Hatch-Waxman Act: Overview

Lisa Barons Pensabene and Dennis Gregory, Fitzpatrick, Cella, Harper and Scinto, with PLC Intellectual Property & Technology

This Practice Note provides an overview of the Hatch-Waxman Act, formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, P.L. 98-417. This Note also summarizes the relevant regulatory provisions concerning branded and generic drugs, including the drug approval process, exclusivities for both branded and generic drugs, patent term extension and patent litigation under the Hatch-Waxman Act.

Congress adopted the Hatch-Waxman Act, formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, P.L. 98-417, to expedite and streamline both generic drug approvals and patent litigation involving generic drugs.

Before its adoption, no streamlined Food and Drug Administration (*www.practicallaw.com/3-501-7065*) (FDA) approval process existed for generic drugs. Rather, generic drug companies were required to conduct the same kinds of expensive, time-consuming clinical trials that drug companies conducted for new brand-name drugs. In addition, the unlicensed investigation and testing of a patented drug by the generic drug company to obtain FDA approval for a generic version could subject the generic drug company to patent infringement liability (see *Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984)*). The Hatch-Waxman Act changed this and, in doing so, is often credited with creating the modern generic drug industry.

The Hatch-Waxman Act has been amended several times since its enactment. Nevertheless, its basic structure remains the same. This Note provides an overview of the following four main features of the Hatch-Waxman system:

- An expedited FDA approval process for generic drug applications.
- Certain market and patent exclusivity periods for both branded and generic drug companies.
- Patent term extension to adjust for delays caused by the FDA approval process.
- A unique patent litigation process triggered by a generic drug company's submission of an application for FDA approval.

Biologic drugs are subject to different FDA requirements and a different patent litigation mechanism that are beyond the scope of this Note.

DRUG APPROVAL

The FDA requires every new drug, including generic drugs, to be safe and effective (*21 U.S.C. § 355(a)*). Before the adoption of the Hatch-Waxman Act, the FDA required branded and generic drug companies alike to demonstrate the safety and efficacy of their products in the same manner through a New Drug Application (NDA) (*21 U.S.C. § 355(b)(1)*). The Hatch-Waxman Act changed certain aspects of the new drug application process and the new drug's patent term. In addition, the Hatch-Waxman Act created an abbreviated process to allow generic drug companies to obtain FDA approval of generic drugs. Because of this, today it is far easier for generic drug companies to demonstrate the safety and efficacy of their generic drugs.

New Branded Drug Approval

A branded drug company seeking FDA approval to market a new drug must submit an NDA to the FDA. The information provided in the NDA allows the FDA to determine whether:

- The new drug is both safe and effective.
- Certain other regulatory requirements are met, such as those concerning labeling and good manufacturing processes.

Obtaining and submitting this information frequently is a time-consuming process requiring the branded drug company to conduct many extensive and expensive clinical trials. Branded, new drug companies must conduct these trials even though there may be a significant risk that the new drug could fail the clinical trial.

Generic Drug Approval

The FDA reviews generic drug applications for compliance with the appropriate scientific and regulatory criteria. If an application meets those criteria, the FDA may grant either:

- Tentative approval, which means that the application meets the scientific, labeling and other approval criteria but some unexpired exclusivity prevents final approval (see *New Drug Exclusivity* and *21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)*).
- Final approval, which is full clearance to enter the market, allowing the applicant to begin selling the generic drug immediately.

Under the Hatch-Waxman Act, generic drug companies can typically file one of two different kinds of abbreviated applications for approval of a generic drug:

- An Abbreviated New Drug Application (ANDA) (*21 U.S.C. § 355(j)*).
- A Section 505(b)(2) application, which is often called a paper NDA (*21 U.S.C. § 355(b)(2)*).

Abbreviated New Drug Applications

Under an ANDA, a generic drug company must establish that the generic drug is effectively a duplicate of the branded, NDA drug, which is referred to as the Reference Listed Drug (RLD). Specifically, the generic drug company must show that the proposed generic drug:

- Has the same active ingredient, route of administration, dosage form, strength and intended use as the RLD. It also must have the same labeling, except that the generic drug company sometimes may remove information related to a patented method or use subject to exclusivity from its label (see *Section viii Statements*). However, the generic drug is not required to have the same inactive ingredients as the RLD (*21 U.S.C. § 355(j)(2)(A)*).
- Is bioequivalent with the RLD, so that it performs in the same manner as the RLD in the body. Generally, a drug is bioequivalent when it delivers the same amount of active ingredient in a patient's bloodstream over the same amount of time as the RLD. Different but analogous rules apply to drugs that are not delivered in the bloodstream, for example, by topical application (*21 U.S.C. § 355(j)(8)*).

