Licensing Executives Society International Inc.

LESI BOARD OF DIRECTORS 2008/2009

President
Adam Liberman
Phone +61 2 9490 8239
Fax +61 2 9490 8260
E-mail adam.liberman@csiro.au

Past President
Chikao Fukuda
Phone +81 3 3575 8051
Fax +81 3 3575 8054
E-mail fukuda.and.kondo@nifty.ne.jp

President Elect
Pat O'Reilley
Phone +1 202 408 4100
Fax +1 202 408 4400
E-mail pat.oreilley@finnegan.com

Secretary
James Malackowski
Phone +1 312 327 4410
Fax +1 312 327 4401
E-mail
jmalackowski@oceantomo.com

Treasurer
Peter Hess
Phone +49 8992 8050
Fax +49 8992 8054
E-mail hess@bardehle.de

Vice Presidents
Stephen Powell
Phone +44 20 7936 3300
Fax +44 20 7936 3311
E-mail
stephen.powell@williamspowell.com

Kevin Nachtrab
Phone +32 2 749 2544
Fax +32 2 749 2557
E-mail nachtrab@jppbe.jnj.com

Clarisse Escorel
Phone +55 21 2518 2264
Fax +55 21 2518 3152
E-mail cescorel@leonardos.com.br

www.lesi.org

Comments of the LESI European Committee in Response to the Pharmaceutical Sector Enquiry Preliminary Report Published by the European Commission (DG Competition)

Commission Reference 39.514

Executive Summary

Having carefully considered the Preliminary Report, the Licensing Executives Society International (LESI) has a number of concerns.

The Preliminary Report:

- complains that businesses in the pharma industry use an apparently anti-competitive "toolkit" of practices, in particular:
  - accumulating portfolios of patents and allegedly "bad patents"
  - patenting improvements products
  - delaying patent filings
  - litigating patents and entering into settlements
- suggests that these practices create a number of problems in the market for pharmaceutical products including a reduction in the introduction of innovative products and delay in the entry of generics.

But these approaches, which are not unique to the pharma industry, are used by all industries with a view to lawfully protect the developments that they make to enable the industry to make and get a reward from the making of improved products. All manner of goods, iPods, cameras, videos, televisions, as well as drugs, benefit from this process and it is the consumer who wants to have the fruits of this process.

Nor are these approaches and problems at all recent. Lord Justice Jacob of the English Court of Appeal quoted a publication of 1947 which sets out exactly the same situation. There is little doubt that these approaches and problems go back to the beginning of patent law. And there is equally no doubt that patent law has developed various and sophisticated ways of dealing with them. The common feature of these solutions under patent law principles is their balanced nature: patent law is characterised by its continual aim at achieving the correct balance between public and private interests and keeping a reasonable equilibrium between what is given to the owner of the patent and what is taken for the public interest at large.

The great problem in the European Union (EU) is the absence of a single central procedure in which patents can be tested once they have been granted. Such a procedure has been proposed since the beginning of the European patent system in 1973, but political pressures have prevented this.

Taking the analysis in the Preliminary Report to its logical conclusion seems to lead to the following propositions:

- that once a product has been developed improvements to it should not be protected; and
- that patent holders should not use litigation or settlements, the only routes they have, both of which are specifically sanctioned in European law (and indeed in the laws of all the industrialised nations of the world), to enforce their rights.

If these propositions are used as a basis for the development and application of the competition rules, LESI is concerned that the way is opened to the risk of:

- discouraging the protection of innovation;
- as a result reducing the inducements to innovate in the EU;
- as a result driving innovative industries away from the EU;
- as a result of that reducing the levels of employment in and the GDP of the EU; and
- delaying, or possibly denying, EU consumers the benefits of innovation,

and across all technical sectors, not just the pharma industry.
The "Lisbon Strategy" aimed at making the EU the most competitive economy in the world and achieving full employment by 2010. To propose ideas that will run directly contrary to that strategy in 2009 must be undesirable.

While no-one, least of all LESI which is set up to develop the free flow and use of technology, wishes to see competition being unlawfully stifled and markets for innovative products operate in an inefficient manner, there are a number of well-established means available to the Commission and to companies and individuals by which to address these issues and we believe that it is appropriate to rely on them to resolve cases rather than necessarily expanding the ambit of competition law.

Background

In January 2008, DG Competition of the European Commission launched an enquiry (Case No Comp/D2/39.514 Commission Decision of 15 January 2008 initiating an inquiry into the pharmaceutical sector pursuant to Article 17 of Council Regulation No 1/2003 [2008] OJ C59/06) into the European pharmaceutical industry prompted by concerns at the declining number of new drugs brought to market in the EU and the apparent difficulties for generic drug producers to introduce copies of new drugs once initial patent and data exclusivity protection had expired.

