



*Making Medicines Affordable*

# POSITION PAPER

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**PATIENTS MUST HAVE IMMEDIATE ACCESS TO AFFORDABLE  
GENERIC MEDICINES AT DAY ONE AFTER PATENT EXPIRY**

**31 JANUARY 2009**

**EGA RESPONSE TO THE PUBLIC CONSULTATION  
DG Competition Pharmaceutical Sector Inquiry: Preliminary Report**

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## CONTENTS

<b>1. EXECUTIVE SUMMARY .....</b>	<b>3</b>
1.1. Introduction: The findings of the preliminary report confirm the experiences of the generic medicines industry .....	3
1.2. EGA recommendations .....	4
1.3. Comments on settlement agreements.....	6
1.4. Comments on bottlenecks in the regulatory framework.....	7
<b>2. DETAILED RESPONSE .....</b>	<b>8</b>
2.1. Introduction (scope and nature of the sector inquiry) .....	8
2.2. Market Characteristics and Structure of the Pharmaceutical Sector.....	8
2.3. Competition between Originator and Generic Companies.....	10
2.4. Comments on the Regulatory Framework.....	22
2.5. Settlement Agreements.....	23

## EGA POSITION PAPER

### PATIENTS MUST HAVE IMMEDIATE ACCESS TO AFFORDABLE GENERIC MEDICINES AT DAY ONE AFTER PATENT EXPIRY

#### 1. EXECUTIVE SUMMARY

##### 1.1. Introduction: The Findings of the Preliminary Report Confirm the Experiences of the Generic Medicines Industry

In her speech launching DG Competition's preliminary report on the pharmaceutical sector inquiry (the 'Report') on 28 November 2008, Commissioner Neelie Kroes clearly identified the Report's unspoken conclusion:

*“competition in this industry does not work as well as it should”.<sup>1</sup>*

Among others, the Report rightly identifies delays to generic entry as an important failure of the competitive process in the pharmaceutical sector. The result is that national healthcare systems (and patients) pay unnecessarily high prices for pharmaceuticals and, ultimately, that patients are unable to obtain the medicines they need.

The behaviour of originator companies is correctly stated to be a significant factor in delays to the entry of generic medicines. As set out in the Report, originator companies have a “tool-box” of strategies which they deploy to frustrate the entry of generic medicines. In the opinion of the EGA, the following strategies are the most significant in creating hurdles to generic competition:

- interference in the grant (and/or activation) of marketing authorizations and pricing and reimbursement status;
- seeking weak or invalid patents, particularly second-generation patents – which may form part of a ‘patent thicket’ or be used to block the entry of generic medicines in other ways;
- evergreening – e.g., switching patient demands by launching second-generation products with little or no added therapeutic value;
- information and marketing campaigns that question the quality, safety and efficacy of generic alternatives;
- vexatious litigation whose primary purpose is to delay the entry of generic medicines (e.g., by obtaining interim injunctions keeping generic companies off the market).

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<sup>1</sup> Neelie Kroes, “Antitrust: Report of sector inquiry into pharmaceuticals”, Speech 08/659, Brussels, 28 November 2008, available at: [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/speech\\_nk\\_hearing.pdf?reference=SPEECH/08/659&format=HTML&aged=0&language=EN&guiLanguage=en](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/speech_nk_hearing.pdf?reference=SPEECH/08/659&format=HTML&aged=0&language=EN&guiLanguage=en)

In highlighting these strategies, the Report confirms the experiences of generic companies operating in Europe. The EGA's members regularly encounter use of each of these strategies when seeking to launch new generic products in EU markets, and will frequently encounter the use of multiple strategies by an originator company in relation to a single medicine and across a range of Member States.

## 1.2. EGA Recommendations

Where originator companies' use of strategies within the 'tool box' give rise to an infringement of EU competition rules, enforcement action by the European Commission will be appropriate. However, the EGA believes that such action will not, alone, resolve the serious issues identified in the Report. Regulatory changes will be required in addition and will, in many cases, be more effective.

There are a number of reasons for this. First, the barriers to generic entry identified in the Report are not purely the result of originator behaviour: weaknesses in the existing EU regulatory structures play a crucial role. Second, the pursuit of enforcement action under competition rules is a burdensome process: it will not be possible to address all potential infringements via this route. Third, originator behaviour that delays generic entry has a significant negative impact on the cost of healthcare and patient welfare even where the originator responsible is not considered dominant and, as a result, no infringement of competition rules can occur.

The EGA therefore calls on DG Competition to seek the following changes to the regulatory framework in the EU, which the EGA regards as both urgent and critical:

### • In Relation to Interference in Regulatory Procedures of Generic Medicines

Processes for the grant of marketing authorizations and pricing and reimbursement status currently represent a severe bottleneck to generic entry, a situation made worse by originator interference in these processes. Existing EU (and Member State) legislation in relation to both marketing authorization and pricing and reimbursement processes should be clarified to make it unambiguously clear that:

- national authorities should not receive or take account of third party submissions when considering the grant of marketing authorizations or pricing and reimbursement status – pharmaceutical legislation should therefore include a provision clearly prohibiting third party interventions;<sup>2</sup> and
- it is contrary to EU law to take account of the patent status of the originator's reference product in the context of applications for pricing and reimbursement status. This tactic is known as patent linkage and is contrary to the so-called 'Bolar provision' in the pharmaceutical legislation<sup>3</sup>. The EGA urges the European

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<sup>2</sup> Absent an absolute ban, changes should be introduced (i) to prevent third party interventions delaying the activation of marketing authorizations once granted and (ii) to give generic companies access to complete information as to the existence and content of third party interventions.

<sup>3</sup> Article 10(6) of Directive 2001/83/EC (as amended by Directive 2004/27/EC) ("Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential

Commission to modify existing EU legislation to include (a) an express mention of price and reimbursement procedures in the Bolar provision and (b) an equivalent provision (or provisions) in the Transparency directive.<sup>4</sup>

#### • In Relation to Applications for Weak or Invalid Patents

The majority of the strategies within the originator ‘tool-box’ – including patent thickets, evergreening and vexatious litigation – are only viable because it is currently too easy to obtain weak and ultimately invalid patents through the patent granting process. Therefore, the EGA recommends “raising the bar” in terms of the assessment of patent applications at the EPO and national patent offices by:

- ensuring more rigorous assessment of existing patentability requirements – including in particular application of the inventive step requirement;
- ensuring that applications for divisional patents do not cover essentially the same subject-matter as the parent application;
- increasing the resources available to the EPO in order to allow more rigorous assessment;
- imposing a ‘duty of candour’ on patent applicants requiring them to disclose all information known to them which is material to the patentability of the invention; and
- introduction of measures to reduce the length of opposition procedures and appeals to the Board of Appeals at the EPO, such as the introduction of strict timetables and measures to reduce delaying tactics.

#### • In Relation to Evergreening Strategies

Where evergreening strategies give rise to an infringement of EU competition rules, the EGA strongly supports enforcement action by the European Commission.

In particular the EGA supports action against originator strategies which are based on the introduction of second-generation products which have little or no added therapeutic value and are often designed to frustrate generic entry by misleading patient or prescribing choice. Examples include strategies in which:

- the original version of the product is withdrawn from the market without objective justification as a means to facilitate the switching of patients to the follow-on product; and/ or
- misleading claims are made as to the added therapeutic value of the follow-on product in order to induce the switching of patient or prescribing intentions

Second generation products with little or no added therapeutic value should be distinguished from incremental innovations which involve changes to existing products

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practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products”).

<sup>4</sup> Council Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems (the “Transparency Directive”).

that bring proven added therapeutic value to patients. (e.g. through improved formulations or delivery mechanisms).

- **In Relation to Information and Marketing Campaigns that Call into Question the Efficacy, Quality or Safety of Generic Products**

Information and marketing campaigns by originators that call into question the efficacy, quality or safety of generic products cause significant harm to generic entry and are, by their very nature, misleading given the need to establish the quality and the bio-equivalence of generic products as part of the marketing authorization process. Therefore, the EGA requests the introduction of a specific prohibition on negative information and marketing campaigns (including negative comparative advertising vis-à-vis originator products).<sup>5</sup>

- **In Relation to Vexatious Litigation**

Where litigation – or the threat of litigation – is used by originators purely as a tactic to delay generic entry (rather than a serious attempt to enforce legal rights), the EGA believes that action under EU competition rules may be appropriate. However, bringing individual competition law cases will not address the underlying structural issues in relation to patent litigation in the EU.

In terms of reducing unnecessary and inappropriate delays to the launch of generic medicines, the critical actions are steps to ensure that:

- in all jurisdictions, patent cases are handled by specialized patent judges with the necessary technical knowledge and expertise to decide cases quickly and correctly; and
- the current over-readiness of certain jurisdictions to grant interim injunctions excluding generic products from the market is addressed (the introduction of suitably expert specialist judges would represent a major step forward in this regard).

The Report suggests that the structural issues in relation to patent litigation in the EU may best be addressed through the introduction of a Community patent and a unified judiciary. Whether or not this is the case will depend crucially on the detail of the proposals. Proposals that do not address the urgent need for expert judges and the over-use of interim injunctions will not resolve many of the key problems identified in the Report. The EGA will therefore carefully monitor any detailed proposals once they emerge.

