



INTELLECTUAL PROPERTY INSTITUTE

Response to the invitation to submit comments to the preliminary findings in the
European Commission Pharmaceutical Sector Inquiry

(reference: 39514)

A Introduction

About the Intellectual Property Institute (“the Institute”)

The Intellectual Property Institute is the UK’s leading, independent research body addressing all aspects of intellectual property law and regulation and its economic and social effects. The Institute was established in 1983 as an independent, not-for-profit, organisation at the instigation of the UK government, to provide high quality, sector-independent and evidence-based research to inform the development of IP law and policy, particularly in the UK and other “common law” based countries. Since its foundation the Institute’s research has been wide ranging in scope¹ and it has been used to help frame policy initiatives by both the UK and other governments, such as the extent of patent protection for pharmaceutical products in India in the work of the Mashelkar Committee. Over the past twenty five years, the Institute has carried out considerable research in the patents field, including numerous studies directed towards pharmaceuticals. This work encompasses the major legal, economic and business-related issues which have affected the sector during that time: it informs the comments that we make here.

When the Institute was established, the significance of the intellectual property system as a driver of European economic wellbeing was just beginning to be understood. Today, it is widely accepted that an effective IP regime is crucial to Europe’s competitiveness and economic success across most industrial sectors and especially those like pharmaceuticals and crop protection where sustained investment in high technology is needed in a highly regulated environment.

¹ Illustrative research publications from the Intellectual Property Institute can be found at <http://www.ip-institute.org.uk/pub.html>

Reasons for the Inquiry

In its Preliminary Report (“the Report”), the Commission rightly acknowledges the significance of the pharmaceutical industry to Europe’s economy and to the wellbeing of its citizens. This industry is characterised by its dependence on, and commitment to, research and development (R&D) over an extended period to develop innovative products and processes in a highly regulated environment. The high cost of R&D required to discover and bring to the market new products, coupled with the relative ease of copying and low cost of manufacture (once the products have been invented, developed and shown to be clinically effective), necessarily lead to an industry sector which is highly dependent upon patents and related intellectual property rights.

In instituting this extensive Inquiry, the Commission has stated² that it believes that competition in the European pharmaceutical sector might be distorted and that this might be linked in some way to fewer new chemical entities reaching the market and to delayed market entry of generic versions. Concerns about issues such as patent strategy, patent prosecution practices and litigation in the pharmaceutical sector seem to be central to the Commission’s belief³. However, such patent related issues pervade many sectors of industry that use the patent system in Europe. Consequently, the outcome of the Inquiry will resonate far beyond pharmaceuticals, ultimately affecting many patent-dependent sectors.

The Institute does not underestimate the wider significance for other sectors and urges the Commission to ensure that the findings of the Inquiry should be made on an objective assessment of the available evidence.

B General Remarks about the Preliminary Findings

A major aim of the Institute is to provide empirical data and analysis to support or counter presumptions which are often based on anecdote (as is the case for many issues in the IP arena). Given the role and expertise of the Institute, we will confine our detailed comments to the sections of the Report which specifically address intellectual property issues. Before doing so, we wish to make two general comments about the Report, concerning first the Commission’s methodology and the presentation of data and second, the process and sequence of events involved in drug discovery by the innovator companies.

First, whilst the Institute welcomes the considerable efforts made by the Commission and the industry to compile an extensive set of data against which to test some of the issues chosen by the Commission for their potential to distort competition within the pharmaceuticals sector in Europe, it is unfortunate that

² See for example, paragraph 6 of the Report and the opening remarks from Commissioner Kroes at the public hearing in Brussels on 28th November 2008.

³ See for example paragraph 9 of the Report.

some of the analysis and preliminary conclusions presented in the Report seem to us to be unsatisfactory and not soundly based on the evidence.

The normal research process is to start with a hypothesis, collect and analyse the relevant data and then form conclusions about the hypothesis. This process does not seem to have been properly followed in this Inquiry⁴. Rather, some of the data analyses seem to have been skewed to fit preconceived theories. Further, the use of unnecessarily pejorative language⁵ in the Report and the way it has been presented to the public⁶ detract from the impartiality and validity of the preliminary findings. The potentially valuable evidence is inconsistently presented with actual numbers and percentages seemingly used arbitrarily in places to lend support to what appear to be preconceived ideas⁷. Although there is an extended discussion of methodology in the Annexes to part A of the Report, the standard of statistical analysis and interpretation presented in the Report is generally inadequate with sample sizes and ranges being missing. The Institute urges the Commission to address these general points when presenting its final findings if they are to be credible.