A preliminary report was issued by DG Competition on 28 November 2008 (Pharmaceutical Sector Enquiry – Preliminary Report (DG Competition Staff Working Paper), referred to in our comments as the "Preliminary Report") setting out a number of findings and possible areas of concern.

The Preliminary Report invited comments on its findings and this paper sets out the response of the Licensing Executives Society ("LESI") European Committee to the Preliminary Report.

Introduction

LESI is a global, not-for-profit, professional association made up of 32 national and regional societies, representing 93 countries. These national LES societies count altogether 12,000 individual members (including 3,500 in Europe) involved in the licensing, transfer and management of intellectual property rights. It is the largest professional organisation in the intellectual property field. Its aims include:

- Setting and promoting consistent, high professional standards for licensing executives on a global basis; and

- Informing and interacting with global organisations and policy forums concerning the economic significance and importance of licensing, technology transfer and intellectual property rights.

LES members comprise mainly licensing professionals, consultants, lawyers and patent attorneys drawn mainly from business, ranging from large multi-national organisations to SMEs

but also from universities, the public sector as well as law firms. LESI therefore occupies a unique position in representing such a wide variety of interests rather than the special interest nature of many other industry and professional organizations.

It is important in particular to note that LESI does not exist to advance the interests of a particular sector, but rather seeks to promote a properly functioning system of intellectual property protection suitable for all sectors. LESI, through the national LES societies, includes members working in both the innovative pharmaceutical industry and the generics industry. Consequently LESI in responding to the Preliminary Report must remain impartial as between the two industries and has focused instead on findings in the Preliminary Report regarding the functioning of the patent system and how it is used in practice.

Summary of Comments

We are aware that other respondents intend to comment on the Preliminary Report's statistical analysis – we intend to focus in our submission on issues of principle potentially affecting the patent system as a whole.

In summary, we believe that the Preliminary Report:

- inappropriately questions perfectly lawful practices that are neither new nor unique to the pharmaceutical industry;

- displays a misconception of the nature and particularly the functioning of the patent system in Europe and world-wide;

- shows potential in its reasoning to distort the patent system through inappropriate and uncertain use of competition rules; and

- demonstrates that the European Union at the very least needs a streamlined, efficient, centralised system for deciding questions of European patent validity and infringement, which preferably would embrace a unitary Community patent right as its cornerstone.

We believe the fundamental principles of the European patent system are robust and, subject to the introduction of a pan-European litigation system for patents, capable of addressing the inefficiencies in the pharmaceuticals market identified by the Preliminary Report.

We would urge the European Commission to think carefully before using the competition rules to remedy apparent inefficiencies in the pharmaceutical market perceived to be caused by the patent system when a much more certain and proportionate outcome can be achieved by enabling the patent system to function more effectively. In short, we would ask the European Commission to act in a co-ordinated and concerted manner to bring about a Community patent system for the benefit of the knowledge-based economy as a whole.

Detailed Analysis

We have set out below each of our main areas of interest together with commentary on specific aspects of the Preliminary Report's findings that give us cause for concern.

1. Practices Identified Are Neither New nor Unique to the Pharma Industry

(a) The components of the "tool box" are lawful, normal features of every industry in the knowledge-based economy

The Preliminary Report implies that the creation of patent portfolios that are then asserted by their owners (and possibly then resulting in settlements), together with patenting of improvements to existing products adding to those patent portfolios, are practices peculiar to the pharma industry that only recently have been unmasked by the Commission. As an organisation with members drawn from many disciplines and sectors, we are well placed to observe that such practices are standard practices in all industry sectors and have been for some time. The Commission has not suggested that these practices might be anti-competitive in those other sectors.

(b) Businesses in all industries need to maintain a portfolio of patents in order to keep up with unexpected changes in innovative products

It is a reality in every innovative industry that the company which first makes an invention will likely be first to file patent applications on that invention, thereby starting to build up a portfolio of patents blocking its competitors. The complaint is made that these patents are obtained solely to block competitors. In all industries, but particularly those with longer R&D timeframes such as the pharma industry, it can be difficult, if not impossible, for the patentee to predict which inventions will ultimately fulfil the needs of the market. Two interesting examples can found in the consumer electronics industry: in both the case of the VHS/Betamax and HD-DVD/Blu-ray format wars, we are not aware of anyone seriously suggesting that the retention of patents by the various parties involved would be anti-competitive whilst it became clear which format would dominate and hence where product development would be directed.

