Contributory Infringement and the Molecular Biologist

*Karl Bozicevic**

INTRODUCTION

The science of molecular genetics is capable of producing inventions beyond the present imagination of mankind. In that it deals with the manipulation of biomolecules which make each living organism physically and chemically unique, it provides the potential of creating new life forms—not just oil eating bugs[1] and genetically unique plant life[2] but supermen. With such ominous potential comes equally ominous responsibilities—not the least of which involves protecting the intellectual property rights of molecular biologists so that those financing their research will see a return on their investment. Without money to fund, not just the research but the development of new inventions in this field, progress would slow to a crawl.

Some of the progeny of molecular genetics are patentable via product per se claims. However, the biomolecules produced are often naturally present in an organism and as such may be "discovered" rather than invented making them unpatentable "products of nature."[3] Accordingly, patent protection may be obtainable only via method of use claims.[4] For example paramount inventions such as the discovery of DNA sequences responsible for human disorders,[5] might be unpatentable except for method of use claims. *Hodosh v. Block Drug Co.*

*B.S. (Chemistry) Tulane University 1974; J.D. The Center for the Study of Law, Nova University 1978; LL.M. National Law Center, George Washington University 1985; Admitted Florida, D.C., Ohio, USPTO; employed at Lubrizol/Agrigenetics. The views expressed herein are solely those of the author and not Lubrizol or its affiliates and subsidiaries including Agrigenetics.

1 U.S. Patent 4,259,444 issued 3/31/81 to *Chakrabarty* and see the landmark case related thereto—*Diamond v. Chakrabarty*, 193 USPQ 206 (S. Ct. 1980).

2 See U.S. Patent 4,581,847 issued 4/15/86 and 4,642,411 issued 2/10/87 to *Hibberd et. al.* and see the landmark case related thereto—*Ex parte Hibberd*, 227 USPQ 443 (Bd. App. & Int. 1985).

3 Bozicevic, K. *Distinguishing "Products of Nature" from Products Derived from Nature*, 69 J. Pat. & Tm. Off. Soc'y 415 (1987).

4 Differences between "method of use" and "compound" or "product" types claims are discussed in detail infra. Method of use claims are generally enforceable only under 35 USC Sec. 271 (b) and/or (c), but not 271 (a). Reasons for this are discussed in detail infra.

5 U.S. Patent 4,666,828 to *Gusella*-Test for Huntington's Disease.

Inc.[6] (hereinafter *Hodosh*) is a recent decision which aids in interpreting the law surrounding the enforceability of these claims. Notwithstanding the *Hodosh* decision the enforceablity of patents using this important claiming mechanism remains clouded by the complexities of contributory infringement law. This paper endeavours to shed some light on this area of law, specifically as it might affect the biotech industry.

Because contributory infringement law is complex,[7] background information will be provided on the early case law and legislative proceedings leading to the enactment of legislation which became 35 USC. Sec. 271(b), (c) and (d). Since the enacted patent statute[8] was intended in part to be a codification of some of the earlier case law[9] a review of significant pre-1952 cases should provide insight with respect to interpreting the statute. Further, an analysis of how the law surrounding the enforcement of method of use patents developed and the direction of such development provides some indication of future trends.

There has been relatively little case law interpreting Sec. 271(b), (c) and (d). However, it is important to discuss the case law that does exist in that present economic and technological conditions[10] may result in disputes requiring the interpretation of 271(b), (c) and (d). The entire field surrounding the use of pieces of DNA referred to as restriction fragment length polymorphisms (RFLPs) appears particularly amenable to protection via method of use claims. This quickly developing area of molecular biology will provide methods which will not only detect genetic defects but predict with uncanny accuracy the

6 *Hodosh v. Block Drug Co. Inc.*, 4 USPQ 2d 1935 (CAFC 1987). See also *Hodosh v. Block Drug Co. Inc.* 226 USPQ 645 reversed at 229 USPQ 182 (CAFC).

