ANNEX I

OVERVIEW OF ALENDRONATE LITIGATION IN THE EC

INTRODUCTION

Merck & Co. and its subsidiaries (MSD, etc.) have been conducting during the last four years a series of judicial and extra judicial activities with the aim of preventing or, failing that, at least delaying the introduction to the markets of the EU Member States the generic equivalent of Merck’s Fosamax Alendronate osteoporosis drug. While other generic companies were also targets of such activities, the brunt of Merck’s efforts focused on Teva and its European subsidiaries. Against this background, Teva has compiled and encloses herewith an overview of such litigations and other activities for the attention of the EC Commission.

The litigations launched by Merck against Teva relating to FOSAMAX have focused on regulatory issues and two patents. The regulatory issues concern whether Teva’s generic product is bioequivalent and therefore substitutable for Merck’s Fosamax (10mg or 70mg). The patent litigations relate to: (i) the basic patent (and SPC) protecting Alendronate sodium, and/or its use; and (ii) the 70mg dosing regime.

The litigations have forced Teva to incur significant expenses and have required substantial time and attention from Teva’s executive leadership, even though Teva has continually succeeded in the litigations. Indeed, Teva has incurred more than 7 million euros in legal fees for outside counsel alone, in addition to sizeable fees for testifying experts and a countless number of in-house counsel’s working hours and management time, to litigate more than forty lawsuits with Merck. The litigations have also impeded Teva’s entry into several Member States and raised considerably Teva’s cost of competing with Merck.

Teva has faced or continues to face repeated patent infringement litigations, including costly revocation proceedings, and has established, where the merits have been decided, that the patents that Merck invoked were invalid. More specifically, Teva has litigated patent infringements in eight countries.¹ In the five 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. 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),² Merck has sought preliminary injunctions to prevent

¹ The countries are: (1) the Netherlands; (2) Italy; (3) the United Kingdom; (4) Germany; (5) France; (6) Belgium; (7) Sweden; and (8) Spain.
² The countries are: (1) the Netherlands; (2) Italy; (3) France; (4) Belgium; (5) Germany; and (6) Sweden.
generic entry. In two of those countries, Merck has succeeded in that effort; in Belgium, the court granted Merck a preliminary injunction, in Italy, an appeals court reversed the district court's decision to deny Merck's subsidiary a preliminary injunction. And in two other cases, injunctions were initially issued, though later revoked.3

Teva also has faced and continues to face regulatory litigation concerning various aspects of its Alendronate products. Much of these challenges to Teva's market authorizations (MAs) were based on allegations that Teva's generic products were not bioequivalent to Merck's FOSAMAX and that they constituted a hazard to public health and safety and that the various regulatory authorities illegally granted the marketing authorizations to Teva. As with the patent infringement litigations, Teva has been universally successful on the merits of the regulatory litigations in all the decided cases.4

Yet the regulatory litigations have hindered Teva's market access in several instances. For example, in a litigation concerning The Netherlands 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. And in Denmark, the lower court initially denied Merck's application for a preliminary injunction, but the lower court's findings were overturned on appeal, and the case was remanded. On remand, the lower court again ruled against the injunction.

Lastly, Teva has been a party to litigation concerning defamatory conduct. In one instance, Teva was forced to resort to the Dutch courts to force Merck to retract no less than twelve thousand (12,000) letters it sent to pharmaceutical wholesalers, pharmacists and physicians warning them about the consequences for them in using or dealing with Teva's alleged infringing product. These letters claimed that Teva's generic Alendronate was of inferior quality and posed a health and safety risk to the public. In addition, Merck also sued Teva for unfair competition in Germany, claiming that Teva illegally compared its product to those of Merck's in advertisements. Though Merck initially obtained an ex parte preliminary injunction, the injunction was later revoked. An attempt by Merck to obtain monetary damages from Teva in The Netherlands by alleging Teva's earlier entry into the market by illegal application for marketing authorization was dismissed by the competent Dutch court.

The Commission should investigate such conduct and, if found to be vexatious and anticompetitive, declare it a violation of EC competition law.

3 A noticeable development has occurred during the period covered by this report concerning the criteria for granting and maintaining in force temporary injunctions in various jurisdictions. The original, almost universal rule was to grant temporary injunctions to a registered patent owner without taking into consideration the probability that the patent might be found invalid. In such cases, the injunction remained in force until final adjudication of an annulment or infringement action even when the first instance ruled to revoke the patent. This very narrow rule has changed in some of the Member States where now the court must consider upon request of the defendant the likelihood that the patent owner would succeed with the successive claims of infringement or the likelihood that the patent would be revoked.

4 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.
This overview is structured as follows. Section I provides a brief background to the patents. Section II contains a summary of the proceedings that took place in each of the Member States concerned. Sections III closes this overview with a timeline of relevant procedural events (from September 2002 up to September 2008).

I. **THE ALENDRONATE PATENTS UNDER DISPUTE**

1. **National Basic patents**

   The basic patent protecting alendronate and/or its use was filed by Instituto Gentili (Gentili) in 1982. No application was filed at the EPO but national patents were filed in many EU countries. These national patents were subject of Supplementary Protection Certificates (SPC’s) upon approval of Alendronate (the “Gentili Patent”).

2. **EP patents relating to the 70mg dosing regime**

   In 1997 Merck filed an international PCT patent application relating to the weekly administration of bisphosphonates, in particular, the 70mg per week administration of alendronate. This application proceeded in the EPO and was granted as EP 998,292 (hereinafter: “EP 292”).

   Teva Pharmaceutical Industries Ltd opposed the grant of EP 292 in the European Patent Office. The Opposition Division decision refusing to maintain the grant of EP 292 was handed down in August 2004. Merck appealed against that decision to the Board of Appeal. The appeal was dismissed by the Board of Appeal in March 2006.

3. **Divisional Patent**

   MSD filed the following four divisional applications relating to EP 292:

   (a) the use of a 70 mg weekly dose of alendronate in the treatment of osteoporosis (EP 1 175 904, hereinafter: “EP 904”);
   (b) a kit containing a 70 mg dosage for weekly administration (EP 1 175 903);
   (c) a pharmaceutical composition containing a 70mg dose of alendronate (EP 1 151 752); and
   (d) the use of risedronate for the weekly treatment of osteoporosis (EP 1 132 088).

   For the applications under (a) and (b), the examiner has acknowledged an inventive step based upon unpublished post-marketing pharmacovigilance data accumulated by MSD for the 10mg/day and 70mg/week. EP 904 has thus been granted on March 28, 2007. Teva filed its opposition to the patent on the same day. More than 15 other opponents also filed their oppositions to the EP 904 patent later on. The hearing in the EPO’s Opposition Division with regard to the EP 904 patent is scheduled for March 17-19, 2009, and the decision will probably be rendered immediately afterwards. So far, no patents have been granted by the EPO for the other divisional patent applications.
Right after having been granted EP 904, Merck has started a new round of litigation against Teva and its subsidiaries for infringement of this divisional patent.

Yet, for the reasons set out below, Teva considers that this patent has the same defects as the original parent patent and is vigorously contesting these actions. In sum, during the opposition proceedings, Merck amended some of the original claims granted in patent EP998292B. The claims were first revoked by the Opposition Division as lacking inventive step. The claims were in turn revoked by the Technical Board of Appeal as containing subject-matter extending beyond the content of the application as filed (Art. 123 EPC). Hence, the Technical Board of Appeal did not even hear arguments and, thus, did not decide on the inventive step.

To overcome the objection of the Technical Board of Appeal, Merck again reworded the relevant claim when prosecuting the divisional application that has given rise to EP1175904B. Yet, except for the deletion of the words “for inhibiting bone resorption” the claim as ultimately revised is in fact identical to the claim already rejected by the Opposition Division. Clearly, the “inventive concept” underlying the claim and that of the parent patent is the same and actually consisted of a combination of claims 1, 3, 14 and 15 of the granted parent patent.

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5 The relevant amended claims read as follows (additions to the claims as granted claim are underlined and deletions appear in strikethrough): “[u]se of alendronate acid or a pharmaceutically acceptable salt thereof, or a mixture thereof, for the manufacture of a medicament for inhibiting bone resorption for treating osteoporosis in a human wherein said medicament is adapted for oral administration according to a continuous schedule having a dosing interval of once-weekly, which medicament is in the form of a tablet comprising about 70mg in a unit dosage form which comprises from about 8.75mg to 140mg of alendronic acid or a pharmaceutically acceptable salt thereof, on an alendronic acid active weight basis, according to a continuous schedule having a periodicity from about once every 3 days to about once every 16 days.”

6 The claim as revised read as follows: “[u]se of alendronate in the manufacture of a medicament for treating osteoporosis in a human in need of such treatment, wherein said medicament is orally administered to said human, as a unit dosage form comprising about 70mg of the alendronate compound, on an alendronic acid active weight basis, according to a continuous schedule having a once-weekly dosing interval.”
II. COUNTRY REPORTS

1. THE NETHERLANDS

Patent Litigation, round I (Gentili patent / SPC)

(1) Preliminary injunction proceedings

On March 31, 2005 MSD instituted preliminary injunction proceedings against Teva Pharmaceuticals Europe B.V., Teva Pharma B.V. and Phar machemie B.V. (hereinafter collectively referred to as "Teva"), alleging infringement of Dutch SPC 970038. On April 25, 2005, the preliminary relief judge of The Hague District Court refused to issue the injunction upon finding of a realistic chance that the patent and SPC will be revoked following proceedings on the merit initiated by Teva.

On May 23, 2005, MSD filed an appeal with the Court of Appeal in The Hague against the above decision but, as of now, has failed to file a statement of grievances. The case is therefore dormant.

(2) Combined infringement and revocation proceedings on the merits

Teva filed a suit in The Hague District Court on April 13, 2005 for the revocation of the above SPC and its basic patent NL 192562. MSD filed a counter claim on September 14, 2005 asking for injunction against Teva. By judgment of May 17, 2006 the above SPC and patent were revoked and MSD's counter claim denied.

On July 14, 2006, MSD filed an appeal with the Court of Appeal in The Hague against the above judgment. The case is presently dormant since MSD has so far failed to file a statement of grievances.

Patent Litigation, round II (Divisional Patent EP 904)

(1) Combined infringement and revocation proceedings on the merits

On March 30, 2007, MSD filed an infringement suit in The Hague District Court against - inter alia - Teva relating to the new divisional patent for Fosamax 70 mg, EP 904. On July 18, 2007 Teva counterclaimed for a revocation of the Dutch part of EP 904. On September 12, 2007, a further counterclaim was filed by Teva seeking a declaratory judgment that its Alendronate 70 mg was obvious to the average skilled person in view of the prior art on 22 July 1997 (this date being the first priority date of EP 292, EP 904 and the other divisionals). By judgment of February 13, 2008 MSD's claim was denied and (the Dutch part of) EP 904 was revoked. Further, in the same judgment, The Hague District Court has declared for law that - inter alia - Alendronate 70 mg was obvious to the average skilled person over the prior art on July 22, 1997, also taking into
account that Merck did not wish to undertake not to use its divisionals against that product if and when such divisionals are granted.

On April 3, 2008 MSD filed an appeal with the Court of Appeals in The Hague against the above judgment. The case is presently dormant as MSD has so far failed to file a statement of grievances.

Regulatory Litigation - 10/70 mg

(1) On June 16, 2005, MSD filed an objection with the Dutch Medical Evaluation Board (CBG) against the registration of Alendronate 10 mg in the name of Pharmachemie B.V. (hereinafter: PCH) on the grounds that the PCH Alendronate is not essentially similar to MSD’s Fosamax and may present risk to public health. May 11, 2006, CBG rejected MSD’s objections as being unfounded.

(2) In June of 2005, MSD sued CBG in the Administrative Section of the Haarlem Court requesting the Court for a preliminary injunction to suspend the registration of Alendronate 10 mg. The Court found no reason to assume that PCH’s product constituted a risk to public health and denied MSD’s request. That decision of the Court was not appealed.

(3) On August 16, 2005, MSD filed another objection with the CBG, this time against the registration of the PCH’s Alendronate 70 mg on the same grounds on which it previously objected to the registration of the 10 mg. On May 11, 2006, CBG rejected the objection finding, in line with a recent Supreme Court decision, that MSD had no legitimate interest in this action relating to granting of a MA by the CBG.

On June 20, 2006, MSD filed an appeal against the CBG’s decision with the District Court of Haarlem’s administrative section. The appeal was withdrawn by MSD on August 22, 2008 (after the filing of CBG’s and PCH’s defences).

