4A.1 PATENTABILITY OF SOFTWARE AND BUSINESS METHODS IN THE CONTEXT OF THE INTERNET

Recent highly publicized court cases have reminded patent practitioners and their clients of the importance of patents in connection with Internet software and Internet business methods. For the press, a watershed event was the U.S. Court of Appeals decision in State Street Bank & Trust Co. v. Signature Financial Group, Inc. In this case, an accused infringer asserted as a defense that the patent-in-suit was invalid—that it should never have been granted because it impermissibly claimed unpatentable subject matter, namely a business method. In upholding the patent, the Court of Appeals construed 35 U.S.C. Section 101, which says:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The Court of Appeals for the Federal Circuit ruled that the software and business method content of the invention did not render it ineligible for patent protection and that nothing in Section 101 excludes software or business methods from patent coverage. The Federal Circuit emphasized that “the usual conditions and requirements of this title” nonetheless apply, such as the requirements that an invention be “novel” and “non-obvious” for the grant of a patent. As related to e-commerce, computer programs and algorithms relating to Internet applications, data processing systems, and financial products can be patented if they are novel and non-obvious. In a later case that can be viewed in a similar vein to the State Street case, AT&T Corp. v. Excell

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1 149 F.3d 1368 (Fed. Cir. 1998).
Communications, the Federal Circuit ruled that a method of generating electronic messages in a telecommunication system was patentable subject matter under Section 101. In fact, patent practitioners in the United States have been obtaining software and business method patents for more than two decades. Merrill Lynch, for example, obtained a patent (U.S. Patent 4,346,442) on its Cash Management Account in 1982. In that sense, the State Street case did not change the law, but merely affirmed the principles set out in the U.S. “Examination Guidelines for Computer-Related Applications” issued by the U.S. Patent and Trademark Office (USPTO) in 1996 (two years before the State Street decision), namely that methods of doing business should be treated as any other method.

The State Street case, nevertheless, coincided in time with the marriage of commerce and the Internet, resulting in e-commerce, which was perfectly suited for the creation and development of an incredible variety of computerized business methods. This confluence of circumstances has jump-started a dramatic increase in the number of patent applications directed to various business models implemented on the Internet. For example, the total number of cases filed in class 750 for business method–related software, rose from just under 1,300 in 1998 to 2,600 in 1999, a 100 percent increase in one year. According to Gerald Goldberg of USPTO Technology Center 2700 (which includes class 750), 583 patents were issued in fiscal year 1999 in class 750.

The following list of some e-commerce–related patents granted by the Patent Office is illustrative of the kind of subject matter patented by various companies:

**Sales and Purchasing**
- Patent No. 5,960,411 to Amazon.com on “one-click” shopping.
- Patent No. 5,715,314 to Open Market on “e-shopping cart.”
- Patent No. 5,895,454 to Juliette Harrington on a single shopping cart for use in multiple sites.
- Patent No. 6,029,141 to Amazon for its affiliate program.
- Patent No. 5,963,916 to Intouch on methods to preview prerecorded music samples over the Internet.

**Web Auctions**
- Patent No. 5,778,367 to Network Engineering Software on database technology on the Web (eBay sued).
- Patent No. 5,794,207 to Priceline.com on reverse auctions.
- Patent No. 5,890,138 to Bid.com on price and availability decrease.

**Financial Transactions**
- Patent No. 5,870,721 to Affinity Technology Group on real-time loan approval.
- Patent No. 6,006,207 to Mumick et al. on loan repayment.

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2 172 F. 3d 1352 (Fed. Cir. 1999).
3 61 FR 7478, 7479 (February 28, 1996).
4 Class 750 is entitled “Data Processing: Financial, Business Practice, Management, or Cost/Price Determination.” Comment of Q. Todd Dickinson, the then director of the USPTO.
5 http://ipcenter.bna.com/pic/document/1,1103,1,452,00.html.
Consumer Reward Models
Patent No. 5,794,210 to Cybergold on attention brokerage, also known as pay-for-view ads.
Patent No. 5,774,870 to Netsentives on award redemption system (frequent-flier miles for on-line shopping).

