



COMMENTS BY TEVA PHARMACEUTICALS EUROPE B.V.

ON THE

PRELIMINARY REPORT ON THE PHAMACEUTICAL SECTOR INQUIRY

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## INTRODUCTION

On 28 November 2008, the European Commission published its Preliminary Report on the Pharmaceutical Sector Inquiry ('Preliminary Report'). The Preliminary Report is the result of intensive investigations into common practices employed by the pharmaceutical industry, and provides a wealth of information on competition between originator companies and generic companies, on competition between originator companies, and on the functioning of the regulatory framework.

Teva Pharmaceuticals Europe B.V. ('Teva') welcomes the findings in the Commission's Preliminary Report. Teva also appreciates the opportunity to comment on those findings in this submission.

In Section 1, Teva briefly comments on how Teva's own experience accords with the Commission's findings and conclusions. Teva has observed first-hand how originator companies have used the tool-box to block or delay generic entry and the benefits to competition and consumers that accompany such entry. In one example that illustrates the use of the tool-box, Merck & Co Inc. adopted a strategy for delaying Teva's launch of generic Alendronate that included secondary patent clusters, vexatious patent litigation and regulatory conduct, and other interventions.

In addition, Teva suggests that the Commission consider the effect of buyer power on the prices of generic products and on the long-term growth and vitality of the generic industry.

In Section 2, Teva offers several concrete suggestions that could mitigate the problems identified in the Preliminary Report and expedite generic entry. Teva believes that antitrust enforcement action can and should be undertaken to reduce the economic incentive of originator companies to employ the tool-box. To that end, Teva proposes a series of criteria for the application of Article 82 EC, as well as Article 28 EC, to vexatious litigation by dominant firms. Those elements should also be applied by national courts when originator companies seek to rely, in interim or main proceedings, on patent rights to prevent or delay generic entry.

In addition, Teva suggests improvements to the regulatory framework that would encourage and expedite generic entry. First, to address the problems inherent in the lack of a unified judiciary and the absence of a Community Patent, Teva believes that a European patent court should be established with the competency to rule efficiently on patent disputes.

Second, to increase the incentives for generic entry, Teva suggests changes to the current regulatory regime to reward generic companies for incurring the cost and risk of entry prior to patent expiration. In Teva's experience, challenging an originator company's patent to facilitate the launch of the first generic drug requires generic companies to undertake substantial investments and to take



significant patent litigation risks. After the first generic company successfully revokes or designs around the originator company's patent, however, subsequent generic entrants can benefit from, or "free ride" on, the investments made by the first generic entrant.

The grant of a temporary marketing exclusivity period for the first generic entrant prior to patent expiration provides a reasonable reward to the first generic entrant for making those substantial investments and taking such risks. Further, as shown in the United States, such a period of marketing exclusivity has significantly accelerated generic entry and greatly reduced consumer healthcare costs. For originator companies, increased generic competition will likely spur innovation, leading to more robust product pipelines and more successful product launches. Both of those effects benefit European patients and taxpayers, who obtain lower prices on pharmaceutical products subject to generic competition, and who benefit from the improved treatments that result from increased innovation.

## 1 MAIN COMMENTS ON THE PRELIMINARY REPORT

### 1.1 The importance of generic entry.

The Preliminary Report shows that generic entry results in price decreases of about 20% in the first year and about 25% after two years.<sup>1</sup> In addition, although not reported in the Preliminary Report, prices continue to decline, resulting in dramatic price drops after five years. In some cases, prices may fall by 90%. Those price decreases demonstrate the importance of generic entry. Indeed, official data show that generic entry have resulted in significant price decreases, resulting in €14 billion in public savings over eight years (2000 - 2007).<sup>2</sup>

When generic entry does not occur, prices remain at the same level or even increase, as is demonstrated by Figure 19 in the Preliminary Report<sup>3</sup> and acknowledged by the Commission: "*Comparison of the two lines clearly shows that the average price index drops considerably on markets with generic entry, but not on markets without.*"<sup>4</sup>

Delays in generic entry therefore cause immediate and significant losses to society. The Preliminary Report estimates a loss of €3 billion over eight years: "*Had entry been immediate following loss of*

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<sup>1</sup> Preliminary Report, point 180. As the Commission noted, the numbers reported above are the "result of the combination of average price levels coming down quickly in those markets, where entry took place quickly and average price levels coming down later because entry took longer."

<sup>2</sup> Preliminary Report, point 186.

<sup>3</sup> Preliminary Report, point 179.

<sup>4</sup> Preliminary Report, point 180. Teva underlines.



*exclusivity instead of delayed, this expenditure could still have been more than 5% or €3 billion lower*<sup>5</sup>. In Teva's opinion, the actual loss to society in reality is much higher.