Second, there seems to be a fundamental misunderstanding by the Commission of the process and sequence of events involved in drug discovery and development. Much as innovator companies might wish discovery of new medicines to be a predictable process, it is not – it is still largely based on serendipity. Consequently, given the intensely competitive activity directed against many disease targets it is not surprising that soon after a biologically active compound (the so-called “lead” compound) is found, an initial patent application is often filed to protect a range of compounds, including and related to the lead compound. Thus, it may be some time (months to years) before a potential candidate new chemical entity (“NCE”) is found for development and further patent applications will have been filed as the “lead” is explored.

Similarly, developing an NCE towards a marketable product is not straightforward and many problems of scale-up manufacture, formulation and handling will occur, requiring technical solutions. If these are novel and inventive, then patent applications will again be sought to protect these developments. So, given the extended period of years of R&D effort by large teams of scientists and technologists, it is not surprising that any particular new product should have a range of separate patents protecting the NCE, its different features, formulation and manufacture. The existence of such a group of patents (“clusters” in the Report’s terminology) does not demonstrate the presence of any improper

⁴ For example, in terms of the analysis, we note that the Commission does not appear to have considered the impact of the lack of Bolar type provisions in all EU countries until 31 October 2005 on the average 7 month delay noted in the Report for the launch of new generic products.

⁵ The Report refers, for example, to a “vicious circle of patenting” (see paragraph 415).

⁶ For example, in the Commission’s Press Release and at the public hearing on 28th November 2008.

⁷ For example, the statement about “filing for up to 1300 patents EU-wide in relation to a single medicine” in the Conclusion (Section E) is misleading. It implies the patents are for separate inventions since it takes no account of the 30+ separate countries for which essentially identical patents must be obtained to secure protection across the EU. Taking that into account, the real number of separate patent families on different inventions is probably nearer to 43.

strategy – it is rather an inevitable result of the existence of the patent system and the R&D process in a competitive environment. No viable commercial enterprise in any industry sector can afford to ignore seeking protection for the innovative developments in which they are investing significant resources.

C Detailed Comments about the Preliminary Findings

Our detailed comments are directed to the three intellectual property related issues described in Sections 2.1-2.3 of the Report, namely:

1. Patent filing strategies;
2. Patent-Related Exchanges and Litigation;
3. Oppositions and Appeals.

Where appropriate, we have put forward our suggested recommendations for further consideration or action by the Commission in response to the findings in the Report. Finally, we have addressed in brief the matter of Settlements and Other Agreements (referred to in Section 2.4 of the Report), since these often arise as a consequence of patent-related disputes.

1 Patent Filing Strategies

1.1 Patent Filings during the Drug Discovery and Development Process

The description of the patent filing procedures for the innovator companies as described in the Report appears somewhat superficial.

First, as mentioned earlier, the patent filing process will typically begin following discovery of initial lead activity and before the actual NCE for the eventual marketed product has been indentified. This is because, at the point of making this first patent filing to establish early priority for the invention, it is not usually known whether any marketable product will result. Consequently, the breadth of protection sought will be relatively wide. This is not primarily to restrict competition but to allow the applicant some choice of possible development candidates as research continues. It is true that the claim in any patent granted in this application may still be broader than the eventual NCE under development, but this is the normal situation for patents in all technology sectors i.e. the claims represent a reasonable prediction of embodiments based on what has been actually described in the patent specification in relation to the prior art.

Second, there is no description of the interrelationship between the research departments within the innovator companies and their patent advisors (internal and/or external), indicating the workflows involved from identification of an NCE, to the filing of an initial patent application (in the language of the Commission, “the base patent”) and the development of a patent strategy for the protection of the product as it approaches the date of expiry of the base patent.