Advertising
Patent No. 5,948,061 to DoubleClick on targeted advertising.
Patent No. 5,761,648 to CoolSavings.com on distributing targeted coupons via the Internet.

As the professional saying goes, where there are patents, there are lawsuits. Shortly after obtaining its patent, Priceline sued Microsoft, alleging that its airline ticket Web site infringed Priceline’s patent, and Amazon sued on-line bookseller Barnes & Noble, alleging that its Web site infringed Amazon’s patent. The case is still pending. CoolSavings filed eight patent infringement suits in the Northern District of Illinois to enforce its patent on e-marketing services. So far settlements have been reached with e-centives, iVillage, CouponSurfer, Xadvantage, and Planet U.

Trilogy Software sued CarsDirect on Trilogy’s patent 5,825,651 for a method allowing customers to select options for an Internet-ordered car. DoubleClick filed suit against L90 Inc. and Australian rival Sabela Media on its patent on delivering targeted advertising. San Francisco-based Intouch filed patent infringement suit against Amazon.com, Liquid Audio, Listen.com, AOL Time Warner, and DiscoverMusic.com. At press time Liquid Audio and Amazon have settled the lawsuit with Intouch on confidential terms.

At the very least, these examples emphasize the importance of obtaining and enforcing e-commerce/Internet-related patents for established as well as start-up companies. What strategies can be used to obtain Internet-related patents, enforce them against others, or defend your company against a competitor trying to enforce its Internet-related patent in litigation?

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7 This case was settled in January 2001.
9 Amazon v. Barnesandnoble is still pending. It was filed October 21, 1999. A preliminary injunction was granted December 1, 1999, just in time for the Christmas shipping season, conditioned on a $10,000,000 bond. The following day, December 2, 1999, the bond was posted, and the same day the injunction was appealed. Defendant moved to stay proceedings pending the outcome of the appeal, motion denied. Trial was set for May 22, 2001. In January of 2001, trial was reset for September 10, 2001. In February of 2001, the mandate came down from the court of appeals, vacating the injunction and remanding the case. In August 2001, the court denied a motion for bifurcation as to damages and willfulness. In November of 2001, a “tutorial” was held as to the technology. On November 30, 2001, the judge issued an order as to claim construction.
11 Trilogy Software Inc. v. CarsDirect.com, 1:99cv690 (W.D. Tex.).
12 2:99cv1914 (E.D. Va.).
13 www.internetnews.com/intl-news/article/0,6_257201,00.html.
4A.2 CLAIM AND SPECIFICATION DRAFTING APPROACHES FOR INTERNET-RELATED PATENTS

It is true that in the 1970s and early 1980s patent practitioners had to be very cautious in drafting claim language for software and business method inventions. During these years, a claim that merely recited performance of “mental steps” with no physically tangible inputs or outputs often faced a Patent Office rejection as being directed to a mere algorithm. In successfully obtained patents in this area, practitioners had to be sure to include nouns such as “processor” or “memory” to avoid “algorithm” rejections. In colloquial terms, so long as the claim recited something tangible, such as an apparatus, it was usually safe from being rejected as unpatentable subject matter. In method or process claims, practitioners had to be sure to recite input or output steps that made clear that practicing the method or process actually changed something tangible. A method or process that resulted in a report printed on paper, or that led to a finished article of manufacture, was likewise usually safe against such rejection.

An e-commerce invention usually involves creative use or application of existing business transactions to the infrastructure created by the Internet, when electronic transmissions become natural substitutes for voice communication, written orders, radio or TV advertising, written financial documents, and so on. Therefore, many e-commerce patents involve new methods or processes rather than new structural elements. It is also quite obvious that creation and patenting of the new business methods very often will involve dealing with software-based algorithms. Since patent drafting always should be done by keeping in mind who a potential infringer might be, it is important to be aware of the parties who can infringe an e-commerce patent.

For example, one of the classes of the potential infringers is the people or companies who actually use the software or practice the patented method. Such users are typically the patentee’s existing or potential customers, so enforcing claims aimed against existing clientele may not be a very attractive business goal. The USPTO has addressed the problem by allowing a patent applicant to obtain claims covering the manufacture, use, and sale of software on tape, disks, and other storage media. In the context of an Internet patent, such an object can be a hard drive of a certain computer. By drafting claims to cover such manufacture, use, and sale, the patent applicant ensures that the claims can be enforced directly against software developers or other e-commerce companies, which are usually the parties competing with the patent owner.