The Preliminary Report seems to suggest that the first inventor has to make a once and for all choice as to which of its inventions are viable, handing the rest to rivals. No company would want effectively to make available the results of its research to rivals while it is still possible the invention might be useful. Moreover, this seems to conflict with European case law that states that mere accumulation of patents, no matter how many, is not in and of itself illegal (Case T-83/91 *Tetra Pak International SA* v. *Commission* [1994] ECR II-755, para. 242).

The Preliminary Report similarly postulates that "webs", "clusters" or "thickets" of patents may be delaying generic copies from entering the market. It also finds examples of patents filed near to expiry of the "primary patent" protecting a product and suggests that patenting late in a product's lifecycle is evidence of suspicious deterrence of imitation products, rather than legitimate patenting of new and inventive developments during a product's lifecycle.

We would point to the fact that modern technologies rely upon extremely complex patented inventions, which are developed and improved through their lives, potentially leading to further patentable improvement inventions. Consumer electronics, semiconductors, computers and, indeed, pharmaceuticals have numerous patents applicable to them. Their respective patent portfolios will grow over time with ongoing R&D. This has long been the

case without the need for expanded intervention of competition law. We are concerned that competition law intervention would weaken intellectual property protection and deter innovative research, precisely what the European Union's Lisbon Agenda is supposed to promote.

We would, therefore, respectfully agree with the comment of Lord Justice Jacob ("Patents and Pharmaceuticals", Presentation to the Pharmaceutical Sector Inquiry Hearing, 28 November 2008) when he stated that, "*Any experienced patent lawyer will tell you that clusters of improvement patents are a feature of nearly all industries. It is a bit worrying that the Commission seems to think that it has discovered something new and special to the pharma industry.*"

(c) Patent law already provides the mechanisms to deal with patents that are subsequently shown to be invalid

We do not disagree with the apparent assumption of the Preliminary Report that even patent offices employing the rigour similar to that displayed by the European Patent Office may grant patents that a court later concludes should not have been granted. Often, this is because the court (and often the patentee) becomes aware of prior art or other facts which the patent office could not reasonably have been expected to know. Equally, it could be because the applicant's patent agent was able to convince the examining officer on an issue of patentability, whereas the judge ultimately takes a different view. In fact our experience of pan-European patent litigation has shown that even national courts can legitimately take differing views on questions such as obviousness without the patents being characterised as "bad".

It is perfectly rational for a business actively to seek patent protection wherever possible and neither of these circumstances appears to us to infringe any competition rules. Moreover, where a "bad patent" is granted, any third party that is affected can oppose it at the EPO for a centrally granted European patent or seek its revocation before national courts.

We would also draw attention to the fact that other sectors routinely experience patents being revoked under opposition or by the courts. Indeed, the Preliminary Report notes that there are stricter grant rates for pharmaceutical patents in the EPO (33% compared to the 50% EPO average) and higher levels of opposition (8% compared to the 6% average), which we submit could in fact indicate a disproportionately lower percentage of poor quality pharmaceutical patents ultimately issued.

2. **The Preliminary Report Displays a Misunderstanding of the Functioning of the Patent System**

(a) Continuous improvement of products and patenting of incremental improvements is a normal part of the patent system

One of the most worrying insinuations made by the Preliminary Report is that the improvement of pharmaceutical products and the patenting of those improvements could be characterised as anti-competitive. The Commission's reasoning would appear to be that next generation products with, for example, greater potency, fewer side-effects or reduced dosing regimens are illegitimately extending the market share gained by the original product, despite in most cases the conclusion from a competent patent office such as the EPO that the improved product is patentable over the prior art, including the first generation product. The illegitimacy seems to derive from the fact that such improvements would remain patent protected once the first generation product goes off patent, disadvantaging the generic manufacturer insofar as it would only be able to copy the first generation drug. The unacceptable alternative however would be that once a product is introduced, it could never be improved further for fear of disadvantaging competitors.

We are not aware of any competition case law which condemns second-generation or improved products or their marketing. Moreover in our experience such improved products routinely fulfil the criteria for patentability and, as a consequence, gain quite legitimate patent protection *where the scope is necessarily limited to the improvement.* Furthermore, we would certainly challenge the assumption that seems to be underlying the Preliminary Report's

thinking that patents on improvements to aspects of a product or how it is produced are inherently of little or no intrinsic value.

(b) Patent filings tend to be dictated by when innovation takes place and when sufficient supportive data is available

It is suggested in the Preliminary Report that innovative pharmaceutical companies delay filing patent applications on improvements to a particular product in order to prolong the monopoly on that product. We believe that such a strategy runs counter to how the patent system works since the innovator risks losing any chance of patent protection if a competitor discovers, and applies to patent, or publishes, the same invention first. There is in reality little incentive and much risk in delaying.