## 1.2 The Commission has correctly identified the originator companies' tool-box and its effects on generic entry.

The Preliminary Report correctly establishes that originator companies rely on a "tool-box" approach to delay generic entry.<sup>6</sup> As the Commission properly found, the tools available to originator companies to delay generic entry are frequently used cumulatively.<sup>7</sup> Teva agrees with the Commission's characterization of how originator companies use that tool-box, as reflected at point 888 of the Preliminary Report: *"(...) cumulative use of these tools for a given INN . . . will normally render generic entry more difficult than if only a single tool is used. Typically, such effects would take the form of delays in or disincentives for such entry."*

Teva also agrees with the following conclusions of the Commission:

- That *"[s]econdary patent clusters may be efficient means to deter or prevent generic entry and are also a cornerstone of other tools, most notably litigation and settlements."*<sup>8</sup>
- That innovator companies may file subsequent patents when the main patent is about to expire, that such filings can be used strategically to create further uncertainty and delays for generic entrants, and that procedures to oppose those patents are, on average, lengthy and subject to delay tactics by originator companies.<sup>9</sup>
- That patent litigation *"may be instigated with the purpose of creating obstacles to generic entry, particularly when the patent-holder knows that his chances of success in court are low"*.<sup>10</sup>
- That patent litigation, in combination with interim injunctions, *"can be an effective way for originator companies to delay the entry or expansion of rivals."*<sup>11</sup>
- That interventions before regulatory bodies, while potentially addressing legitimate concerns, are also *"a standard tool in originator companies' tool-box"* that can be *"used to*

<sup>5</sup> Preliminary Report, point 186.

<sup>6</sup> Preliminary Report, points 369, 887.

<sup>7</sup> Preliminary Report, point 903.

<sup>8</sup> Preliminary Report, point 890.

<sup>9</sup> Preliminary Report, point 891.

<sup>10</sup> Preliminary Report, point 893.

<sup>11</sup> Preliminary Report, point 893.



*delay or block the marketing authorisation or the pricing or reimbursement status of the generic product.*<sup>12</sup>

- That the tool-box of originator companies includes other types of interventions, such as “[q]uestioning the reputation of generic competitors and their products”<sup>13</sup> or making “approaches downstream to wholesalers and upstream to API (active pharmaceutical ingredient) producers, with the intention of managing/limiting access by generic companies to distribution channels and sources of active ingredients.”<sup>14</sup>
- That the basic effect of the use by originator companies of multiple “tools” is to delay generic entry and increase legal uncertainty.<sup>15</sup>
- That when legitimate generic entry is delayed, either by litigation or by other practices, originator companies succeed in capturing a part of consumers’ welfare.<sup>16</sup>
- That patent linkage, at both the marketing authorization and the price and reimbursement levels, is a cause of concern. Both types of patent linkage are unlawful.<sup>17</sup> As the Preliminary Report notes, however, patent linkage occurs in several Members States at both levels.<sup>18</sup> Originator companies often take advantage of such patent linkage to delay generic entry by suing or threatening to sue generic companies and regulators. Further, in countries in which such patent linkage occurs, Teva has found that originator companies exploit regulatory provisions to get access to highly sensitive information about future generic competitors.

The foregoing measures constitute a powerful arsenal with which originator companies can defer or delay generic entry that would otherwise be ready to serve consumers. In Teva’s experience, those measures are often used in situations that do not involve a legitimate business purpose or the vindication of legitimate legal rights.

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<sup>12</sup> Preliminary Report, point 895.

<sup>13</sup> Preliminary Report, point 897.

<sup>14</sup> Preliminary Report, point 898.

<sup>15</sup> Preliminary Report, point 909.

<sup>16</sup> Preliminary Report, points 920, 923.

<sup>17</sup> Preliminary Report, points 715, 757.

<sup>18</sup> As the marketing authorization level, see, e.g., Hungary, Italy, Portugal, Slovak Republic. Preliminary Report, point 716, Table 22. At the price and reimbursement level, see, e.g., Portugal, France and Austria. Preliminary Report, point 755.



### 1.3 The Alendronate case: an illustration of the tool-box in use

One striking example of the use of the tool-box by an originator company is offered by the litigation between Merck & Co Inc. (Merck) and Teva relating to Alendronate. Merck's strategy for delaying Teva's launch of generic Alendronate, as summarized in Annex I, has included secondary patent clusters, vexatious patent litigation and regulatory conduct, and other interventions.<sup>19</sup>

Alendronate is a drug patented by Merck, which is used for the treatment of osteoporosis and other bone diseases. As the Preliminary Report identified, Alendronate is the fifth best-selling drug in the European Union (EU27).<sup>20</sup> In 2007, sales of generic Alendronate totaled more than €80 million.

Merck's litigation and regulatory conduct has, in numerous instances, delayed Teva's ability to launch generic Alendronate. The litigations have also forced Teva to incur significant expenses—including more than 7 million euros in legal fees to litigate approximately forty lawsuits—and have required Teva's executive leadership to expend substantial time and attention. Teva has been continually successful in its opposition to such litigations.