Two recent changes in U.S. patent law make it all the more critical that the practitioner drafting a patent application draft good patent claims from the outset.

The first change is Subtitle E of the American Inventors Protection Act (AIPA), which provides for publication of patent applications at 18 months and which further provides for infringement damages starting from the date of publication. The second is a decision by the Court of Appeals for the Federal Circuit in Festo v. Shoketsu. Each of these developments is discussed below.

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18 234 F. 3d 558, 56 USPQ 1865 (Court of Appeals for the Federal Circuit, 1999). Oral argument was heard before the U.S. Supreme Court in January 2002.
Historically, U.S. patent applications have never been published until issuance of the patent. Any damages calculation necessarily began no sooner than the date of issuance (grant) of the patent. As such, the United States was somewhat out of step with most other industrialized nations, whose patent systems published applications at 18 months and provided for infringement damages from the date of publication. One effect of Subtitle E was to harmonize U.S. practice with that of other industrialized countries, providing for 18-month publication and for pregrant damages.

The language of Subtitle E imposes conditions that must be satisfied before a patent owner can collect pregrant damages. One of the conditions is that the claim said to be infringed must be substantially identical in the published application and in the granted patent. Therefore, it becomes important to draft and file in the application a range of claims of varying scope and with various combinations of limitations, so as to maximize the chances that a claim in the issued patent that turns out to be infringed will be substantially identical to the corresponding claim from the publication.

As mentioned in connection with pregrant damages, it will be advantageous for many inventors of Internet-related inventions to maximize the prospect of pregrant damages (and licensing revenue) by requesting or accelerating the pregrant publication of their patent applications. For Internet- and software-related patents, which often cover inventions that will be obsolete within only a few years, a historical problem was that the prosecution time for the patent might well exceed the economic life of the invention. Stated differently, it was commonplace for a patent on such an invention to be issued only after the invention had been replaced by subsequent technology. Now the availability of pregrant damages in the United States offers an opportunity for a patentee to collect damages upon issuance of the patent for infringement occurring during the pendency of the corresponding patent application.

Under the recent changes in U.S. law, pregrant damages are available for any patent application that is published. Most U.S. patent applications filed after November 29, 2000, will be published as a matter of course 18 months after the priority date. The owner of a U.S. application that was pending on November 29, 2000, may obtain a publication (and thus the prospect of pregrant damages) by requesting so-called “voluntary” publication and paying a fee. Finally, the owner of a U.S. application who prefers not to wait for the 18-month publication may obtain an earlier publication by filing a request and paying a fee. Each of these measures adds to the prospect of pregrant damages. In addition, such inventors will want to try to file a range of well-designed claims to maximize the chances that the issued claims that turn out to be important will have identical counterparts in the filed application.

_Festo_ adds to the importance of designing such claims well. _Festo_ makes important changes to the Doctrine of Equivalents (DOE) that had its origins in the case of _Graver Tank v. Linde Air Products_. Under the Doctrine of Equivalents, a patent owner who failed to show that a would-be infringer is literally infringing a claim of a patent might nonetheless prevail by showing that the accused method or device is an equivalent of what is literally covered by a claim. For a patent owner asserting a patent, DOE has been a useful part of the law, because it has had only a fuzzy and indistinct boundary. Who can possibly say, prior to litigation and trial, whether some accused method or device is or is not an “equivalent” of the elements literally covered by the patent?

_Festo_ held, _inter alia_, that _any_ change to patent claims made during prosecution that was related to any statutory requirement of patentability (even changes made to comply with merely formal requirements such as the definiteness requirement of 35 U.S.C. Sec-
tion 112) would bar a later application of DOE to the amended element. Therefore, the *Festo* case makes it clear that the best strategy to try to maximize the scope of the claims in a patent is to devise a wide range of claims of varying scope. That strategy increases the chances that each issued claim will be identical to (that is, unchanged from) some claim that was in the application when it was filed. Such claims presumably will not fall under the *Festo* holding and thereby can continue to enjoy the full benefit of DOE.