Further, as mentioned earlier, drug discovery and development are risky and protracted processes. Once lead biological activity has been discovered, further

research then has to take place to identify the best NCE for development and then progress over several years into the eventual drug optimised for human use. Because of the technical problems likely to be encountered, this development process will necessarily lead to further inventions, leading to opportunities for further patent filings (or in the terminology of the Commission, “secondary patents”⁸). Still further patentable inventions may arise once the drug is used in humans leading to further patents for new uses (illustrated for example by the discovery of the use of the cardiovascular agent sildenafil (VIAGRA®) for the treatment of erectile dysfunction). So called “secondary patents” will be addressed further below, although we note here that the Report adopts a rather simplistic approach to these patents, apparently premised on the assumption that all patent filings subsequent to the base patent are made with the objective of producing a “patent cluster” that will prevent generic competition at some point in the future⁹.

It must be pointed out that a so-called “secondary patent” may not necessarily be secondary in importance to a “primary” or “base patent” protecting the NCE. For example, a secondary patent may protect the only economically feasible process for manufacture or alternatively the only formulation capable of administering the NCE effectively to humans. Furthermore, such secondary patents may initially be held by a competitor company originator or a generic company (which is free to patent inventions based on the NCE once its identity is known with publication of the so called base patent application 18 months after first filing).

Whilst we acknowledge that patent filing strategies aimed *solely* at excluding generic competition (i.e. without any *bona fide* belief in the fact that an invention has been made) may be the subject of valid complaint, we see no clear evidence of this type of conduct in the Report.

1.2 Generic Competition on Expiry of the Base Patent

The Report envisages that the generic companies will seek to challenge the “base patent”¹⁰ (i.e. the patent which covers the active ingredient). There is no firm evidence for this within the Report. A more likely scenario would be that generic companies will wait until the expiry of the base patent (plus any supplementary protection certificate) before contemplating a generic launch. This view is supported by the fact that the majority of patents that are the subject of litigation are secondary patents: further, the Commission’s finding that secondary patents are likely to be litigated early in their life¹¹ would also seem to support that view.

1.3 Secondary Patents

⁸ We believe that the Commission overstates the position with regard to the timing of the filing of secondary patent applications in its Report at paragraph 390. Patent applications are not generally filed by reference to a competitor’s activity, but rather, as soon as an innovation has been made.

⁹ See paragraph 376.

¹⁰ See paragraph 375.

¹¹ Paragraph 496.

1.3.1 Patent Clusters and the Response of Generic Companies

When reviewing potential IP constraints on a generic product before market launch, the generic companies will usually be dealing with so called “secondary patents”, such as process patents, patents protecting a particular physical form of the active pharmaceutical ingredient (the NCE) used in the originator product, second medical use patents or formulation patents. Such “secondary patents” *may* delay generic entry, but it is not a matter of *inevitable infringement* in the face of a patent web, or a patent thicket¹². The statement to this effect in the Report is too simplistic. Furthermore, it must be understood that a generic company is immediately free to use the active ingredient in its own developed formulation once the “primary” or base patent on the active ingredient has expired – in other words, the generic company does not have to copy the latest marketed version of the product which may be the subject of “secondary patents”.

It may be necessary for a prospective generic competitor to put in place its own patent strategies involving patent clearance activities (oppositions, litigation, settlements) to enable their launch to proceed in a timely fashion after expiry of the base patent. There is little if any mention of the content of such strategies in the Report and yet these could also bear significantly on competition within the sector. However, there is evidential support in the Report for the general effectiveness of the generic companies’ strategies in this regard, for example:

- in successful generic company-originated litigation^{13,14}; and
- in concentrating oppositions on secondary patents¹⁵.

We are not convinced that a generic company would *abandon* a development¹⁶ solely because of the uncertainty created by (ungranted) patent applications. A project is more likely to be abandoned because the generic company took the view that a patent would ultimately be *granted* and held *valid*, rather than just because of uncertainty. It is however impossible to assess the weight of the Commission’s evidence in the Report, since the quotations are unattributed.

Whilst generic companies are generally aware of the date of expiry of the base patent, we accept that there may be a case for making the secondary patent landscape within the EU specific to a marketed drug more transparent. The “Orange Book” system operated in the USA allows all patents relevant to a particular pharmaceutical product to be listed, thereby clarifying the patent landscape and allowing competitors to assess clearly any patent obstacles prior to launching a generic product. A central EU database of pertinent patent and supplementary protection certificate information provided by the originator companies coupled with an obligation on behalf of the regulatory authorities to provide information on the filing of applications for generic marketing approvals

¹² Paragraph 387.

¹³ Paragraph 469.

¹⁴ Paragraph 508.