Teva has faced, and continues to face, repeated patent infringement litigations and has established, where the merits have been decided, that the patents that Merck invoked were invalid. Specifically, Teva has litigated patent infringement or invalidity in eight countries.<sup>21</sup> In five countries, Teva engaged in separate litigations concerning both the basic patent and the dosing regime.<sup>22</sup> In five of the six cases that have reached a judgment on the merits of a patent (including a lower court judgment), Teva has in each case successfully had the challenged patent revoked.<sup>23</sup> Teva believes that those decisions demonstrate that the fundamental basis on which Merck has sought to bar Teva from commencing generic sales of Alendronate is unmeritorious.

Despite Teva's success on the merits, Teva has confronted circumstances in which courts have issued preliminary relief to Merck denying Teva market access on the basis of the assumed validity of the pertinent patents. In the majority of countries in which Merck has commenced patent litigation (6 of 8),<sup>24</sup> Merck has sought preliminary injunctions to prevent generic entry. In two of those countries, Merck has succeeded in that effort. For example, in Belgium, the court granted

<sup>19</sup> The patent litigations relate to either or both, *i.e.* the basic patent (and SPC) protecting Alendronate and/or its use and/or the 70mg dosing regime. The Regulatory issues concern whether Teva's generic product is substitutable for Merck's Fosamax (10mg or 70mg).

<sup>20</sup> Preliminary Report, point 76.

<sup>21</sup> The countries are: (1) the Netherlands; (2) Italy; (3) the United Kingdom; (4) Germany; (5) France; (6) Belgium; (7) Sweden; and (8) Spain.

<sup>22</sup> The countries are: (1) the Netherlands; (2) Italy; (3) France; (4) Belgium; and (5) Sweden.

<sup>23</sup> The sole exception is Belgium, where a lower court found Merck's patent and supplemental protection certificate ("SPC") valid. The judgment was issued one week before the expiration of the SPC. Teva expects to appeal the decision in the near future, and an appeal by Merck Generics (now known as Mylan) has already been filed.

<sup>24</sup> The countries are: (1) the Netherlands; (2) Italy; (3) France; (4) Belgium; (5) Germany; and (6) Sweden.



Merck a preliminary injunction.<sup>25</sup> In Italy, an appeals court reversed the district court's decision to deny Merck's subsidiary a preliminary injunction. In Germany and Sweden, injunctions were initially issued, though later revoked.

Teva also has faced, and continues to face, regulatory litigation concerning various aspects of its Alendronate products, such as challenges to market authorizations and the effects of its products on health and safety. As with the patent infringement litigations, Teva has been successful on the merits of the regulatory litigations in all decided cases.<sup>26</sup>

Yet the regulatory litigations have hindered Teva's market access in several instances. For example, in a litigation concerning the Dutch regulatory authority, a preliminary injunction was granted but subsequently reversed on appeal. In Sweden, the regulatory agency found Teva's medicine to be substitutable for Merck's under the Swedish reimbursement system, but the decision was not given immediate effect.

Teva has been forced to obtain injunctions to prevent Merck from intervening in other ways. In one instance, Teva was forced to resort to the Dutch courts to cause Merck to send rectification letters (and publish the same in a medical journal) to wholesalers to whom Merck had issued a formal warning letter about Teva's alleged patent infringement, and to enjoin such conduct in the future. In another instance, Teva challenged Merck's decision to send 12,000 letters claiming that generic Alendronate was of inferior quality and posed a safety risk to Dutch physicians and pharmacies. Teva was successful in both instances. Merck also sued Teva for unfair competition in Germany, claiming that Teva illegally compared its product to Merck's in advertisements. Though Merck initially obtained an *ex parte* preliminary injunction, the injunction was later revoked.

Finally, Merck, having delayed but not prevented generic entry using its original patent covering Alendronate, has launched another wave of litigation and regulatory attacks using a divisional patent covering the same invention. That divisional patent is invalid for the same reasons as the original patent, and has already been revoked in Belgium and the Netherlands.<sup>27</sup>

The practices described above can considerably delay generic entry. Teva notes in that regard the Commission's findings in the Preliminary Report that generic medicines reach the market, on average, *twelve months* (in absolute terms) after patent expiry. Even when weighted by value, the average time between patent expiration and generic entry is still approximately seven months.<sup>28</sup>

<sup>25</sup> In the Belgium case in which the preliminary injunction was granted, the court ultimately found in Teva's favor on the merits of the infringement proceeding.

<sup>26</sup> This total excludes Hungary, which has unique facts. There, Teva's marketing authorization was withdrawn by agreement of Teva for reasons not directly related to the merits of the Hungarian regulatory proceedings. A new marketing authorization was issued approximately six months after the withdraw of the prior marketing authorization.

<sup>27</sup> As explained by Sir Robin Jacob in his speech on 28 November 2008, the EPO is not always able to identify whether a patent application cover substances identical to those covered by earlier patents.

<sup>28</sup> Preliminary Report, point 165.