Section 505(b)(2) Applications

A proposed generic drug may differ in significant ways from the RLD, such as:

- Having either:
  - a different route of administration;
  - dosage form;
  - strength; or
  - dosage regimen.
- Including a different version of the active ingredient such as a:
  - salt;
  - ester; or
  - chelate.

Under these circumstances, the proposed generic drug must be approved through the Section 505(b)(2) paper NDA application process, which is a hybrid of a full NDA and an ANDA. This application includes less data than an NDA but more data than an ANDA.

Drugs approved under a Section 505(b)(2) application rely on studies both:

- That were not conducted by or for the applicant.
- For which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

NEW DRUG EXCLUSIVITY

The Hatch-Waxman Act provides for certain market exclusivity periods for new drug applicants based on both non-patent and patent-based factors.

Non-patent Exclusivities

The Hatch-Waxman Act, among other legislation, allows new drug applicants to obtain certain non-patent exclusivities, including:

- Orphan drug exclusivity, which is granted to drugs:
  - that treat a disease or condition that affects less than 200,000 people in the US; or
  - for which it is unlikely that US sales of the drug will recoup its development costs.

  This exclusivity period is seven years, but only applies to use in treating the specific rare disease or condition (*21 U.S.C. §§ 360aa to 360ee*).
- **New chemical entity (NCE) exclusivity.** This is granted if the FDA has not previously approved the "active drug moiety." The active drug moiety is the molecule's active portion and not its variations such as salts or esters. NCE exclusivity bars a generic drug company from filing an application for approval of a generic drug five years from the first approval of the relevant NDA. However, a generic drug company may file an ANDA with a Paragraph IV certification (see *Paragraph IV Certification*) four years after the first NDA approval (*21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii)*).
- **New clinical study exclusivity.** This applies when new clinical studies lead to new or changed formulations, dosing regimens or patient population. The applicant is entitled to this exclusivity if an application or supplement contains reports of new clinical investigations conducted or sponsored by the applicant that were essential for approval. This exclusivity, sometimes called data exclusivity, prohibits the FDA from approving a generic drug application for the new dosage form or use for three years after the first NDA approval. However, it does not otherwise bar approval of generic drug applications (*21 U.S.C. § 355(c)(3)(E)(iii), (j)(5)(F)(iii)-(iv)*).

- **Pediatric exclusivity.** This applies if the FDA requested that the NDA holder conduct studies with the drug in pediatric populations. Pediatric exclusivity adds six months of exclusivity to any marketing or patent exclusivity (*21 U.S.C. § 355a* and see *Patent Exclusivity and the Orange Book*).

Patent Exclusivity and the Orange Book

Branded drug companies typically obtain patent protection for their approved drugs so they have a period of exclusivity that prevents unlicensed third parties from making, using, offering for sale, selling or importing the patented invention. For more information on patent protection generally, see *Practice Note, Patent: Overview: Scope of Rights* (*www.practicallaw.com/8-509-4160*).

An NDA holder must provide the FDA with the patent number and expiration date of any patent that claims either:

- The drug, including the active ingredient and the formulation for the active ingredient.
- A method of using the drug, but not other inventions such as:
  - metabolites;
  - synthetic intermediates; or
  - methods of making the drug.

(*21 U.S.C. § 355(b)(1)(G)* and *21 C.F.R. § 314.53*.)

The NDA holder must also identify whether the relevant patents claim the drug substance, a polymorph or a method of using the drug.

For patents claiming methods of using the drug, the applicant must submit a use code, which is a description of the approved method. The use code must accurately describe the method of use claimed in the patent (*Caraco Pharm.Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670 (2012)* and *21 C.F.R. § 314.53(c)(2)(ii)(P)(iii)*).