### **1.3. Comments on Settlement Agreements**

The EGA is concerned by the chapter of the Preliminary Report dealing with patent settlement agreements. The chapter appears to suggest that DG Competition may be

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<sup>5</sup> Although such information and marketing may be prohibited under national rules on unfair advertising or competition in some Member States, the position varies across the EU and the general prohibitions are insufficiently precise to constitute an effective deterrent to this form of behavior.

considering following the approach of the US Federal Trade Commission (“FTC”) under US antitrust law in the Schering-Plough litigation and pursuing cases against so-called ‘reverse payment’ settlements (i.e., settlements involving a payment from an originator to a generic). The EGA does not believe that such a course of action would be appropriate. The FTC’s approach in Schering-Plough has been rejected – and subject to serious criticism – by both the US Department of Justice (“DOJ”) and the US Courts.

For the reasons of law and policy articulated by the US Courts in particular, the EGA believes that settlement agreements which do not delay generic entry beyond the term (or scope) of patent exclusivity should not be considered to infringe EU competition law (absent exceptional circumstances).

If, despite this, DG Competition decides to pursue individual cases against reverse payment settlements, it should follow the approach of the FTC in its most recent litigation and do so on the basis of a monopolization theory under Article 82 of the EC Treaty.

#### **1.4. Comments on Bottlenecks in the Regulatory Framework**

As mentioned above, the EGA recognizes that the barriers to generic entry identified in the Report are not purely the result of originator behaviour. An important source of delays not caused by originator behaviour is the existing procedures for granting marketing authorizations and price and reimbursement status. The EGA has constructively collaborated in several projects, e.g. The High Level Pharmaceutical Forum, with EU and national authorities on these issues and is committed to continuing such collaboration. The two main issues to be resolved in this area are:

- failure of the concept of mutual recognition between Member States with regard to registration procedures, which has led to a lack of resources and access to quality assessment resulting in difficulties in booking slots for new applications and delays in approvals; and
- the absence of processes for granting automatic price and reimbursement status to generic medicines (which by definition lead to increased competition with the reference product) after the expiry of patent exclusivity.

## 2. DETAILED RESPONSE

In the following detailed response, the EGA has confined its comments to areas of the Report relating to the generic sector of the pharmaceutical industry, with particular focus on those sections of the Report dealing with competition between originators and generics.

The EGA's detailed response largely follows the structure of that Report, with the exception of the chapter on patent settlement agreements. The EGA has specific concerns about the implications of DG Competition's analysis in relation to settlement agreement and this chapter of the Report is therefore dealt with in a separate section towards the end of the response.

### 2.1. Introduction (Scope and Nature of the Sector Inquiry)

DG Competition establishes a very clear scope for the sector inquiry – to identify whether there are:

- obstacles to market entry for prescription medicines for human use, focusing on obstacles for generic products; and/or
- obstacles to competition between originator companies.

DG Competition emphasizes that, as an investigation carried out under EU competition law rules, the focus of the sector inquiry is on the behaviour of companies rather than the regulatory framework.

The EGA believes that in focusing on these issues, and in particular on obstacles to generic entry, DG Competition is addressing some of the major problems affecting competition in the sector.

### 2.2. Market Characteristics and Structure of the Pharmaceutical Sector

#### • Nature of the Pharmaceutical Sector

The Report correctly identifies the unique nature of the pharmaceutical sector in the EU, stating:

*"[The pharmaceutical sector] is characterized by a great variety of stakeholders, significant involvement of the State and a high degree of regulation aimed at achieving different objectives ... The sector itself is R&D-driven and continued innovation is only possible when the protection of intellectual property rights (primarily patents) is adequately ensured."*<sup>6</sup>

While this structure, and in particular the high degree of state intervention and regulation, may limit the scope for undistorted competition in the sector, it should not result in undertakings active in markets within the sector obtaining special treatment under EC competition rules. The active competition which undoubtedly does exist within

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<sup>6</sup> Report, para 24.

the sector – not least between originator companies and generics – should be protected from distortion by anticompetitive behaviour. In particular, where patents or other IP rights lead to positions of market dominance, care must be taken to ensure that such dominance is not abused.

#### • The Importance of Biosimilar Medicines

The EGA wishes to emphasize the importance of biopharmaceutical-based medicines, including biosimilar medicines. The EGA believes that, going forward, such products will play an important role in the development of new medical treatments, in improving patient care and, as a result, in the future of the pharmaceutical sector. It is notable in this respect that 60% of originator companies surveyed by DG Competition are involved in or intend to extend activities to biopharmaceutical-based medicines in the immediate future because they expect this field to grow faster than the traditional segment of the market.<sup>7</sup> Similarly, more than half of the generic companies surveyed are, or will in the near future be, involved in the biosimilar medicines market.<sup>8</sup>

Biosimilar products are also important for two other reasons. First, existing biopharmaceutical products are very high priced medicines and biosimilar products therefore provide the opportunity to achieve major cost savings for national health care systems and increase the availability of these high-tech life saving medicines. Second, the requirement to submit extensive “comparability data” with the originator biopharmaceutical product means that the R&D costs for biosimilar products are significantly higher than for generic products.<sup>9</sup>

Since the patents of the first biopharmaceuticals have recently expired or are about to expire, competition in the biopharmaceutical sector is rather new and biosimilar products have therefore become a new target for originator companies. Indeed as for generic products, biosimilar products face unjustified attacks on quality, safety and efficacy by certain interested parties. Scare tactics are the most commonly used tool by originator companies to hamper market entry of biosimilar medicines.

#### • Generic Medicines Companies

The Report recognizes three important facts in relation to generic companies. First, that:

*“Since generic companies provide cheaper versions of pharmaceutical products, they are an important pillar in cost containment measures of national health policies.”<sup>10</sup>*

In fact, even this understates the importance of generic companies. Generic medicines play an important role not just in “cost containment”, but in ensuring the affordability and sustainability of European healthcare systems.

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<sup>7</sup> Report, para 65.

<sup>8</sup> Report, para 82.

<sup>9</sup> Report, para 80.

<sup>10</sup> Report, para 72.

Second, that generic companies active on the European market tend to be significantly smaller than originator companies.<sup>11</sup> The generic sector is diverse. It includes a number of large global companies as well as a significant number of SMEs. However, the imbalance in size and resources when compared to the leading originator companies remains and colours many of the interactions between originators and generics.

Third, that the generic sector provides an important spur to originator innovation.<sup>12</sup> Without the threat of generic competition, originator companies might be tempted to focus their attention (even more than is currently the case) on extracting profits from their existing blockbuster products rather than the development of new products.

- **The Impact of Generic Entry**

The Report rightly emphasizes the significant impact of generic entry. When originator patents expire, provision of the relevant medicine moves from a position of monopoly supply by the originator to one of competition between a number of generic companies (particularly in the case of top-selling products) and (typically) the originator as well.<sup>13</sup>

The impact of this change in market structure is generally both a substantial decrease in prices for the relevant product and in increase in the quantities dispensed.<sup>14</sup> According to the figures in the Report, in markets where generic entry occurred, average prices dropped by almost 20% after the first year following loss of exclusivity and about 25% after two years.<sup>15</sup> In rare cases, for some medicines in some Member States, the decrease in the average price index was as high as 80-90% (generally cases where Government policies ensure higher generic uptake.<sup>16</sup> This is in line with the experience of the EGA and its members that generic entry and competition has a dramatic effect on the price of medicines.

### 2.3. Competition between Originator and Generic Companies

- **Patent Filing and Patent Enforcement Strategies**

DG Competition correctly identifies a pattern in relation to blockbuster drugs of large numbers of patents being filed (up to 1,300 in at least one case) and increased applications for secondary patents towards the end of the life of the primary patent.<sup>17</sup> It has become common among holders of patents over blockbuster drugs to seek to extend their monopoly beyond the period of the primary patent, and one important strategy is

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<sup>11</sup> Report, para 68.

<sup>12</sup> Report, para 72 (“Originators and generic companies also agree that generic competition creates and maintains incentives for innovation.”)

<sup>13</sup> Report, para 76.

<sup>14</sup> See figure 29, at page 82 of the Report, which shows that generic entry typically increases volumes of product sold.

<sup>15</sup> Report, para 180.

<sup>16</sup> Report, para 180.

<sup>17</sup> Report, para 391 (“a significant increase in the number of patent applications filed is seen towards the end of the lifetime of the first patent in the portfolio”).

the filing of large numbers of secondary (or follow-on) patent applications in the hope that some will be granted.

A large number of the resulting patents will be weak and/or trivial.<sup>18</sup> This is clear from the results of litigation and opposition procedures between generics and originators in relation to secondary patents. Nearly two thirds (64%) of all litigated patents in DG Competition's sample were secondary patents<sup>19</sup> and generics were successful in nearly three quarters (74%) of all cases concerning secondary patents.<sup>20</sup> (Medical use patents are a particular concern, with generics being successful in 88% of challenges to this form of patent.<sup>21</sup>) In opposition procedures, generic companies prevail in 75% of cases, and almost all cases (106 out of 109 in the sample considered by the Report) relate to secondary patents.<sup>22</sup> It is also clear from the internal attitude of originator companies to patent strength: the policy of at least one originator that it "*prefer[s] to communicate opinions regarding the strength of our patent property verbally, rather than in writing*" is extremely telling.<sup>23</sup> As DG Competition concludes:

*"The comment by generic companies that the quality of (secondary) patent applications by originator companies is not ideal is confirmed by the fact that the average grant rate for patent applications in the pharmaceutical field is lower than the EPO average. From the internal strategy documents of originator companies it transpired that they themselves consider their patent applications nowadays to be less solid."*<sup>24</sup>

One consequence of the originator strategy is often an extensive patent 'cluster' or 'thicket' around a drug. The effect – and indeed the purpose – of such patent clusters is to create legal uncertainty for generic entrants and to delay generic entry.<sup>25</sup> This is acknowledged in one of the strategy documents quoted by DG Competition in the Report which refers to clustering:

*"protecting the companies (sic) products and process"*<sup>26</sup>

Patent clusters or thickets are not, however, the only problematic consequence of the strategy of multiple filings for secondary patents. Weak or trivial patents can form the basis of litigation strategies with the sole purpose of frustrating generic entry. Such litigation strategies are well described in the Report:

*"[W]hen enforcing patent clusters and/or divisionals, an originator company may bring numerous patent infringement actions against a generic ... even where the originator does not believe to [sic] have a chance of being successful."*<sup>27</sup>

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<sup>18</sup> Report, para 393 ("a consequence ... can also be an increase of weak patents ... This seems to be confirmed by the fact that in the patent litigation cases between originator and generic companies reaching a final judgment, the majority of litigated patents were revoked").