¹⁵ Paragraph 564.

¹⁶ Paragraph 421.

might, we suggest, go a considerable way towards addressing the concerns identified in the Report as to uncertainty.

1.3.2 Patent Quality

The statement in the Report that patent clusters can give rise to an increase in “weak patents”¹⁷ is, we respectfully suggest, pejorative and unhelpful. Any valid patent is a “strong” patent. An invalid patent is not a “weak” patent – it is largely valueless.

Furthermore, it is not possible to draw the general conclusion that because the majority of the patents litigated between originator and generic companies was revoked, that the novelty and inventive step requirements at the EPO are too easily met. Self-evidently, the generic companies will usually litigate on the patents where they believe that they will have the greatest chance of success. This is why the generic companies won 71% of all patent cases that they initiated¹⁸. The litigation statistics are more reflective of the generic companies’ ability to assess patent validity and their effectiveness at litigation, rather than an accurate determinant of patent quality.

The Commission has acknowledged that the issue of “patent quality” is on the agenda of the EPO¹⁹ but we would qualify this by noting that concerns about patent quality are not confined to the pharmaceutical industry – patent quality is an issue of concern to all technology sectors with an interest in securing an efficient system for the grant of patents.

1.3.3 Divisional Patent Filings

The Report appears to make the assumption that because there is evidence of the voluntary filing of divisional applications by some originator companies, such practices must necessarily form part of a broader strategy to delay generic entry²⁰. There is no evidence in the Report to support this assumption.

The basis for filing divisional applications is described briefly²¹ in the Report but it does not explain properly the purpose of such filings. The mechanism for divisional applications is there to deal with a formal requirement of EPC Article 82 that an application may relate to a single invention or group of inventions with the same inventive concept.

Divisional applications are most usually required by the Examining Division when the claims are examined, but it is also currently possible to file such applications on a voluntary basis whilst the application is still pending. However, the claims in the divisional application must be distinct from the parent application and no new matter may be added. Further, any eventual patent will have the same expiry

¹⁷ Paragraph 393.

¹⁸ Paragraph 503.

¹⁹ Paragraph 1112.

²⁰ See for example the Summary after paragraph 432.

²¹ Paragraph 230

date as the parent patent; i.e. no extension of term can result from filing a divisional application.

The existence of new divisional applications is published on the European Patent Register which is freely available to anyone to inspect on-line. Consequently, the filing of divisional applications is simply a useful procedural option, helpful to all patent applicants across all technology sectors. The Commission's evidence of the filing of divisional applications does not, in our view, form any kind of compelling picture of inappropriately conceived patent strategies on the part of originator companies in the pharmaceutical sector²².

We acknowledge that there may be potential scope for misuse of the system, using a strategy of routine filing of divisional applications (for example, before oral hearings in opposition proceedings). That said, there are sometimes situations where, because of very short periods for response specified by the EPO, filing a divisional application may be the only means open to preserve the applicant's rights and allow time for a considered response.

We stress that in any event, this is a feature of the patent system that is common to all areas of technology. However, modification to the situation in which all applicants for patents can file divisional applications on a voluntary basis is under active discussion on the initiative of the President of the European Patent Office and so the procedural option of late divisional applications may effectively be limited for all industry sectors in the future.

2 Patent-Related Exchanges and Litigation

2.1 Patent-Related Information Exchanges

In relation to patent-related exchanges of information between generic and innovator companies, we would observe that there is missing from the Report any attempt to analyse the purpose of such exchanges. The Report appears to proceed on the assumption that many of these exchanges are initiated by the innovator companies, simply asserting their rights. However, many of these exchanges might be better characterised as a request for information which may lead to discussions that resolve the matter in dispute. In particular, the innovator company is often faced with a generic launch and may only have incomplete information, e.g. as to the process of manufacture. The contentious nature of many of these exchanges may lead to litigation, without the opportunity for a full exchange of information to take place.

There may therefore be a case for putting in place more formalised procedures for the exchange of information between opposing parties as a precursor to patent litigation, but this is something that requires further study.

2.2 Litigation

The Report finds that the top ten products accounted for 59% of all contacts and disputes between originator and generic companies during the relevant period

²²As is suggested in the Report, for example at paragraph 398 ff.

under review²³. We note also that the 20 most litigated products accounted for the majority of all patent litigation in the EU (80%)²⁴. Furthermore, the top six INNs were the object of nearly half of all reported litigations (49%). It is not surprising that the best-selling medicines represent the most promising and rewarding targets for generics, in relation to which litigation risk will more readily be undertaken.