In any event, subsequent patent applications cannot extend the scope of the original monopoly of the product patent covering the innovator's compound since the application must be for a different invention. The claims of the subsequent patent covering further developments of and improvements to the medicinal product will inevitably be different, possibly also of narrower scope (to avoid being anticipated by, or otherwise regarded as non-inventive over, the earlier disclosure that led to the original patent) and so cannot be characterised as an illegitimate extension. Further, the subsequent patent will still have to satisfy the usual criteria of patentability, notably that it is novel and inventive over the prior art, that the original compound patent had to satisfy.

The only rational basis for delaying a filing is to enable sufficient data to be generated that will exemplify the invention in order to provide sufficient support to the claims in the patent application. We suggest that this is a perfectly legitimate ground on which to delay filing. First it would also be reckless to file an application which did not contain sufficient information to support the application as otherwise the application would be rejected. Second it is fundamental to the *quid pro quo* mantra of the patent system, namely, requiring a patent disclosure to teach others how to adequately make and use the invention in exchange for receiving a time-limited monopoly.

(c) Existing procedures can be used to clear the path to market

We believe that the Preliminary Report gives insufficient weight to the procedures already available in European patent law to clear "bad" patents from the path to market, namely:

- Third party observations during EPO examination
- Opposition before the EPO
- Application to a national court to revoke a patent and/or declare it not infringed

The observation and opposition procedures before the EPO are almost risk-free, notably because the EPO does not have the power to make any award of costs against the opponent. There is however no denying in the latter case that something needs to be done to reduce the inordinately long time to final resolution.

We would also query the report's view that interim relief has "very serious" consequences for generics, given that they are typically entitled to claim damages for lost profits if the innovator ultimately loses at trial.

(d) European patent prosecution strategy cannot be used indefinitely to extend a monopoly

We would caution against trying to identify and distinguish between good patenting practice and bad patenting practice, the latter serving somehow illegitimately to extend the term of patent protection. In our experience, the rules governing patent prosecution in Europe simply do not allow this to happen. The Preliminary Report claims that divisionals "*serve to prevent or delay generic entry*", but it is difficult to see how this could be the case, given that there is only a limited period of time in which to file a divisional application and that the filing date for the purpose of calculating the period of protection is the same as for the parent application, making patent term extension by means of divisional applications impossible.

(e) The most important number when examining the extent of patent protection for a product is the number of families, not overall number of patents

Finally, we believe that in assessing the size of a patent portfolio, it is misleading to cite the total number of individual patents and patent applications, such as in the case of LIPITOR, which is mentioned several times in the Preliminary Report. The number 1,300 is mentioned, but this is because in Europe a separate patent for the same invention has to be obtained in each market. Rather, this number should be divided by the number of markets in which protection is sought to give number of patent families (group of patents (even within different countries) claiming priority to a common priority document) and hence inventions that have been made with respect to a product.

3. Potential to Distort Patent System

(a) The Preliminary Report impugns certain aspects of the patent system without setting out any legal basis

The purpose of the Preliminary Report, as we understood it, was to set out findings of fact that would then inform further investigations into whether any breaches of the European competition rules had occurred. However, the Commission has apparently gone further and either explicitly condemns certain practices or implies that they are somehow suspicious, but without considering how an anti-competitive agreement has been put in place or how a dominant position has been abused.

EC competition law as regards to patent portfolios, litigation and settlements clearly finds that intrusion into intellectual property can only be justified in the most "exceptional circumstances" (in cases such as Cases 241 & 242/91 *RTE & ITP* v. *Commission* [1995] ECR 743 and Case C-418/01 *IMS Health GmbH & Co OHG* v. *NDC Health GmbH & Co* KG [2004] ECR 5039). Accordingly, if certain practices raise antitrust concerns in exceptional circumstances, *those circumstances must be articulated*. The Preliminary Report offers no such

guidance while threatening "cases against companies where there are indications that the antitrust rules may have been breached." In fact there is already guidance in paragraphs 204 *et seq* of the Intellectual Property Guidelines (Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements (2004/C 101/02)) of the Commission which in our experience do already provide a reasonable degree of legal certainty.