Those findings, supported by objective information gathered during the sector inquiry, contradict the allegation made by the European Foundation of Pharmaceutical Industries and Associations that generic entry occurred within three months after loss of exclusivity for a majority of generic products over the period of 2000-2007.<sup>29</sup>

#### 1.4 Litigation by originator companies will likely increase.

As Teva showed in its submission of 7 October 2008 (attached hereto as Annex II),<sup>30</sup> and as the Preliminary Report confirms,<sup>31</sup> delaying generic entry is an economically rational strategy for originator companies. The supracompetitive profits that an originator company maintains by delaying generic competition almost always substantially exceed the costs of litigation. For a drug with hundreds of millions of euros in annual sales and a substantial profit margin (in many cases more than 70%), the potential lost profits from generic entry are substantial. Thus, litigation that delays generic entry, even if for only a few weeks or months, is profitable for the originator company and acutely harmful to consumers. Indeed, the supracompetitive profits that an originator company maintains by delaying generic competition almost always substantially exceed the costs of litigation.

In addition, generic manufacturers face a structural disadvantage in bearing litigation costs compared to originator companies. For the latter, the litigation costs can be paid from the gains that arise from delaying generic competition. By contrast, for generic manufacturers, litigation costs are high in absolute and relative terms, and cannot be recouped from present revenue streams, which would not exist prior to market entry.

The European regulatory environment provides opportunities for originator companies to delay generic entry through vexatious litigation or regulatory conduct. As Teva discussed in its previous submission, rules in the European Community that allow originator companies to initiate litigation in multiple Member States foster an environment conducive to vexatious litigation.

Further, as Teva's experience has shown, and as the Preliminary Report confirms, originator companies are frequently able to obtain temporary injunctions, which can substantially delay generic entry. Requesting temporary injunctions is a riskless affair for originator companies. Generic companies are rarely if ever able to obtain damages for the profits lost during the time that they are prevented from entering the market. In addition, unlike jurisdictions such as the United States, the courts of the Member States typically do not require originator companies to post a bond

<sup>29</sup> European Foundation of Pharmaceutical Industries and Associations ("EFPIA"), Submission to the European Commission in Relation to the Pharmaceutical Sector Inquiry (June 13, 2008), point 168(ii). EFPIA's measurements are by pre-expiry value.

<sup>30</sup> Teva, Facilitating Initial Generic Entry: A Submission By Teva Pharmaceuticals Europe B.V. In Connection With The Pharmaceutical Section Inquiry By the European Commission (Oct. 7, 2008), section 2.1.

<sup>31</sup> As the Preliminary Report found, originator companies use the tool-box to "maximise the revenue stream from existing pharmaceutical products by delaying or dampening the effect of generic entry." Preliminary Report, point 887.



to obtain a temporary injunction that would revert to the generic company if the injunction was improvidently granted.

As the Preliminary Report shows, originator companies frequently use the tool-box against generic companies. Given the economic incentives of originator companies, their use of tactics to delay or defer generic entry is likely only to increase, as litigation and other “tools” are economically rational means to preserve the high prices and sales volume that are associated with the absence of generic competition.

The large number of patent infringement suits that typically confront generic entrants (and their associated costs), however, also makes it desirable for generic companies to have flexibility to settle patent infringement actions initiated by originator companies. Such settlements are generally beneficial to consumers and the pharmaceutical sector. Settling a patent litigation can allow the generic company to enter sooner than otherwise possible or practicable, as many settlements provide for generic entry prior to patent expiration.

Settlements have also permitted generic companies to market lower-priced versions of generic products other than the generic product at issue, or to license patents other than the asserted patent. In addition, settling costly litigations can free generic companies to spend their relatively limited resources developing and bringing to market other generic products.

Finally, settlements also provide a societal benefit by reducing the resources and costs that must be otherwise devoted to the judicial system to resolve complex patent disputes. Indeed, United States courts have recognized that “the associated benefits of settlements [ ] include the avoidance of the burdensome costs and the resolution of uncertainty regarding the respective rights and obligations of party litigants.”<sup>32</sup> Similar considerations underlie settlement agreements in Europe.<sup>33</sup>

### 1.5 Effects of buyer power

The price decreases following generic entry reported in the Preliminary Report concern retail prices, *i.e.*, the prices paid by the patients and their insurers. They include the distribution margins made by wholesalers and pharmacists. The ex-factory prices charged by the generic companies are therefore even lower. As will be discussed below, those prices are under constant pressure and may, at a certain stage, lead to generic market exit.<sup>34</sup>

<sup>32</sup> *Schering Plough v. FTC*, 402 F.3d 1056, 1075 (11th Cir. 2005), *cert denied*, 126 S.Ct. 2929 (2006); *id.* at 1076 (“Given the costs of lawsuits to the parties, the public problems associated with overcrowded court dockets, and the correlative public and private benefits of settlements, we fear and reject a rule of law that would automatically invalidate any agreement where a patent-holding pharmaceutical manufacturer settles an infringement case by negotiating the generic’s entry date, and, in an ancillary transaction, pays for other products licensed by the generic.”).

