

Patent-Registration Linkage¹

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CPTech Discussion Paper - No. 2

3 April 2006

Traditionally, countries have allowed second and later drug applicants (generic manufacturers) to register their product with regulatory authorities during the patent term for different purposes: a) to early register so that the generic drugs are prepared to promptly enter the market when the originator's patent expires³; b) to register when the drug has been produced/imported under a compulsory license or government use order; or c) to register when the second applicant has modified the drug so it does not infringe the patent but it is still bio-equivalent.

Patent-Registration Linkage ("linkage") is the practice of linking drug marketing approval to the patent status of the originator's product and not allowing the grant of marketing approval to any third party prior to the expiration of the patent term unless by consent of the patent owner. This practice requires that "second applicants" for marketing approval demonstrate that the pharmaceutical product for which they are applying is not protected by a valid patent. Under this kind of regulation, national regulatory authorities have the obligation to prevent the registration and marketing of a generic pharmaceutical when a patent covers the product.

Under the TRIPS Agreement, there is no requirement for WTO Member States to recognize this practice. Until recently, linkage was only included in the United States and the Canadian pharmaceutical legislation.

The United States is including requirements to recognize this practice in Trade Agreements, including those it has signed with Australia and several developing countries⁴. The United States is also using the unilateral trade tool of the Special 301 Report to pressure countries to recognize this practice in their national laws by placing

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² Helpful comments were received from Michael Palmedo, Jon Merz and James Love.

³ This is a broadly recognized exception to patent infringement, known as the "Bolar" or "Early Working" exception. Certain tests related to obtaining FDA approval that would otherwise constitute patent infringement are exempted from infringement liability. The U.S. Bolar exception is in Section 35 U.S.C. 271(e)(1), which reads in part: "It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products".

⁴ To compare linkage language contained in some FTAs, see the table available at <http://www.cptech.org/ip/health/trade/>

countries in the report when they do not prevent marketing approval of generic products during the term of the originator's patent. Several major pharmaceutical patent holders and brand-name drug manufacturers in the U.S. are seen as influencing U.S. trade policies on this issue.

UNITED STATES

Linkage regulation was introduced in the United States in 1984 by the Drug Price Competition and Patent Term Restoration Act,⁵ a major amendment of the Federal Food, Drug and Cosmetic Act. This legislation is commonly known as the Hatch-Waxman Act.

The inclusion of linkage regulations in U.S. law has been attributed to a political bargain that took place when the United States sought several changes in drug registration practices. These included mechanisms to allow generic drug manufacturers to register products when they establish bioequivalence with a product that had already received marketing approval⁶; and the "Bolar" exception to patent rights, two measures that were recognized in the U.S. law to promote competition from the generic industry.

In practice, linkage is applied through the publication of "Approved Drug Products with Therapeutic Equivalence Evaluations", commonly known as the **Orange Book**⁷. This publication identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration ("FDA"). Pioneer drug applicants are required⁸ to file with the FDA the number and expiration date of any patent which claims the drug that is the subject of the application, or a method of using such drug.

Which patents? Not all the patents are listed. The Orange Book clarifies that "the patents that FDA regards as covered by the statutory provisions for submission of patent information are: patents that claim the active ingredient(s); drug product patents which include formulation/composition patents; use patents for a particular approved indication or method of using the product; and certain other patents as detailed on FDA Form 3542⁹."

The FDA can not approve a second application if there is a patent listed in the Orange Book for the originator/ pioneer drug on which the second application is relying. Therefore, when a second applicant submits an ANDA¹⁰ or a 505(b)(2) application¹¹, it must include appropriate certifications that they have permission to use all of the patents

⁵ Pub. L. No. 98-417 (98th Congress, 1984)

⁶ Generic applicants are permitted to rely on the brand-name company's trade secret data demonstrating the safety and efficacy of the brand-name drug product.