It is quite common for software, business method, or other Internet-related patents to contain claims with elements defined in the means-plus-function language. Means-plus-function claims are authorized by the language of 35 U.S.C. Section 112, allowing a drafter to define a claim element by its function, and not its specific structure. With Internet-related patents, as with many algorithm-based patents, quite often it is advantageous to describe a function of a step or an element, rather than the particulars of the step or the structure of the element, since such patents are indeed related more to functions than to structures.

According to the statutory language of Section 112, the scope of the means-plus-function claims covers the structures disclosed in the specification performing the described function and the equivalents of the structures. It is possible that even in light of the *Festo* ruling, the statutory language of Section 112 still allows the means-plus-function claims to encompass equivalents even if the claims were amended during prosecution for the reasons related to patentability. Because of this statutory language, it is all the more important for claim drafters to be sure to provide means-plus-function claims (or claims containing means-plus-function elements) and method claims in addition to structure claims.

**4A.3 PRIOR USER DEFENSE**

Many patents of concern relating to the Internet are business method patents. Indeed, business method filings have increased to a level that has prompted the U.S. Patent Office to set up seven new examining group art units (2160 through 2166) to handle them. At least 44 examiners were assigned to these art units. Consequently, anyone conducting business relating to the Internet will need to be concerned about the possibility that a business method patent may issue and be asserted against one’s business.

Subtitle C of the American Inventors Protection Act creates a new 35 U.S.C. Section 273. This new Section 273 provides a defense against charges of patent infringement for a party who had, in good faith, actually reduced the subject matter to practice at least one year before the effective filing date of the patent, and commercially used the subject matter before the effective filing date. The defense is limited to methods, and in particular is limited to methods of “doing or conducting business.”

Establishment of this defense does not invalidate the subject patent. Stated differently, the patent owner who is unable to enforce its patent against a particular defendant under

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19 The Court explained: “We hold that prosecution history estoppel acts as a complete bar to the application of the doctrine of equivalents when an amendment has narrowed the scope of a claim for a reason related to patentability. Our decision to reject the flexible bar approach adopted in Hughes I comes after nearly twenty years of experience in performing our role as the sole court of appeals for patent matters. In those years, the notice function of patent claims has become paramount, and the need for certainty as to the scope of patent protection has been emphasized. A problem with the flexible bar approach is that it is virtually impossible to predict before the decision on appeal where the line of surrender is drawn.”
this defense may nonetheless enforce the patent against others who do not qualify for the defense (e.g., who had not reduced the subject matter to practice or commercially used the subject matter early enough).

The defense is available against any and all issued U.S. patents regardless of their filing date or issue date. It is available, however, only with respect to actions initiated after November 29, 1999. Stated differently, the subtitle does not apply to any pending infringement action or to any subject matter for which an adjudication of infringement, including a consent judgment, has been made before November 29, 1999.

The defendant who wishes to assert this defense faces a statutory burden of “clear and convincing evidence.” It is prudent, therefore, for anyone engaged in Internet-related business methods to maintain good records of the dates on which each business method was reduced to practice and used commercially.

4A.4 PRODUCTS OF PATENTED PROCESSES

It is important to note that a common delivery model on the Internet is the client-server model, where a customer uses a client (typically a Web browser) to receive something of value from a server (located distant from the customer, and operated by a merchant). The thing of value is thus delivered to the customer electronically rather than physically. An inventor seeking patent protection regarding an invention relating to the provision of such nonphysical goods and their delivery may thus be quite justifiably concerned that an infringer might move its server to a location where the inventor has no patent coverage. If this happens, direct enforcement of patent rights against such an infringer may be impossible.

A simple example will help to illustrate the problem. Suppose, for example, that for some industrial process it is extremely economically valuable to determine whether some intermediate product is suitable for further processing into a final product. An inventor may devise an analytical test that makes this determination more quickly than previous tests, or more accurately, or more cheaply. Process patent coverage on this test would permit the inventor to obtain remedies against someone who performs this test. Indeed, the inventor may well obtain patent coverage in each country where factories are located in which this industrial process is performed.