<sup>33</sup> Preliminary Report, points 589 to 600.

<sup>34</sup> The consistent downward pressure on the prices of generic drugs is inconsistent with any alleged collusion to fix prices in the



The Preliminary Report does not discuss the threat to the viability of generic competition posed by the significant buyer power wielded by buying groups or governmental agencies, such as the National Health Service in the UK or the AOK in Germany, and its significant impact on price formation. Although the buyer power and purchasing practices in some cases concern both originator and generic medicines alike, they have a greater impact on generic companies, which, unlike originator companies, do not enjoy a period of market exclusivity during which their substantial initial investments could be recouped. Further, the exercise of buyer power is more effective and acute with respect to generic drugs than branded drugs. Branded drugs often have unique applications and no substitutes, which limit the exercise of buyer power. Generic products, by contrast, are readily substitutable for one another and their prices are significantly constrained by buyer power.

In the Netherlands, for example, health insurers have recently revised their reimbursement policies by limiting the reimbursement for certain generic drugs to the price of the least expensive generic drug available at the retail (pharmacy) level. This so-called “preferential policy”, however, does not apply to the reimbursement of originator drugs.

The policy has already shown signs of two adverse consequences for consumers. First, the “preferential policy” appears to be leading to shortages of the “preferred” generic drugs and to the market exit of generic companies that are unable to cover their costs at the “preferred” price. Second, pharmacists are dispensing a larger share of originator drugs because, under the generic pricing policy, they do not have an incentive to substitute generic drugs for originator drugs. As a result, in the long term, the “preferential policy” reduces competition, has an output-reducing effect, and favors originator companies -- all to consumers’ ultimate detriment.

The unlimited exercise of buying power thus can lead to price levels that do not allow generic companies to recover important development and litigation costs. Sub-competitive prices due to market power among insurers and collective purchasers of generic pharmaceuticals will deter generic market entry and, even where generic entry has occurred, discourage wholesalers and pharmacists from selling generic instead of originator medicines.<sup>35</sup>

The exercise of buyer power will thus undermine the long-term growth and vitality of the generic industry. Consumers ultimately bear the cost of more expensive medicines in a less competitive market. The unlimited exercise of buyer power can drive down prices of generic products to unprofitable levels, causing generic companies to exit the market or deterring entry of new generic

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generic industry.

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This finding appears to be shared by other market participants as well. Indeed, Mr. Velzel, CEO of UVIT, a Dutch health insurance company, stated that prices they have obtained for generics may be too low because they have affected the incentives for pharmacists to sell generics.



products. That reduction in generic competition would enable originator companies to maintain higher prices for longer periods of time and deprive consumers of lower cost alternatives.

## 2 NEED FOR FURTHER ACTION AFTER THE PRELIMINARY REPORT

Teva applauds the Preliminary Report's finding that patent litigation and the use of regulatory procedures may adversely affect competition. Teva encourages the Commission to include those findings in its Final Report.

The Final Report presents an opportunity for the Commission to delineate possible remedies available to generic companies that have had the entry of their products unjustifiably delayed. Some of the problems presented by originator companies' unjustifiably delaying generic entry could be solved through individual proceedings under Article 82 EC or Article 28 EC. In its submission of 7 October 2008, Teva has indicated how those provisions could be applied to tool-box practices. (See Annex II). Indeed, the Commission's findings form the predicate of Teva's prior submission. The main points of Teva's position on individual enforcement measures will be summarized in section 2.1 below.

Enforcement in individual cases will not, however, suffice to make pharmaceutical markets truly competitive. Since most of the problems identified by the Commission are rooted in regulation, the solutions should also concern the regulatory framework. Indeed, the sector inquiry has demonstrated the need to reform the regulatory framework under which the industry operates.<sup>36</sup> Such a revision, however, cannot practicably be accomplished on a short- to medium-term time horizon. Teva therefore recommends two regulatory changes that would facilitate competition in the pharmaceutical industry and that could be accomplished simply by amending the regulatory framework that currently exists.

### 2.1 Enforcement in individual cases

#### (a) Article 82 EC

The Community courts have established a standard for determining when conduct is vexatious under Article 82. In *ITT Promedia N.V. v. Commission*, the Court of First Instance ruled that litigation by a dominant firm is vexatious under Article 82 if two conditions are fulfilled.<sup>37</sup> First, the action cannot reasonably have been considered as an attempt to establish the rights of the

<sup>36</sup> See Section D of the Preliminary Report

<sup>37</sup> Case T-111/96, *ITT Promedia NV v Commission*, 17 July 1998, ECR [1998] II-2937.



undertaking concerned and can therefore serve only to *harass* the opposite party. Second, the action had to be conceived in the framework of a plan whose goal is to eliminate competition.