(4) On November 14, 2005, and December 19, 2005, in two separate civil proceedings, MSD filed complaints with the Court in Haarlem: (i) one requesting preliminary injunctions against the sale of PCH’s Alendronate 70 mg product; and (ii) the other requesting the recall of the products in the possession of wholesalers and pharmacies. The Court granted MSD’s requests in both proceedings.

On September 21, 2006, the Court of Appeal in Amsterdam found that PCH had not acted unlawfully against MSD and reversed both temporary injunctions and the recall order to be quashed.

(5) On February 23, 2006, while the above appeal proceedings were pending, MSD filed a civil action suit on the merits against PCH claiming damages as a result of PCH’s alleged unlawful registration of its Alendronate 70 mg product. By judgment of March 27, 2007, the Court rejected MSD’s claim.
MSD appealed against this decision with the appeal court in Amsterdam. The hearing on MSD's appeal was held on January 8, 2009 and the judgment is set for 17 February 2009.

Out of court actions (mailings) MSD – civil (injunctive) counteraction Teva/PCH

(1) In June 2005, by means of out of court letters, MSD issued formal warnings to wholesalers (that are also customers of Teva) claiming that selling generic alendronate drugs infringes MSD's patent and SPC rights. Notably, these warnings were also based on patents that had previously been revoked or held invalid in at least some jurisdictions. These letters comprised threats of patent infringement proceedings and recovery of damages from these parties. The wholesaler were also ordered to submit within 8 days a confirmation that they will respect, and not infringe MSD's SPC and patent rights. On June 22, 2005, Teva filed preliminary relief proceedings against MSD with the preliminary relief judge of the District Court of Haarlem. Amongst others, Teva requested that MSD shall be enjoined from sending such warning letters to Dutch wholesalers and, furthermore, that MSD should be ordered to send a rectification letter to the underlying wholesalers, and publish the same in a national professional magazine. By judgment of July 12 2005, the preliminary relief judge: (i) ruled that MSD acted tortuously against Teva; (ii) awarded injunctive relief against MSD; and (iii) ordered MSD to send rectifying letters to all wholesalers that had received the original tortuous letter, in addition to a publication thereof in a designated national professional magazine.

MSD did not appeal this decision.

(2) Shortly thereafter, MSD again embarked on a false advertising campaign against Teva on its website, and by sending 12,000 (twelve thousand) letters to Dutch physicians and pharmacies falsely claiming that generic Alendronate is of inferior quality to MSD's own branded product Fosamax, and falsely casting doubt about the safety of the generic drug. Again, Teva filed preliminary relief proceedings against MSD with the preliminary relief judge of the District Court of Haarlem to counter this new campaign. By judgment of September, 23 2005, the preliminary relief judge decided that: (i) MSD acted tortuously against Teva; (ii) prohibited MSD from such further tortuous actions; and (iii) ordered MSD to issue a rectifying statement on its website and furthermore to send a rectification letter to all 12,000 physicians and pharmacies that received the original tortuous letters.

(3) On October 4, 2005, MSD applied to the preliminary relief judge of the District Court of Haarlem for an injunction to release it from its obligation of carrying out the September 23, 2005 judgment. MSD's request for the injunction was denied by the judge on October 5, 2005. On October 21, 2005 MSD filed an appeal against the aforementioned judgment. On March 9, 2006, MSD's appeal was denied.
2. ITALY

Patent Litigation, round I (Gentili patent / SPC)

(1) Preliminary Injunction Proceedings

On October 24, 2006, the Istituto Gentili SpA (a subsidiary of Merck & Co) filed an action in the Court of Genoa for a preliminary injunction against Teva’s marketing of Alendronate, and against the marketing of Alendronate by the Union of Ligurian Pharmacists (on behalf of Teva) and against the introduction of Teva’s Alendronate products onto AIFA’s “Transparency List” for generic products, i.e. the list of generic drugs available on the Italian market with the indication of the prices reimbursed by the National Health System.

Teva notes that, after an action was initiated in Milan for summary revocation, a second set of proceedings appears to have been filed in Genoa (rather than in what would be the natural forum of Milan, considering that Teva’s Italian offices are in Milan) precisely in order to avoid that Gentili’s request for a preliminary injunction be joined with Teva’s earlier request for a summary revocation decision..

The judge in Genoa has rejected Gentili’s request for a preliminary injunction, essentially ruling that it is inappropriate for the Court to decide on the validity of the patent in view of the various (summary and ordinary) validity proceedings pending in Milan. It has also held that the damage suffered by Gentili would be quantifiable.

Gentili filed an appeal on November 22, 2006. The appeal hearing took place on December 19, 2006. On January 10, 2007, the Genoa Appeal Court reversed the decision of the Court of first instance and awarded Gentili a preliminary injunction with regard to IT 2 201 087. The Preliminary Injunction expired on April 15, 2007. Gentili did not file for an extension.

(2) Substantive litigation


The following schedule has been set by the Court:
- September 30, 2008 – filing of the parties’ first technical briefs
- December 10, 2008 – hearing regarding the preliminary findings of the Technical Expert

In the meantime, the Technical Expert has set the date of December 19, 2008 for the submittal of the parties’ second technical briefs. The hearing of December 19,
2008 was then postponed to January 15, 2009. The parties' second technical briefs were filed on January 15, 2009 and the deadline for the parties' third technical briefs is now set for March 9, 2009. The deadline for filing the Technical Expert's report has been postponed to June 15, 2009 and the hearing for discussing the report has been set for June 23, 2009.

**Patent Litigation, round II (Divisional Patent EP 904)**

(1) Teva has joined the invalidity action commenced by other generic firms against Merck’s EP 904. The case is at an early stage with a hearing on formal issues that took place on December 10, 2008. At that hearing, the parties have set forth their initial positions and requests for the appointment of an official technical expert to report on the patent's validity. The judge is to issue a decision shortly. It is expected that he will appoint such expert as is the case in all such actions in Italy.

(2) Merck counterclaimed for infringement against all companies involved in the invalidity action.

3. **DENMARK**

**Regulatory Litigation – 10 mg**

(1) Preliminary Injunction Proceedings

In September 2002, MSD applied for an injunction against Teva Pharma B.V. and Pharmachemie B.V. Specifically, MSD sought to obtain an injunction against Teva’s use of its Danish marketing authorizations for Alendronate "Teva" 10 mg and Alendronate "PCH" 10 mg, including the use as reference under the mutual recognition procedure.

Initially, the Danish courts considered whether MSD could file a case against two Dutch companies in Denmark on the basis of Danish marketing authorizations. The Glostrup Bailiff’s Court and subsequently the Copenhagen Bailiff’s Court and the High Court ruled in Teva’s favor in 2003, but in a decision of August 9, 2004, the Danish Supreme Court overturned the rulings of the lower courts and sent the case back to the Copenhagen Bailiff’s Court.

In a decision of December 16, 2005, the Copenhagen Bailiff's Court found in favour of Teva and Pharmachemie so that MSD’s application for injunction was denied. According to the court's decision, MSD had not demonstrated that Alendronate "Teva" and Alendronate "PCH" were not essentially similar to FOSAMAX, in particular with regard to the products' safety profiles.

MSD did not appeal the decision on the merits, but filed a separate appeal against the Bailiff's Court's ruling on costs awarded to Teva. This appeal was later decided by the High Court, resulting in a reduction of the costs awarded to Teva. The case is now closed.
(2) **MA Invalidation Proceedings**

In January 2003, MSD filed invalidation proceedings against the Danish Medicines Agency. The case is pending before the High Court. MSD claimed that Teva's and Pharmachemie's Danish marketing authorizations for Alendronate 10 mg should be invalidated since Teva's products allegedly had an inferior safety profile which significantly differed from that of FOSAMAX. Thus, following MSD, the Medicines Agency should not have granted the authorizations in the first place.

The Medicines Agency rejected MSD's claim, and Teva and Pharmachemie intervened in the proceedings in support of the Agency.

MSD also requested the Court to appoint an expert witness in order to evaluate the Medicine's Agency's assessment of Teva's and Pharmachemie's applications. The Agency and Teva have objected against the appointment of an expert witness and, by decision of November 24, 2006, the High Court found in favor of the Agency and Teva and refused to appoint an expert witness.

MSD applied for leave to appeal the decision of the High Court's decision of November 24, 2006, to the Supreme Court. The Danish Appeals Board, on June 8, 2007, refused to grant MSD the permission to appeal.

4. **UNITED KINGDOM**

**Regulatory litigation – 70 mg**

(1) In September 2004, Merck applied for judicial review of a decision by the Medicines and Healthcare products Regulatory Agency (MHRA) to change the circumstances in which it would cross-refer to innovator's data and thereby prevent the grant of a marketing authorization for a once weekly alendronate formulation to APS (Teva UK). That application for judicial review was refused in a decision handed down on April 28, 2005. The marketing authorization had in the meantime been granted to Teva UK on March 8, 2005. MSD did not seek leave to appeal that decision.

**Patent Litigation (Gentili patent and EP 292)**

(1) Teva Pharmaceutical Industries Ltd commenced an action against Istituto Gentili SpA (a subsidiary of Merck & Co) for revocation of UK Patent number 2, 118, 042 (basic patent) and Merck & Co for revocation of EP 292 in the High Court (Patents Court (part of the Chancery Division)). The decision at first instance revoking both patents was handed down in January 2003.

Merck was given leave by the first instance judge to appeal against the decision to the Court of Appeal. Merck duly appealed to the Court of Appeal against the
decision. The appeal was dismissed by the Court of Appeal in November 2003. Merck was refused leave to appeal to the House of Lords by the Court of Appeal but proceeded to apply to the House of Lords itself for leave to appeal. That application was dismissed in March 2004.

Patent Litigation, round II (Divisional Patent EP 904)

(1) MSD had given up (not designated) the UK part of EP 904. As a consequence, no litigation was commenced in the UK regarding this particular patent.

5. BELGIUM

Patent Litigation, round I (Gentili patent / SPC)

(1) Preliminary Injunction Proceedings

On July 27, 2006, MSD filed a request with the Antwerp Court for preliminary injunction on the basis of Belgian SPC 96C0027. On December 5, 2006, MSD's claim was rejected, because MSD did not convince the Court that the underlying Belgian basic patent no. 896.453 is new, original, or inventive. In this respect, the preliminary relief judge also expressly referred to the judgments of the preliminary relief judges in DE, NL, FR and SW, wherein similar conclusions were drawn, to the judgments on the merits in DE, NL and GB, whereby the respective national SPCs (in GB, the basic patent) were revoked.

On January 5, 2007, MSD lodged an appeal against the decision of the Antwerp Court. On May 23, 2007, the appeal was dismissed by the Antwerp Court of Appeal.

(2) Combined infringement and revocation proceedings on the merits

On September 8, 2006, MSD filed an infringement action on the merits against the Belgian Teva companies for infringement of the above mentioned SPC. On September 13, 2006, Teva filed a revocation claim against MSD to declare patent claims 1-5 and 7 of MSD's Belgian basic patent and MSD's Belgian SPC invalid. The Court decided to join the two cases. By interlocutory judgment of September 7, 2007, at MSD's request, the Antwerp Court decided to refer the joined infringement and revocation cases to the Brussels court, to be joined with other combined infringement and revocation proceedings between MSD and others regarding the same SPC. Oral hearings were held before the Brussels court February 14, 2008. By judgment of April 8, 2008 (one week before the expiry of the SPC) the Belgian basic patent and the SPC were declared valid. The appeal against this decision should be filed shortly. Merck Generics (now, Mylan) has appealed that decision.
Patent Litigation, round II (Divisional Patent EP 904)

(1) Preliminary Injunction Proceedings

On July 3, 2007, MSD filed a request with the Brussels Court for preliminary injunction. In defense, Teva disputed the validity of EP 904. By judgment of October 9, 2007, the Brussels court handed down a preliminary injunction against Teva. Notably, the court found some merit in Teva’s arguments against the validity of EP 904, but considered that it merely had to assess the prima facie validity of the invoked right, and that a material assessment of the validity should be left to the court ruling on the merits. As a consequence of this preliminary injunction, Teva Belgium had to stop all marketing of their products (the Alendronate 70 mg tablets).

Teva has lodged appeal against this judgment. The appeal case has been introduced with the Brussels court of appeal February 29, 2008. However, the appeal was withdrawn by Teva after the judgment rendered on the merits on April 8, 2008 (see below item (2) in favor of the generic companies. By decision of June 16, 2008, the Court of Appeal of Brussels ordered that the renunciation of the appeal on behalf of Teva, as well as the renunciation of the original action in summary proceedings on behalf of MSD will be entered into the records.