But suppose further that a would-be infringer carefully locates its testing facility in a country where there is no patent coverage for the invention. A sample of the intermediate product might simply be delivered by courier from the factory country (where there is patent coverage) to the testing facility (where there is not). The test is carried out, and the result (perhaps simply an e-mail message containing the word “yes” or “no”) is sent back to the factory. On the assumptions made here, there would be no prospect of direct enforcement against the provider of the test, even though enforcement would have been a straightforward matter had the provider of the test been in a country where there is patent coverage.

It might seem odd to imagine samples being shipped to another country for such testing to be done. But in recent times, many patented diagnostic and analytical tests (such as genetic testing) command royalties that dwarf the underlying cost of the test itself, and that would easily justify the modest cost of an overnight courier delivery of analytes.

For many companies, the United States is a chief market and in some cases the largest market. This prompts us to consider patent strategies that may be fruitful under U.S. law with respect to the above-described fact patterns. Where a U.S. patent is concerned, a typical fallback position where direct enforcement of patent rights is difficult or impossible is to charge the infringer with “inducement to infringe” (35 U.S.C. Section 271(b)) or
contributory infringement” (35 U.S.C. Section 271(c)). (At the end of the chapter, 35 U.S.C. Section 271, which is central to much of the discussion that follows, is reproduced in its entirety for the reader’s convenience along with Sections 287 and 295.) The infringer who has eliminated all direct contacts with the United States, however, is likely to escape enforcement activities under inducement and contributory infringement as well as under direct infringement. This is the case in our example.

The usual next step in efforts to enforce patent rights where the infringer has moved to a country where the inventor has no patent coverage is to attempt to block importations at the border. For physical goods this is a realistic goal, but for nonphysical goods such blockage may well be impossible. The Internet, after all, was designed to survive nuclear attack by automatically rerouting traffic in the event that some part of the network is destroyed. Mere lawyers, attempting to block an offending e-mail message at some particular point of entry into the country of patent coverage, are unlikely to succeed where nuclear weapons cannot.

In many cases where it is difficult or impossible to enforce a patent against the manufacturer of an offending product, a next enforcement approach is to go after the customers. Yet where the product is not itself covered by the patent, but is merely the product of a patented process, it might well be that the customer is not a direct infringer. In our example, the only thing that comes into the possession of the customer is a mere e-mail message containing the word “yes” or “no” and is thus very likely not covered by the patent of our example.

A careful reading of 35 U.S.C. Section 271(g), however, shows one remaining possible enforcement approach for use in this example. This section provides that:

Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product that is made by a process patented in the United States shall be liable as an infringer.

In our example, the patent owner may wish to argue that the offending e-mail message (containing a “yes” or “no”) is “a product that is made by a process patented in the United States.” In this view, the end-user customer who receives the e-mail message arguably “imports” it “into the United States,” presumably “uses” it “within the United States,” and is thus directly liable as an infringer.

For processes that may be practiced either over the Internet or with some involvement of the Internet, then, it is important for the patent practitioner to give thought to patent application language that maximizes the prospect of a court finding a mere electronic message to be a “product” of a patented process. For example, the drafter of the patent application may wish to refer to such a message explicitly, within the patent specification, as a “product” of the process. As for the claims, it is clear that the patent drafter should not only draft apparatus claims but should also be sure to draft process or method claims directed to the electronic transmission over the Internet, as described in the example.

In litigation, the question naturally arises how the patent owner will be able to prove that the process performed to make the imported product was in fact the patented process. To address this problem, U.S. law provides a presumption that it was made by the patented process. See 35 U.S.C. Section 295, also reproduced at the end of the chapter.

The importance of the Internet in recent years, together with press coverage such as that discussed earlier, has led to a great increase in client interest in patent coverage for Internet-related software and business methods. The transnational nature of the Internet means that clients who 5 or 10 years ago would never have needed patent coverage in more than one or two core countries may well need coverage in many other geographic areas, such as China or India or Russia. How should the practitioner respond to such client needs?
As a general rule, unless the client has stated unequivocally that it is interested only in U.S. patent coverage, the practitioner should draft claims that include claims with apparatus that can be characterized as having something tangible in it and processes that make tangible changes. Such claims are important despite the relaxation in the United States and in Europe regarding such inventions, because the client may well choose later to pursue patent coverage in other countries that are not so inclined. China, for example, tends to reject claims that appear to be directed to software. The tips and tricks that experienced U.S. practitioners used 10 or 20 years ago to get software- and business-method-related subject matter through the U.S. Patent Office are important today to get such subject matter through other patent offices.