Further, the Commission has applied Article 82 in the pharmaceutical context, holding that vexatious conduct by a brand pharmaceutical company that delays generic entry may violate Article 82. In *AstraZeneca*,<sup>38</sup> the Commission implicitly applied the *Promedia* criteria and found that AstraZeneca held a dominant position in the market for proton pump inhibitors and infringed Article 82 by abusing its dominant position. The abusive conduct consisted of making deliberate misrepresentations before national patent offices and courts in connection with procuring and maintaining its extended patent protection for its omeprazole-based products.

As Teva showed in its submission of 7 October 2008, the standard established in *Promedia* for determining whether litigation and regulatory conduct is vexatious is functionally equivalent to that applied in the United States. Teva's 7 October 2008 submission also distilled several principles from EC and United States precedents, which can form the basis of a sensible competition policy in the European pharmaceutical sector.

The applicable criteria, which are discussed in detail in Teva's prior submission, can be summarized as follows:

- Patent infringement claims based on misrepresentations to patent authorities or courts are likely to be vexatious.
- Patent infringement claims that clearly exceed the scope of the patent are likely to be vexatious.
- Patent infringement claims that have already been rejected in a parallel case are likely to be vexatious. That criterion applies regardless of whether the parallel case occurred in the same Member State or in a different Member State.
- The patent enforcement strategy may indicate baselessness. For instance, an originator company could enforce its patents selectively in jurisdictions where preliminary relief is easily granted, or adopt a shotgun strategy of engaging in litigation in multiple jurisdictions without regard to the validity of its patents in different jurisdictions. The first such tactic might indicate that the patent holder is seeking to avoid or postpone the review of the merits of its claim and the second such tactic might indicate a broad-based strategy to impede generic entry.

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<sup>38</sup> Commission decision of 15 June 2005, Case COMP/A. 37.507/F3, *AstraZeneca*. The case is under appeal before the Court of First Instance and registered under case number T-321/05.



- In addition to the above criteria, competition authorities and courts can consider whether the originator company has engaged in a pattern of litigious behavior directed against initial generic entrants. While an isolated litigation can be vexatious, repetitious litigations may signify that the originator company is waging a war of attrition against the generic entrant. That is particularly the case if the practices of the tool-box are used cumulatively.
- Competition authorities should also be cognizant of the financial incentives of the originator company to engage in vexatious conduct. The fact that the asserted patent or the alleged infringement relates to a so-called “blockbuster” drug that generates substantial revenue increases the incentives for vexatious conduct.

The above list of indicia and criteria, while not complete, can guide courts and competition authorities in applying Article 82. Although the question of whether vexatious conduct is abusive under Article 82 must be determined on a case-by-case basis, the presence of any factor listed above may be probative of conduct that is designed to restrain competition and not vindicate legitimate legal rights.

By scrutinizing the conduct of originator companies under Article 82, the Commission can deter originator companies from using the tool-box to delay generic competition. Because the supracompetitive profits that an originator company maintains by delaying generic competition always substantially exceed the costs of litigation, Teva suggests that the Commission consider the use of vexatious conduct to be an aggravating circumstance warranting an increase of fines. That practice would help to counter the economic incentive for originator companies to engage in such conduct.<sup>39</sup>

#### (b) Article 28 EC

The European Commission and national courts can and should also apply Articles 28 and 30 of the EC Treaty. According to established case law, the exercise of intellectual property rights can constitute an obstacle to trade within the meaning of Article 28, if such rights are invoked to oppose the marketing of goods that circulate freely in other Member States. This principle has consistently been applied since the Court’s ruling in *Centrafarm/Winthrop* as regards the use of patent rights to oppose parallel imports.<sup>40</sup> *Generics v. Smith Kline* held that the same principle applies where patent rights are used to oppose generic marketing authorisations,<sup>41</sup> regardless of whether the generic

<sup>39</sup> Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation, No 1/2003, 2006/C 210/02, points 28, 30, 31.

<sup>40</sup> Case 15/74, *Centrafarm v. Sterling Drug*, 31 October 1974, ECR [1974], p. 1147, ground 5.

<sup>41</sup> Case C-316/95, *Generics v. Smith Kline*, 9 July 1997, ECR [1997], p. I-3929, grounds 14 to 17.



products in question are imported or originate from local production. The prohibition of Article 28 EC can be triggered even where the effect on interstate trade is only potential, not actual.<sup>42</sup>

Although restrictions to interstate trade can be justified under Article 30, the European Court of Justice has systematically held that derogations to the fundamental freedoms of the Treaty must be interpreted strictly. Article 30 EC justifies the exercise of patent rights only insofar as it does not constitute either a means of arbitrary discrimination or a disguised restriction on interstate trade.

That explicit condition implies that the exercise of patent rights under the circumstances noted is abusive and serves only to delay generic market entry. Teva submits that the same criteria and factors as those proposed above for the application of Article 82 EC to vexatious litigation can be used in the context of Article 30 EC. If one or more those elements reveals the existence of vexatious litigation, patent rights cannot be relied upon under Article 30 to block generic entry.