When the FDA approves the NDA, the FDA publishes the patent information in the FDA's Approved Drug Products with Therapeutic Equivalence Determinations publication (also called the Orange Book) (*21 U.S.C. § 355(b)(1)(G)* and *21 U.S.C. § 355(j)(5)*). The Orange Book also lists any non-patent exclusivity concerning the RLD (see *Non-patent Exclusivities*) and is publicly available on the FDA's website.

CHALLENGING PATENT EXCLUSIVITY

The Hatch-Waxman Act provides generic drug companies with certain procedures for challenging a new drug company's patent exclusivity for the RLD. For example, the generic drug company can file a Paragraph IV Certification (see *Paragraph IV Certification*) or a Section viii Statement (see *Section viii Statements*) in connection with the RLD.

Patent Certification

A generic drug company submitting either an ANDA or a Section 505(b)(2) application must make one of the following four certifications as to each patent listed in the Orange Book for an RLD:

- Paragraph I certification that no relevant patent is listed in the Orange Book.
- Paragraph II certification that the listed patent has expired.
- Paragraph III certification that the listed patent, plus any other exclusivity, will expire before the requested approval.

Paragraph IV certification that the listed patent is invalid or will not be infringed by the commercialization of the generic drug (see *Paragraph IV Certification*).

(*21 U.S.C. § 355(b)(2)(A)(i)-(iv)* and *21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV)*.)

A generic drug company also may make a statement that the listed patent does not claim a use for which the applicant is seeking approval, which is known as a Section viii Statement (*21 U.S.C. § 355(b)(2)(B), 21 U.S.C. § 355(j)(2)(A)(viii)* and see *Section viii Statements*). A generic drug company can make both a Paragraph IV certification and a Section viii Statement, for example, when the patent covers both the product and a method of use.

Paragraph IV Certification

A Paragraph IV certification is a potential trigger for Hatch-Waxman Act patent litigation (see *Patent Litigation Under the Hatch-Waxman Act*) because the filing of an application with that certification is a statutory act of patent infringement (*35 U.S.C. § 271(e)(2)*). Specifically, it is an act of patent infringement to submit an application with the FDA:

> For a drug claimed in a patent or the use of which is claimed in a patent ... if the purpose of such submission is to obtain approval ... to engage in the commercial manufacture, use, or sale of the drug ... before the expiration of such patent.

(*35 U.S.C. § 271(e)(2)*.)

A Paragraph IV certification meets that definition because it means that the generic drug company intends to engage in the commercial manufacture, use or sale of the generic drug before the RLD's exclusivity expires.

A generic drug applicant making a Paragraph IV certification must provide a Notice Letter to the NDA holder and the patentee, if different from the NDA holder, setting out:

- The existence of the ANDA.
- A detailed statement of its basis for believing that the listed patents are invalid or not infringed.

(*21 U.S.C. § 355(b)(3)* and *21 U.S.C. § 355(j)(2)(B)*.)

The generic drug company must provide the Notice Letter within 20 days after the FDA accepts the ANDA for filing.

The certification requirement imposes a duty of care on a generic drug company (*Yamanouchi Pharm. Co., Ltd. v. Danbury*

Pharmacal, Inc., 231 F.3d 1339 (Fed. Cir. 2000)). A baseless Notice Letter may lead to the award of attorneys' fees for an exceptional case if the generic drug applicant loses the patent litigation (*35 U.S.C. § 271(e)(4)*). Rule 11 sanctions are also possible (see *FRCP 11*).

Section viii Statements

A Section viii Statement, in contrast, ordinarily is not a trigger for patent litigation. Typically, the generic drug applicant attempts to remove from its label, or carve-out, anything related to the patented method in the RLD's label. As a result, there is no certification or notice requirement. Generic drug companies may use the same procedure to avoid the three-year new clinical study exclusivity (see *Non-patent Exclusivities*) by carving out the information that relates to the clinical trials and relevant approval. The FDA will approve these so-called skinny labels if it does not make the proposed drug less safe or effective than the listed drug for all remaining, non-protected conditions of use (*21 C.F.R. § 314.127*).

This labeling carve-out tactic can be seen as a mere technical way of generic drug applicants avoiding the branded drug manufacturer's method patent and use exclusivity since doctors may use an approved generic drug for any use, including uses omitted from the generic label but present in the RLD label. Following the expiration of the method patent or exclusivity, generic drug applicants often attempt to amend their labels to add back any formerly carved-out uses.