7 Judge Gee writing for the Fifth Circuit in *Rohm and Hass Co. v. Dawson Chemical Co.* 203 USPQ 1, 9 (5th Cir 1979) stated:

With this we have about exhausted our present capacity for rational thinking on patent matters. As we noted during the oral argument of this case, patent cases are the only cases argued by professionals and decided by amateurs. We take some comfort in noting that any shortcomings of our effort can safely be laid to the difficulty of the subject matter. Mr. Giles S. Rich observed on several occasions during the hearings on Sec. 271 that patent law is "the metaphysics" of the law and that contributory infringement/patent misuse issues are the metaphysics of patent law.

8 Title 35 of the United States Code.

9 Senator McCarran, as spokesman for the legislation now enacted as title 35 stated that the act "codifies the patent laws." 98 Cong. Rec. 9323 (1952). See also *Jervis B. Webb, Co. v. Southern Systems, Inc.*, 211 USQ 528 (E.D. Mi. 1980).

10 Patents of potentially enormous economic importance continue to issue every week and concomitant therewith new products are developed. New biotech companies are formed and others merged, acquired or reorganized. See *Reorganizations, Patents, and New Products*. Biotechnology Jan. 1988, p. 6–7.

future development of an organism, e.g. will a plant produce a high yield, or will a human have heart failure before age forty or have a high I.Q. The enforcement of a method of use patent wherein the method of use is a method of treating humans with a naturally occurring compound produced via molecular biology would also require interpretation of these sections of the patent law. If the interpretation of 271(b), (c) and (d) remains unclear the enforceability of method of use patent would be uncertain. Such uncertainty could restrict the development of biotech products by placing a veil of doubt over the market exclusivity the product developer might hope to obtain. Unless there is a reasonably good chance of obtaining some degree of market exclusivity for the product, there will be a reluctance to invest in research and development.

The relationship between the potential market exclusivity and a decision to develop a product is not unique to the biotech industry. However, molecular biologists do have some unique problems due to factors such as the time, money, and effort required to develop a new biotech product[11] and the moral obligations of the industry to the public. The unique position of the industry, regarding the development of pharmaceuticals, has in part been recognized by the passage of legislation, allowing for patent term extension.[12] Although such legislation may promote new drug development in certain instances, the extension of a patent whose enforceability is questionable does little to encourage the development of new drugs; and important issues remain unresolved with respect to the enforceability of method of use patents.

Background on Contributory Infringement Law Pre-1952 Act Case Law

The early Supreme Court cases do not involve patents with method of use claims but rather patents containing combination claims[13] in

11 Estimates for the average cost of developing a new drug run as high as $50 million. Hansen. *The Pharmaceutical Development Process: Estimates of Development Costs and Times and the effects of Proposed Regulatory Changes*, in Issues in Pharmaceutical Economics 151, 180 (R. Chien ed. 1979).

12 Amendments to 35 USC Sec. 156 (PL 98-417 effective September 24, 1984). The length of patent term extension possible is related to the regulatory review period prior to commercial marketing or use and reviews are often lengthy and costly. (See PL 98-417.)

13 The meaning of the term "combination claim" will be further clarified in view of the cases discussed below. At this point it is important to note that such claims specially recite or claim individual components which are, by themselves, unpatentable. Similarly, present day method claims may claim a method of using a compound such as a pharmaceutical drug, which is itself unpatentable.

that a new method of using a known compound was unpatentable prior to 1952.[14] However, these cases still act as precedent in an area where patents are rarely litigated.

Leeds & Catline Co. v. Victor Machine Co.[15] (hereinafter *Leeds*) was an action to enforce a court ordered injunction against contributory infringement. The defendant was found guilty of contempt for manufacturing unpatented records that could be played in plaintiff's patented record player. The defendant had previously been ordered not be make records which could be played in plaintiff's patented player. Although the records themselves were not patented per se, they were claimed as part of the patented combination.[16] The Court recognized the need to allow the patentee the right to enforce the combination which were not individually patented. Without the ability to enforce the patent against such contributory infringers, the combination claims of the patent would be meaningless in that two or more manufacturing entities could produce and sell "unpatented" components of the patented combination without infringing the combination claims.