⁷ The electronic version of the Approved Drug Products with Therapeutic Equivalence Evaluations/ Orange Book is available at: <http://www.fda.gov/cder/ob/default.htm>

⁸ 21 U.S.C § 355(b)(1)

⁹ Effective August 18, 2003, information must be submitted to the FDA on "FDA Form 3542. Patent Information Submitted Upon and After Approval of an NDA or Supplement", available at: <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>

¹⁰ ANDA: Abbreviated New Drug Applications/ 21 U.S.C. § 355(j) / Applications for typical generic drugs

¹¹ Paper NDA: Paper New drug application/ 21 U.S.C. § 355(b)(2) / Applications that relies on published literature to satisfy the requirements of animal or human studies demonstrating safety and effectiveness.

listed in the Orange Book with respect to the drug which serves as the basis for their petition.

Section 21 U.S.C. § 355(b)(2)(A) and 21 U.S.C. § 355(j)(2)(A)(vii) provide that second applicants have four certification options:

- (I) that the required patent information has not been filed by the originator;
- (II) that the patent has expired;
- (III) that the patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- (IV) that the patent is invalid or will not be infringed by the generic drug for which the applicant seeks approval.

If the applicant includes a certification under paragraph I or II, the FDA may approve the ANDA immediately. If the applicant includes a paragraph III certification, the FDA may approve the ANDA effective on the date that the patent expires.

However, if the applicant includes a paragraph IV certification indicating that it intends to market the drug as soon as the FDA approves the application, the patent holder and the pioneer/originator must be notified¹² and an automatic “**30 month stay of FDA approval**” is given if two conditions are met:

- a) the patent information was **submitted before** the date that the ANDA or 505(b)(2) application (excluding an amendment or supplement) was submitted to the FDA, and
- b) the patent holder or originator brings an **infringement suit**¹³ **within 45 days** of the date that it receives notice of the certification.

Filing of the lawsuit stays the FDA’s approval of the application until the earliest of the following:

- (1) the expiration of 30 months from the receipt of notice of the paragraph IV certification.
- (2) the date the patents expire (which can be sooner than 30 months);
- (3) the date of the court determination of non-infringement or patent invalidity in the patent litigation (which can be sooner than 30 months);

¹² The Second applicant is required to give notice stating that an application has been filed seeking approval to engage in the commercial manufacture, use or sale of the drug before the expiration of the patent, and setting forth a statement of the factual and legal basis for the applicant’s opinion that the patent is invalid or will not be infringed. 21 U.S.C § 355(b)(3)(B) and 21 U.S.C § 355(j)(2)(B)(ii)

¹³ The action of infringement and its limit consequences is set out in 35 U.S.C. § 271 (e)(2) and 35 U.S.C. § 271 (e)(4)

(4) the date of a settlement order or consent decree signed and entered by the court stating that the patent is invalid or not infringed (which can be sooner than 30 months); or

(5) (if a trial court determines that a valid patent has been infringed and the decision is reversed on appeal) the date on which the court of appeals decides that the patent is invalid or not infringed, or the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent is invalid or not infringed (which can be sooner than 30 months); or

U.S regulation allows generic manufacturers to go to market under certain circumstance while a patent challenge is pending in court. For example, the 30 month stay period may be shortened or lengthened by the court if “either party to the action fails to reasonably cooperate in expediting the action.”¹⁴

Remember: if the patent is infringed, the generic approval process is not over. The ANDA application may be approved later based on the date the patent expires and any extension or exclusivity that remains.

Following the recommendations presented by a report of the U.S. Federal Trade Commission¹⁵, the 30-Month Stay Provision is now **per drug per application**. Before, the patent submission and listing requirements system permitted more than one patent holder challenge to the application, leading to a succession of 30 month stay periods (phenomenon commonly know as “several bites of the apple”). The system was amended in 2003¹⁶ to prevent successive stays. Now, the rule is that, in most cases, there is only one opportunity for a 30 months stay of the approval date of each ANDA and 505(b)(2) application.