ANDA EXCLUSIVITY

The first filer of an ANDA with a Paragraph IV certification concerning an RLD is potentially entitled to a 180-day period during which the FDA will not approve any other ANDA having a Paragraph IV certification for a generic version of the RLD. However, the first filer may forfeit this exclusivity (see *Exclusivity Forfeiture*)).

A Section 505(b)(2) applicant (see *Section 505(b)(2) Applications*) is not entitled to this 180-day exclusivity. Depending on the circumstances, however, a Section 505(b)(2) applicant still may be entitled to NCE, a new chemical study or orphan drug and pediatric exclusivity (see *Non-patent Exclusivities*).

Eligibility

The term "first ANDA filer" refers to all of the applicants who submit substantially complete ANDAs with Paragraph IV certifications on the same day that is earlier than any other ANDA filing (*21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb)*). A substantially complete application is one that:

- On its face is sufficiently complete to permit substantive FDA review.
- Contains all information statutorily required in an ANDA.

(*21 U.S.C. § 355(j)(5)(B)(iv)(II)(cc).*)

Multiple ANDA applicants may hold exclusivity concurrently on the same drug if they each apply on the same day and file Paragraph IV certifications concerning at least one of the Orange Book listed patents for that drug. This most commonly occurs when multiple applicants file ANDAs on the four-year anniversary of FDA approval of an NDA subject to NCE exclusivity (see *Non-patent Exclusivities*).

Exclusivity can also be split among different ANDA filers. For example, different ANDA filers can hold exclusivity on different dosage strengths of the same RLD (*21 U.S.C. § 355(j)(5)(B)(iv)* and *21 C.F.R. § 314.107(c)(1)*).

Exclusivity Period

First-filer exclusivity blocks final approval of other ANDAs with Paragraph IV certifications for 180 days (*21 U.S.C. § 355(j)(5)(B)(iv)*). However, first-filer exclusivity does not apply against an applicant who has filed a Section viii Statement (see *Section viii Statements*) because it is not a Paragraph IV certification. For example, if one applicant holds first-filer exclusivity concerning a method patent and another applicant filed a Section viii Statement concerning the same method patent, the first-filer exclusivity does not prevent the other applicant from commercially launching its product on the same day as the first-filer exclusivity holder (*Purepac Pharm. Co. v. Thompson, 354 F.3d 877 (D.C. Cir. 2004)*).

Exclusivity Forfeiture

A generic drug company may forfeit ANDA exclusivity if it fails to market the generic drug by the later of 75 days after:

- Final FDA approval of the ANDA or 30 months after the ANDA filing, whichever is earlier.
- One of the following occurs for the first ANDA filer, or any other ANDA filer with tentative approval for each patent where the ANDA filer qualifies as a first ANDA filer:
  - the court enters a final decision, from which no appeal has been or can be taken, that the patent is invalid or not infringed;
  - the court signs a settlement order or consent decree that enters final judgment that the patent is invalid or not infringed;
  - the first filer amends or withdraws the Paragraph IV certification that qualified it for exclusivity; or
  - the NDA holder withdraws the patent information.

(*21 U.S.C. § 355(j)(5)(D)* and *21 U.S.C. § 355(q)(1)(G).*)

In addition, a first filer forfeits its exclusivity if it fails to obtain tentative FDA approval within 30 months of the filing of its application, unless either its:

- Failure to obtain approval was caused by a change or review of approval requirements imposed after the application's filing.
- Approval was delayed by a citizen petition.

Congress recently enacted a temporary extension to this 30-month period because of concerns that FDA delays beyond the applicants' control were causing first filers to forfeit their exclusivity. The specific extension depends on when the ANDA was filed or amended to include a Paragraph IV certification (*Food and Drug Administration Safety and Innovation Act of 2012, Pub. L. No. 112-144, 126 Stat. 993 § 1133 (2012)*).

Finally, where all first filers forfeit the 180-day exclusivity period, no exclusivity exists and the FDA will not delay the effective approval of any subsequent ANDAs (*21 U.S.C. § 355(j)(5)(D)*).