To maintain the rights of the patentee in *Leeds*, the judicial doctrine of contributory infringement was applied. (The initial concept of contributory infringement law was based in earlier tort law).[17] Today the rights of "method of use" patentees are maintained by contributory infringement actions.[18] In today's biotech industry (under the

14 *In re Thuau*, 57 USPQ 324 (CCPA 1943).

15 *Leeds & Catline Co. v. Victor Machine Co.*, 213 U.S. 325 (1909) (hereinafter cited as *Leeds*).

16 Claims 5 and 35, see *Leeds* at 333.

17 If a chemical compound is known or obvious in view of the prior art, the inventor of a new use or method of treatment using such a compound would only be able to obtain method of use claims. Method of use patents are analogous to combination patents in that enforcement is generally only practical if brought against a contributory infringer. Such method claims would only be directly infringed by taking the drug or administering the treatment which would be done by patients and doctors respectively. It would clearly be impractical for the drug developer patentee to attempt to enforce the method claims against such patient/doctor direct infringers. The only practical means of enforcement of such claims would be a contributory infringement action against the manufacturer of the drug used in the method of treatment. An extremely large number of patient/doctor defendants would have to be found. Further, the negative public relations resulting from such an attempt at enforcement might prove commercially disastrous.

18 The reasoning behind allowing a patentee to enforce combination claims against the manufacturer of a component is based in early tort law. *Wallace v. Homes*, 29 F. Chase 74 (no. 17,000) (CC conn. 1871). More specifically, contributory infringement law is an outgrowth of case law related to joint tortfeasors. *Thomas-Houston Electric Co. v. Ohio Brass Co.*, 80 F. 712, 721 (CA6 1897) (contributory infringement as a tort). Patent misuse is an outgrowth of the case law related to the doctrine of "unclean hands"). Clearly, no court before or now would enforce combination claims against the maker of a component where the maker had no reasonable

holding of *Leeds*) a seller of an RFLP probe useful in a patented method of detecting desirable characteristics in a plant genome[19] or genetic abnormalities in a human[20] would be a contributory infringer.

In *Carbice Corp of America v. American Patents Development Corp.*,[21] hereinafter (*Carbice*) the Court refused to allow the patentee plaintiff the right to enforce combination claims against the manufacturer of a component of the claims. Although *Carbice* did not overturn *Leeds*, it did indicate a limitation on the scope of contributory infringement.

In *Carbice*, the relevant combination claims were directed to a package in which ice cream could be kept cold and transported using dry ice. The defendant sold dry ice to be used in the patented package combination. The court refused to hold that the seller of the dry ice was a contributory infringer because the dry ice was a common article of commerce, i.e. a staple product. Although the seller of such a staple might realize that some of the staple articles (dry ice) were finding their way into infringing combinations (refrigerated ice cream packages); such a seller would have no reasonable expectation that the staple would be included in such a package since a staple has many uses.[22] Thus the seller of the dry ice could not be held to be a joint

---

expectation that the component would be used in the patented combination. *Wallace v. Homes* held that contributory infringement was found in *Morgan Envelope Co. v. Albany Paper Co.*, 152 U.S. 425 (1984) against the supplier of "perishable commodities used in a patented toilet paper dispenser." The paper could apparently be used without the dispenser. In a similar manner, no court before or now would find one to be joint tortfeasor if there were no reasonable expectation that an act might be construed as a tort when taken in combination with the act of another. W. Prosser on the Law of Tort Sec. 52 (4th ed. 1971). Contributor infringers are joint tortfeasors and although their acts taken by themselves are not tortious: when combined with the acts of another, they result in the commission of a tort. Prosser points out that "[i]f several defendants independently pollute a stream, the impurities traceable to each may be negligible and harmless, but all together may render the water entirely unfit for use." Accordingly, patentees must be afforded a remedy against contributory infringers in the same manner which anyone subjected to a tort of joint tortfeasors must have a remedy against such joint tortfeasors individually.