In a few words: The U.S. Linkage system provides 4 “opportunities” for second/generic applicants trying to obtain marketing approval during the term of a patent affecting the product they are relying on. They can declare that:

- I. the required patent information has not been filed by the originator; or
- II. the patent has expired; or
- III. the patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- IV. the patent is invalid or will not be infringed by the generic drug for

¹⁴21 U.S.C. § 355(c)(3)(C) and 21 U.S.C. § 355(j)(5)(b)(iii)

¹⁵ “Generic Drug Entry Prior to Patent Expiration: An FTC Study (July 2002)”. Available at: <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>

¹⁶Medicare Prescription Drug, Improvement, and Modernization Act of 2003

which the applicant seeks approval (“Paragraph IV certification”)

The regulation grants a 30-month stay of approval on second/generic applications if:

- a) the patent holder submitted the patent information to be included in the Orange Book before the second application was presented; and
- b) the second application includes a paragraph IV certification challenging a patent listed in the Orange Book that claims the approved drug on which the generic application relies; and
- c) the patent owner or originator sues the second applicant for patent infringement within 45 days of receiving notice of the paragraph IV certification.

Recommended Reading: On October 2004, the FDA distributed a draft “Guidance for Industry. Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Questions and Answers.” Available at:
<http://www.fda.gov/cder/guidance/6174dft.htm>

EUROPE

Patent-Registration Linkage is not recognized in Europe, but there is growing pressure on European health authorities to apply it. Recently, the European Generic Medicines Association released a press release about this: “New strategy on patent linkage is contrary to EU law and threatens access to competitive generic medicines“, available at:
<http://www.egagenerics.com/pr-2006-02-02.htm>

OBJECTIONS TO PATENT-REGISTRATION LINKAGE

The use of Patent-Registration Linkage to protect brand-name pharmaceutical companies' research and development and to prevent patent infringement is subject to several critiques. The most important is that linkage creates many problems if the national patent office grants low quality patents, a problem in many countries, including the United States¹⁷, which is struggling to deal with a plethora of fraud and abuse allegations relating to the registration of patents of dubious merit or relevance in the FDA Orange Book.

In many cases, pharmaceutical companies file information on additional patents with the U.S. FDA that do not stand up to subsequent legal challenges concerning the validity of the patent, or that are not actually relevant to the pharmaceutical product. But even if the patents were inappropriately registered in the Orange Book, the U.S. law grants a 30 month stay, extending the originator's monopoly and the period when consumers pay higher prices. The only way to overcome the U.S. 30 month stay, is to litigate the patent dispute, which is time consuming and expensive. The system of linkage changes the status quo, so the patent owner gets an automatic barrier to generic competition, without having to persuade a judge that the patent is both valid and relevant. The costs of patent litigation can be an even greater problem in some developing countries.

Consumer interests, including health plans or government programs that pay for medicines, then pay much higher prices for medicines than they would otherwise, as the linkage effectively extends pharmaceutical companies monopolies rights.

An example: FTC v. Bristol Myers Squibb (2003)

<http://www.ftc.gov/opa/2003/03/bms.htm>

The U.S. Federal Trade Commission (FTC) and Bristol Myers Squibb (BMS) settled on illegal use of the U.S. linkage rules. BMS agreed to a \$670 million payment and a 10 year ban on using FDA's orange book listing of patents to block registration of generic competitors. The commission's chairman, Timothy Muris, told on a news conference, "Bristol's illegal conduct protected nearly \$2 billion in yearly sales from the three monopolies, forcing cancer patients and others to overpay by

¹⁷ In the United States several academics recognize this problem and are advocating for a patent reform. For example, Lemley, Mark A., Lichtman, Douglas Gary and Sampat, Bhaven N., "What to do About Bad Patents". Regulation, Vol. 28, No. 4, pp. 10-13, Winter 2005-2006. Available at SSRN: <http://ssrn.com/abstract=869826>. Other useful readings on U.S. patent reform are the FTC Report "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy", available at <http://www.ftc.gov/opa/2003/10/cpreport.htm>. And the NAS Report on "A Patent System for the 21st Century", available at: <http://darwin.nap.edu/books/0309089107/html>

hundreds of millions of dollars for important and often life-saving medications."