(2) Combined infringement and revocation proceedings on the merits

Shortly before the institution of the preliminary injunction proceedings, on April 26, 2007, MSD had already filed an infringement action on the merits, with the same court, against the Belgian Teva companies for infringement of EP 904. On July 14, 2007, Teva counterclaimed for revocation of (the Belgian part of) EP 904. A hearing was fixed for November 16, 2007, but delayed at Merck & Co.’s request. Finally, the hearing was held on February 15, 2008.

By judgment of April 8, 2008 the Belgian part of the EP 904 has been revoked. Like the The Hague District Court in the Netherlands, the Belgian court declared for law that Alendronate 70 mg was obvious to the average skilled person over the prior art on July 22, 1997. Merck & Co lodged an appeal with the Brussels Court of appeal on June 13, 2008. The court has determined the following procedural agenda:

- September 30, 2008: Teva to submit its first written submissions in appeal;
- January 15, 2009: Merck & Co to submit its first written submissions in appeal;
- March 13, 2009: Teva to submit its second written submissions in appeal;
- May 15, 2009: Merck & Co to submit its second and final written submissions in appeal;
- June 15, 2009: Teva to submit its third and final written submissions in appeal;
Regulatory litigation – 70mg

(1) On September 1, 2006, MSD lodged a complaint with the Belgian Administrative Court against the Minister of Health with the purpose to annul the MA granted to Teva Belgium for Alendronate 70mg on grounds of alleged public health hazard.

Teva, as a party with a legitimate interest was allowed to intervene in the case on behalf of the Minister and submitted a vigorous defense alongside the regulatory authority. Before a hearing date can be set, the Court must receive the brief of the Advocate General of the Administrative Court. According to the information received by Teva, this brief is expected for March or April 2009.

6. GERMANY

Patent Litigation (Gentili patent / SPC)

(1) Preliminary Injunction Proceedings

On April 25, 2005, the Hamburg District Court, upon MSD’s motion, had issued an ex parte injunction against the (then) managing director of GRY-Pharma GmbH, a Teva subsidiary (“GRY-Pharma”), Mr. Hehl, based on an alleged infringement of German SPC DE 196 75 047, owned by MSD.

Shortly thereafter, on May 11, 2005, also upon MSD’s motion, a second ex parte injunction was issued by the Hamburg court, this time against the company (GRY-Pharma).7

A court hearing was held on June 1, 2005. After that hearing the Hamburg District Court lifted the two injunctions on June 2, 2005. The court stated that it is more likely than not the MSD’s patent will not be upheld in a separate proceeding before the Federal Patent Court and, thereby, no basis for a patent infringement exists. MSD did not appeal against this ruling of the Hamburg District Court.

(2) Infringement proceedings on the merits

On July 6, 2005, MSD instituted proceedings on the merits against GRY-Pharma at the District Court of Mannheim for alleged infringement of German SPC DE 196 75 047. In its decision on June 29, 2006 the Court suspended proceedings in this action until a final decision in the revocation proceedings before the Federal Supreme Court.

7 In this context MSD had certainly in mind that protective letters are usually not submitted on behalf of managing directors but only on behalf of the company. In addition, they probably desired two titles in order to put more pressure on Teva.
(3) Revocation proceedings

On July 8, 2005, Teva filed a revocation action with respect to DE 3,313,049 and its SPC. Two other generic companies also filed a revocation action, which was consolidated with Teva's at the Federal Patent Court. On June 27, 2006 the court revoked the patent. As a result of this decision, the infringement proceedings were suspended (see above).

On October 31, 2006, Merck appealed the decision to the Federal Supreme Court and a substantiation on April 12, 2007. Teva submitted its reply on October 1, 2007. An oral hearing is expected in the course of 2009.

Unfair competition litigation

(1) Preliminary Injunction Proceedings

MSD initiated a second proceeding before the Hamburg District Court. Upon MSD's motion the Hamburg District Court issued an ex parte injunction against GRY-Pharma on the basis of an alleged violation of unfair competition rules. MSD argued that GRY-Pharma had illegally compared certain effects and costs of its product Tevanate® with effects and costs of MSD's product FOSAMAX®. For most of the "incriminating" statements, the Hamburg District Court, after a hearing held on August 30, 2005, lifted the injunction on the same date. The court supported Teva's arguments that GRY-Pharma is free to use such statements for marketing purposes. The judgment was served on MSD Germany on September 28, 2005.

MSD Germany appealed the judgment to the Hamburg Court of Appeals which was filed on October 28, and November 28, 2005. Teva responded with a brief dated January 19, 2006. As a result of a judgment rendered on April 20, 2006, in which the Court of Appeals made it clear that it is not prepared to accept MSD's arguments, MSD decided to withdraw its appeal.

Regulatory litigation – 10 mg

(1) On June 24, 2005, MSD filed an objection with BfArM, the German regulatory authority, against the approval of Tevanate® 10 mg on the same basis as the Danish Mutual Recognition Procedure (MRP); for reasons of public health safety risks. On July 20, 2005, the Federal Institute for Drugs and Medical Devices (BfArM) rejected MSD's opposition and permitted GRY-Pharma to market the product immediately.
On August 5, 2005, MSD filed a lawsuit against BfArM in the Administrative Court of Cologne against the BfArM's decision. On November 11, 2005, the Court dismissed MSD's claim. It is interesting to note that, as its main reason, the Court stated that insofar as public health issue is concerned, a "person with standing" is someone who belongs to the group of persons protected by it; a condition that MSD does not fulfill.

On November 11, 2005, MSD filed an appeal with the Superior Administrative Court in Münster which, by decision of May 3, 2006, denied MSD's appeal.

7. FRANCE

Patent Litigation, round I (Gentili patent / SPC)

(1) Combined infringement and revocation proceedings on the merits

On May 6, 2005, MSD started litigation against TEVA CLASSICS and TEVA SANTE, for infringement of its French SPC 96C0032, which is based on French patent FR-B-2 525 223 (83 05858), a Gentili patent, before the 3rd Chamber of the Paris District Court. Teva filed submissions in response, and counterclaimed for revocation of SPC 96C0032. The case was heard on October 26, 2007. By decision of February 15, 2008, the Court revoked MSD's SPC for lack of inventive step, and denied the infringement relief sought by MSD. This decision was appealed by MSD Somerset Ltd. on May 30, 2008. On September 8, 2008 MSD withdrew its appeal. The decision of revocation of the patent and SPC is thus final.

(2) Preliminary Injunction Proceedings

After starting the case discussed in (1) above, MSD filed on June 3, 2005 a request for preliminary injunction against TEVA CLASSICS and TEVA SANTE. This request was heard on September 15, 2005. By decision of November 9, 2005 the judge rejected MSD's request for preliminary injunction, for the reason that the validity of SPC 96C0032 was doubtful. The decision was not appealed by MSD.

Patent Litigation, round II (Divisional Patent EP 904)

(1) On May 23, 2007, Merck & Co and MSD Manufacturing (MSD) filed an infringement claim against TEVA CLASSICS, TEVA UK Ltd. and PHARMACHEMIE B.V. (Teva) based on the new divisional patent, before the 3rd Chamber of the Paris District Court. Teva is vigorously contesting the claim. Teva requested a stay of the action pending a final decision by the EPO in the opposition proceedings (main request), and counterclaimed for revocation of EP 904 (auxiliary request). MSD contested Teva's request for a stay of the action, arguing that EP 904 is valid, and that Teva infringes the patent. A hearing regarding Teva's main request for stay of the proceedings was held July 4, 2008. The decision was
rendered on September 26, 2008 and has stayed the proceedings until the final decision of the EPO in the opposition proceedings.

As of today, this decision to stay was not appealed by MSD.

8. **HUNGARY**

**Regulatory litigation – 70 mg**

(1) On January 28, 2005, the Hungarian regulatory authority (OGYI) issued a MA to PharmaConsult Kft. as Facilitator for TRABECAN 70 mg which is a Teva Alendronate product. On April 20, 2005, MSD Hungary filed a complaint with the Metropolitan Court against OGYI, the Hungarian regulatory authority for unlawfully granting the MA to PharmaConsult. In its complaint MSD requested that the court annul the MA, primarily on the grounds of MSD’s arguing that the 6 year data exclusivity period had not yet expired.

Under Hungarian law as was in force at the time of filing, a law suit against an administrative decision automatically suspends the performance of such decision until the case is finally adjudicated by the court. (It should be noted that, as of November 1, 2005, this automatic suspension feature has been repealed. Henceforth, suspension can only be affected by court order as a temporary injunction.) The Court set the hearing on MSD’s complaint for August 30, 2005. However, in the interest of protecting the then ongoing UK registration under MRP procedures (MHRA, the UK regulatory authority, prompted by MSD, started to ask Teva UK questions regarding the grant of MA for Alendronate 70 mg to PharmaConsult in Hungary at about the same time as the filing of MSD’s complaint in Hungary), it was decided, after consultation with all Teva related persons, to withdraw the MA which was cancelled by the concurring order of OGYI dated June 24, 2005.

On December 8, 2005 an MRP based MA was granted to Teva by the Hungarian regulatory authorities.

9. **PORTUGAL**

**Regulatory litigation – 10/70 mg**

(1) On October 7, 2005, MSD filed a complaint with the Portuguese regulatory authority (INFARMED) protesting the issuance of marketing authorizations to four companies (including Teva), for generic alendronate products in 10 mg and 70 mg doses. By decision of November 23, 2005, INFARMED rejected MSD’s claim and reaffirmed the validity of the issued MA’s.
On March 15, 2006, MSD sued INFARMED before the Administrative and Fiscal Court of Sintra requesting that the Court annul the MA’s on the grounds that INFARMED did not properly investigate and take into consideration various facts which should have prevented the granting of the MA’s, among them infringement of MSD’s patent, existence of data exclusivity and a host of other factual and legal points. Teva Portugal, as an interested party had the legal right to join in the lawsuit on the side of INFARMED. Its answer and counterclaim was filed on April 27, 2006.

On November 9, 2007 the Court of Sintra handed down a partial decision dealing only with the jurisdictional issue of the lawsuit. The Court found that it is competent to handle the case. The Court has made no determination in any of the substantive issue and set no deadline for the continuation of the proceedings.

10. SWEDEN

Patent Litigation, round I (Gentili patent / SPC)

(1) Revocation action

As in several other jurisdictions, notably in the UK, Teva has instituted a revocation action in Sweden on October 27, 2004 with respect to MSD’s Swedish SPC and the underlying Gentili patent (SE 463,2390). Merck filed a response on March 24, 2005. Thereafter, only a limited exchange of briefs has taken place while the parallel infringement case has been in focus. Nonetheless, the parties have now exchanged their statement of evidence. The revocation action will be most likely decided at the same time as the infringement case.

(2) Infringement proceedings; request for interlocutory injunction – 10 mg

On January 14, 2005 MSD sued Teva for the infringement of the above Gentili patent and SPC. Since Merck submitted the request for the interlocutory injunction, the case has been focused on this matter. The parties have exchanged a large number of briefs and new expert reports. An oral hearing was held on December 13, 2005. On February 7, 2006 the court granted the injunction whereby Teva was prohibited from marketing any medicines containing the Alendronate compound.

Teva appealed against the injunction. By judgment of October 13, 2006, the Court of Appeals lifted the injunction granted to MSD at first instance stating that the SPC appears not likely to be valid.

Although the revocation action started in 2004 and the SPC expired on April 15, 2008, no trial date has yet been set by the court for hearing the Gentili cases on their merits.
Regulatory litigation – 10 mg

(1) On March 23, 2005, MSD filed a complaint with the Administrative County Court in Uppsala against the Swedish Medical Products Agency (MPA), Teva and two other holders of generic 10 mg MA’s. Merck appealed the MPA’s decision according to which Alendronate Teva 10 mg (and other generic Alendronate 10 mg products) is substitutable to Fosamax 10 mg. Merck also requested that the MPA’s list of substitutable Alendronate product should be revoked in its entirety (parallel imports of Fosamax are listed as substitutable, i.a., for Alendronate Teva). The County Administrative Court in Uppsala rendered its judgment on December 7, 2005. The Court upheld the MPA’s decision that Alendronate Teva is substitutable for Fosamax within the Swedish reimbursement system and Merck’s claim that the MPA’s decision should be set aside was dismissed. However, the Court did not grant Teva’s claim that the substitution decision should be given immediate effect.

Teva appealed the decision only in so far as it did not to give the substitution decision immediate effect. The appeal was dismissed by the Administrative Court of Appeal. The Administrative Supreme Court did not grant leave to appeal.