19 Canadian Patent 1,224,391 to *Herentian et. al.* Genetic Mapping for plant identification by using restriction fragments and detection of polymorphisms.

20 See note 5 supra.

21 *Carbice Corp. of America v. American Patent Development Corp.* 283 U.S. 27 (1931) (thereafter cited as *Carbice*).

22 In the same manner, a car dealer might realize that some of the cars he sells will be used by the buyer to commit torts such as battery. However, the car dealer does not have a reasonable expectation that such torts will be committed in that the car has many other uses which do not result in the commission of a tort. Accordingly, neither the seller of the dry ice used in the patented ice cream packages or the car used to commit a battery are liable as joint tortfeasors (see Note 17 supra).

tortfeasor. Analogizing to the present day biotech industry—it would appear that the seller of a staple host plasmid useful in making a patented recombinate organism would not be a contributory infringer.

A logical progression of the case law from *Leeds* and *Carbice* to the present would have undoubtedly provided a clearer understanding of issues such as what constitutes a "staple." "Contributory infringement" and "patent misuse." Although these two cases provided a logical base from which to proceed, the case law does not logically proceed from these cases: perhaps because they left many issues unresolved due to the vastly different factual setting. In *Leeds*, the defendant was under a prior court injunction not to make the records which were a component of, and useful only in combination with the patented player/record combination. In *Carbice* the defendant was under no prior order and was making a basic molecular compound, useful by itself and in a vast number of non-infringing combinations. In today's biotech industry the seller of conventional pBR 322 plasmids[23] would not be a contributory infringer of a specific method patent which made use of such a plasmid.

Rather than making logical progress to fill in the gap between *Leeds* and *Carbice* the Court deviated from both cases in 1944 with its holdings in the *Mercoid* cases (Mercoid I & II).[24] In *Mercoid I*, the plaintiff attempted to enforce the combination claims of a patented home heating system against a defendant whose licensees sold switches, a component of the patented system. The switches were useful only in connection with the patented system and the patentee collected royalties from licensees to which the patentee sold the switches for use in the system. Since the switches themselves were not separately claimed, the Court found that the patentee committed patent misuse by collecting royalties on the patented combination made with switches supplied by the patentee.

The holding of *Mercoid I* is clearly contrary to *Leeds* wherein the records, like the switches, were not covered by a separate claim and not subject to use in any manner other than within the claimed combination. Thereafter, *Mercoid II* clarified that a patentee could not enforce combination, regardless of whether the component was essen-

23 The DNA of most microorganisms is present in the form of a circular piece of DNA called a plasmid. p BR 322 is a widely used and well known E. coli plasmid often used as a cloning vector containing about 4362 base pairs. The complete base pair sequence of p BR 322 is known.

24 *Mercoid Corp. v. Mid-Continental Inv. Co.*, 320 U.S. 661 (1944) (hereinafter cited as Mercoid I) and *Mercoid Corp. v. Minneapolis-Honeywell Regulator Co.*, 320. U.S. 680 (1944) (hereinafter cited a Mercoid II).

tial to the claimed combination and useful only within it. Accordingly, the Court left patentees (with combination claims) without a remedy against joint tortfeasors,[25] i.e. "contributing infringers" as we know them today, could not be successfully sued. If *Mercoid* remained the law today the seller of a hybridoma[26] capable of making a patented monoclonal antibody[27] would not be held to be a contributory infringer.

The apparent elimination of contributory infringement by the *Mercoid* decisions was not accepted well by the patent bar[28] or others likely to make use of contributory infringement actions to enforce their patents.[29] Patent attorneys found it difficult to advise their clients on questions relating to contributory infringement, especially if such questions involved the validity of proposed licensing agreements.[30] Accordingly, legislation was proposed, Congressional hearings held, and in 1952, new legislation was enacted[31] which attempted to balance the concepts of contributory infringement and patent misuse.