<sup>19</sup> Report, para 491.

<sup>20</sup> Report, para 508.

<sup>21</sup> Report, paras 512 and 513.

<sup>22</sup> Report, paras 569 and 566.

<sup>23</sup> Report, para 396.

<sup>24</sup> Report, para 1111.

<sup>25</sup> Report, paras 412, 413 and 414. See also Report, para 423 ("patent clusters and divisionals may deter or delay generic entry merely by their existence.")

<sup>26</sup> Report, para 384.

Secondary patents also constitute an “essential” step in successful evergreening strategies.<sup>28</sup> Such strategies are dealt with in more detail below. However, it is important to note that the availability of weak and trivial patents is crucial to their success and anything that can be done to limit the granting of inappropriate patents would also assist in that area.

In the context of patent thickets, divisional patent filings are a particular problem. Once a divisional application is filed, it is effectively treated as an independent filing and will survive – and must be separately challenged – even if the parent application is refused or revoked. Divisional filings therefore can be, and are, used by originators to create additional legal uncertainty and delay. The Report quotes one originator company reporting that:

*“The divisional was filed in order to reset the acceptance deadline clock and allow more time for prosecution.”<sup>29</sup>*

The intended purpose of the divisional filing process is to separate out claims for distinct inventive steps that were originally filed as part of a single application. However, it is clear that originators can and do file divisional applications in relation to essentially identical subject matter as a delaying tactic. One originator quoted in the Report clearly acknowledges this:

*“The three divisional applications are identical or practically identical to each other.”<sup>30</sup>*

As generic companies have already explained to DG Competition, this tactic is very hard to counter as it is virtually impossible to predict when which divisional application will be granted.

In a response to questions at the Oral Hearing on 28 November, Philipp Gasparon (Deputy Head of the DG Competition Task Force running the sector inquiry) stated that patent thickets do not, of themselves, constitute an infringement of EU competition rules. The EGA would not necessarily challenge that view. However, the EGA is of the view that an abuse of dominance may occur where for example a dominant originator:

- makes applications for secondary patents which it knows, or ought reasonably to know, should not be granted; and/or
- deliberately withholds evidence from the examiner that it knows, or ought reasonably to know, is relevant to the application and may result in its not being granted.<sup>31</sup>

This is a relatively high standard, but there are examples where it would appear to be met.

Competition law enforcement alone will not, however, fully address the problems resulting from the proliferation of patent applications and grants of weak patents. It is

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27 Report, para 432.

28 Report, para 845.

29 Report, para 405.

30 Report, para 419.

31 Cf. Case COMP/37.507 AstraZeneca, OJ L 332, 2006, p. 24.

currently too easy to obtain weak and ultimately invalid patents through the EPO (and national) patent processes. Action should be taken to ‘raise the bar’ in terms of the assessment of patent applications at the EPO and at the national level. This does not necessarily mean changing the fundamental rules as to the patentability of innovation. Much of the problem is caused by patent assessments at the EPO taking place under great time pressure and with limited information available to the examiner. The situation could, and should, be improved by:

- ensuring more rigorous assessment by the EPO of existing patentability requirements – including in particular application of the inventive step requirement;<sup>32</sup>
- ensuring that applications for divisional patents do not cover essentially the same subject-matter as the parent application;
- increasing the resources available to the EPO in order to allow more rigorous assessment; and
- imposing a ‘duty of candour’ on patent applicants requiring them to disclose all information known to them which is material to the patentability of the invention.

These measures should not be controversial. Staff unions at the EPO have themselves recognized the need to “*raise the bar*” and are calling for action and resources to do so.<sup>33</sup>

#### • Patent-Related Exchanges and Litigation

The impact and importance of the strategic use of litigation by originators to delay generic entry is well summarized at para 466 the Report:

*“the threat of lengthy and costly patent litigation across EU Member States can dissuade smaller generic companies from launching a competing product before patent expiry, even if they consider the patent to be invalid or not to have been infringed. Most importantly, interim injunctions can have a very serious effect on generic companies whose product is taken off the market and all further production and commercialization are forbidden.”*

When cases are litigated, generics are extremely successful. Generic companies won the majority (62%) of all patent litigations in the sample examined by DG Competition<sup>34</sup> –

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<sup>32</sup> Application of the inventive step requirement is particularly important in the pharmaceutical field. A great deal of drug development activity derives from widely used and generally understood methods and practices (so called ‘common general knowledge’). The inventive step criteria requires that an invention must not be obvious in light of the prior art. Examiners are often not well equipped to assess the obviousness or otherwise of a product: while they are technically qualified, they do not generally possess the relevant common general knowledge or practical experience. Increasing the number of senior examiners as well as the quality of examiners and their training would lead to a more stringent application of the patentability requirements.

<sup>33</sup> See, e.g., SUEPO Central Executive Committee Paper ‘Raising the Bar: Core Products with Core Quality’, 15 November 2007.

<sup>34</sup> Report, para 502.

and were even more strikingly successful in relation to litigation concerning secondary patents (74%)<sup>35</sup> and medical use patents (88%)<sup>36</sup>.

However, a range of factors mean that litigation remains a serious barrier to fast and effective generic entry. These include:

- **Cost** – originator companies pay up to an average of € 993,000 in legal fees per litigation in certain Member States, legal fees which the generic company may become responsible for if it loses the litigation;<sup>37</sup>
- **Complexity** – since the European patent is in fact a bundle of national rights, generic companies may potentially find themselves in litigation in all 27 EU Member States (and indeed in all 35 EPO member states) in relation to the same patent;<sup>38</sup>
- **Uncertainty** – the complexity of the system, together with a lack of knowledgeable and experienced patent judges in many Member States, results in inconsistent and unpredictable results. For example, the rates at which interim injunctions are granted vary widely between Member States – from 75% to 77% of cases in Belgium, Germany and Sweden, down to between 10% and 15% of cases in the Netherlands and Poland.<sup>39</sup> Similarly, DG Competition identified contradictory judgments between Member States in 11% of the cases litigated to final judgment in its sample.<sup>40</sup>

Costs and delays are a particular burden on generic companies, many of which are SMEs that may have difficulty meeting even their own legal costs. More seriously, if unsuccessful, they are at risk of bearing the – generally very much larger – legal costs of the originator. Given the high cost and inherent risk of litigation, this is potentially a significant disincentive to pursuing or defending even relatively strong cases. The situation is further stacked against generics by the fact that originators have much more to gain from litigation: a successful originator gets to maintain its patent-protected monopoly and the high profit margins associated with it, while a successful generic is likely to end up competing on the market with both the originator and other generic entrants at much lower prices.

One important effect of the imbalance between the interests of the originator and the generic is the impact on originators' incentives to seek interim injunctions. When an originator obtains an interim injunction against a generic it risks having to compensate the generic for its lost profits in the event that the generic prevails (and should

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<sup>35</sup> Report, para 508.

<sup>36</sup> Report, para 512 and 513.

<sup>37</sup> Report, para 532.

<sup>38</sup> The problems and consequences of complexity are well described at para 1086 of the Report, where DG Competition states “the fact that European patents granted by the EPO are subsequently transformed into a bundle of national patents is seen as a major problem, as these national patents are then enforced (or have to be challenged) in each Member State separately. As patents are often covered by multiple patents, trying to obtain market entry for a generic product can become very costly and time-consuming.”

<sup>39</sup> Report, para 522.

<sup>40</sup> Report, para 536.

therefore have been entitled to sell its product during the period of the litigation). In some Member States, e.g., the UK, the originator company must give an up-front undertaking in damages offering such compensation, in others, e.g., Belgium, the generic must seek compensation via a separate tort action in the event it is successful. In either case, because the profits the originator stands to make if it succeeds in the litigation are likely to vastly exceed the damages it might have to pay the generic if it is not, the risk of having to pay compensation does not act as a significant disincentive to seeking interim injunctions, even where the originator's case is weak. This reflects that fact that much of the damage inflicted by such interim injunctions is suffered, not by the individual generic companies concerned, but by the national health care systems and insurers who are deprived of access to cheaper medicines during the period of the injunction (and must therefore pay inflated prices to the originator). If originator companies were forced to compensate national health care systems and insurers as well as generics, this would act as a much more effective disincentive to seeking interim injunctions in inappropriate cases.

In jurisdictions such as the UK, this could be achieved by the national health system joining the interim injunction proceedings and seeking its own undertakings in damages – as indeed occurred when the UK's National Health Service intervened in the case of *Generics (UK) and others v. Abbott Laboratories* (2004). However, this is a costly, time-consuming and unfamiliar option for national health care systems (and insurers) whose main activities are far removed from patent litigation. In jurisdictions such as Belgium where compensation must be sought via a subsequent tort action, the barriers to national health systems and insurers seeking compensation are even higher. The EGA would therefore urge the Commission to seek European legislation giving national health systems and insurers an automatic right to compensation from originators (either by way of an automatic undertaking in damages or otherwise) in cases where they are ultimately unsuccessful but nonetheless obtain interim injunctions delaying generic entry.