PATENT TERM EXTENSION

Most US patents have a 20-year term measured from the original application's filing date. For more information, see *Practice Note, Patent: Overview: Duration (www.practicallaw.com/8-509-4160)*. Since the application process for most patents typically takes about three years, a patent's effective life is usually about 17 years from its issuance. This term is subject to patent term adjustment for *US Patent and Trademark Office (www.practicallaw.com/9-383-7926)* (USPTO) delays during patent prosecution that shrink the effective life below 17 years (*35 U.S.C. § 154(b)*).

Virtually all RLDs are covered by one or more patents. The useful term for patents covering a RLD is typically much shorter than 17 years because the time-consuming FDA approval process typically occurs during part of the patent term. As a result, branded drug companies do not enjoy the full benefit of the patent until the FDA approves the drug and sales can begin.

As a partial remedy, the Hatch-Waxman Act provides a patent term extension for patents covering certain products and methods, including human drug products, that are subject to FDA approval (*35 U.S.C. § 156* and *Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990)*). The patent's term can be extended by a maximum of five years or 14 years of effective patent life, whichever is less. Specifically, the patentee is entitled to a credit for the time the FDA was reviewing the first drug application. Only one extension can be granted in connection with a particular product, and it must be for a patent that claims either a:

- Drug product, which means the active ingredient and any approved drug using that active ingredient.
- Method of using a drug product.
- Method of manufacturing a drug product.

(*35 U.S.C. § 156(a) and 35 U.S.C. § 156(f)(1)(A) and (2)(A).*)

PATENT LITIGATION UNDER THE HATCH-WAXMAN ACT

Patent litigation may be triggered under the Hatch-Waxman Act when the generic drug manufacturer files a Paragraph IV certification (see *Paragraph IV Certification*). Hatch-Waxman Act patent litigation differs from non-drug related patent litigation in many respects. For example, in Hatch-Waxman Act patent litigation there are:

- Various time periods concerning aspects of the litigation that may affect the FDA's approval process (see *Commencing Litigation and Approval Stays*).
- Certain defenses and counterclaims that drug companies may raise (see *Potential Litigation Claims and Defenses*).
- Specific remedies the parties tend to seek (see *Preliminary Remedies* and *Final Remedies*).
- Unique challenges in entering into settlement agreements (see *Settlement and Unfair Competition Challenges*).

Commencing Litigation and Approval Stays

The patentee has the right to sue the generic drug applicant immediately on receipt of the Notice Letter. However, the generic drug applicant cannot file a declaratory judgment action against the NDA holder for 45 days after the date of the Notice Letter (45-day period) (*21 U.S.C. § 355(c)(3)(D)(i)(aa)*, *21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)* and *35 U.S.C. § 271(e)(5)*).

The generic drug company may include with its Notice Letter an offer to the NDA holder to allow it to confidentially review the ANDA. The generic drug company may redact irrelevant information and place other restrictions on the review.

If the patentee sues within the 45-day period, the FDA may not grant final approval of the generic application for 30 months from the NDA holder and patentee's receipt of the Notice Letter (30-month stay). However, if the RLD has NCE exclusivity, the 30-month stay does not begin to run until the NCE exclusivity expiration. This 30-month stay is intended to:

- Allow for parallel resolution of the patent case and the FDA's review of the ANDA.
- Provide certainty for the branded drug company because the generic drug company cannot launch the generic drug during this period while there is ongoing litigation.

The court may shorten or lengthen the 30-month stay period in a pending patent case if either party fails to reasonably cooperate in expediting the case. The 30-month stay terminates if a court issues a final order determining that the patent is invalid, unenforceable or not infringed (*21 U.S.C. § 355(c)(3)(C)* and *21 U.S.C. § 355(j)(5)(B)(iii)*).

A generic drug applicant may file a declaratory judgment action against the NDA holder or the patentee only if the NDA holder or patentee does not sue on all of the Orange Book listed patents within the 45-day period. If the Notice Letter alleged noninfringement, the generic drug applicant must also have provided an offer of confidential access to the application. The generic drug applicant can bring the declaratory judgment action only where the defendant has its principal place of business or a regular and established place of business (*21 U.S.C. § 355(c)(3)(D)(i)* and *21 U.S.C. § 355(j)(5)(C)(i)*).