Merck also appealed the judgment and requested: (i) that the appeal court should find that, inter alia, Alendronate Teva is not substitutable for Fosamax; and (ii) that the appeal court should, in an interlocutory decision, withdraw the existing substitution list regarding Alendronate products, since generic Alendronate is listed as substitutable with parallel imported Fosamax.

The latter request was denied by the appeal court. The Administrative Supreme Court decided on April 10, 2006 not to grant Merck leave to appeal this decision.

The main issue, whether Alendronate Teva 10 mg is substitutable for Fosamax 10 mg was decided by the Administrative Appeal Court on February 16, 2007. Merck’s appeal was rejected and the MPA’s decision that Alendronate Teva 10 mg is substitutable for Fosamax 10 mg entered into immediate effect. Merck appealed to the Administrative Supreme Court. By decision of July 25, 2008, the Administrative Supreme Court did not grant leave to Merck’s appeal.

Patent Litigation, round II (EP 1 175 904)

(1) Revocation action

On April 5, 2007, Teva filed a revocation action with regard to the Swedish part of EP 904, which is one out of several divisional patents of EP 0 998 292, which was revoked by the Board of Appeal of the EPO on March 14, 2006. On June 26, 2007,
MSD filed a response. Since then, a large number of submissions and expert reports have been exchanged by the parties.

(2) Infringement proceedings

On April 20, 2007, MSD commenced proceedings against Teva alleging infringement of EP 904. Teva is vigorously contesting the claim. It is likely that both infringement and revocation actions will be heard at the same time. The court, however, has not yet set any date for a main hearing of the cases.

11. SPAIN

Patent Litigation (Divisional Patent EP 904)

(1) On September 7, 2007, MSD commenced proceedings against Teva Genericos SL in the Barcelona Court for alleged infringement of its 904 patent. At the same time, Merck requested a stay in the proceedings pending decision of the EPO on the oppositions filed by various generic companies. The Court denied Merck’s request and a preliminary hearing is scheduled for April 23, 2009.

12. POLAND

Opposition proceedings

(1) On September 10, 2007, Teva filed an opposition against Merck’s PL 195,272 (the Polish counterpart of EP 998,292, which was revoked at the European Patent Office (EPO) and of EP 1,175,904), relating to the Alendronate 70 mg product. Several other companies have also filed parallel oppositions. On November 25, 2008, Merck filed its reply. Oral hearing has not been scheduled yet, and is expected not earlier than September, 2009.
### III. TIMELINE OF RELEVANT EVENTS

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*Unless otherwise stated, the actions mentioned here were initiated by MSD.*
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* * *
FACILITATING INITIAL GENERIC ENTRY:
A SUBMISSION BY
TEVA PHARMACEUTICALS EUROPE B.V.
IN CONNECTION WITH
THE PHARMACEUTICAL SECTOR INQUIRY
BY THE EUROPEAN COMMISSION
# INTRODUCTION

1. **INITIAL GENERIC COMPETITION BENEFITS CONSUMERS AND DOES NOT THREATEN INNOVATION**

   1.1 Introduction
   
   1.2 The benefits of generic competition
   
   1.3 Europe has a high level of intellectual property protection

2. **initial GENERIC ENTRY SHOULD BE ENCOURAGED BY REMOVING THE OBSTACLE OF VEXATIOUS CONDUCT**

   2.1 Delaying initial generic entry is an economically rational strategy
   
   2.2 Vexatious conduct can be prohibited under Article 82
      
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   2.3 Examples of vexatious conduct
      
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3. **SUGGESTED REGULATORY REFORM**

   3.1 First generic entrants incur substantial risks and costs
   
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   3.3 An exclusivity period can be implemented in Europe

# CONCLUSIONS
INTRODUCTION

On 16 January 2008 the European Commission ("Commission") launched a sector inquiry in the pharmaceutical industry. The opening decision refers to several factors that suggest that competition in the pharmaceutical industry does not function optimally. Those factors include commercial practices, such as vexatious litigation and misuse of regulatory proceedings, which impede initial generic competition.

Teva Pharmaceuticals Europe B.V. ("Teva") welcomes the Commission's inquiry. It shares the Commission's concern that competition is distorted by practices that unduly delay the initial market entry of generic drugs, which in turn increases the cost of drugs paid by European patients and taxpayers. For several of its products, when Teva has sought to introduce the first generic alternative to a brand pharmaceutical, the manufacturer of the brand pharmaceutical has resisted entry in a manner that cannot be considered legitimate attempts to enforce patent rights. Teva believes that such practices may violate the competition rules of the EC Treaty, in particular Article 82.

More generally, Teva notes that numerous regulatory issues impede and encumber initial generic entry throughout Europe. In many important respects, the regulatory regime applicable to generic drugs is fragmented among the twenty-seven Member States. That fragmentation requires duplicative filings and approvals, raises costs, and provides numerous venues for brand pharmaceutical companies to attempt to thwart initial generic competition.

Although Teva recognizes that centralizing the regulatory regime is beyond the scope of the sector inquiry, it notes the difficulties that accompany fragmentation to emphasize the importance of the two main issues addressed in this paper:

- The need to clarify the application of competition rules to vexatious litigation and misuse of regulatory proceedings (hereafter collectively referred to as "vexatious conduct") that is designed to deter initial generic competition and that may be instituted in numerous of the twenty-seven Member State venues; and

- The call for a modification of the European Union’s regulatory regime to introduce a limited period of marketing exclusivity for the first generic company to enter before patent expiry.

Teva focuses its comments in this paper on impediments to the first generic company’s commencing the sale of a generic version of a drug sold by a brand pharmaceutical company. Such initial generic entry is particularly important, and should be encouraged, because the first generic entrant that succeeds in introducing generic competition often affects significantly the price and availability of the relevant drug and frequently is followed by other generic entrants that are able to enter with diminished risk and lower costs.
Section I of this paper explains the two key premises that form the predicate for the discussion that follows. First, generic competition, and particularly initial generic entry, benefits consumers by reducing the price of drugs. Second, generic competition and pharmaceutical innovation are not incompatible.

Section II of this paper discusses how initial generic competition can be encouraged by removing the obstacle of vexatious conduct. Initial generic entry in Europe would benefit from the Commission's clarifying its approach to such conduct. The Community courts have established a standard for determining when vexatious conduct is abusive under Article 82. Indeed, the Commission has applied Article 82 in the pharmaceutical context, holding that vexatious conduct by brand pharmaceutical companies that delays generic entry may violate Article 82. The Community courts, however, have not had extensive opportunities to consider the specific circumstances in which conduct will be considered vexatious so as to give rise to a potential Article 82 violation.

United States precedents offer guidance on how Article 82 can apply to vexatious conduct. The United States standard for determining when a lawsuit or regulatory proceeding constitutes vexatious conduct and, therefore, is subject to antitrust scrutiny is functionally equivalent to that of the EC. Applying that standard, United States courts have recognized the legal sufficiency of antitrust claims based on vexatious litigation in a variety of factual circumstances.

The principles derived from United States precedents, as well as from EC precedents, can form the basis of a sensible competition policy in the European pharmaceutical sector. Such a policy should seek to promote initial generic entry through EC and private enforcement and industry guidance.

Section III of this paper explains how initial generic entry could be further promoted by constructing a limited period of generic exclusivity to encourage generic companies to launch the first competing generic drug before the expiration of purportedly applicable brand company patents that may not withstand scrutiny if challenged. That limited period of generic exclusivity would compensate generic entrants for the unique costs and risks incurred in launching the first generic drug before the expiration of allegedly applicable patents. The European rules in force today could be amended to provide the first generic company to enter before patent expiration with a temporary period of marketing exclusivity.

The experience of the United States under the Hatch-Waxman Act confirms that a limited period of marketing exclusivity would promote initial generic entry. The introduction of a comparable system at the European level would benefit European patients and taxpayers.
INITIAL GENERIC COMPETITION BENEFITS CONSUMERS AND DOES NOT THREATEN INNOVATION

1.1 Introduction

From the 1930s through the present, Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") has been a leading producer of generic drugs and active pharmaceutical ingredients. It started in Israel, and has since expanded its activities worldwide, particularly in the United States and Europe. Teva Ltd.'s stock is now listed on exchanges in Tel Aviv, New York (NASDAQ), London and Frankfurt, and Teva Ltd. has a market capitalization of approximately 35 billion USD. Teva Ltd. has also expanded its activities into other areas of production, including research and development of innovative products.

Teva believes that generic and innovative activities are compatible. Patent laws grant innovators an exclusive right to their innovations as a reward for their creative efforts. That exclusive right allows innovative companies to obtain a return on their investment. It also benefits society, because the exclusivity encourages innovation and is limited in time. Upon the expiration of the patent, inventions fall into the public domain. When patent rights on a pharmaceutical product expire, third parties should be able to compete with the former patent holder. And the onset of competition that occurs following the expiration of the patent spurs new innovation.

In Teva's experience, however, initial generic entry in the European pharmaceutical industry frequently does not occur immediately upon the expiration of pharmaceutical patents. Among the factors that delay initial generic entry is vexatious conduct by brand pharmaceutical companies. As discussed in Section II, Article 82 prohibits such conduct under certain circumstances.

A second reason for the delay in initial generic entry across Member States is the existence of regulatory obstacles that confront generic pharmaceutical companies. Such obstacles include the absence of drug substitution rules in many Member States, the time required to obtain reimbursement rights, persistent disparities in marketing authorization regimes, and incorrect implementation of European directives into national law. Although suggesting solutions to those regulatory obstacles is beyond the scope of this paper, we propose in Part III a regulatory incentive

1 Teva Ltd. is one of the top 20 companies on the NASDAQ.

2 The European Federation of Pharmaceutical Industries and Associations ("EFPIA") characterizes the entry of generic competition as "almost immediate." EFPIA, Submission to the European Commission in Relation to the Pharmaceutical Sector Inquiry 88 (June 13, 2008). Teva's experience in commencing generic competition, however, has been significantly to the contrary.

3 For example, the registration of medicines for price and reimbursement purposes in some Member States can take several months after the granting of the initial marketing authorization.
that would promote the prompt entry of the first generic competitor despite assertions by brand companies that patent rights preclude such entry.

The regulatory fragmentation noted above also underscores the importance of addressing vexatious conduct. Brand pharmaceutical companies have as many as twenty-seven venues in which to attack the first generic entrant. Teva has experienced as many as forty lawsuits relating to a single drug.

1.2 The benefits of generic competition

Generic competition, and in particular initial generic entry, benefits consumers. The introduction of the first generic drug allows patients and insurance reimbursement schemes to obtain significantly lower drug prices, and facilitates subsequent generic entrants. Generic medicines are sold at prices that are twenty percent to ninety percent lower than those charged for the branded product. Lower generic drug prices save drug purchasers considerable sums. For example, in countries such as the Netherlands, the United Kingdom and Sweden, generic medicines account for approximately fifty percent of pharmaceutical consumption, but only approximately twenty percent of total pharmaceutical spending. According to estimates of the European Generics Association ("EGA"), generic drug consumption saves European patients and healthcare systems over twenty billion euros per annum.

1.3 Europe has a high level of intellectual property protection

European patent laws are among the most protective of pharmaceutical inventions. Moreover, a comparison between the levels of patent protection in the United States and Europe shows that promoting initial generic entry is unlikely to dampen incentives for innovation.

In Europe, pharmaceutical companies have several options for patenting their inventions. Patents can be obtained through either a European or a national procedure. Further, patent protection can be very broad. Pharmaceutical products essentially consist of chemical substances, which have various properties. Those properties can often be patented both alone and in combination with

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5 Id.

6 In some Member States patent procedures are open to abuse. Pharmaceutical companies can obtain patents in certain Member States, such as Belgium, without the patent authority examining whether the substantive patent conditions are fulfilled. As a result, pharmaceutical companies can obtain patent protection on substances in certain jurisdictions that may not be patentable in other jurisdictions.
other substances. As a result, an innovation with respect to a single substance can yield between twenty and forty patents.7

Patent laws in the European Union also ensure that pharmaceutical companies enjoy exclusive use of their innovations for a substantial period of time. In addition to the twenty-year period of exclusivity provided by the patent, European law permits innovators to obtain supplementary protection for a maximum of five years.8 Pharmaceutical inventions can thus formally enjoy patent protection for twenty-five years.