Bristol-Myers illegally blocked generic versions of the anti-anxiety drug BuSpar and the cancer drugs Taxol and Platinol by filing new patents for the three drugs that did not meet the standard for listing in the Orange Book of patent-protected drugs published by the Food and Drug Administration. The cases of BuSpar, Taxol and Platinol are three of eight instances cited by the commission in which brand-name drug makers have put new listings in the F.D.A.'s Orange Book after a generic competitor sought F.D.A. approval.

Other general critiques to the linkage system are that:

- It may make compulsory license or government use orders ineffective unless the government makes it clear that linkage is waived when governments or courts issue non-voluntary authorizations to use patents.
- It pushes national regulatory authorities, administrative agencies traditionally only concerned with scientific quality, efficacy and safety issues, into a completely new arena they do not have expertise and mandate: the assessment and enforcement of patent rights. In fact, the U.S. FDA has already admitted that it does not have the capacity for this.¹⁸
- It changes the nature of patent law from a private right, where the enforcement depends on the patent holder diligence, to a public right, where the enforcement depends on the public national authorities financed by the taxpayers.
- It can undermines the Bolar/ Early Working exception which seek to encourage quick access to the post patent market for generic medicines.
- It is arguably contrary to the TRIPS Article 27 requirement that patents are available without discrimination by field of technology, since the linkage system is not available outside of the pharmaceutical sector, or in the US, even for biologic products.

RECOMMENDATIONS:

The general recommendation is to not include linkage provisions in national laws. The European Union approach is this one.

¹⁸ United States House of Representatives Committee on Government Reform – Minority Staff Special Investigations Division, 'Trade agreements and access to medications under the Bush administration', prepared for Rep. Henry A. Waxman, June 2005. Available at: <http://democrats.reform.house.gov/Documents/20050609094902-11945.pdf>

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However, if such a linkage regulation is agreed, for example during the negotiation of a Trade Agreement with the United States, there are several actions that can be taken to reduce its negative effects:

- Reduce the linkage regulation to a “Mandatory Notification System”. The Australia-U.S. FTA is an example: its article 17.10(5) only imposes a notification system to the patent holder and does not stay the regulatory approval procedure.
- The 30 month stay period should not be considered a model. The Canadian model can be useful because the Canadian legislation only recognizes a 24-month stay period.
- A developing county might also consider even shorter periods, such as six or 12 months, particularly if the shorter time is sufficient for the patent owner seek enforcement of patents from the courts (the situation that faces patent owners in other fields of technology).
- If a stay period exists, the system should only recognize ONE stay period for drug and application, like the U.S. regulations as amended in 2003.
- The type of patent affects the linkage mechanism. If the patent is on the compound/composition, it is easier to determine if there is an infringement. However, if the patent is for a “process,” the regulatory authorities should not be put in the position of needing to make a determination. Linkage should not be applied for second use or dose patents. The U.S. example in the Form 3542 is a great starting tool during a FTA negotiation or implementation process.
- Under certain circumstances, the system should allow the marketing of a generic drug while a patent challenge is pending in court: U.S. Example.
- Pro-public health Orange Book - The listing of patents should be mandatory, but the listing should not create a government right to enforce the patents

MORE INFORMATION

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ANNEX: RELEVANT U.S. LAW

FEDERAL FOOD, DRUG, AND COSMETIC ACT
21 USCS § 355 New drugs¹⁹

New Drug Applications (NDAs) / Section 505(b)(2) applications

(b) Filing application; contents.