It is clear that litigation – and the threat of litigation – is used by originators purely as a tactic to delay generic entry. Examples from the Report itself include a letter from an originator to a generic threatening legal action if the generic did not refrain from placing its product on the market – the generic product remained on the market but no such legal action ensued.<sup>41</sup> Another example is the internal originator communication stating:

*“Our strategy is clear. We want to send a signal (by applying for interim injunctions well knowing that that we will not be granted a ban) that we do not accept early [generic] entry”.*<sup>42</sup> (emphasis added)

DG Competition's existing (but untested) case law suggests that, in order to establish that litigation constitutes an infringement of EU competition rules, it must be shown that the litigation was:

- “manifestly unfounded”, in the sense that it cannot reasonably be considered an attempt to establish the rights of the undertaking concerned; and
- conceived as part of a plan to eliminate competition.<sup>43</sup>

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<sup>41</sup> Report, paras 457 and 458.

<sup>42</sup> Report, para 432.

This is a high standard, but the examples from the Report mentioned above suggest that there are cases where it will be met.

Bringing individual competition law cases will not, however, address the underlying issues relating to the cost, complexity and uncertainty of the current system for patent litigation in the EU. The Report suggests that the structural issues in relation to patent litigation in the EU may best be addressed through the introduction of a Community patent and a unified judiciary. Whether or not this is the case will depend crucially on the detail of the proposals. In particular, the proposals relating to the unified judiciary are key. To be successful in reducing unnecessary and inappropriate delays to the launch of generic medicines, proposals relating the Community patent and unified judiciary would need to ensure that:

- in all jurisdictions, patent cases are handled by specialized patent judges with the necessary technical knowledge and expertise to decide cases quickly and correctly; and
- the current over-readiness of certain jurisdictions to grant interim injunctions excluding generic products from the market is addressed (the introduction of suitably expert specialist judges would represent a major step forward in this regard).

The unified judiciary must also have jurisdiction over disputes involving existing European Patents as well as the new Community patent.

Proposals that do not address the urgent need for expert judges and the over-use of interim injunctions will not resolve many of the key problems identified in the Report. The EGA will therefore carefully monitor any detailed proposals once they emerge.

#### • **Opposition and Appeals**

The process of oppositions and appeals to the Board of Appeals at the EPO is intended as a check and balance on the grant of weak and inappropriate patents. The need for an effective process of this kind is demonstrated by the proportion of cases (75%) in which generic companies prevail when they oppose originator patents.<sup>44</sup> As in the case of patent litigation, the figures make it clear that the real problems lie in relation to weak applications for secondary patents: “practically all” (106 out of 109) patent oppositions launched by generics in the sample gathered by DG Competition related to secondary patents.<sup>45</sup>

Unfortunately, as set out in the Report, the existing process is not effective. It is subject to unacceptable delay: in most cases (approximately 79%), it takes more than two years to reach a final decision and, for some cases, it can take up to nine years in total.<sup>46</sup> In DG Competition’s sample of cases, the opposition procedure lasted on average 3.6 years

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<sup>43</sup> Case T-111/96 *ITT Promedia v. Commission* [1998] ECR II-2937.

<sup>44</sup> In 59.6% of all final cases, the originator company’s patent was revoked and in 15.4% the patent was reduced in scope, Report, para 569.

<sup>45</sup> Report, para 566.

<sup>46</sup> Report, para 554.

(including appeals).<sup>47</sup> Moreover, in some Member States national courts regularly stay national proceedings challenging EPO patents during the opposition/appeal procedure, meaning that the generic company is effectively kept from the national market until the procedure is resolved.<sup>48</sup>

In the circumstances, it is not surprising that originators have an incentive to submit large numbers of secondary patent applications, often on speculative or dubious grounds. If some of them are granted, they will take years to knock out through the EPO opposition process. Nor is it surprising that the Report found that originator companies “may, in some instances, prolong the opposition procedure”.<sup>49</sup>

Where dominant originator companies can be shown to have prolonged or otherwise abused the opposition process, they should face individual enforcement action under EU competition rules. However, here again, competition law enforcement action alone will not be sufficient. The EPO’s regulatory processes are fundamentally flawed and should be reformed. Measures should be introduced to reduce the length of EPO opposition procedures and appeals to the Board of Appeals, such as the introduction of strict timetables and measures to reduce delaying tactics.

#### • Intervention Before Marketing Authorization Bodies

As the Report recognizes, intervention by originator companies in the processes of marketing authorization bodies when considering applications from generic companies is widespread.<sup>50</sup> The problem is particularly severe in Portugal, Spain and Germany.<sup>51</sup>

The Report suggests that this “may, in certain instances” be a deliberate strategy pursued by some originator companies to delay generic entry.<sup>52</sup> This is far too weak a conclusion. In fact, both the regularity and nature of such interventions make it clear that a deliberate strategy exists. As recorded in the Report, the most common allegations made by originators in the context of interventions before marketing authorization bodies are that generic products infringe patent rights, that generic medicines are not equivalent to the originator medicines or that the generic medicines pose health risks to patients.<sup>53</sup> EU law specifically prohibits the linking of the grant of marketing authorization to the patent status of the originator company’s reference product (so-called “patent linkage”).<sup>54</sup> There can therefore be no merit in an originator intervention on this basis. Similarly, EU law requires a generic company to demonstrate the equivalence of its product with the originator’s reference product. Generic companies must provide all the information necessary for assessment of the safety,

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<sup>47</sup> Report, para 1100.

<sup>48</sup> Report, para 552.

<sup>49</sup> Report, para 555.

<sup>50</sup> Report, para 706.

<sup>51</sup> In Germany, in particular, the most significant issue is with interventions from originator companies after the grant of the marketing authorization that lead to the activation of the marketing authorization being suspended by the marketing authorization authority.

<sup>52</sup> Report, para 707.

<sup>53</sup> Report, para 706.

<sup>54</sup> Article 10(6) of Directive 2001/83/EC (the so-called ‘Bolar provision’).

quality and efficacy of generic products in the dossier submitted to market authorization authorities, and these dossiers are assessed by experts within the authorities. Interventions from originators on these issues cannot, therefore, add anything to these processes and can have no merit.

It follows that the real justification for such interventions must be the desire to delay generic entry. This appears to be confirmed by some of the originator documents quoted in the Report, such as the document describing:

*“Actions aimed at interacting with the registration procedures of generics attempting to delay entry”.*<sup>55</sup>

The lack of real substance behind the concerns expressed in interventions by originators is further confirmed by the outcomes in those cases where litigation occurs. In DG Competition’s sample, originators were unsuccessful in 98% of court cases relating to patent linkage and safety issues and in 81% of court cases relating to data exclusivity.<sup>56</sup>

Originators’ delaying strategies in these cases are very successful: interventions before marketing authorization authorities result in significant delays in generic entry.<sup>57</sup> This is a particularly serious problem for generics because obtaining marketing authorization is already a major bottleneck in the process of launching a new generic product. As noted elsewhere in the Report, the problem is particularly severe in those Member State authorities which generally act as the reference Member State (‘RMS’), such as Austria, Germany and the UK.<sup>58</sup> This is to a significant degree due to the unwillingness of many other marketing authorization bodies to act as RMS.

Where it can be shown that intervention by a dominant originator in marketing authorization processes has no sound basis and forms part of a plan to delay generic entry (which should not be a high burden), DG Competition should pursue enforcement action under EU competition rules.

However, in view of the generally unjustified nature of originator interventions and the difficulties of successfully pursuing competition infringement cases, the EGA considers it critical that DG Competition also seek legislative action clarifying that national authorities should not receive or take account of third party submissions when considering the grant of marketing authorizations.<sup>59</sup>

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<sup>55</sup> Report, para 708.

<sup>56</sup> Report, paras 727 and 734.

<sup>57</sup> See, e.g., Report, para 742 (“On average it took 9.2 months longer than expected to obtain the marketing authorization for each of the 52 analyzed cases where intervention has taken place”). Actions in administrative courts taken (or threatened) by originator companies in relation to the handling by marketing authorities of generic company applications are a further source of delay.

<sup>58</sup> Report, para 252.

<sup>59</sup> In the event that the Commission considers an absolute ban on third party interventions inappropriate, the EGA would propose the following alternatives. First, it should be made clear that third party interventions should not lead to the activation of marketing authorizations that have already been granted being suspended. Second, applicants for marketing authorizations should have access to all information reviewed by the authority assessing the application. In the event of an intervention by a third party in an application, this should include access to the name of the intervener (unless this is personal data covered by data protection rules) as well as the subject matter of the intervention.

### • Intervention Before Pricing and Reimbursement Bodies

The position in relation to originator interventions in the processes of pricing and reimbursement bodies considering applications from generics is similar to that in relation to marketing authorization bodies. As the Report notes, originator companies are bringing an increasing number of actions before pricing and reimbursement bodies against generic products.<sup>60</sup> The problems are particularly severe in Portugal.

As in the case of interventions before marketing authorization bodies, originators often seek to make patent-linkage arguments and to bring into question the safety or effectiveness (bioequivalence) of the generic product.<sup>61</sup> Arguments based on the safety or effectiveness of generics are even less appropriate in the context of pricing and reimbursement applications, since bioequivalence with the reference originator product must be established separately (and generally before the application for pricing and reimbursement status) as part of the marketing authorization process. Such arguments are therefore fundamentally unjustified.

The position is similar in relation to arguments based on patent linkage. As the Report says *“Under EU law, patent protection is not a criteria to be considered by the authorities when approving prices or granting reimbursement status”*.<sup>62</sup> Unfortunately, the legal position in relation to patent linkage in the context of pricing and reimbursement processes is not made as clear as it is in relation to marketing authorization processes.