In addition to providing a substantial period of formal patent protection, European law also ensures that pharmaceutical companies have an effective period of ten to eleven years in which the marketing of their drugs is protected from competition. That protection is provided through administrative rules on “data exclusivity,” which limit pharmaceutical regulators in their use of scientific data contained in the files of the patent holder for eight years.9 And even after the expiry of the data exclusivity period, the brand company further benefits from marketing exclusivity for an additional period of two to three years.10

The strong intellectual property rights and substantial period of marketing exclusivity that exist in Europe duly protect pharmaceutical companies’ incentives for innovation. Innovation is thus not threatened by encouraging initial generic entry by removing the obstacle of vexatious conduct and providing a limited period of generic exclusivity. That conclusion is reinforced by a comparison between the United States and European pharmaceutical industries.

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7 See EGA, "Myths and Realities of the Pharmaceutical Industry".


9 The issue of data exclusivity is not relevant when the generic manufacturer opts for the normal authorization procedure. However, the normal authorization period can entail substantial additional costs and further delays to entry.

TABLE 1 – Comparison of IP protection in the US vs. the EU

<table>
<thead>
<tr>
<th>Market Environment for Generic medicines</th>
<th>USA</th>
<th>EU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic Medicines as % of Total Pharmaceutical Market Volume</td>
<td>63%</td>
<td>42%</td>
</tr>
<tr>
<td>Basic Product Patent</td>
<td>Yes 20 years</td>
<td>Yes 20 years</td>
</tr>
<tr>
<td>Data Exclusivity</td>
<td>Yes 5 years</td>
<td>Yes 8+2+(1) years</td>
</tr>
<tr>
<td>Patent Extensions</td>
<td>Yes 5 years</td>
<td>Yes 5 years</td>
</tr>
<tr>
<td>Bolar Provision</td>
<td>Yes (but not correctly implemented in all member states)</td>
<td>No</td>
</tr>
<tr>
<td>Immediate Generic Competition</td>
<td>Yes</td>
<td>No (due to Price &amp; Reimbursement procedures in many member states)</td>
</tr>
<tr>
<td>Fees for Generic Registrations</td>
<td>No (between $0,000 - $20,000 (euros))</td>
<td>Yes</td>
</tr>
<tr>
<td>Free Price Competition</td>
<td>Yes</td>
<td>No (not in most member states)</td>
</tr>
<tr>
<td>Harmonized Regulatory and IP Requirements</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

As the preceding table shows, intellectual property protection for innovative pharmaceuticals is at least as strong in Europe as in the United States. As discussed below, the United States has taken an aggressive approach in prohibiting vexatious conduct and in encouraging initial generic entry through a period of marketing exclusivity for first generic entrants that challenge purportedly applicable patents. Generic penetration is consequently more prevalent in the United States than in Europe. Yet the United States has experienced no decline in innovation.

In sum, initial generic entry should be encouraged because it benefits patients, taxpayers, and Member States. Additionally, promoting initial generic entry by removing the obstacle of vexatious conduct and by providing a period of marketing exclusivity to first generic entrants would not threaten innovation, as confirmed by the experience in the United States.

12 Source: IMS Health MIDAS MATQ106 Ethical Market only (Nordics – Preview (MK TSG4)) and EFPIA, “The Pharmaceutical Industry in Figures 2006”.
INITIAL GENERIC ENTRY SHOULD BE ENCOURAGED BY REMOVING THE OBSTACLE OF VEXATIOUS CONDUCT

Vexatious conduct poses a genuine threat to the initial entry of generic competition, particularly in the European Union where brand pharmaceutical companies have as many as twenty-seven venues in which to attack the first generic competitor. That threat is confirmed by basic economic insight, courts and competition authorities in Europe and the United States, as well as by Teva's own experience. Thus, the protection of initial generic entry from vexatious conduct should be an important goal of EC competition policy.

2.1 Delaying initial generic entry is an economically rational strategy

The incentives are high for brand pharmaceutical companies to delay initial generic entry by vexatious conduct. Experience shows that sales of brand pharmaceutical products frequently decline sharply following the onset of generic competition. The supracompetitive profits that a brand pharmaceutical company maintains from protecting its monopoly position by delaying initial generic competition often substantially exceed the costs of litigation. For a drug with hundreds of millions of dollars in annual sales and a substantial profit margin, the potential lost profits caused by the first generic entrant are substantial. Thus, vexatious conduct that delays initial generic entry only for a few months may be profitable for the brand company and acutely harmful to consumers.

Competition regulators and scholars in Europe and the United States have recognized that vexatious conduct is a viable anticompetitive strategy for brand pharmaceutical companies seeking to forestall initial generic entry. According to competition Commissioner Neelie Kroes, the need for innovative products to enjoy strong intellectual property protection does not authorize a dominant company to extend that protection beyond its lawful limits. Misleading regulators to gain longer protection acts as a disincentive to innovate and is a serious infringement of EU competition rules. Health care systems throughout Europe rely on generic drugs to keep costs down.


14 EFPIA’s claim that vexatious litigation should not be subject to scrutiny under the competition laws because “the judicial process provides protections for litigation and remedies to dispose of allegedly unfounded claims quickly” ignores the economics of abusive conduct. EFPIA, supra, at 108. So too does EFPIA ignore the fact that, as discussed below, brand pharmaceutical companies are frequently able to obtain a temporary injunction on the premise that patents are presumed valid.

15 For full statement of Mrs. Kroes, see Press release IP/05/737 of 15 June 2005.
manipulating United States pharmaceutical regulations to delay generic entry illustrates a "cheap" exclusionary practice that a sensible enforcement policy should prohibit. Indeed, the Federal Trade Commission has made the protection of generic competition from vexatious conduct an enforcement priority.

The European legal and regulatory environment also provides opportunities for brand pharmaceutical companies to delay initial generic entry through vexatious conduct. Patent litigation in Europe is a complex and lengthy process. Procedural rules in various Member States typically provide for lengthy court proceedings. In addition, various Member States' courts face considerable backlogs that further delay rulings on patent infringement and revocation actions. Brand pharmaceutical companies frequently seek temporary injunctions to prohibit initial generic entry for at least the duration of those proceedings. While courts in some Member States examine requests for temporary injunctions critically, courts in other Member States routinely grant interim relief on the premise that patents must be presumed valid. Teva's experience comports with the findings of the EGA report that:

"national courts quickly feel uncomfortable in interim injunction proceedings, meaning that decisions which uphold the status quo are more than likely, ie, interim injunctions are easily awarded in certain countries. This is often due to the fact that the courts in injunction proceedings cannot make a full legal analysis of the parties’ (patent) rights and can only make a prima facie

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By "cheap," Ms. Creighton is referring to conduct that both is inexpensive for the excluding firm and does not have countervailing efficiencies. Id. Other scholars also have recognized that the costs of predation through misusing government processes are frequently outweighed by the potential benefits. See ROBERT H. BORK, THE ANTITRUST PARADOX, at 348 (1978) (arguing that, even if the goal of sham litigation is to delay a competitor's entry, it is "a useful tactic against any size firm... for it may be worth the price of litigation to purchase a delay of a year or several years in a rival's entry into a lucrative market"); Noah, supra, at 2 (noting that, in the pharmaceutical industry, "[t]he financial stakes... are often enormous, and even relatively short delays in FDA approval of competing products could prove extremely valuable to a company with an approved product already on the market").

assessment of the rights involved. In interim injunction proceedings courts are not even always fully informed about the parties' rights and their argument.\(^9\)

The same report found that:

"[i]n various countries European patents are deemed to be prima facie valid, sometimes even when opposition proceedings are pending before the EPO and even when foreign decisions exist that revoke parallel national patents stemming from the same European bundle patent. This is not surprising as many of the judges are not technically qualified to decide questions of infringement and/or validity on the face of the issue, and do not have the benefit of a court-appointed technical expert as would be the case in full proceedings on the merits."

The combination of temporary injunctions and lengthy proceedings can substantially delay initial generic entry. For example, Teva has been confronted with interim injunctions that have barred its generic products from the market for several years, thereby protecting the brand company's monopoly from initial generic competition, on the basis of patents that were later considered to be invalid or not infringed.

In the absence of scrutiny under the competition laws, requesting temporary injunctions is a riskless affair for brand pharmaceutical companies. Initial generic competitors are rarely if ever able to obtain damages for the profits lost during the time that they are prevented from entering the market.\(^{20}\)

Rules in the European Community that allow brand pharmaceutical companies to initiate litigation in multiple Member States also foster an environment conducive to vexatious conduct. The effect of those rules is to allow brand pharmaceutical companies to re-litigate issues in a second Member State that they have already lost against the same generic entrant in a prior litigation in a different Member State. In principle, community jurisdictional rules provide a safeguard against the possibility of concurrent or consecutive proceedings leading to irreconcilable judgments in two Member States. Specifically, community jurisdiction rules state that, in the case of *lis pendens*, only the first court can rule on the case and subsequent courts must stay proceedings.\(^{21}\)

\(^{19}\)EGA report, supra, pp. 19-20.

\(^{20}\)This problem has been recognized in Australia. Australian legislation grants courts the authority to award damages, both to the enjoined party and the public authority, in cases where a patent holder initiates proceedings that are vexatious or unreasonably pursued. Another safeguard against vexatious litigation in Australia is that prior notification to the Attorney General is required where an injunction is sought by a patentee to prevent the infringement of an Australian pharmaceutical patent. See Therapeutic Goods Act 1989 Act No. 21 of 1990 as amended, see in particular Section 26D.

\(^{21}\)See Article 27 of Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, OJ L 012, 16/01/2001, p.1-23. The principle provided by article 27 is that "[w]here proceedings involving the same cause of action and between the same parties are brought
The *lis pendens* safeguard, however, is ineffective in practice. The European Court of Justice (*ECJ*) recently ruled (under the former Brussels convention) that *lis pendens* "does not apply in European patent infringement proceedings involving a number of companies established in various States in respect of acts committed in one or more of those States even where those companies, which belong to the same group, may have acted in an identical or similar manner in accordance with a common policy elaborated by one of them." The ECJ thus refused to allow the consolidation of the patent infringement actions, based on the same European patent, before a single court on the basis of *lis pendens*. The result is that a brand pharmaceutical company, simply by using different subsidiaries, may be able to sue for patent infringement of the same European patent in as many as twenty-seven different Member States, irrespective of the outcome of the infringement actions.

Thus, vexatious conduct aimed at delaying initial generic entry, rather than enforcing legitimate intellectual property or other rights, is an economically rational strategy for brand pharmaceutical companies. Further, the fragmented judicial and regulatory environment of the European Union, as well as the limited application of *lis pendens*, provide ready opportunities for brand pharmaceutical companies to engage in vexatious conduct.

### 2.2 Vexatious conduct can be prohibited under Article 82

**(a) The EC Standard**

The EC recognizes that vexatious conduct can form the predicate for liability under competition laws. In *ITT Promedia N.V. v. Commission*, the Court of First Instance ("CFI") ruled that vexatious litigation by a dominant firm infringes Article 82 if two conditions are fulfilled:

1. First, the action cannot reasonably be considered as an attempt to establish the rights of the undertaking concerned and can therefore serve only to harass the opposite party; and
2. Second, the action is conceived in the framework of a plan whose goal is to eliminate competition.

*in the courts of different Member States, any court other than the court first seised shall of its own motion stay its proceedings until such time as the jurisdiction of the court first seised is established.*


23 Justice Pumfrey from the UK Chancery Division suggested that the principles set out in the text above apply to patent litigation: "[w]here there is no dispute that the patents have been granted to the patentee, it seems [...] that the enforcement action can be considered to be merely harassing in the sense explained above [referring to ITT Promedia] if the patent is obviously not infringed or if the patent is invalid and in either case the patentee either knows or believes that to be the case." Judgment of the UK High Court of Justice Chancery Division, *Sandisk Corp.*, 2007 WL 675385, para. 46.
The Commission applied those principles to the pharmaceutical sector in the AstraZeneca case. The Commission inferred from Promedia that "[t]he use of public procedures and regulation, including administrative and judicial processes, may also, in specific circumstances, constitute an abuse, as the concept of abuse is not limited to behavior in the market only and misuse of public procedures and regulations may result in serious anticompetitive effects on the market." The Commission found that AstraZeneca had abused its dominant position in the market for proton pump inhibitors and therefore infringed Article 82. 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.

The Commission’s decision implicitly applied the Promedia criteria to AstraZeneca’s conduct. Because AstraZeneca’s lawsuits in national courts were intended to enforce patent protection that was procured through deliberate misrepresentations, those lawsuits could not reasonably be considered as an attempt to establish its rights. Further, the Commission found that “the misleading representations before certain national courts [were] part of the implementation” of “a plan to eliminate competition.” The Commission also found that AstraZeneca had abused its dominant position by deliberately misusing the rules and procedures applied by national medicine agencies when issuing market authorizations for medicines.