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include----

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)----

- (i) that such patent information has not been filed,
- (ii) that such patent has expired,
- (iii) of the date on which such patent will expire, or
- (iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted

(3) Notice of opinion that patent is invalid or will not be infringed.

(A) Agreement to give notice. An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

(B) Timing of notice. An applicant that makes a certification described in paragraph (2)(A)(iv) shall give notice as required under this paragraph----

- (i) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or
- (ii) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(C) Recipients of notice. An applicant required under this paragraph to give notice shall give notice to

- (i) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

¹⁹ Titles and emphasis added. Only most relevant sections included.

(ii) the holder of the approved application under this subsection for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(D) Contents of notice. A notice required under this paragraph shall----

(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order.

(2) If the patent information described in subsection (b) could not be filed with the submission of an application under subsection (b) because the application was filed before the patent information was required under subsection (b) or a patent was issued after the application was approved under such subsection, the holder of an approved application shall file with the Secretary the patent number and the expiration date of any patent which claims the drug for which the application was submitted or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. If the holder of an approved application could not file patent information under subsection (b) because it was not required at the time the application was approved, the holder shall file such information under this subsection not later than thirty days after the date of the enactment of this sentence, and if the holder of an approved application could not file patent information under subsection (b) because no patent had been issued when an application was filed or approved, the holder shall file such information under this subsection not later than thirty days after the date the patent involved is issued. Upon the submission of patent information under this subsection, the Secretary shall publish it.

(3) The approval of an application filed under subsection (b) which contains a certification required by paragraph (2) of such subsection shall be made effective on the last applicable date determined by applying the following to each certification made under subsection (b)(2)(A):

(A) If the applicant only made a certification described in clause (i) or (ii) of subsection (b)(2)(A) or in both such clauses, the approval may be made effective immediately.

(B) If the applicant made a certification described in clause (iii) of subsection (b)(2)(A), the approval may be made effective on the date certified under clause (iii).

(C) If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in subsection (b)(3) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection

(b)(1) before the date on which the application (excluding an amendment or supplement to the application) was submitted. If such an action is brought before the expiration of such days, the approval may be made effective upon the expiration of the **thirty--month period** beginning on the date of the receipt of the notice provided under subsection (b)(3) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that----

(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on----

(I) the date on which the court enters judgment reflecting the decision; or
(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(ii) if before the expiration of such period the district court decides that the patent has been infringed----

(I) if the judgment of the district court is appealed, the approval shall be made effective on----

(aa) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(bb) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(II) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under *section 271(e)(4)(A) of title 35, United States Code*;

(iii) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in clause (i); or

(iv) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in clause (ii).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

Abbreviated New Drug Applications (ANDAS)

(j) Abbreviated application for new drug approval; required information and certification; approval of application; hearing.

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)

(A) An abbreviated application for a new drug shall contain----

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)----

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; _____

(B) Notice of opinion that patent is invalid or will not be infringed.

(i) Agreement to give notice. An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) Timing of notice. An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph----

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) Recipients of notice. An applicant required under this subparagraph to give notice shall give notice to----

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) Contents of notice. A notice required under this subparagraph shall----

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(5)

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the **thirty--month period** beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that----

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on----

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed----

(aa) if the judgment of the district court is appealed, the approval shall be made effective on----

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under *section 271(e)(4)(A) of title 35, United States Code*;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

PATENT ACT

*35 USCS § 271(e) Patent Infringement*²⁰

(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 USCS § 355(j)] or described in section 505(b)(2) of such Act [21 USCS § 355(b)(2)] for a drug claimed in a patent or the use of which is claimed in a patent, or

(B) an application under section 512 of such Act [21 USCS § 360b] or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and

²⁰ Titles and emphasis added. Only most relevant sections included.

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285 [35 USCS § 285].

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.