Where it can be shown that intervention by a dominant originator in pricing and reimbursement processes has no sound basis and forms part of a plan to delay generic entry, DG Competition should pursue enforcement action under EU competition rules.<sup>63</sup> However, in view of the generally unjustified nature of originator interventions and the difficulties of successfully pursuing competition infringement cases, the EGA considers it critical that DG Competition also seek legislative action clarifying that:

- national authorities should not receive or take account of third party submissions when considering the grant of pricing and reimbursement status; and

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Disclosure should be made at the time of the intervention. Subsequent applicants for marketing authorizations in relation to the relevant product should also have access to information regarding the intervention.

<sup>60</sup> Report, para 747. Actions in administrative courts taken (or threatened) by originator companies in relation to the handling by pricing and reimbursement authorities of generic company applications are a further source of delay.

<sup>61</sup> Report, para 749.

<sup>62</sup> Report, para 758. See also, the judgment of the Swedish Supreme Court in *Pfizer Aktiebolag v. STADapharm AB*, December 23, 2008, Case No. T 4705-07 and the judgments of the Belgian Courts A.R. 05/12386A, A.R. 06/352/A and A.R. 07/10852/A (Court of Brussels, April 8, 2008), A.R. 06/117/C (President of the Court of Brussels, June 21, 2006) and 2006/KR/399 (Court of Appeals of Brussels, July 2, 2007), all finding that the Bolar provision extends to applications for pricing and reimbursements states. Note, however, that the Danish Courts have taken a conflicting view.

<sup>63</sup> A related issue which is particularly prevalent in Germany is the conclusion, shortly before patent expiry, of rebate or price contracts that last beyond the date of patent expiry and frustrate generic entry and/or generic competition. Such contracts potentially raise issues under Articles 81 and 82 of the EC Treaty and, where they are found to infringe these provisions, should be the subject of enforcement action by the European Commission.

- it is contrary to EU law to take account of the patent status of the originator's reference product when granting pricing and reimbursement status to a generic product.<sup>64</sup>

#### • Marketing and Promotion Strategies of Originator Companies Affecting Generic Entry

As noted in the Report, it is a “*widespread practice*” on the part of originator companies to send warning letters to pharmacists, wholesalers, hospitals or doctors about the generic versions of their product and some originator companies or associations of originator companies also launch marketing campaigns which, at least by implication, call into question the equivalence and/or quality of generic products.<sup>65</sup> In the EGA's experience, practices in the latter category are also widespread. The Report cites an example from France of an originator company facing the launch of a competing generic product that systematically criticized the generic product via its sales staff, alleging, inter alia, lack of effect, inferior quality and a negative impact on patients' health.<sup>66</sup>

Such allegations can have no basis in fact. In order to obtain marketing authorizations, generic products must pass stringent bioequivalence testing demonstrating that, in terms of safety, quality and efficacy, they are equivalent to the reference originator product (and generic companies are required to submit detailed documentary proof to marketing authorization bodies in this regard).

A related practice is to write to doctors and pharmacists implying that they would be infringing patent law if they were to prescribe or dispense the generic product, which in many cases will not be the case.<sup>67</sup>

Dominant originators should be pursued under EU competition rules where they make false or misleading claims in marketing or informational campaigns with a view to delaying generic entry. Moreover, given the demonstrable absence – in view of the need to establish bioequivalence – of any proper basis for information or marketing that calls into question the effectiveness, quality or safety of generic medicines, the

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<sup>64</sup> This should be achieved through (i) modification of the Bolar provision (Article 10(6) of Directive 2001/83) to include an express mention of price and reimbursement procedures and/or (b) inclusion of an equivalent provision (or provisions) in the Transparency Directive (Directive 89/105). For example, the Bolar provision could be amended to include the following text (in bold) “Conducting the necessary studies and trial with a view to the application of paragraphs 1, 2, 3 and 4 and the consequently practical requirements, **including applications for pricing and reimbursement status**, shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products”. In the case of the Transparency Directive, Articles 2 and 6 could for example be amended to provide that, in the context of applications covering generic products, considerations relating to potential infringement of patents relating to the reference product shall not be taken into account in granting, respectively, approval of the price of the product and inclusion of the product in a positive list of medicinal products covered by the national health insurance system.

<sup>65</sup> Report, para 783.

<sup>66</sup> Report, para 795.

<sup>67</sup> Report, para 788. Prescription would appear to be a non-commercial act and, more specifically, see, e.g., article 28, §1, c of the Belgian Patent Act, which expressly excludes from the scope of the patent “preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared”.

EGA believes that DG Competition should call for the introducing of a prohibition on negative information and marketing campaigns by originators that call into question the safety and/or efficacy of generic products.<sup>68</sup> This could be achieved through an appropriate amendment to Directive 81/2003.<sup>69</sup>

#### • Life Cycle Strategies for Follow-on Products (Evergreening)

What the Report refers to as “life cycle strategies for follow-on products”, and is more commonly known as ‘evergreening’, is a significant issue affecting generic entry in EU markets. As the Report observes, strategies involving the launch of follow-on products may be motivated by a desire to prevent generic companies entering the market rather than to market a genuinely innovative product.<sup>70</sup> In some cases the strategy is very clear. The Report quotes one originator document which states:

*“[Our second generation product] represents the most effective strategic initiative to counter generic [versions of the first generation product]”.*<sup>71</sup>

The basic strategy is simple: to switch patients on to a second generation product before a generic version of the original product appears on the market. Once switched to a second generation product for which no generic equivalent exists, patients are very unlikely to switch (or be switched) back to a generic version of the original product, even if the second generation product offers very limited or no therapeutic benefits.

As the Report recognizes, there are three critical elements to a strategy of this type:

- obtaining one or more secondary patents protecting the second generation product (even if these patents are weak or trivial);<sup>72</sup>
- timing the launch of the second generation product before the generic versions of the original product emerge, so that switching can be achieved smoothly and in the absence of effective generic competition;<sup>73</sup> and
- substantial marketing and promotional efforts to ensure that patients switch.<sup>74</sup>

In some cases, the originator will facilitate the process of switching patients to the second generation product by withdrawing the original product from the market shortly

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<sup>68</sup> Although such information and marketing may be prohibited under national rules on unfair advertising or competition in some Member States, the position varies across the EU and the general prohibitions are insufficiently precise to constitute an effective deterrent to this form of behavior.

<sup>69</sup> For example, inclusion of a new Article 87(4) in Directive 81/2003 providing that “All advertising that calls in to question the quality, safety or efficacy of a generic medicinal product relative to the reference medicinal product shall be deemed misleading”.

<sup>70</sup> Report, para 833.

<sup>71</sup> Report, para 833.

<sup>72</sup> Report, para 845 (“Patenting of originator incremental innovation ... is essential, as it will provide for the necessary exclusivity of the follow-up product.”).

<sup>73</sup> Report, para 862 (“Once generics are on the market, it becomes more difficult to switch patients to the second generation products”).

<sup>74</sup> Report, para 874 (“Switching patents from a certain product to a second generation product does not happen automatically and needs a lot of marketing and promotion efforts.”).

before the expiry of its period of patent protection. DG Competition has apparently identified three such instances during its inquiry.<sup>75</sup>

The EGA considers evergreening practices of the type outlined above to be a particularly serious barrier to effective generic competition. The EGA strongly supports enforcement action by the European Commission where the introduction of second-generation products with little or no added therapeutic value is used by a dominant originator company as a means to frustrate generic entry or where patient or prescriber choice is constrained. Examples include strategies in which:

- the original version of the product is withdrawn from the market without objective justification as a means to facilitate the switching of patients to the follow-on product; and/or
- misleading claims are made as to the added therapeutic value of the follow-on product in order to induce the switching of patient or prescribing intentions.

#### • Cumulative Use of Practices Against Generic Companies

As the Report observes, originators very often deploy several items from the “tool-box” of the strategies to delay generic entry in combination.<sup>76</sup> In the EGA’s experience, the effect on generic entry of the use of multiple strategies is to significantly increase the delay to generic entry.

The Report therefore rather understates the significance of combining strategies from the tool-box when it states that:

*“the basic effect of multiple actions can however be that entry will tend to occur later and, more generally, the overall uncertainty will tend to be higher than in situations where only one instrument, or none, is used.”<sup>77</sup>*

The EGA recognizes that strategies which are individually lawful cannot become unlawful when used in combination. However, the EGA believes that DG Competition should regard the use of multiple strategies in relation to a single INN to be prima facie evidence of an intention to frustrate generic entry, and that where behaviour that infringes EU competition rules can be established, the cumulative use of practices intended to delay generic entry should be considered an aggravating factor in the calculation of fines.

## 2.4. Comments on the Regulatory Framework

The majority of the EGA’s specific comments with regard to the overall regulatory framework are incorporated in its comments on the sections of the Report dealing with competition between originators and generics. Otherwise, the EGA generally endorses the description of the regulatory framework set out in the Report.

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<sup>75</sup> Report, para 882.

<sup>76</sup> Report, para 905.

<sup>77</sup> Report, para 909.

There are, however, a small number of points on which the EGA wishes to deal with specifically. First, the Report correctly identifies a significant issue for generics when it states, in relation to its assessment of pricing and reimbursement regulation, that:

*“Another potential obstacle for generic entry lies in the need for absolute equivalence between generic versions and the originator, requested by pricing and reimbursement authorities in some Member States ... These requirements go much further than the bio-equivalence requested for marketing authorizations, and can include for example, identical pack sizes”.*<sup>78</sup>

Second, the EGA wishes to record its agreement with the suggestion at para 1163 of the Report that the equivalence between generics and originators should be taken to be sufficiently proven for pricing and reimbursement purposes once a marketing authorization is granted.