Potential Litigation Claims and Defenses

Once Hatch-Waxman Act patent litigation begins, it proceeds just as any other patent litigation with the court considering

substantive patent issues. For more on patent litigation generally, see *Practice Note, Patent Infringement Claims and Defenses (www.practicallaw.com/0-507-2685)*. Similar to most patent litigations, key issues in Hatch-Waxman Act patent litigation include:

- Proving infringement (see *Proof of Infringement*).
- Patent litigation defenses (see *Patent Litigation Defenses*).

In addition, the court may consider specific Hatch-Waxman Act related counterclaims, such as a delisting counterclaim (see *Delisting Counterclaim*).

Proof of Infringement

Proof of infringement is slightly different in a Hatch-Waxman Act case than in a typical patent case. As in any patent case, the patentee has the burden to prove infringement by a preponderance of the evidence. For more information, see *Practice Note, Patent Infringement Claims and Defenses: Patent Infringement Claims (www.practicallaw.com/0-507-2685)*. Typically, however, the generic drug company has not actually marketed a product by the time the case has reached trial. As a result, infringement is based on the product that the generic drug company is likely to market if the FDA approves the generic drug application. Sometimes the ANDA by itself defines the generic drug in a way that mandates a finding of infringement. If the ANDA is not determinative, the court determines infringement just as in any other patent litigation (see *Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562 (Fed. Cir. 1997)* and *Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241 (Fed. Cir. 2000)*).

Patent Litigation Defenses

The court determines invalidity and unenforceability in Hatch-Waxman Act patent litigation just as in any other patent litigation case. For more information on invalidity and unenforceability defenses in patent litigation generally, see *Practice Note, Patent Infringement Claims and Defenses: Key Patent Infringement Defenses (www.practicallaw.com/0-507-2685)*. The burden rests on the generic drug company to prove invalidity or unenforceability by clear and convincing evidence.

Delisting Counterclaim

If sued, the generic drug company may bring a counterclaim alleging that a patent was wrongly listed in the Orange Book because it does not claim the RLD or a method of using the RLD. The Supreme Court confirmed that a generic drug company may also sue if the Orange Book use code is wrong (see *Legal Update, Generic Drug Manufacturer May Force Correction of Inaccurate Orange Book Patent Information: Supreme Court (www.practicallaw.com/7-517-3488)*). However, the only relief available for a delisting counterclaim is a court order requiring the FDA to remove or correct the Orange Book listing, including correction of the use code (*21 U.S.C. § 355(j)(5)(C)(ii)(I)* and *Caraco Pharm.Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670 (2012)*). Monetary damages are prohibited (*21 U.S.C. § 355(j)(5)(C)(iii)*).

Safe Harbor

The Hatch-Waxman Act includes a safe harbor provision that allows a generic drug company to conduct certain activities to develop its product without significant risk of patent infringement liability (*35 U.S.C. § 271(e)(1)*). This safe harbor provides immunity from infringement liability for acts reasonably related to the development and submission of any information to the FDA, including the development of a generic drug application (*Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005)* and *Eli Lilly & Co. Inc., at 661*).

The precise scope of the safe harbor is not clear. Some court decisions give it an expansive interpretation, holding for example that it immunizes certain post-approval activities required by the FDA (see *Momenta Pharms., Inc. v. Amphastar Pharms., Inc., 686 F.3d 1348 (Fed. Cir. 2012)* and *Legal Update, Federal Circuit Expands Hatch-Waxman Safe Harbor to Include Post-approval Commercial Manufacturing (www.practicallaw.com/5-520-7818)*). Other decisions give it a narrower interpretation, holding for example that it does not cover information routinely reported to the FDA after marketing approval (see *Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057 (Fed. Cir. 2011)* and *In Dispute: GlaxoSmithKline v. Classen Immunotherapies (www.practicallaw.com/6-518-5482)*).

Role of Judge and Jury

Hatch-Waxman Act patent litigations typically are tried to a judge, not a jury, because these cases often proceed before:

- An infringing product has been marketed.
- Actual damages accrued.