---

25 "The *Mercoid* decisions came from a court with a strong predilection against monopolies in general. Odi, Samuel A., Contributory Infringement/Patent Misuse: Metaphysics and Metamorphosis U. Pitt. L.R. vol. 44: 73, 80 (1982) which was irrationally extended to the limited exclusivity provided by patents under the constitution to "promote progress and the useful arts" see U.S. const. Art. I. Sec 8. Par 8.

26 A hybridoma is a hybrid cell-line. The cell-line is produced by fusing some type of myeloma cell (cancerous) with a normal lymphocyte. After the fusing various selection procedures are carried out in order to obtain a particularly desired hybridoma. This hybridoma is cloned and will produce a single type of antibody known as a monoclonal antibody.

27 A myeloma is a tumour of the immune system which normally produces antibodies. By fusing a myeloma cell with a lymphocyte, selecting and cloning a cell line which produces a desired antibody of a single type, (i.e. a monoclonal antibody) can be obtained.

28 Mathews, *Contributory Infringement and the Mercoid Case*, 22 J. Pat Off. Soc. 260 (1945).

29 *Dawson Chemical Co. v. Rohm & Hass Co.*, 448 U.S. 176 (1980) (hereinafter called as *Dawson*) see numerous amici curiae briefs submitted to the court in favor of overturning *Mercoid*.

30 Id. at 200.

31 Title 35 of the U.S.C. see Section 271.

(a) Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States 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 sells 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 non-infringing 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: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement. (Recent amendments to Sec. 271 are not recited here but are discussed infra).

The apparent conflict between the *Mercoid* cases and earlier Supreme Court decisions relating to contributory infringement was discussed in detail during numerous hearings[32] leading to the enactment of 35 USC Sec. 271. With respect to the new legislation, it has been said that "[q]uite candidly the Court believes that Congress when it answered *Mercoid* and *Leeds* adopted *Leeds*."[33] "And the Court thinks that the Congress just said to Justice Douglas, we don't agree with you, we don't like your views and we reject them, we're passing a new statute and *Leeds & Catlin* is once more the law."[34]

Assuming the above is true, i.e. Congress discarded *Mercoid* and embraced *Leeds*, then Congress reestablished a patentee's ability to bring a contributing infringement action without being subject to a sustainable patent misuse counterclaim. Such right was established at least under the facts of *Leeds*: although not apparently under the facts of *Carbice*.[35]

Assuming the 1952 legislation did codify *Leeds* and *Carbice*, but not *Mercoid*, many questions remained unresolved in the area of contributory infringement due to the vastly different factual situations of these cases. An examination of the congressional hearings prior to enactment and commentary of those hearings sheds some light on how 35 USC Sec. 271 might be interpreted with respect to method of use patents.

Congressional Hearings on Section 271

The New York Patent Law Association had supervised the original drafting of the legislation and submitted a memorandum to the

32 Hearing on H.R. 3760 before Subcommittee No. 3 of the House Committee on the Judiciary, 82nd Congress, 1st Sess., 150–151 (1951) (1951 Hearings) (testimony of Giles Rich). See also Giles Rich's testimony during hearing of 1948 and 1949, portions of his testimony referred to in *Dawson* at 204–211, see note 22 supra.

33 *Entec Plastics Engineering Corp. v. Gates Rubber Co.*, 206 USPQ 525, 533 (D.C. Col. 1980).

34 Ibid.

35 See note 32 supra. Rich explained to Congress that Sec. 271 would correct the definition of contributory infringement left by *Mercoid* without giving sanction to practices such as those in the *Carbice* case. More specifically, when a party is under a prior court ordered injunction not to make an article covered by the combination claims of a patent and useful only in that combination, (record useful only in patented record/player combination) it is contributory infringement to make the article. Accordingly, an action for such contributory infringement can be brought without fear of a sustainable patent misuse counterclaim. It is pointed out above that *Carbice* was in line with and actually specifically confirmed *Leeds*. Accordingly, it would appear a sthough a patentee whose combination claims (refrigerated ice cream holder with dry ice) covering components (such as dry ice) useful by themselves and in various other combinations cannot bring a successful contributory infringement action, and that if such an action was brough, the patentee might be subject to valid patent misuse counterclaims.