4A.5 APPENDIX

35 U.S.C. Section 271
Infringement of Patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following:

• derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent;
• licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent;
• sought to enforce his patent rights against infringement or contributory infringement;
• refused to license or use any rights to the patent; or
• conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e)

(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 biological products.

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

• an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or
• an application under section 512 of such Act 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.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

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

• 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,
• 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
• 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.

(f)

(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product that is made by a patented process will, for purposes of this title, not be considered to be so made after—
• it is materially changed by subsequent processes; or
• it becomes a trivial and nonessential component of another product.

(h) As used in this section, the term “whoever” includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

(i) As used in this section, an “offer for sale” or an “offer to sell” by a person other than the patentee, or any designee of the patentee, is that in which the sale will occur before the expiration of the term of the patent.

35 U.S.C. Section 287
Limitation on Damages and Other Remedies; Marking and Notice

(a) Patentees, and persons making, offering for sale, or selling within the United States any patented article for or under them, or importing any patented article into the United States, may give notice to the public that the same is patented, either by fixing thereon the word “patent” or the abbreviation “pat,” together with the number of the patent, or when, from the character of the article, this can not be done, by fixing to it, or to the package wherein one or more of them is contained, a label containing a like notice. In the event of failure so to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice. Filing of an action for infringement shall constitute such notice.

(b)

(1) An infringer under section 271(g) shall be subject to all the provisions of this title relating to damages and injunctions except to the extent those remedies are modified by this subsection or section 9006 of the Process Patent Amendments Act of 1988. The modifications of remedies provided in this subsection shall not be available to any person who—

• practiced the patented process;
• owns or controls, or is owned or controlled by, the person who practiced the patented process; or
• had knowledge before the infringement that a patented process was used to make the product the importation, use, offer for sale, or sale of which constitutes the infringement.

(2) No remedies for infringement under section 271(g) of this title shall be available with respect to any product in the possession of, or in transit to, the person subject to liability under such section before that person had notice of infringement with respect to that product. The person subject to liability shall bear the burden of proving any such possession or transit.

(3)

(A) In making a determination with respect to the remedy in an action brought for infringement under section 271(g), the court shall consider—

(i) the good faith demonstrated by the defendant with respect to a request for disclosure,
(ii) the good faith demonstrated by the plaintiff with respect to a request for disclosure, and
(iii) the need to restore the exclusive rights secured by the patent.

(B) For purposes of subparagraph (A), the following are evidence of good faith:
(i) a request for disclosure made by the defendant;
(ii) a response within a reasonable time by the person receiving the request for disclosure; and
(iii) the submission of the response by the defendant to the manufacturer, or if the manufacturer is not known, to the supplier, of the product to be purchased by the defendant, together with a request for a written statement that the process claimed in any patent disclosed in the response is not used to produce such product.

The failure to perform any acts described in the preceding sentence is evidence of absence of good faith unless there are mitigating circumstances. Mitigating circumstances include the case in which, due to the nature of the product, the number of sources for the product, or like commercial circumstances, a request for disclosure is not necessary or practicable to avoid infringement.

(4)

(A) For purposes of this subsection, a “request for disclosure” means a written request made to a person then engaged in the manufacture of a product to identify all process patents owned by or licensed to that person, as of the time of the request, that the person then reasonably believes could be asserted to be infringed under section 271(g) if that product were imported into, or sold, offered for sale, or used in, the United States by an unauthorized person. A request for disclosure is further limited to a request—

(i) which is made by a person regularly engaged in the United States in the sale of the same type of products as those manufactured by the person to whom the request is directed, or which includes facts showing that the person making the request plans to engage in the sale of such products in the United States;
(ii) which is made by such person before the person’s first importation, use, offer for sale, or sale of units of the product produced by an infringing process and before the person had notice of infringement with respect to the product; and
(iii) which includes a representation by the person making the request that such person will promptly submit the patents identified pursuant to the request to the manufacturer, or if the manufacturer is not known, to the supplier, of the product to be purchased by the person making the request, and will request from that manufacturer or supplier a written statement that none of the processes claimed in those patents is used in the manufacture of the product.