Third, an issue not highlighted in the Report is the impact on generic entry of the complexity of the EU case law that has built up around supplementary protection certificates (“SPCs”). In newer Member States in particular, authorities charged with granting SPCs struggle to master the complexity of this case law, resulting in unmerited and/or overlong SPCs being granted and generic entry being delayed. The situation could be considerably improved if the Commission were to bring forward consolidating legislation (or guidance) codifying the existing case law and clarifying the legal position.

Finally, an important source of delays not caused by originator behaviour are the existing procedures for granting marketing authorizations and price and reimbursement status. The EGA has constructively collaborated in several projects, e.g. The High Level Pharmaceutical Forum, with EU and national authorities on these issues and is committed to continuing such collaboration. The two main issues to be resolved in this area are:

- failure of the concept of mutual recognition between Member States with regard to registration procedures, which has led to a lack of resources and access to quality assessment resulting in difficulties in booking slots for new applications and delays in approvals;
- the absence of processes for granting automatic price and reimbursement status to generic medicines (which by definition lead to increased competition with the reference product) after the expiry of patent exclusivity.

## 2.5. Settlement Agreements

In contrast to the other chapters of the Report discussed above, the EGA has concerns about the chapter dealing with patent settlement agreements.<sup>79</sup> The Report states that:

*“the aim of this chapter is not to provide guidance on whether certain types of settlement agreements could be deemed compatible or incompatible with EC competition law.”*<sup>80</sup>

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<sup>78</sup> Report, para 1159.

<sup>79</sup> Report, paras 573 to 699.

<sup>80</sup> Report, para 574.

However the Report suggests that DG Competition is considering adopting an analysis of patent settlement agreements under EU competition rules inspired by the approach to reverse payment settlements adopted by the FTC in some of its early cases (the “FTC approach”).<sup>81</sup> This would not be appropriate. As set out further below, the FTC approach has been rejected and severely criticized by both the DOJ (the FTC’s sister competition enforcement agency in the US) and the US Courts. Indeed, the FTC has itself abandoned its original approach in its most recent enforcement action.<sup>82</sup>

In addition, the Report does not accurately reflect the significance – from a competition law perspective – of the different legislative environment within which settlement agreements in the US take place. As set out further below, this different environment appears to be a key factor in the only recent judgment of a senior US court finding that a reverse payment patent settlement agreement violates US antitrust rules.

#### • The position of the FTC

The FTC’s original position in relation to reverse payment patent settlement agreements is best illustrated by the Schering-Plough litigation referenced in the Report. Between 2001 and 2006, the FTC pursued litigation in relation to settlement agreements between the originator company Schering-Plough and, respectively, the generic companies Upsher-Smith and ESI. The FTC alleged that the two agreements, each of which involved a reverse payment from Schering-Plough to the generic company, infringed Section 1 of the Sherman Act (the US equivalent of Article 81 of the EC Treaty). Specifically, the FTC argued that:

*“[i]f ... the patent holder makes a substantial payment to the challenger as part of the [settlement] deal, absent proof of other offsetting considerations, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable compromise”<sup>83</sup>*

In other words, even in its original form, the FTC approach was that a settlement involving delayed entry and a reverse payment violates competition rules only if:

- the reverse payment is substantial; and
- there is no proof of any motive for the payment other than to defer generic entry.

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<sup>81</sup> See, e.g., Report, para 579 (“as is shown by the enforcement action of the USA competition authorities, in particular the Federal Trade Commission, it might also be argued that settlements contain arrangements that could fall within the scope of competition rules. A patent settlement agreement might, for example, lead to a delay in a generic product’s entry in a specific market in return for a payment by the originator company to the generic company”).

<sup>82</sup> Complaint for Injunctive Relief, *FTC v. Cephalon, Inc.*, No. 1:08-cv-00244 (D.D.C. Feb. 13, 2008) (“*Cephalon*”), available at: <http://www.ftc.gov/os/caselist/0610182080213complaint.pdf>.

<sup>83</sup> FTC Petition for a writ of certiorari, *FTC v Schering-Plough Corp.*, 126 S. Ct. 2929 (2006).

Importantly, the FTC did not take the view that such reverse payments constitute a per se infringement.<sup>84</sup> Rather, it relied on a rule of reason analysis based on a presumption that generic entry had been deferred:

*“beyond the date that represents an otherwise reasonable [settlement] compromise”.*<sup>85</sup>

As set out further below, the US Courts have comprehensively and consistently rejected the FTC approach both in the Schering-Plough litigation and elsewhere.

In its most recent (and ongoing) case, the FTC has abandoned its approach in the Schering-Plough litigation and is pursuing a significantly different legal analysis under Section 5(a) of the Federal Trade Commission Act.<sup>86</sup> Importantly, this new approach is based on unlawful monopolization of the relevant pharmaceutical market by the originator company involved, Cephalon, Inc. The FTC is not pursuing the four generic companies with which Cephalon entered into reverse payment settlement agreements. Specifically, the FTC is pursuing Cephalon for:

*“wilfully maintain[ing] its monopoly power through its course of anticompetitive conduct, including its agreements with [the generics]”.*<sup>87</sup>

In other words, the FTC is arguing that it is Cephalon’s attempt to maintain its monopoly position through a course of conduct including a number of reverse payment settlement agreements with generics which infringes competition rules.

The analysis adopted by the FTC in *Cephalon* has the merit of recognizing:

- the asymmetric interests of originator and generic companies in the context of patent litigation; and
- the limited impact that an individual settlement agreement between one generic company and the originator is likely to have (see further below).

#### • The Position of the DOJ

The DOJ has firmly rejected the FTC approach. In the Schering-Plough litigation, the DOJ submitted an amicus curiae brief to the US Supreme Court, which argued that:

*“the public policy favouring settlements, and the statutory right of patentees to exclude competition within the scope of their patents, would potentially be frustrated by a rule of law that subjected patent settlements involving reverse payment to automatic or near-automatic invalidation.”*<sup>88</sup>

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<sup>84</sup> See, e.g., *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11<sup>th</sup> Cir. 2005)(“*Schering-Plough*”), (“[b]oth the ALJ and the Commission analyzed the agreements according to the rule of reason analysis”).

<sup>85</sup> FTC Petition for a writ of certiorari, *FTC v Schering-Plough Corp.*, 126 S. Ct. 2929 (2006).

<sup>86</sup> Cephalon, supra.

<sup>87</sup> Cephalon, supra.

<sup>88</sup> Brief for United States as Amicus Curiae, *FTC v. Schering-Plough Corp.*, 126 S. CT. 2929 (2006) (No. 05-273).

In the same brief, the DOJ set out an alternative approach to reverse payment settlements that is both more permissive and more fact based:

*“an appropriate legal standard should take into account the relative likelihood of success of the parties’ claims, viewed ex ante.”*<sup>89</sup>

Specifically, the DOJ suggests that an appropriate competition law analysis would involve assessment of *“the strength of the patent in the context of the [patent] infringement settlement itself”*.<sup>90</sup>

#### • The Position of the US Courts

The US Courts have also clearly and consistently rejected the FTC approach holding that the existence of a reverse payment in a settlement agreement *“cannot be the sole basis for a violation of anti-trust law”*.<sup>91,92</sup>

The Report states that:

*“the judiciary has not taken a uniform line, but the 11th Circuit Court in particular has taken the opposite view to that [of the] FTC”*.<sup>93</sup>

In fact, the US Courts of Appeals in each of the 2<sup>nd</sup>, 11<sup>th</sup> and Federal Circuits have explicitly rejected the FTC approach – and the US Supreme Court has so far refused to accept an appeal from these decisions.<sup>94</sup>

The clear position of the US Courts is that reverse payment settlement agreements that do not delay generic entry outside the scope of the relevant patent – i.e. beyond the period of patent exclusivity or outside the scope of infringing products – do not infringe Section 1 of the Sherman Act (absent exceptional circumstances such as sham litigation or fraud on the patent office).<sup>95</sup>

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<sup>89</sup> *Ibid.*

<sup>90</sup> *Ibid.*

<sup>91</sup> *Schering-Plough*, (“[reverse payments] cannot be the sole basis of a violation of antitrust law”); See also *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2<sup>nd</sup> Cir. 2006) (“*Tamoxifen*”) (“[w]e do not think that the fact that the patent holder is paying to protect its patent monopoly, without more, establishes a Sherman Act violation”).

<sup>92</sup> The US Courts have also rejected the DOJ’s suggestion that the strength of the parties claims (ex ante) should be assessed, see e.g. *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, No. 08-1097, 2008 WL 4570669 (Fed. Cir. Oct. 15, 2008) (“*Ciprofloxacin*”) (“We disagree that analysis of patent validity is appropriate in the absence of fraud or sham litigation. Pursuant to statute, a patent is presumed to be valid ... and patent law bestows the patent holder with ‘the right to exclude others from profiting by the patented invention’”).

<sup>93</sup> Report, para 654.

<sup>94</sup> See, respectively, *Tamoxifen*, *supra*, *Schering-Plough*, *supra*, *Ciprofloxacin*, *supra*, and *Schering-Plough*, cert. denied, 126 S. Ct. 2929 (2006).