The limit imposed by Article 30 EC also affects the regulatory reference framework under which a national court must assess the exercise of intellectual property rights. As a rule, national courts should always take due account of the regulatory regime under which the imported goods were marketed in the exporting Member State. National courts accordingly must duly consider the circumstances in the exporting Member State before applying Article 30.

Although courts in one Member State are not necessarily bound by the findings of their counterparts in another Member State, they cannot ignore their findings. National courts should consider whether a patent for the same chemical substance has already been declared invalid in another Member State or the ruling has been made that the conduct of the importing generic manufacturer does not infringe the patent for a certain substance. Those factors may be relevant where a national court in the importing State is asked to rule on any patent related claim that would result in blocking imports of generic medicines.

Articles 28 and 30 apply not only to the use of patent rights in main proceedings, but are also relevant for the practice of granting temporary or final injunctions against the marketing of generic products without any assessment of the validity of the patents invoked by the brand owner. As noted above, that practice invites and unduly favors vexatious litigation. It also raises obstacles to trade that are incompatible with Articles 28 and 30.

## 2.2 The need for a European Patent Court

Teva subscribes to the comments in the Preliminary Report on the absence of a Community Patent<sup>43</sup> and of a unified judiciary.<sup>44</sup> Teva is aware that efforts were undertaken in the past to create a

<sup>42</sup> Case C-321-324/94, *Criminal proceedings against Jacques Pistre a.o.*, 7 May 1997, ECR [1997], p. I-2343, ground 45.

<sup>43</sup> Preliminary Report, points 1084-1088.



Community Patent, thus far with little success. Therefore, Teva suggests, as a first step, the formation of a European Patent Court ('EPC') that is competent to rule on disputes concerning the validity of patents granted by the EPO. Subsequently, if the Community Patent comes into force, the EPC will be competent to rule on disputes concerning that patent.

Ideally, the EPC would render high-quality judgments within a rapid time frame, thus allowing a swift resolution of patent-related disputes. An acceptable time frame would be a first-instance decision within twelve to eighteen months from the start of the action and decisions on appeal within nine to twelve months after the first instance decision.

Interim and final injunctions should be available only with adequate safeguards to the alleged infringer. The injunctions should reflect an assessment of the merits of the claim and should be as narrow as is necessary to protect the party whose patent is allegedly infringed. Territorial restrictions on injunctions should be such that only the countries in which the infringement is alleged should be included in the injunction.

Further, if an interim injunction is granted, the originator company should be required to post a bond that would compensate the generic company for any losses incurred if it is later determined that the interim injunction was improvidently granted.<sup>45</sup> When the originator company considers the downside risk that the bond may be used to compensate the generic company, the bond requirement transforms the request for an interim injunction from a riskless proposition to one in which the originator company may be penalized, if warranted under the circumstances, for seeking and obtaining an interim injunction. Because consumers and the generic company bear the cost of an interim injunction, the originator company should likewise be exposed to financial loss if it seeks and obtains an improvidently granted interim injunction.

As for opposition procedures at the EPO, granting patents at the EPO, and patent linkage, Teva supports the comments made by the generic industry in general and the conclusions the Commission has drawn from those comments, e.g., as noted above, when the Commission concludes: *"The sector inquiry has confirmed that originator companies file secondary and divisional patent applications as a strategy to prevent or delay generic entry and to create uncertainty for generic competitors as to whether they may develop a generic copy without infringing a potential patent."*<sup>46</sup>

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<sup>44</sup> Preliminary Report, points 1089-1096.

<sup>45</sup> Members States, of course, could independently establish a requirement of posting of a bond before issuing an interim injunction in patent infringement proceedings without regard to EU-wide reforms.

<sup>46</sup> Preliminary Report, point 1116.



### **2.3 Introducing a period of generic exclusivity in Europe would encourage generic entry.**

The sector inquiry provides the Commission with an opportunity to amend the regulatory framework to increase the incentives for generic entry. Under the current European regulatory framework, prospective generic entrants must incur substantial costs, which are frequently increased by originator companies' efforts to delay generic entry. Further, the price at which generic companies can sell their drugs is generally low (and sometimes below competitive levels due to the exertion of substantial buyer power), further diminishing incentives for generic entry.

The first generic entrant that succeeds in opening a market to generic competition is almost always followed by other generic entrants that were able to enter with diminished risks and costs. Subsequent generic entrants thus benefit from, or "free-ride" on, the investment made by the first generic entrant.

Establishing a period of marketing exclusivity in favor of generic companies that are first to market potentially infringing drugs would promote generic competition and benefit generic companies, originator companies, and pharmaceutical consumers. Revenues during the period of exclusivity would allow generic companies to recoup their investments, fund additional drug development, and pursue new patent challenges. For originator companies, increased generic competition will likely spur innovation, leading to more robust product pipelines and more successful product launches. Both of those effects benefit European patients and taxpayers, who obtain lower prices on pharmaceutical products subject to generic competition, and who benefit from the improved treatments that result from increased innovation.