(B) In the case of a request for disclosure received by a person to whom a patent is licensed, that person shall either identify the patent or promptly notify the licensor of the request for disclosure.

(C) A person who has marked, in the manner prescribed by subsection (a), the number of the process patent on all products made by the patented process which have been offered for sale or sold by that person in the United States, or imported by the person into the United States, before a request for disclosure is received is not required to respond to the request for disclosure. For purposes of the preceding sentence, the term “all products” does not include products made before the effective date of the Process Patent Amendments Act of 1988.

(5)

(A) For purposes of this subsection, notice of infringement means actual knowledge, or receipt by a person of a written notification, or a combination thereof, of information sufficient to persuade a reasonable person that it is likely that a product was made by a process patented in the United States.

(B) A written notification from the patent holder charging a person with infringement shall specify the patented process alleged to have been used and the reasons for a good faith
belief that such process was used. The patent holder shall include in the notification such information as is reasonably necessary to explain fairly the patent holder’s belief, except that the patent holder is not required to disclose any trade secret information.

(C) A person who receives a written notification described in subparagraph (B) or a written response to a request for disclosure described in paragraph (4) shall be deemed to have notice of infringement with respect to any patent referred to in such written notification or response unless that person, absent mitigating circumstances—

(i) promptly transmits the written notification or response to the manufacturer or, if the manufacturer is not known, to the supplier, of the product purchased or to be purchased by that person; and

(ii) receives a written statement from the manufacturer or supplier which on its face sets forth a well grounded factual basis for a belief that the identified patents are not infringed.

(D) For purposes of this subsection, a person who obtains a product made by a process patented in the United States in a quantity which is abnormally large in relation to the volume of business of such person or an efficient inventory level shall be rebuttably presumed to have actual knowledge that the product was made by such patented process.

(6) A person who receives a response to a request for disclosure under this subsection shall pay to the person to whom the request was made a reasonable fee to cover actual costs incurred in complying with the request, which may not exceed the cost of a commercially available automated patent search of the matter involved, but in no case more than $500.

(c)

(1) With respect to a medical practitioner’s performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

(2) For the purposes of this subsection:

(A) the term “medical activity” means the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent.

(B) the term “medical practitioner” means any natural person who is licensed by a State to provide the medical activity described in subsection (c)(1) or who is acting under the direction of such person in the performance of the medical activity.

(C) the term “related health care entity” shall mean an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic.

(D) the term “professional affiliation” shall mean staff privileges, medical staff membership, employment or contractual relationship, partnership or ownership interest, academic appointment, or other affiliation under which a medical practitioner provides the medical activity on behalf of, or in association with, the health care entity.

(E) the term “body” shall mean a human body, organ or cadaver, or a nonhuman animal used in medical research or instruction directly relating to the treatment of humans.

(F) the term “patented use of a composition of matter” does not include a claim for a method of performing a medical or surgical procedure on a body that recites the use of a composition of matter where the use of that composition of matter does not directly contribute to achievement of the objective of the claimed method.
(G) the term “State” shall mean any state or territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(3) This subsection does not apply to the activities of any person, or employee or agent of such person (regardless of whether such person is a tax exempt organization under section 501(c) of the Internal Revenue Code), who is engaged in the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician’s office), where such activities are:

(A) directly related to the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician’s office), and
(B) regulated under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act.

(4) This subsection shall not apply to any patent issued before the date of enactment of this subsection.

35 U.S.C. Section 295

Presumption: Product Made by Patented Process. In actions alleging infringement of a process patent based on the importation, sale, offer for sale, or use of a product which is made from a process patented in the United States, if the court finds—

• that a substantial likelihood exists that the product was made by the patented process, and
• that the plaintiff has made a reasonable effort to determine the process actually used in the production of the product and was unable to so determine,

the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made.