<sup>95</sup> See, *Schering-Plough*, *supra*, (“[w]hat we must focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patents protection ... Here, we find that the agreements fell well within the protections of the ‘743 patent, and were therefore not illegal”), *Tamoxifen*, *supra*, (“[w]e generally agree, then, with the Eleventh Circuit insofar as it held in *Valley Drug* that “‘simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money

In adopting this permissive attitude to reverse payment settlements, the US Courts have had regard to the following factors, all of which should find resonance under EU law:

**(i) Dissatisfaction with the FTC's counterfactual analysis**

As set out above, the original FTC analysis rests on the assumption that, absent the reverse payment, the parties would have reached a compromise involving earlier generic entry.<sup>96</sup> In fact, no such assumption is justified. As held by the Court of Appeals for the 11<sup>th</sup> Circuit:

*“the [FTC] grounds its decision in the untenable supposition that without a payment there would have been different settlements ... resulting in earlier entry dates.”<sup>97</sup>*

Difficulties with the FTC supposition arise as a result of the imbalance in the interests of the parties in the outcome of the litigation: if the originator prevails it will continue to make 100% of all sales of the patented product at high prices; if the generic prevails, it will make only a proportion of the sales of the relevant product and only at a lower price. As a result, a reverse payment may be necessary in order to achieve a settlement. This can best be illustrated by way of example, and the facts alleged by the FTC in the Schering-Plough litigation in relation to the settlement agreement between Schering-Plough and ESI provides a clear example. According the FTC, Schering-Plough had made a US\$ 10 million payment to ESI in return for delayed entry as part of the settlement.<sup>98</sup> Since there was no evidence that the parties would settle other than on terms equivalent to those of the actual settlement, the FTC's case must have been that Schering-Plough could have made an equivalent offer to ESI by allowing it to enter the market sufficiently earlier than the date agreed in the actual settlement to allow ESI to make additional sales worth the equivalent to US\$ 10 million. However, there is a problem with this assumption. Because ESI must make sales worth US\$ 10 million at prices lower than Schering-Plough would achieve during patent exclusivity, such a settlement would cost Schering-Plough substantially more than US\$ 10 million in lost sales.<sup>99</sup> Since such a settlement would cost Schering-Plough more than the US\$ 10 million it was prepared to

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cannot be the sole basis for a violation of antitrust law,' unless the 'exclusionary effects of the agreement' exceed the 'scope of the patent's protection.'”), *Ciprofloxacin, supra*, (“we agree with the Second and Eleventh Circuits and with the district court that, in the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment.”)

<sup>96</sup> FTC Petition for a writ of certiorari, *FTC v Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (“it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable compromise”).

<sup>97</sup> Schering-Plough, *supra*.

<sup>98</sup> See, e.g., FTC Petition for a writ of certiorari, *FTC v Schering-Plough Corp.*, 126 S. Ct. 2929 (2006) (“[t]he Commission pointed out, however that there was no proffered justification for the \$10 million payment”).

<sup>99</sup> Indeed, Schering-Plough's lost profit will be exacerbated by the fact that it would almost certainly have to reduce the price on all sales of the relevant product once it allows ESI to enter, so its profits would be reduced on actual sales as well as a result of lost sales.

pay under the actual settlement, there is no evidence that Schering-Plough would agree to accept it and therefore no evidence that an alternative settlement was possible.<sup>100</sup>

An additional concern in relation to the counterfactual arises where the settlement involves a license of the disputed patent from the originator to the generic. As the Court of Appeals for the 2<sup>nd</sup> Circuit stated in *Tamoxifen*:

*“the Settlement agreement did not entirely foreclose competition in the market for tamoxifen. It included a license from Zeneca to Barr that allowed Barr to begin marketing Zeneca’s version of tamoxifen eight months after the Settlement Agreement became effective ... By licensing tamoxifen to Barr, Zeneca added a competitor to the market, however limited the competition may have been. Unlike reverse payment settlements that leave the competitive situation as it was prior to the litigation, the reverse payment in this case was pursuant to an agreement that increased competition in the market”.*

Since such agreements increase competition as compared to the status quo ante – and are therefore prima facie pro-competitive – any allegation that they are in fact anti-competitive would have to be based on clear evidence that an even more competitive outcome would have arisen absent the settlement. This is likely to be an impossible burden to discharge.

The same analysis can be applied in relation to settlement agreements involving supply arrangements for the active substance between the originator and the generic, since such agreements permit at least some degree of competition between the generic and the originator in relation to the relevant product.

#### ***(ii) Difficulties in identifying or attributing value transfers***

In *Schering-Plough*, the Court of Appeals for the 11<sup>th</sup> Circuit strongly disagreed with the FTC’s conclusion that the US\$ 60 million reverse payment to Upsher had to be attributed to payment for delay:

*“To borrow from the [FTC’s] own words, we think its conclusion that Niacor was not worth \$ 60 million, and that settlement payment was to keep Upsher off the market is ‘not supported by law or logic.’”<sup>101</sup>*

The ability of the Court and the FTC to disagree so strongly on such a fundamental issue underlines the difficulties with the FTC approach.

The US courts have also identified difficulties with identifying the amount of a value transfer, particularly in the context of settlements involving additional elements such as licenses or distribution agreements. As the Court of Appeals for the 2<sup>nd</sup> Circuit stated in *Tamoxifen*:

*“[the settlement] included a license from Zeneca to Barr ... [which] ensured that money also flowed from Barr to Zeneca, decreasing the value of the reverse payment.”<sup>102</sup>*

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<sup>100</sup> The same argument applies, mutatis mutandis, to an alternative settlement involving earlier entry that would cost Schering-Plough \$ 10 millions in lost profit but offer ESI less than \$ 10 millions worth of increased sales: there is no evidence that ESI would accept such a settlement.

<sup>101</sup> supra.

<sup>102</sup> supra.

### **(iii) The public interest in allowing settlement of litigation**

A key issue in the position adopted by both the US Courts and the DOJ (see above) is the public interest in the settlement of litigation.<sup>103</sup> As noted by the Court of Appeals for the 11<sup>th</sup> Circuit:

*“There is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation ...*

*[T]he associated benefits of settlements ... include the avoidance of the burdensome costs and the resolution of uncertainty regarding the respective rights and obligations of the party litigants”.*<sup>104</sup>

In part, this reflects a concern about the impact that a rule limiting the ability of generic companies to settle litigation would have in discouraging litigation challenging weak patents:

*“A prohibition on reverse-payment settlements would ‘reduce the incentive to challenge patents by reducing the challenger’s settlement options should he be sued for infringement, and so might well be thought anti-competitive.’”*<sup>105</sup>

### **(iv) The legal presumption of patent validity**

An additional factor in the position of the US Courts is the legal presumption of patent validity (pending a successful challenge). This is not, however, simple deference to the presumption. As set out by the Court of Appeals in *Tamoxifen* (citing, with approval, the reasoning of a lower court), it reflects the fact that if the presumption was reversed – and the patent assumed to be invalid – then any individual patent settlement agreement has no significant adverse effect on competition:

*“If courts do not discount the exclusionary power of the patent by the probability of the patent’s being held invalid, then the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity. This concern, on its face, is quite powerful. But the answer to this concern lies in the fact that, while the strategy of paying off a generic company to drop its patent challenge would work to exclude that particular competitor from the market, it would have no effect on other challengers of the patent, whose incentive to mount a challenge would also grow commensurately with the chance that the patent would be held invalid.”*<sup>106</sup>

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<sup>103</sup> See, e.g., *Schering-Plough, supra*, (“[t]he general policy of the law is to favor the settlement of litigation, and this policy extends to the settlement of patent litigation suits”), *Tamoxifen, supra*, (“[w]e begin our analysis against the backdrop of our longstanding adherence to the principle that ‘courts are bound to encourage’ the settlement of litigation ... It is well settled that ‘[w]here there are legitimately conflicting [patent] claims ..., a settlement by agreement rather than litigation, is not precluded by the [Sherman] Act, although such a settlement may ultimately have an adverse effect on competition’. *Ciprofloxacin, supra*, (“there is a long-standing policy in the law in favor of settlements, and this policy extends to patent infringement litigation”).

<sup>104</sup> *Schering-Plough, supra*.

<sup>105</sup> *Tamoxifen, supra* (citing *Asahi Glass Co.*, 289 F. Supp. 2d at 994).

<sup>106</sup> *Tamoxifen, supra*, (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, F. Supp. 2d 514, at 535 (“Cipro III”).

**(v) Any anti-trust injury would be limited**

US Courts have recognized that a settlement that does not limit the ability of other generic companies to launch generic versions of the patented product or otherwise challenge the patent are unlikely to result in significant antitrust harm. In *Ciprofloxacin*, the Court of Appeals for the Federal Circuit upheld the reasoning of the lower court to the effect that:

*“even though Bayer settled with Barr, other generic companies could still challenge the ‘444 patent and their incentive to challenge the patent would grow with the chance that the patent would be held invalid, rendering any anticompetitive effects of the Agreements short-lived.”*

Similarly, in *Tamoxifen*, the Court of Appeals for the 2<sup>nd</sup> Circuit noted:

*“it is unlikely that the holder of a weak patent could stave off all possible challengers with exclusion payments because the economics simply would not justify it.”<sup>107</sup>*

In particular in the context of the public interest in settlement, US Courts have concluded that the pro-competitive benefits of settlement necessarily outweigh any weak anti-competitive effects.