We have already observed that the statistics presented on success in patent litigation are not convincing as an indicator of patent quality²⁵. More likely, these statistics reflect the fact that an originator company often has much more to lose than a generic company opponent.

Furthermore, there is a fundamental misconception in the notion that because courts find some patents invalid, the patent granting system is flawed. Any patent granting office is limited in terms of the resources that can be expended in assessing whether a particular patent application should be granted. However, in litigation, the intense scrutiny directed at the issue of a patent's validity is much greater than can ever be justified for the examination of each and every patent application (long before it is known whether it has any value)²⁶.

Finally, an underlying implication in the Report (for which no hard evidence is provided) is that the litigation statistics demonstrate that a significant proportion of the legal cases brought (or defended) by the originator companies are objectively baseless, i.e. that such cases are not a *bona fide* attempt to enforce (or defend) exclusive rights, but rather an attempt to take advantage of litigation enforcement procedures simply to delay generic entry. There is only limited competition law jurisprudence on this issue²⁷, but clearly, if convincing evidence of such activities has been found by the Commission, then it falls to the Commission to undertake whatever enforcement action it deems appropriate in the circumstances of a particular case, on a case-by-case basis. We do not recommend any regulatory or policy change in light of the Commission's observations on this topic.

2.2.1 Features of Litigation: Cost, Variance of National Procedures, Inconsistency of Decisions

We note the finding in the Report that the cost of litigation may deter small generic companies²⁸. However, cost is often a bar to access for SMEs to the litigation process, irrespective of the area of technology.

²³ Paragraphs 441-445.

²⁴ Paragraph 482. See also paragraph 487.

²⁵ Furthermore, whilst the bare litigation statistics are noteworthy, they do not reveal details either of individual behaviour by the litigating firms or the specific products that were the subject of the cases.

²⁶ 95% of granted patents turn out to be valueless, with the passage of time.

²⁷ *ITT Promedia NV v Commission* [1988] 5 CMLR 491-529.

²⁸ Paragraph 436.

Similarly, the different litigation procedural rules followed in the different Member States are part of the legal playing field for all companies, large and small, irrespective of the area of technology.

The Report also refers to the difficulties caused by conflicting decisions by the courts in different Member States²⁹. Again, this is a feature of the patent system in the EU which all companies have to endure for the time being.

We note the Report's positive conclusions on the need both for a Community Patent³⁰ and a unified and specialised patent judiciary in the Community³¹ and we welcome and endorse the Commission's conclusions on those issues.

2.2.2 Interim Injunctions

We agree that interim injunctions can have a very serious effect on generic companies³², but usually the innovator will be required to post a bond (or to give security) so that the generic company will be compensated, if the innovator ultimately loses the case on the merits.

We would observe that interim injunctions are not generally provided without cogent evidence of irreparable harm by the courts in those countries with a developed and specialised patent judiciary. In our view, the Report is somewhat deficient in that it does not attempt to tackle in any substantive detail the rationale for the grant of interim injunctions in pharmaceutical cases³³. In brief, where an originator's product is the only one on the market, the entry of a generic competitor may cause irreversible harm, such as loss of market share and price depression, which may not be recovered if it later transpires after a full trial on the merits that the patent monopoly should have been respected.

Whilst it is not possible to generalise for all cases, clearly the availability of interim injunctive relief is vitally important for the originator companies. The Commission has not put forward adequate evidence of abuse of such public procedures such as to merit consideration of EU-wide reform. Should the Commission have identified specific cases of abuse during the inquiry, then it falls to the Commission to undertake enforcement action, on a case-by-case basis.

3. Oppositions and Appeals³⁴

The relatively high opposition rate in pharmaceuticals compared to other sectors is noted³⁵, but in our view is unsurprising, given the nature of the sector, with its

²⁹ We observe that the statistic cited - 16 conflicting decisions out of 149 reviewed (11% of cases) was not as high as we expected, although clearly there is room for improvement.

³⁰ Paragraph 1088.

³¹ Paragraph 1096.

³² Paragraph 466.

³³ See Section 2.2.2.7 of the Report.