Another form of abusive conduct found in AstraZeneca consisted of selectively withdrawing market authorizations for Losec capsules in certain Member States and replacing capsules with tablets while maintaining the same dosage. The Commission suggested that such use of rules and procedures did not involve government-petitioning activities — the act of withdrawing market authorizations was instead more akin to a ministerial act to which the Promedia criteria need not be applied. Indeed, the Commission stated that AstraZeneca’s “requests to the public authorities to deregister the market authorizations are not requests addressed to the public authorities in the framework of an overtly political process or an attempt to influence decisions taken in a field where such authorities have a margin of discretion.” The Commission further found “abundant documentary evidence” that the objective of AstraZeneca’s vexatious conduct was “to prevent or at least delay generic omeprazole market entry as well as to stop parallel trade in Losec capsules thereby artificially partitioning markets.”

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24 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.

25 AstraZeneca, supra, para. 328.

26 AstraZeneca, supra, para. 737.

27 AstraZeneca, supra, para. 743.

28 AstraZeneca, supra, para. 819.

29 AstraZeneca, supra, para. 789.
Several principles can be inferred from the Commission’s findings. First, the Commission specified that “[i]nitiating legal proceedings may, in certain circumstances, be abusive in so far as the aim is to harass the opposing party, as it imposes upon that party costs and delays.” Second, it construed the CFI judgment in *ITT Promedia* as “mak[ing] clear that both the acquisition of a right and its enforcement may in themselves constitute an abuse.” Third, the Commission stated that “[t]he use of public procedures and regulations, including administrative and judicial processes, may, in specific circumstances, constitute an abuse, as the concept of abuse […] is not limited to behaviour in the market only.” And, finally, the Commission confirmed that initiating proceedings in several Member States may constitute a single and continuous abuse. That was found to be the case where “submissions before the three courts originate in and are the logical continuation of a proactive exclusionary strategy.”

(b) *The US Standard*

United States cases also provide guidance as to what constitutes vexatious litigation or regulatory conduct. Indeed, the United States standard for determining whether litigation is vexatious and, consequently, whether the conduct can violate antitrust law is functionally equivalent to the European standard.

In *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49 (1993) (“PRE”), the United States Supreme Court articulated a two-part test for “sham” or vexatious litigation. First, the lawsuit must be “objectively baseless” in the sense that no “reasonable litigant could realistically expect success on the merits.” Second, the party’s motive for commencing the litigation must have been to “attempt to interfere directly with the business relationships of a competitor.” Proving that a party engaged in vexatious litigation deprives it of the immunity from antitrust liability that is generally granted to those petitioning the government to redress grievances or to vindicate their rights. For a competitor to prevail on its antitrust claim,

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10 *AstraZeneca*, para. 738 (emphasis added).
11 *AstraZeneca*, para. 742, n. 601.
12 *AstraZeneca*, para. 743.
13 *AstraZeneca*, para. 775.
14 *AstraZeneca*, para. 736 (emphasis added). Similarly, the Commission found that costs and delays imposed on the opposing party were the result of misconduct before regulatory authorities, which was deemed “the continuation of the pattern of misleading representation.” *Id.* at para. 738 (emphasis added).
15 PRE, 508 U.S. at 60-61.
16 *Id.*
however, it must also prove that the defendant’s conduct — which may include the vexatious litigation — violated an antitrust law.\textsuperscript{37}

2.3 Examples of vexatious conduct

In addition to the Commission’s decision in AstraZeneca, examples of vexatious conduct to delay initial generic competition can be found in Teva’s own experience, in the courts of Member States, and in the United States.

Teva has encountered vexatious conduct in its efforts to launch generic drugs in Member States. As an example of such conduct, Teva offers its litigation against Merck Sharpe Dome ("MSD") concerning its efforts to market generic alendronate-related products, which compete with MSD’s branded products Fosamax and Fosavance. The alendronate litigations involved three types of conduct and combinations thereof:

(i) Patent infringement litigation: MSD has initiated substantial litigation throughout the EU. That litigation has attempted to pursue infringement claims for patents that have already been held invalid and challenged conduct that has already been held not to infringe valid patent claims. MSD essentially sought temporary injunctions to delay Teva’s initial generic entry.\textsuperscript{38}

(ii) Misuse of regulatory proceedings: MSD has initiated litigation against pharmaceutical regulators to prevent Teva from obtaining marketing authorizations, arguing that the authorizations granted for Teva’s generics jeopardize public health. Such actions further impeded the entry of Teva’s initial generic products.\textsuperscript{39}

(iii) Tortious business practices: In addition, MSD has engaged in various defamatory out-of-court practices. For instance, \textit{inter alia} through large direct mailings to wholesalers, pharmacists, hospitals and general practitioners, and via the internet to the general public, MSD has tried to cast doubt amongst these (potential) purchasers and prescribers about the safety of Teva’s generic drugs, and to portray Teva’s generic drugs as inferior to MSD’s own branded product Fosamax. Further, via written correspondence, MSD has

\textsuperscript{37} Id. at 61.

\textsuperscript{38} See, e.g., in Belgium, MSD sought interim measures before a Brussels court on 9 October 2007. The President of the court granted the requested injunction on the ground that the patent was deemed to be \textit{prima facie} valid, and that its validity should be assessed in the main proceedings. In its judgment in the main proceedings of 8 April 2008 the Brussels Court declared the patent invalid.

\textsuperscript{39} See, e.g., the action whereby MSD on 16 June 2005 filed an objection with the Dutch Medical Evaluation Board against the registration of Alendronate 10 mg in the name of Pharmachemie B.V. on the grounds that the PCH Alendronate is not essentially similar to MSD’s Fosamax and may present risk to public health. On 11 May 2006, CBG rejected MSD’s objections as being unfounded.
issued formal warnings to wholesalers and pharmacists that selling Teva’s generic drugs constitutes patent infringement, with an order to them to sign contractual non-infringement obligations, even with regard to patents that had previously been revoked or held invalid. These warning letters included threats of patent infringement proceedings and recovery of damages from these parties. MSD’s practices were without merit, and merely designed to prevent or hinder Teva’s initial generic competition.49

While the preceding categories do not exhaust the possible types of vexatious conduct, they illustrate the kinds of tactics that brand pharmaceutical companies can use to impede the onset of generic competition. Further, Teva has not been the only generic firm to confront such vexatious practices. As shown below, courts have experience with each type of vexatious conduct.

(a) Vexatious patent infringement litigation

Several cases have upheld the legal sufficiency of claims asserting violations of competition law by a brand firm on the basis of objectively unreasonable claims of patent infringement. In the EC, as discussed above, AstraZeneca shows that filing an infringement suit to enforce a SPC obtained by fraudulent misrepresentations can constitute an abusive act punishable under Article 82.

United States cases have also affirmed the legal sufficiency of alleged violations of competition law based on objectively unreasonable claims of patent infringement by brand pharmaceutical companies. For example, in In re Wellbutrin SR Antitrust Litigation, the court applied PRE and refused to grant the defendant brand pharmaceutical company’s motion to dismiss the plaintiffs’ claim that the defendant had violated competition laws by instigating vexatious litigation against the first generic companies that sought to compete with the brand pharmaceutical company.41 The plaintiffs in Wellbutrin alleged that the brand pharmaceutical company had brought an objectively unreasonable claim of patent infringement based on a patent protecting the brand drug’s excipient, notwithstanding that the generic drug contained a different excipient from that contained in the brand drug.42

40 See, e.g., a judgment handed down in the Netherlands by the District Court of Harlem on 12 July 2005, shortly followed by a judgment of 23 September 2005 finding that MSD had (again) acted tortiously and ordering MSD to issue a rectifying statement and send rectifying letters to no less than 12,000 physicians and pharmacists that had been subject to MSD’s initial tortuous letters.

41 No. Civ. A. 04-5525, 04-5898, 05-396, 2006 WL 616292, at *10 (E.D. Pa. Mar. 9, 2006). Under United States rules of procedure, a party can file a motion to dismiss a complaint early in the litigation as a means of testing the legal sufficiency of the opposing party’s claims. In adjudicating a motion to dismiss a complaint, a United States court will assume that the well-pled factual allegations in the complaint are true, and dismiss the complaint only if the reasonable allegations and the inferences drawn therefrom fail to state a legally viable claim. See generally Bell Atlantic Corp. v. Twombly, 127 S. Ct. 1955, 1964-70 (2007).

42 See Wellbutrin, 2006 WL 616292, at *4-5. Wellbutrin involved a substance called bupropion hydrochloride, which acts as an antidepressant. The substance, bupropion, was covered by United States patent number 3,819,706, which expired in 1991. Soon after the patent expired, the brand pharmaceutical company developed a sustained release
The brand pharmaceutical company had previously narrowed its patent on the excipient in response to a rejection of its patent application by the United States Patent and Trademark Office (the "PTO"). After the amendment, the patent did not cover all sustained release mechanisms, but only the excipient used by the brand. Because the court found that, under established law, the brand pharmaceutical company’s narrowing amendment to its patent barred it from asserting infringement based on the generic pharmaceutical company’s different excipient, the court held that the plaintiffs’ allegations, if proved, established that the brand pharmaceutical company’s lawsuit was objectively baseless. Thus, the court found that the brand pharmaceutical company’s filing the patent infringement suit deserved no immunity from allegations of a violation of competition law.

The court reached a similar conclusion in the United States case of Abbott Laboratories v. Teva Pharmaceuticals USA, Inc. In Abbott Labs, the court refused to dismiss the plaintiffs’ allegations that the defendant brand pharmaceutical company had violated the competition laws by attempting to enforce its patent on the substance, fenofibrate, also known by the brand name TriCor. The plaintiffs asserted that the brand pharmaceutical company’s claim of infringement was objectively unreasonable, among other reasons, because it had been rejected in a prior litigation concerning a different formulation of the drug. And, the plaintiffs contended, the brand pharmaceutical company, using an excipient known as hydroxypropyl methylcellulose, or HPMC. In 1999, several generic pharmaceutical companies sought approval of generic versions of Wellbutrin SR. The generic pharmaceutical companies’ version relied on a different excipient, known as hydroxypropyl cellulose, or HPC, from that contained in the brand drug.

43 Id. at 10.
44 Id. at *2-4.
45 432 F. Supp. 2d 408 (D. Del. 2006).
46 Id. at 424-25.
47 Id. at *26. The first litigation had involved Tricor capsules; the subsequent litigation involved Tricor tablets. The brand pharmaceutical company’s original new drug application (“NDA”) for Tricor capsules was approved in 1998. That formulation was listed in the Food and Drug Administration’s (“FDA”) “Orange Book,” along with United States patent number 4,985,726 (the “726 Patent”). In 1999, the generic manufacturer filed an Abbreviated New Drug Application (“ANDA”) for fenofibrate capsules. Litigation commenced, and summary judgment was granted in favor of the generic pharmaceutical company, because the generic pharmaceutical company’s fenofibrate formulations were...
company had not tested the generic products to determine whether they infringed the asserted patent. In denying a motion to dismiss, Abbott Labs found that those allegations stated a claim of vexatious litigation under PRE.

In re Relafen Antitrust Litigation provides yet another example of a US court’s sustaining allegations of vexatious litigation by a brand pharmaceutical company against first generic entrants. The plaintiffs in Relafen claimed that the brand pharmaceutical company could not have reasonably believed that its patent was valid because the substance that was the subject of the patent had previously been disclosed. The brand pharmaceutical company’s argument that its patent was valid was tenuous; it relied on an error in the publication that had allegedly disclosed the substance of the patent — which the brand pharmaceutical company’s scientists had ignored. Relafen concluded that the state of the brand pharmaceutical company’s knowledge at the time it filed its infringement action, on which the objectively baseless element of PRE turned, was a disputed issue of fact. The court therefore denied the brand pharmaceutical company’s motion for summary judgment.

not comminorized with a solid surfactant, as required by the asserted claims under the 726 Patent. Thus, the generic pharmaceutical company did not infringe the 726 Patent. Id. at 416.

While the litigation concerning the capsules was pending, the brand pharmaceutical company had an NDA approved for a tablet formulation of fenofibrate. The generic filed an ANDA for the tablets. The brand pharmaceutical company sued, alleging that the ANDA on the tablets violated the 726 Patent, as well as other patents. Id. at 416-17.

The plaintiffs also asserted that the allegedly infringed patents were unenforceable on account of inequitable conduct before the PTO. Id. at 426-27.

Id. at 426. The plaintiffs also asserted that the allegedly infringed patents were unenforceable on account of inequitable conduct before the PTO. Id. at 428.