(b) The Preliminary Report seems to suggest that seeking to enforce a patent may be an infringement of European competition law

As we noted above, there a number of legitimate reasons why a patent office may grant a patent that is ultimately found to be invalid. If a competitor believes that a patent is invalid then the appropriate route is either to oppose grant before the EPO or to seek its revocation in the courts. The Preliminary Report finds that in the pharmaceutical sector, of the cases examined innovators lost the majority of cases against generics (62% of 149 final judgements), though they won 51% of those they initiated (we are aware that questions have been raised as to the validity of the statistical analysis undertaken). The Commission suggests these statistics show that the patents asserted by innovators may be weak and granted too readily by the European Patent Office. It is argued from this that patent owners are somehow wrong to assert their patents through courts proceedings, yet patent litigation is the only means by which intangible intellectual property can be protected. It has been acknowledged in European jurisprudence (Case T-111/96 *ITT Promedia NV* v. *Commission* [1998] ECR II-2937) that access to the courts is an inalienable right, protected by the European Convention on Human Rights and the ownership of property is protected by article 222 of the Treaty of Rome. We do not believe that it is the place of competition law to assess the validity of a patent and hence whether a patentee is entitled to assert its patent in court. Any attempt to do this could severely undermine the effectiveness of the patent system in encouraging and rewarding innovation.

(c) Settlement of patent litigation should be encouraged since it is consistent with general judicial policy and ensures resources are not wasted

Patent disputes are often complex, time-consuming and expensive and taken with the parties' differing expectations of the appropriate outcome, one can conceive of any number of circumstances in which and arrangements by which parties may seek in good faith to settle their dispute on commercially reasonable terms. In the United Kingdom, parties are under considerable pressure from the courts to settle disputes at an early stage. In Italy, one of the Court hearings before litigation goes into the "technical assessment" phase (the most costly one) is used to seek a possible agreement between the parties. No rational business would in our experience seek to continue litigation with an uncertain outcome where a reasonable settlement of the issues is possible. Indeed the Commission's own guidelines on technology licensing (Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements (2004/C 101/02), paragraph 209) suggest that settlement agreements should be treated more leniently because of the economic benefits of settling litigation.

Comments made in the Preliminary Report suggest that any settlement between innovators and generics must be regarded as inherently suspicious. We believe that each case must be considered on its merits with a certain framework provided by the technology licensing rules.

(d) Pharmaceutical patents should be judged by the same standards as any other patent

We would draw the Commission's attention to Article 27 of the WTO Trade-Related Aspects of Intellectual Property Agreement ("TRIPS"), which states (with emphasis added) that, "*patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.*" We discerned in the Commission's thinking revealed in the Preliminary Report that patentability of inventions in the pharmaceutical sector should perhaps be judged by a higher standard than other patents, whether in terms of substantive

requirements, rigour of examination or the circumstances in which recourse may be had to the courts. This would appear to conflict with EU member states' obligations under TRIPS and provides a further reason for considering the behaviour identified by the Commission in the context of the operation of the knowledge-based economy as a whole. Patents are arguably more, not less, important in the pharmaceutical field given the very high costs of innovation and the importance of the product to consumers' health.

4. **Many Inefficiencies Would Be Addressed by Community Patent and Community Patent Court**

To the extent that there are inefficiencies in the markets for innovative and generic pharmaceuticals, we believe that these should be addressed holistically in all areas where policy is directed at an EU level. This should involve areas such as intellectual property and pharmaceutical regulation as well as competition policy. In particular, we would urge the Commission as a whole to consider whether many of its complaints would not be addressed by the implementation of a Community-wide patent litigation system and indeed the Community patent.

Indeed we welcome the Commission's principal conclusion which recommends a single European patent court and even a single Community patent. A single Community patent would bring a number of advantages such as a less burdensome language regime and an enormous simplification of administrative arrangements for managing portfolios, but for current purposes, the cost saving and efficiencies of having one centralised court for deciding issues of validity and infringement as well as possible compulsory licences cannot be overstated. It seems to us that many of the Commission's implied criticisms flow in essence from the fact that a competitor to a patent owner has to go through multiple parallel proceedings throughout the EU in order to gain certainty on the infringement or otherwise of an apparently blocking patent or seeks its revocation. Such objections would be addressed almost entirely by the adoption of single European court with patent jurisdiction. As an interim measure, we would urge the Commission to support the introduction of the European Patent Litigation Agreement, which could be brought in quickly and allow early experience to be gained of a pan-European patent court and its procedure.

5. Contact Details

The LESI European Committee would be delighted to expand upon any of the points raised in these comments. The Committee can be reached through its chairman, Jean-Christophe Troussel at the following address:

c/o Bird & Bird
Avenue d'Auderghem 22-28
1040 Brussels
Belgium
Telephone: +32 2 282 6000
E-mail: jean.christophe.troussel@twobirds.com.

Jean-Christophe Troussel
Chairman, LESI European Committee
Brussels, 30 January 2009