The exception is if the generic drug applicant has acted outside the scope of the safe harbor provision (see *Safe Harbor*). This typically happens where the generic drug company begins commercial sales of its product before the patent trial occurs. In almost every case, commercial sales of a product fall outside the scope of the safe harbor. If a generic drug company commercially launches its product before the patent infringement and validity issues are fully resolved, known as a "launch at risk," the case becomes a patent infringement case decided under Section 271(a) of the Patent Act with actual damages at issue. Actual damages create a jury trial right in patent cases, including those under the Hatch-Waxman Act (*Sepracor, Inc. v. Dey L.P., No., 06-113-JJF, 2010 WL 2802611 (D. Del. 2010)*).

Preliminary Remedies

The 30-month stay (see *Commencing Litigation and Approval Stays*) provides an opportunity for the parties to resolve the litigation before the generic drug can enter the market. But, this may not be enough time to conclude the litigation. For example, discovery may be extensive or a trial may be difficult to schedule.

Some generic drug companies will agree to stay off the market and not launch at risk during the pendency of the litigation even if

it lasts more than 30 months. However, a generic drug company occasionally will launch at risk (or refuse to state whether they will launch at risk). In response, the branded drug company may choose to seek a preliminary injunction barring the generic drug company from marketing its product until the district court finally decides the case on the merits. If the district court grants a preliminary injunction before the expiration of the 30-month stay, the stay is extended until the court decides the patent infringement and validity issues (*21 U.S.C. § 355(j)(5)(B)(iii)(III)* and *21 U.S.C. § 355(j)(5)(B)(iii)(IV)*).

Final Remedies

For the patentee, the primary reward for winning a Hatch-Waxman Act patent litigation is continued enjoyment of any unexpired exclusivity. The typical remedies for a prevailing patentee are:

- An order directing the FDA not to approve the ANDA before the expiration of the relevant patents and any other exclusivity.
- An injunction against future infringement.

Money damages also may be available if the ANDA filer made actual sales. In exceptional cases, attorneys' fees also are available to a prevailing patentee (*35 U.S.C. § 271(e)(4)*).

For a generic drug company, the primary reward for victory is the ability to enter the market before patent expiration without patent infringement liability. A first filer also enjoys its 180 days of exclusivity against other Paragraph IV-certifying generic drug companies (see *ANDA Exclusivity*). A prevailing generic drug company that has tentative approval usually can immediately gain final approval and enter the market. If not, the prevailing generic drug company can enter the market once any other exclusivity has expired. This is typically the 180 days of exclusivity held by a first filer. A prevailing generic drug company also may obtain attorneys' fees in an exceptional case.

Settlement and Unfair Competition Challenges

Settling Hatch-Waxman Act litigation can have unique challenges.

Any settlement agreement must be submitted to the Federal Trade Commission (FTC), although pre-clearance is not required (*117 Stat. 2461-2464, P.L. 108-173, §§ 1112- 1117*). The FTC opposes settlements involving a reverse payment from the branded drug company to the generic drug company, viewing them as anticompetitive. A reverse payment in its most extreme form is a payment from the branded drug company to the generic drug company in exchange for the generic drug company's agreement to stay off of the market for some period of time.

There is a long-standing split among the appellate courts regarding whether and to what extent agreements including a reverse payment violate antitrust laws (see *Legal Update, Eleventh Circuit Approves Patent "Pay for Delay" Settlements (www.practicallaw.com/0-519-1594)*). The Supreme Court recently granted certiorari in *FTC v. Watson Pharms., Inc. 677 F.3d 1298 (11th Cir. 2012)* to resolve that split.

Finally, there are other antitrust issues that may arise in Hatch-Waxman Act patent litigation that also arise in typical patent litigation. For example, occasionally, a generic drug company will include an unfair competition counterclaim when it is sued for infringement, usually based on a claim that the patent was procured by inequitable conduct. Additionally, if a patentee loses in Hatch-Waxman Act patent litigation, health insurance companies and others may subsequently bring private antitrust actions alleging that the patent was procured by fraud or that the underlying patent litigation was a sham, particularly if the patent was found unenforceable for inequitable conduct.

For the links to the documents referenced in this note, please visit our online version at http://us.practicallaw.com/9-523-2397.

For more information on this topic, search for the following resources on our website.

Practice Notes:

- *In Dispute: GlaxoSmithKline v. Classen Immunotherapies (http://uk.p02edi.practicallaw.com/topic6-518-5482)*
- *Patent Infringement Claims and Defenses (http://uk.p02edi.practicallaw.com/topic0-507-2685)*