Id. at 362. Relafen concerned the drug nabumetone, which is a non-steroidal anti-inflammatory, also known as methoxy ketone. The PTO had previously rejected the brand pharmaceutical company’s patent for nabumetone, citing an article by J.N. Chatterjee and R. Prasad, who had previously named methoxy ketone and described a method for its synthesis. The Chatterjee and Prasad procedure produced a “thick pale yellow oil,” which was an impure form of solid nabumetone. For this reason, the PTO Board of Appeals ruled against the brand pharmaceutical company’s patent application, concluding that it would have been obvious to a chemist of ordinary skill to purify the compound described in Chatterjee and Prasad and arrive at a solid form of nabumetone. Id. at 353.

The brand pharmaceutical company, however, argued that the Chatterjee and Prasad publication did not disclose nabumetone. Although Chatterjee and Prasad described their starting material as methoxy acetate, they referenced an article by R.G. Jones, who, due to an error, had mistakenly described the synthesis of hydroxy acetate, not methoxy acetate. The brand pharmaceutical company argued that an ordinary chemist would have understood the Chatterjee and Prasad publication to describe a method for the synthesis of hydroxy ketone, not methoxy ketone (i.e., nabumetone). The PTO subsequently reversed its position and granted the brand pharmaceutical company a patent on nabumetone.

At a bench trial on the patent infringement issue, the court credited the generic pharmaceutical companies’ expert’s testimony that an ordinary chemist “would not rely on a single, flawed reference in one footnote,” and thus would understand Chatterjee and Prasad to describe the synthesis of methoxy ketone. The court therefore held that the patent was invalid because it could have been anticipated, and was unenforceable on account of the brand pharmaceutical company’s inequitable conduct before the PTO. An appellate court affirmed on the issue of validity without considering enforceability. Id. at 355.

Id. at 364, 370. Under United States rules of procedure, a party can file a motion for summary judgment before trial as
(b) **Misuse of regulatory proceedings**

Brand pharmaceutical companies can also misuse regulatory processes to delay the initial entry of generic competition. As EC and United States cases show, pharmaceutical regulations designed to protect the health and safety of the public or promote other public purposes can be manipulated to delay generic entry. When brand pharmaceutical companies use regulatory devices in bad faith, that conduct is punishable under competition laws.

In the EC, *AstraZeneca* offers an example of the kinds of regulatory abuses that are the proper subject of enforcement by competition authorities. As discussed above, in *AstraZeneca*, the abusive conduct consisted of selectively withdrawing market authorizations for Losec capsules in certain Member States and selectively replacing capsules with tablets while maintaining the same dosage. In response, the Commission stated that “[t]he use of public procedures and regulations, including administrative and judicial processes, may, in specific circumstances, constitute an abuse, as the concept of abuse […] is not limited to behaviour in the market only.”

United States cases provide additional examples of vexatious regulatory conduct. In *Louisiana Wholesale Drug Co., Inc. v. Sanofi-Aventis*, the court sustained allegations of anticompetitive conduct based on the brand pharmaceutical company’s challenge to the safety of the labelling of the first prospective generic entrants. Plaintiffs claimed that the brand pharmaceutical company, which was familiar with the regulations that it sought to enforce, had made an objectively baseless challenge to the labelling of its generic competitors shortly before the competitors were to enter the market.

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53 *AstraZeneca*, supra, para. 743.

54 No. 07 Civ. 7343 (HB), 2008 WL 169362, at *5 (S.D.N.Y. Jan. 18, 2008). *Louisiana Wholesale* concerned the drug leflunomide, which treats rheumatoid arthritis. In *Louisiana Wholesale*, the court refused to dismiss the plaintiffs’ claim that the defendant brand pharmaceutical company had violated § 2 of the Sherman Act by filing an objectively baseless “Citizen Petition.” *Id.* at *1*. A Citizen Petition is permitted pursuant to regulations of the FDA. Citizen Petitions allow any person to request that the FDA take or refrain from taking any action, including the approval of an ANDA based on safety, scientific, or legal concerns. The brand’s Citizen Petition was based on the concern that, if a particular generic manufacturer recommends in its leflunomide labeling a leading dose of 100 mg for three days, it must either (1) provide its own 100-mg product or (2) recommend using five of its 20-mg products — neither of which the generic pharmaceutical companies had the necessary approvals to do. *Id.* at *5 & n 2*. However, the brand pharmaceutical company ignored the possibility that the label could refer to a 100 mg product made by a different manufacturer — a common practice in labeling, which the brand pharmaceutical company had itself used in its labeling. *Id.*

55 Similarly, Article 82 imposes a special responsibility on dominant firms. This implies that brand companies must be scrupulous in submitting information to regulatory authorities that affects generic competition.
market, thereby delaying their entry. The court found that such allegations could form the basis of a violation of competition laws.\textsuperscript{56}

A similar result was reached by the court in \textit{In re Buspirone Patent Litigation}.\textsuperscript{57} In Buspirone, various plaintiffs brought antitrust actions against Bristol-Myers Squibb ("BMS"), including two generic manufacturers that accused BMS of preventing competitors from marketing their generic versions of BMS's anti-anxiety drug, buspirone. Within a day before BMS's patent on buspirone expired, BMS listed a newly obtained patent on a related chemical in the FDA's Orange Book, while allegedly representing fraudulently to the FDA that the new patent covered uses of buspirone. By law, the FDA is temporarily prohibited from approving the marketing of any drug that allegedly infringes a patent listed in the Orange Book.\textsuperscript{58} Shortly thereafter, BMS brought patent infringement actions against generic manufacturers seeking to market generic buspirone.\textsuperscript{59}

The court in Buspirone denied BMS's motion to dismiss the antitrust claims. First, it rejected BMS's contention that listing the new patent in the Orange Book was government-petitioning activity subject to the \textit{PRE} test. Instead, the court held that the FDA's listing of the patent was a "ministerial" act undertaken in reliance on BMS's representations.\textsuperscript{60} It was "much more like the filing of a tariff than the kind of conduct through which private parties seek to influence governmental decision making" that has been traditionally immunized from antitrust liability.

Second, the court held that, even if BMS's Orange Book listing of the new patent could be construed as petitioning the government, under the Buspirone court's companion opinion granting the generic pharmaceutical companies summary judgment on BMS's patent infringement claims, the listing and subsequent litigation were objectively baseless within the meaning of \textit{PRE}.\textsuperscript{61} The infringement actions were objectively baseless because "[t]he language of the claim, its specification and the prosecution history all demonstrate beyond all reasonable dispute that the [new patent] does not cover the use of buspirone."\textsuperscript{62}

The principle that regulatory conduct can violate competition laws is also supported by European precedents holding that regulatory regimes are not intended to protect the commercial interests of dominant firms. For example, the Dutch Supreme Court in \textit{Pharmacia & Pfizer v. Cosmétique Active} has held that pharmaceutical regulation was not meant to protect the commercial interests of

\textsuperscript{56} Id. at \#5.

\textsuperscript{57} 185 F. Supp. 2d 363 (S.D.N.Y. 2002), appeal dismissed, 60 F. App'x 806 (Fed. Cir. 2003).

\textsuperscript{58} Id. at 372 (citation 21 U.S.C. § 355(j)(5)(B)(iii)).

\textsuperscript{59} Id. at 366.

\textsuperscript{60} Id. at 370-72.

\textsuperscript{61} Id. at 376.

\textsuperscript{62} Id.
a competitor under the guise of a public health argument. Pharmacia held a marketing
authorization for Minoxidil, a substance used for the treatment of baldness. Pharmacia alleged that
Cosmétique Active engaged in unfair competition by selling without marketing authorizations two
products as cosmetics that contained Amenixil. Pharmacia argued that the products should have
been registered as medicines and that Cosmétique Active competed unfairly by selling its products
without marketing authorizations.

The Court dismissed Pharmacia’s action, considering that the objectives of the regulatory regime on
marketing authorizations were limited to the protection of public health and that they did not
include protection against damages that producers or traders could incur as a result of unfair
competition (ground 4.2.3). Therefore, invoking the regulatory regime to oppose the marketing of
generic products should be scrutinised for baselessness.

Likewise, in Hilti, the Commission held that dominant firms cannot justify abusive regulatory
conduct by invoking public health considerations. The CFI stated that “[national laws attach] penalties to the sale of dangerous products and to the use of misleading claims as to the characteristics of any product. There are also authorities vested with powers to enforce those laws. In those circumstances it is clearly not the task of an undertaking in a dominant position to take steps on its own initiative to eliminate products which, rightly or wrongly, it regards as dangerous or at least as inferior in quality to its own products.”

The cases discussed above show that, if regulatory processes are used in bad faith to delay the onset
of generic competition, that conduct is subject to prosecution under the competition laws.
Undoubtedly, regulators need to be informed about the risks to public health or other information
pertinent to the regulatory decision making. Pharmaceutical companies thus may bring legitimate
health and safety risks or other relevant information to the attention of the appropriate regulatory
body. But that legitimate interest does not shield brand pharmaceutical companies from liability for
the vexatious use of regulatory processes to delay initial generic entry.

(c) Defamation of the generic version of a pharmaceutical product

A third category of vexatious conduct that can delay or hinder initial generic entry is defamatory
actions by the brand pharmaceutical company. Such practices often seek to discourage generic
sales by wholesalers, pharmacists or general practitioners. For example, a brand pharmaceutical
company may issue letters to those persons threatening them that their sale or prescription of
generic drugs infringes the brand company’s patent, even when the patents have been revoked or
declared invalid. Equally vexatious are unfounded threats or warnings about the alleged danger that

63 Supreme Court of the Netherlands, judgment of 24 March 2006, Pharmacia & Pfizer v. Cosmétique Active, C04/325,
LJNn AU 7935, RvdW 2006/310

64 Hilti v. Commission, T-30/89, ECR 1991 II-1439, ground 118.
generic drugs cause to public health, despite the fact that the generics have obtained regulatory approval.

A French precedent shows that competition rules can be used to punish and deter such practices. The case concerned a complaint and request for interim relief filed by Arrow Generics with the French Competition Council against Schering Plough, the manufacturer of Subutex. The Competition Council found that Schering Plough had engaged in abusive behaviour in violation of the French counterpart of Article 82. Specifically, Schering Plough had defamed Arrow Generics’ generic product by telling pharmacists that it was not safe, even though it had obtained market authorization. The Competition Council ordered Schering Plough to publish correct information in two leading medical journals. That decision was upheld by the Paris Court of Appeal.65

(d) Indicia and criteria

The application of Article 82 to vexatious conduct cannot be established in an abstract manner. Whether that provision applies depends on the specific circumstances of the case. It is possible, however, to distil from the precedents discussed above several indicia and criteria that may be helpful in making that assessment.

First, patent infringement claims based on misrepresentations to patent authorities or courts are likely to be vexatious. That proposition follows from an examination of AstraZeneca and Relafen. In AstraZeneca, the Commission condemned various types of conduct relating to SPCs that involved active deception of the authorities. Relafen also affirmed that the brand pharmaceutical company’s suit based on patents obtained by misrepresentations to the United States patent office may constitute vexatious conduct giving rise to a violation of the antitrust laws.

Second, patent infringement claims that clearly exceed the scope of the patent are likely to be vexatious. Wellbutrin provides an example of such a case. In Wellbutrin the brand pharmaceutical company sued to enforce a patent that, in light of its history, could not have extended to the allegedly infringing conduct. Wellbutrin accordingly affirmed the legal sufficiency of the plaintiffs’ allegations that the infringement suit was objectively baseless.

Third, patent infringement claims that have already been rejected in parallel cases are likely to be vexatious. Abbott Laboratories is illustrative. There, the brand pharmaceutical company’s patent infringement action was previously rejected with respect to the brand company’s capsules. Abbott Laboratories sustained the legal sufficiency of the plaintiffs’ allegations that the brand pharmaceutical company had filed a baseless lawsuit by suing to enforce the same patent in a subsequent case concerning tablets.

Similarly, a patent infringement claim is likely to constitute vexatious conduct where it has already been rejected by a court in the same jurisdiction. Also, the fact that a court revoked a patent or declared it invalid in one Member State should be important to a court in another Member State assessing whether subsequent litigation is vexatious. Likewise, if the commercialization of a generic drug is held to be non-infringing in one Member State, the prosecution of the same conduct in another Member State may be an element indicating vexatious conduct.

Fourth, the patent enforcement strategy may indicate baselessness. For instance, a brand pharmaceutical company could enforce patents selectively in jurisdictions where preliminary relief is easily granted, such as Member States where courts are not required to make a prima facie assessment of the validity of the IP rights invoked, but only check formal requirements of validity. In such a case, the validity of the IP rights is assessed by courts in the main proceedings. In the meantime, a preliminary injunction remains in force. Consequently, the patent holder may pursue delaying tactics seeking to avoid or postpone the review of the merits of its claim so as to further impede initial generic entry.

