2.8 years (para. 516), but is faster than the process in several Member States. As with court decisions, given the complexities (including multi-party Oppositions) that duration is not unduly slow.

In addition, where infringement proceedings are brought in national courts, the parties to any Opposition or Appeal can request accelerated processing by the EPO (see the EPO’s Guidelines for Examination, E.VIII.4 and E.VIII.5, and the Notices dated 17 March 2008 published in OJ EPO 2008, 220 and 221). Also, some national courts will stay infringement proceedings as well as revocation proceedings (see para. 556) pending the outcome of the Opposition and Appeal.

In considering the duration of Opposition and Appeal proceedings, the analysis ignores the nine-month filing period for filing Oppositions (footnote 287). However, it should be noted that very often Oppositions are filed on or around the last possible day of that nine month period, giving the patentee as short a time as possible to consider the Opposition before responding.

4. *Settlements and Other Agreements (paras 573-699)*

As recognized in the Report (para 578), there is a strong public policy reason to encourage settlement of disputes, which is to avoid time, energy and money being wasted in unnecessary litigation. This is encouraged by national courts in various ways. For instance, the High Court in England and Wales will often penalize a party to litigation which fails to accept a reasonable settlement offer by requiring them to pay the other party’s costs. In practice, only the really marginal cases go to trial and the majority of cases settle. It is important that any competition policy intervention does not lead to an increase in unnecessary litigation.

These competing policy goals have been recognized in the United States, where the antitrust analysis of patent settlement agreements is in a state of flux. Not all settlements are viewed with suspicion, the two federal antitrust agencies are not completely in unison on the question of so-called “reverse payment” settlements, and there is disagreement between regulators and courts (paras. 652-655). This should be reflected in the Executive Summary, which at present only mentions the Federal Trade Commission’s approach and might lead the reader to believe this is the settled position in the United States.

Conclusion

In conclusion, AIPLA has attempted to provide a better understanding of the patent practices in the pharmaceutical industry, and their similarity to practices in other competitive industries. AIPLA hopes that this will help the Commission preserve the delicate balance of providing Originators with the necessary incentives to innovate and produce new products, while allowing Generics to flourish in order to reduce prices once exclusive protection expires on existing products, and to consider both sides of this balance carefully.

Sincerely,

A handwritten signature in cursive script, appearing to read 'T. Stanek Rea', written in black ink.

Teresa Stanek Rea
President, AIPLA