As Teva discussed in its submission of 7 October 2008, the existing system for marketing authorizations prescribed by Regulation 116/2004 provides an appropriate legislative framework for implementing an exclusivity period for the first generic company to enter the market before patent expiration. The necessary amendments to that Regulation would not require new harmonization measures.

As the experience of the United States pharmaceutical sector has demonstrated, a period of marketing exclusivity for first generic entrants that launch before patent expiration provides a powerful economic incentive for initial generic entry. As Teva discussed in detail in its prior submission, in the United States, under the Hatch-Waxman Act,<sup>47</sup> the first generic company to file an abbreviated new drug application ("ANDA") for a drug that an originator company has asserted is protected by a patent with an intent to market the generic drug before patent exclusivity (a so-called "Paragraph IV certification") is entitled to a 180-day period of marketing exclusivity.<sup>48</sup>

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<sup>47</sup> The Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2003)).

<sup>48</sup> 21 U.S.C. § 355(j)(5)(B)(iv).



The increasing rate of Paragraph IV certifications confirm the expectations that generic entry responds positively to economic incentives. As generic companies have gained experience with Hatch-Waxman procedures, the filing rate of patent applications challenging originator drugs that are allegedly patent-protected has increased substantially. From 1984 through 1989, only two percent of ANDAs contained Paragraph IV certifications. During the 1990s, that share increased to twelve percent, and from 1998 to 2000, approximately twenty percent of ANDAs contained Paragraph IV certifications.<sup>49</sup>

Teva's own experience illustrates that the incentives provided by the Hatch-Waxman Act have encouraged and facilitated generic product development, patent challenges, and generic entry earlier in the United States than in Europe. Given Hatch-Waxman incentives, Teva has launched its generic products prior to patent expiration more frequently in the United States than in Europe.

In addition, amending the regulatory framework to reward generic companies for incurring the cost and risk of challenging originator companies' patents would partially offset the diminished incentives for generic entry caused by the unlimited exercise of buyer power. Much as originator companies use patent protection to limit the exercise of strong buyer power, a temporary period of marketing exclusivity would allow first generic entrants that launched prior to patent expiration a similar counter.

The implementation in Europe of a marketing exclusivity period for first entrants prior to patent expiration would thus encourage early generic product development and entry, help sustain a robust generic industry, and significantly reduce consumer healthcare costs. The resulting competition benefits all market participants: consumers gain earlier access to cheaper medicines; generic companies are rewarded for taking the risk of launching their products prior to patent expiration; and originator companies would have a stronger incentive to innovate and improve the quality of their patent portfolios.

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<sup>49</sup> Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration 10* (2002); see Teva Submission of Oct. 7, 2008 at

### 3 CONCLUSION

Teva welcomes the Commission's findings. They identify well the tool-box approach followed by originator companies and that such strategy does indeed delay generic entry to the detriment of European patients and taxpayers. The extensive litigation in which Teva is involved as regards the marketing of Alendronate in various Member States offers a specific and striking example of how effective the tool-box can be and how it unduly raises costs and delays entry.

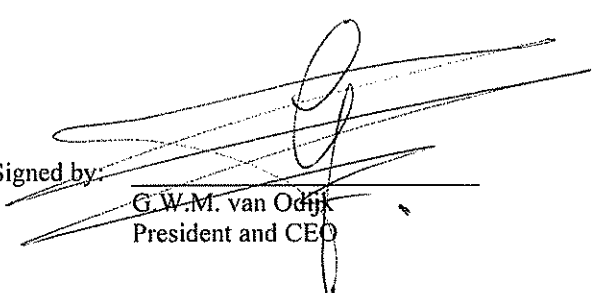
Teva believes that action should and can be undertaken against tool-box practices. First, Teva has proposed a series of elements upon which the Commission can rely when applying Article 82 EC to vexatious litigation by dominant firms. Teva considers that European and U.S. case law have developed converging standards to that effect.

Second, the same elements should be applied by national courts when originator companies seek to rely, in interim or main proceedings, on patent rights to prevent the marketing of generic drugs. Articles 28 and 30 EC prohibit the use of patent rights, where they, actually or potentially, constitute an arbitrary or discriminatory barrier to trade.

Third, the Preliminary Report has revealed a sector-wide consensus for the establishment of a European patent court competent to rule on claims relating to patents granted by the EPO. The formation of such a court should be one of the Commission's main legislative priorities to improve competition in the pharmaceutical industry.

Finally, changes to the current regulatory regime can significantly encourage generic entry and reward generic companies for incurring the cost and risk of entry prior to patent expiration. As shown in the United States, the grant of temporary marketing exclusivity for the first generic entrant prior to patent expiration has considerably accelerated generic entry to the substantial benefit of US patents and tax payers.

Signed by:



G.W.M. van Odiijk  
President and CEO

Date: 29<sup>th</sup> January 2009