In addition to the above criteria, competition authorities and courts can consider whether the brand pharmaceutical company has engaged in a pattern of litigious behaviour directed against initial generic entrants. While an isolated litigation can be vexatious, repetitious litigations may signify that the brand pharmaceutical company is waging a war of attrition against the first generic entrant. That is particularly the case if the vexatious conduct consists of a coordinated mix of the practices identified above.

Finally, competition authorities should be cognizant of the financial incentives of the brand pharmaceutical 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 to forestall the decrease in sales that would likely follow the onset of generic competition.

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

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46 Under Article 50(6) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS): "provisional measures [...] shall, upon request by the defendant, be revoked or otherwise cease to have effect, if proceedings leading to a decision on the merits of the case are not initiated within a reasonable period, to be determined by the judicial authority ordering the measures where a Member's law so permits or, in the absence of such a determination, not to exceed 20 working days or 31 calendar days, whichever is the longer."

67 In the United States, a study by the Federal Trade Commission has found that brand pharmaceutical companies are substantially more likely to file patent infringement suits on high-revenue drugs. Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration, at 14 (July 2002). For the 75 drugs where brand companies brought a patent infringement suit pursuant to Paragraph IV of the Hatch-Waxman Act, discussed below, the median net sales in the year that the ANDA was filed was $190 million. Id. The median net sales for the 29 ANDAs on which brand companies did not file suit was less than $100 million. Id.

68 The United States and EC cases show that EFPIA’s assertion that “[l]itigation based on a patent, necessarily
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.

2.4 Enforcement

As shown above, Article 82 can prohibit vexatious conduct by brand pharmaceutical companies to delay initial generic entry. However, the Commission and national competition authorities have not had many occasions to apply Article 82 to such conduct. To clarify the applicability of Article 82 to vexatious conduct, the members of the European Competition Network should actively pursue conduct of that nature, underscoring that Member States’ authorities themselves will not tolerate vexatious use of their own regulatory framework. The ensuing precedents would not only give guidance to the industry and national courts, but would also deter brand pharmaceutical companies from pursuing vexatious strategies.

In addition to rigorous enforcement in individual cases, the Commission should issue guidelines on the applicability of competition rules to the pharmaceutical sector. Such guidance exists for other sectors of the economy, such as the postal and transport sectors. Alternatively, the Commission could address vexatious conduct in the general guidelines on the application of Article 82 to exclusionary practices, which the Commission’s services are currently preparing. In either case, the guidelines should describe criteria for prosecuting vexatious conduct.

National courts of the Member States have a leading role to play in the application of Article 82 to vexatious conduct against initial generic entry. Generic defendants in patent or regulatory litigation can file counterclaims based on Article 82 Private action is a matter that has attracted the Commission’s attention. The Commission recently issued a white paper on the possibility of awarding damages for competition law infringements. The issue of vexatious conduct could thus also be addressed in that context. The Commission’s white paper covers every type of infringement in all sectors of the economy. The accompanying working paper also establishes a link between

reasonably asserted on the basis that it has been the subject of expert patent scrutiny by the patent office, cannot be an antitrust violation is inconsistent with law and sound policy. EFPIA, supra, at 108. As the cases demonstrate, patent litigation can be abusive in a variety of circumstances. Contrary to EFPIA’s contention, brand pharmaceutical companies should not be free to pursue objectively baseless litigations for the purpose of delaying competition simply because such conduct takes the form of patent infringement actions.


intellectual property law and antitrust law.\textsuperscript{72} It explicitly refers to Directive 2004/48/EC on the enforcement of intellectual property rights in connection with improving access by injured parties to relevant evidence.\textsuperscript{73}

Finally, the possibilities for national courts to assess vexatious litigation against initial generic entrants are not limited to Article 82. 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.\textsuperscript{74} 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.\textsuperscript{75} A patent holder thus cannot rely on intellectual property rights to oppose the imports of goods that were marketed with his consent in another Member State.\textsuperscript{76} As a rule, national courts should always assess the regulatory regime under which the imported goods were marketed in the exporting Member State.\textsuperscript{77}

The above principles imply that national courts 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 should affect whether a national court in the importing State should accept any patent related claim that would result in blocking imports of generic medicines.

Articles 28 and 30 also apply to 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 favours vexatious litigation. It also raises obstacles to trade that are incompatible with Articles 28 and 30.


\textsuperscript{75} Stouff, 13/68, [1968] ECR 453.

\textsuperscript{76} Centrofarm, 15/74, [1974] ECR 1147.

3 SUGGESTED REGULATORY REFORM

As noted above, Teva generally considers the regulatory framework governing the pharmaceutical industry to be too fragmented, cumbersome and restrictive. In many respects, the quantity, intensity and disparity of national regulation in the pharmaceutical sector is at the origin of the problems that the Commission is currently investigating.

In a perfect world, most of the regulatory obstacles to competition could be removed by harmonization or unification measures at the European or international level. Less significant means, however, may also foster the launch of generic competition. Specifically, the European rules presently in force could be amended to provide the first generic entrant prior to the expiration of a purportedly applicable patent with a temporary period of market exclusivity as an incentive to generic competition.

3.1 First generic entrants incur substantial risks and costs

The successful launch of the first potentially infringing generic medicine is a complex and risky affair. First generic entrants must not only obtain the necessary marketing authorizations and the drug reimbursement listing, but also expose themselves to the risk that brand pharmaceutical companies will sue them in various courts throughout the twenty-seven Member States. Taking such risks entails significant costs, which further reduce the low profit margins that initial generic entrants make on their products. In addition, litigation and regulatory risks and costs incurred by the first generic company to market a drug before the expiration of the brand pharmaceutical company’s patent may not be borne by subsequent generic entrants.

Under the present regime, the first company to launch a competing generic drug before the expiration of the brand pharmaceutical company’s patent might not be able to recover its research and litigation costs. The first generic entrant that succeeds in opening a market to generic competition is frequently 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. In the absence of a reasonable reward to the first generic entrant for having taken the entrepreneurial and litigation risk, generic companies have a diminished incentive to incur the risks and costs of launching a potentially infringing product.

3.2 The Hatch-Waxman Act encourages initial generic entry

The United States Drug Price Competition and Patent Term Restoration Act, commonly known as the “Hatch-Waxman Act,” offers an example of how incentives for initial generic entry can be
increased and free-rider disincentives reduced. The most important component of the Hatch-Waxman Act is a limited period of marketing exclusivity, which rewards the first generic entrant. This feature has been successful in promoting generic competition in the United States, and could be implemented in the European regulatory environment.79

In the United States, the Hatch-Waxman Act produces incentives for initial generic entry, structures patent infringement actions between brand and generic pharmaceutical companies, and promotes generic competition. The most important incentive for initial generic entry is the 180-day period of exclusivity afforded to the first generic company to file an ANDA for a drug that the brand pharmaceutical company has asserted is protected by a patent.

Under the Hatch-Waxman Act, a brand pharmaceutical company must provide a list of relevant patents in conjunction with filing a NDA, whereupon the FDA lists those patents in a publication known as the Orange Book. When a generic company files an ANDA, it must reference the relevant patents listed in the Orange Book and make one of four certifications for each patent.90 The most significant of the certifications is the Paragraph IV certification, by which the ANDA applicant states that "the patent is invalid or will not be infringed" by the ANDA.81

Upon filing a Paragraph IV certification, the generic applicant must notify the patent-holding brand pharmaceutical company of its potentially infringing ANDA within twenty days after its application is accepted. The brand pharmaceutical company then has forty-five days to initiate a patent infringement lawsuit.82 If the brand pharmaceutical company elects not to sue, the generic company can seek a declaratory judgment,83 resolving any infringement issues, or it can launch at risk.84 If the brand pharmaceutical company does not sue the generic company in response to its Paragraph IV certification, if the brand pharmaceutical company does sue but the generic company is ultimately victorious, or if the generic company launches while the patent infringement suit is pending, the generic company is entitled to 180 days of generic exclusivity, measured from the date

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79 Many features of the Hatch-Waxman Act are already present in the EU regulatory framework. For example, the Hatch-Waxman Act provides for a procedure for generic drugs to file ANDAs, and allows generics to use brand pharmaceutical company's drugs for testing purposes before patent expiration (the so-called "Bolar exception").


82 21 C.F.R. § 314.95(f).

83 A declaratory judgment is "[a] binding adjudication that establishes the rights and other legal relations of the parties without providing for or ordering enforcement." Black's Law Dictionary 846 (7th ed. 1999). In the Hatch-Waxman context, in the event that the brand pharmaceutical company does not sue the generic company for patent infringement within the time established by the Hatch-Waxman framework, the generic company can, but need not, seek a declaratory judgment establishing that its product does not infringe the brand pharmaceutical company's patent. The benefit of the declaratory judgment to the generic company is that it mitigates the damages risk of launching a potentially infringing drug.

84 See Donald O. Beers, GENERIC AND INNOVATOR DRUGS: A GUIDE TO FDA APPROVAL REQUIREMENTS § 3.03[B] (7th ed. 2008).
of the generic drug’s commercial launch. During that exclusivity period, the FDA will not approve the ANDA of any competing generic drug.

The 180-day exclusivity period provides a powerful economic incentive for initial generic entry. The Hatch-Waxman Act thereby compensates the generic manufacturer for the risks and expenses incurred in bringing the first generic drug to market in the face of patent risk.

The result of the Hatch-Waxman 180-day exclusivity period in the United States has been the development of a robust generic industry, which has been filing Paragraph IV certifications at an increasing rate. 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. Thus, generic companies have increasingly found the benefits of the 180-day exclusivity period to outweigh the risks and costs of filing a Paragraph IV certification.

3.3 An exclusivity period can be implemented in Europe

The United States’ experience with the Hatch-Waxman Act confirms that the Act has promoted initial generic entry and reduced the price consumers pay for pharmaceuticals. Teva respectfully submits that the Commission should propose legislative measures at the European level that would lead to similar results. 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 amendments may require the introduction of the European equivalent of the Orange Book, in which holders of national and community marketing authorizations would list the patents on the substances covered by these authorizations. The listings would identify and confine the scope of the patent protection, and allow the generic applicant to make the equivalent of a Paragraph IV certification. Since patent protection is still governed by national law, a European certification would apply to the State where the entrant intends to market its product first. That fact also implies that marketing exclusivity for the first generic entrant would have to be organized at the national level.

Amendments providing for a limited period of generic exclusivity to the first generic company to market a potentially infringing drug would change the existing European rules and would not require new harmonization measures. They offer a simple solution that would promote initial

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87 Member States could envisage similar steps at the national level.
CONCLUSIONS

Teva welcomes the Commission’s sector enquiry, in particular into the obstacles that delay initial generic entry. Those obstacles include vexatious litigation and misuse of regulatory proceedings. Such acts only harass generic entrants and delay the onset of generic competition, to the detriment of consumers.

The question as to whether litigation or the use of regulatory proceedings is vexatious and should be prohibited under Article 82 EC requires a case-by-case determination. However, existing cases provide a set of criteria that can guide courts and competition authorities in properly and effectively assessing whether particular conduct is vexatious and abusive under Article 82. Such factors include:

- Incorrect submissions and misrepresentations that underlie brand pharmaceutical companies’ intellectual property rights;
- The attempted patent enforcement for applications clearly beyond the scope of the patent;
- Pursuing patent infringement claims that have already been litigated and rejected;
- A pattern or strategy of patent enforcement that avoids assessment on the merits while entry is delayed due to preliminary injunctions;
- A pattern of litigious behaviour that suggests that the brand pharmaceutical company is waging a war of attrition through the recourse to a coordinated mix of vexatious practices;
- A strong financial incentive for delaying the arrival of generic competition in connection with blockbuster products.

Effective enforcement of Article 82 against vexatious conduct will remove an important obstacle to initial generic entry. Similarly, where generic medicines are imported from other Member States, Articles 28 and 30 can also play a significant role in eliminating impediments to initial generic entry.
Initial generic competition could also be facilitated by amending the legislative framework to provide a period of marketing exclusivity for the first generic to enter before patent expiration. First generic entrants face regulatory and litigation risks that are both substantial and unique. Without a countervailing incentive for generic companies to take such risks, the first generic entrant might not be capable of earning a sufficient return to justify such risks. The regulatory system that is already in place at the European level can be amended to introduce a period of marketing exclusivity for first generic entrants. Such amendments would promote initial generic competition.