**(vi) In re Cardizem**

In its summary of the position of the US Courts, DG Competition, states – wrongly – that the US Courts have “not taken a uniform line”.<sup>108</sup> This appears to be a reference to the decision of the Court of Appeals for the 6<sup>th</sup> Circuit in *In re Cardizem*, where the Court found the reverse payment settlement at issue to be a per se infringement of Section 1 of the Sherman Act.<sup>109</sup> However, as pointed out by the Court of Appeals for the Federal Circuit in *Ciprofloxacin* – and confirmed by the Court of Appeals for the 6<sup>th</sup> Circuit in *In re Cardizem* itself – the case is distinguishable from the other cases on reverse payments on its facts, and the decision cannot be taken to be supportive of FTC approach:

*“although the Sixth Circuit found a per se violation of the antitrust laws in In re Cardizem, the facts of that case are distinguishable from this case and from the other circuit court decisions. In particular, the settlement in that case included, in addition to a reverse payment, an agreement by the generic manufacturer to not relinquish its 180-day exclusivity period, thereby delaying the entry of other generic manufacturers ... Furthermore, the agreement provided that the generic manufacturer would not market non-infringing versions of the generic drug ... Thus, the agreement clearly had anti-competitive effects outside the exclusion zone of the patent.”<sup>110</sup>*

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<sup>107</sup> *Tamoxifen, supra*, (again citing *Cipro III*), see also the text cited above in relation to footnote [99].

<sup>108</sup> Report, para 654.

<sup>109</sup> *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6<sup>th</sup> Cir. 2003), cert. denied, 543 U.S. 939 (2004) (“*In re Cardizem*”).

<sup>110</sup> *Ciprofloxacin, supra*.

## • Differences in the EU and US Legislative Contexts

The Report notes that:

*“in the USA, the first generic company to file a paragraph-IV certification is explicitly rewarded by the legislator, while in the EU the first to market enjoys no statutory period during which he is protected against market entry of a second, third or subsequent generic company.”<sup>111</sup>*

Despite this, the Report concludes that:

*“Overall, however, it seems legitimate to conclude that there are more similarities than differences between the two systems.”<sup>112</sup>*

That conclusion fails to recognize the significance of the 180 day exclusivity period granted to the first paragraph-IV filer under US law. In *In re Cardizem*, as part of the settlement, the generics company had agreed not to relinquish its 180 day exclusivity period and not to launch a generic product. This effectively extended the 180 day period of exclusivity – which would run from the date on which the generic launched a generic product – indefinitely and, as a result, created a barrier to other generic companies entering the market (a so-called “bottleneck”). As set out above:

- the Courts of Appeals for both the 6th Circuit and the Federal Circuit have identified use of the exclusivity period to create a bottleneck in this way as a factor distinguishing the facts in *In re Cardizem* from those in the other judgments finding reverse payment settlements lawful; and
- the Courts of Appeals for both the 2nd Circuit and the Federal Circuit have relied on the limited nature of any anticompetitive effect resulting from any settlement that does not create such a bottleneck as one element in their conclusion that reverse payment settlements that fall within the scope of the relevant patent do not infringe antitrust rules.

*In re Cardizem* is the only senior US precedent for the proposition that reverse payment settlement agreements should be considered unlawful, in any circumstances. The fact that a key aspect of that case could not be reproduced in the EU legislative context should raise significant doubt as to whether reverse payment settlement agreements should ever be regarded as contrary to EU competition rules.

## • DG Competition’s Data on Settlement Agreements

One area in which the EGA would strongly agree with the Report in relation to settlement agreements is where it states that “[p]atent settlements are fact-specific, depending on the dispute at issue”<sup>113</sup> and concludes that:

*“an assessment [under EC competition rules] would require an in-depth analysis of the individual agreement, taking into account the factual, economic and legal background.”<sup>114</sup>*

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<sup>111</sup> Report, para 659.

<sup>112</sup> Report, para 661.

<sup>113</sup> Report, para 576.

Facts relating to the content of individual disputes and settlements are an individual matter for EGA members. The EGA cannot therefore either confirm or deny the accuracy of the data gathered by DG Competition in relation to individual settlements. The EGA does however have the following comments on that data.

The EGA would confirm that:

*“Pharmaceutical companies in the EU see patent litigation cases a fact-intensive, legally complex, lengthy and costly. The conclusion of a settlement agreement is seen as an alternative way forward”<sup>115</sup>*

Beyond that, the EGA believes that DG Competition is correct to identify the very different priorities and attitudes to settlements of originators and generics. DG Competition states that the *“fundamental factor”* considered by originator companies when deciding whether to enter into a settlement agreement with generic companies is *“the strength of their position in the patent litigation”*.<sup>116</sup> In contrast, generic companies:

*“are more concerned with the cost of litigation ... they cannot financially afford lengthy and extremely costly litigation.”<sup>117</sup>*

This clearly encapsulates and reflects the fundamental imbalance between the costs and benefits of patent litigation to generics, on the one hand, and originators, on the other. If successful, an originator company will maintain its monopoly position as the supplier of the patented pharmaceutical and the substantial mark-up in price (as compared with a competitive market) that goes with it. A generic company, if successful, will enter the market in competition with at least the originator – and in many cases a number of other generic entrants as well within a short period – at substantially lower prices. As a result, the profits that an originator is seeking to protect through litigation substantially outweigh the profits that the generic is seeking to gain. This affects not only the attitudes of the two sides of the industry to litigation, but also their respective abilities to fund potentially long-lasting and complex litigation.

The EGA believes that the attitude of generic companies to settlement is well captured by the quote from an unnamed generic included in the Report to the effect that:

*“When deciding what type of settlement agreement to conclude, we aim at obtaining the earliest possible entry date with a reasonable degree of certainty”*.<sup>118</sup>

DG Competition identifies two main categories of settlement agreement:

- A-type agreements – which do not limit generic entry; and
- B-type agreements – which, in the view of DG Competition, involve some limit on generic entry.<sup>119</sup>

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<sup>114</sup> Report, para 574.

<sup>115</sup> Report, para 589.

<sup>116</sup> Report, para 591.

<sup>117</sup> Report, para 592.

<sup>118</sup> Report, para 595 (box).

B-type agreements are further subdivided into type B1, which involve no value transfer to the generic company involved, and type B2, which, in the view of DG Competition, do involve some type of value transfer to the generic company.<sup>120</sup> It is to be noted that the report offers no clear definition of what constitutes a limit on generic entry and applies what appears to be a very broad (and doubtful) definition of what might constitute a value transfer (including, e.g. agreements under which the generic is appointed by the originator as a distributor).<sup>121</sup>

The vast majority of settlement agreements in the Commission's sample – 162 out of 207 (or 78%) – are either A-type or type B1.<sup>122</sup> The EGA is not aware of any legal analysis under which these agreements could be considered problematic from a competition law perspective, and it does not appear to be suggested that they are.

For the remaining 45 agreements, the 'value transfer' involved:

- the granting of a patent license in 29 cases (in 20 of which the patent license was the only value transfer);
- supply or distribution arrangements in 9 cases (in 2 of which the supply or distribution arrangement was the only value transfer); and
- a bare payment in 8 cases.<sup>123</sup>

Given (i) the counterfactual difficulties involved in establishing the existence of delayed entry in cases involving patent license, supply or distribution agreements and (ii) the prima facie pro-competitive impact of such agreements (both issues recognized by the US Courts, see above<sup>124</sup>), it seems reasonable to assume that none of the 36 or 37 settlements involving agreements of this sort should be considered anti-competitive.<sup>125</sup>

It follows that, at most, there would appear to be 8 or 9 settlements in relation to which concerns could arise, even if DG Competition were to ignore the reasoning of the US Courts and adopt the FTC analysis in the Schering-Plough litigation.

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<sup>119</sup> Report, para 611.

<sup>120</sup> Report, para 612.

<sup>121</sup> Report, para 612 (box).

<sup>122</sup> Report, para 613 (108 A-type agreements plus 54 type B1 agreements).

<sup>123</sup> Report, paras 633 to 634. One settlement also involved a 'side deal'. It is under whether or not this was in addition to a distribution agreement or patent license.

<sup>124</sup> The data set out in the Report also provides support for the proposition that supply and distribution agreements can be pro-competitive: at paras 688 to 696 the Report discusses a number of supply and distribution agreements entered into between originator and generic companies outside the context of a settlement agreement. These would appear to be pro-competitive, arms-length deals entered into for mutual benefit. There is no obvious justification for a presumption that the same considerations do not motive similar agreements entered into within a settlement context.

<sup>125</sup> The problems involved in applying the FTC analysis are particularly acute in relation to those settlements involving either (i) only a royalty bearing license or (ii) payment plus a supply or distribution arrangement, since in these cases it is unclear that any value transfer has occurred: this part of the settlement may simply represent an arms-length bargain. Conversely, in cases involving only a royalty free license it is unclear what restriction of competition exists, since the generic company has both the freedom to supply product and to set its own prices.

• **Conclusions**

For the reasons set out above, the EGA believes it would be inappropriate for DG Competition to seek to pursue cases against settlement agreements on the basis of the FTC analysis in the Schering-Plough litigation. Instead, for the reasons of law and policy clearly articulated in the US case law, DG Competition should adopt the position of the US Courts, i.e. that settlement agreements which do not delay generic entry beyond the term (or scope) of patent exclusivity – including those involving reverse payments – do not infringe competition law (absent exceptional circumstances).

If, despite this, DG Competition decides to pursue individual cases based on reverse payment settlements, it must at a minimum:

- clearly establish the counterfactual – including the date on which generic entry would have occurred absent the settlement (on the basis of evidence going beyond the mere existence of a reverse payment);
- clearly establish that (i) a genuine value transfer (as opposed to an arms-length business arrangement) exists and (ii) the value transfer represents payment for delayed entry (rather than some other element of the overall settlement);
- pursue cases on the basis of a monopolization theory under Article 82 (rather than Article 81) in line with the most recent position take by the FTC and in recognition of (i) the inability of any single settlement agreement to create a significant restriction of competition and (ii) the asymmetric position of the originator and generic parties to any single agreement; and
- take account of absence of existing EU or US precedents finding reverse payment settlements within the scope of the relevant patent unlawful and refrain from imposing significant fines in relation to such agreements at this stage.

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