³⁴ We believe that the analysis of the results of oppositions (in paragraphs 569-570) may be flawed, because an outcome which results in amendment to patent claims (counted as a success for the generic companies in the Report) will necessarily leave the innovator company with a valid and enforceable patent, albeit with a narrower scope of monopoly.

R&D intensity, dependence upon effective patent protection and the relatively high margins that can be earned by both originator and generic companies. However, there is no analysis in the Report of the breakdown between opponents i.e. whether they are generic or originator companies. Furthermore, the Report does not analyse the proportion of oppositions to patents owned by generic companies.

The delays experienced in relation to EPO opposition procedures are well known across most technology sectors and indeed this has been the focus of attention by the EPO in recent years.³⁶ The Report contains no cogent evidence of deliberate delay in opposition proceedings with the principal objective of frustrating competition.

4. Settlements and Other Agreements

We note that in the Commission's overview of the main characteristics of patent settlement agreements, it is said that it is the consumer who inevitably pays the price for delay in generic market entry, if an originator company and a generic company make an agreement to this effect when making a patent settlement³⁷. We question whether this is necessarily always the case. Thus, an originator may not wish to put the validity of an important patent at risk through litigation: a limited, one-off licence to a generic competitor might be a price the originator would consider worth paying for certainty. In such circumstances, the consumer will then have two possible sources of supply instead of one and presumably the consumer would gain from the resulting increase in competition.

We note in this context that the appetite of a company for litigation risk will determine its attitude to settlement. Thus, according to the Report, only two companies accounted for 85 of the 207 settlements (41%)³⁸, suggesting that these two particular companies have a low appetite for litigation risk. We note further the high percentage of respondents who cited inherent uncertainty in patent litigation as a factor for entering into a settlement, for both originator and generic companies³⁹.

We do not believe that it is possible to conclude from the evidential findings in the Report that patent settlement agreements are being used to mask invalid patents, to the detriment of consumers.

There are clearly many factors that might encourage the parties involved in litigation to reach a deal rather than continue litigation to final judgment in court. In our view, settlements should not be discouraged and we recommend the Commission to maintain a flexible attitude towards the assessment of patent settlement agreements under the competition rules. Nevertheless, it is possible that all industry players (originator and generic) might benefit from greater

³⁵ Paragraph 552.

³⁶ See for example in the European Patent Office's Annual Report (2007).

³⁷ Paragraph 579.

³⁸ Paragraph 584.

³⁹ See Table 19 on page 224 (originators) and Table 20 on page 225 (generics).

transparency from the Commission, in terms of its approach to restrictions in patent settlement agreements, perhaps by issuing Commission guidance for such agreements in this specific sector⁴⁰.

D Concluding Remarks

The patent system with its concept of limited periods of monopoly in exchange for publication of useful inventions has served European society well for many years. It is true that the European patent system might be improved for all industry sectors, for example by instituting a single Community patent and providing improved litigation arrangements. However, the Report does not provide any convincing evidence to support a view that justifies significant changes to the existing patent system or the way that it is used by any sector, including pharmaceuticals.

Patents are a necessary tool for all technology based industries, providing time-limited protection for valuable inventions to sustain their development and commercialisation. The Commission has demonstrated in its preliminary findings that the pharmaceutical sector has a particularly high involvement with the patent system but there is nothing inherently wrong in that. It is not in any way surprising that patent owners develop strategies to optimise the use of their patent portfolios to protect and sustain their commercial activities and that competitors seek to challenge and find commercial solutions to patents which may affect their own activities. Possession of such strategies and the commercial use of valid patents cannot *per se* be anti-competitive – that is what the patent system is for, as is readily apparent in a host of industries where innovation is a key differentiator; for example, automobiles, photography, electronics, mobile phones etc.

In conclusion, the Institute is concerned that the attitude towards the patent system that is apparent from the Report and that appears to have been adopted by the Commission in its preliminary findings in the Pharmaceutical Sector Inquiry may lead to pressure to weaken the patent system not only for pharmaceuticals but for all industry sectors. This would be very damaging to the competitiveness of European companies in global markets. Further, such a move would inevitably make Europe an unattractive option for inward investors in all patent-dependent industries.

⁴⁰ There being only limited published Guidance by the Commission on the subject of patent settlement agreements in the Guidelines on the application of Article 81 of the EC Treaty to Technology Transfer Agreements.