House Committee on the Judiciary in 1948.[36] They explained that the legislation (enacted as 35 USC Sec. 271) was intended to specifically reverse U.S. Supreme Court decisions such as *Mercoid* and again provide some real patent protection for new use inventions. The memo explained:

> [O]ne who supplies a hitherto unused chemical to the public for use in a new method is stealing the benefit of the discovery of the property of this chemical which made the new method possible. To enjoin him from distributing the chemical for use in the new method does not prevent him from doing anything which he could do before the new property of the chemical had been discovered.[37]

The logic of the above statement is clear. There are literally hundreds of thousands of known chemical compounds. However, many thousands of these have no known practical usefulness. Accordingly, if an inventor discovers a new use for the compound, (and in the case of the biotech industry spends considerable time and money proving the safety and efficacy of the compound in that use)[38] the inventor should not be denied patent protection simply because the compound per se was previously known and unpatentable.

Giles Rich, a then prominent patent attorney, testified in 1948 and many other times on the necessity of balancing the concepts of contributory infringement and patent misuse.[39] Rich pointed out that the proposed legislation would allow a patentee to successfully bring a contributory infringement action under the facts of *Mercoid I*, but would not allow such an action under the facts of *Carbice*. Accordingly, a patentee with "*Mercoid* type" facts would not be subject to valid patent misuse counterclaims, however, a patentee with "*Carbice* type" facts would be subject to such misuse counterclaims.

In 1949, Rich again pointed out to Congress the need to balance the rights of those wanting to protect their inventions from contributory infringers with the rights of those wishing to make components of the claimed inventions for use with or in combinations other than

---

36 Hearings on H.R. 5988, etc., before the Sub-committee on Patents, Trademarks and copyrights of the House Committee on the Judiciary, 80th Cong., 2nd Sess., 4 (1948).

37 Ibid.

38 The "Food, Drug and Cosmetic Act" 21 USC Sec. 355 requires that the safety and efficacy of all new drugs be established. Proving these criteria to the satisfaction of the FDA can cost tens of millions (see note 11 supra).

39 See page 9 of the Hearing cited at note 36 supra. (Rich is the most senior judge now sitting on the CAFC).

the claimed use or combination, i.e. balance the doctrines of contributory infringement and patent misuse.[40]

During the 1951 Hearing, Rich continued his theme of emphasizing the need to balance the two doctrines and specifically referred to paragraphs (c) and (d) of Sec. 271.[41] In referring to paragraph (d), Rich said "[i]t goes with, supports, and depends upon paragraph (c)."[42] What was not said here is perhaps more important than that was said. More specicially, Rich referred to (d) as it related to (c) but not (b) leaving open the question of whether a patentee bringing an action of "active inducement" to infringe would be exempted from patent misuse counterclaims by (d).

Case Law Directly Interpreting the Meaning of Section 271(b), (c), and (d)

The landmark case in the area of 271(b), (c) and (d) is clearly *Rohm and Hass Co. v. Dawson Chemical Co.*[43] (hereinafter *Dawson*) and as such an interpretation of *Dawson* relates to the enforceability of method of use patents in the biotech industry.[44] Since there is no case on point[45] a detailed examination of *Dawson* and other Supreme, Appellate and District court cases which have dealt with Sec. 271(b), (c) and (d) and which involve issues which might be analogized to the

40 Hearings on H.R. 3866 before Sub-Committee No. 4 of the House Committee on the Judiciary, 81st Cong., 1st Sess., 11 (1949). Rich explained that in certain business situations such as existed in *Mercoid*, the patentee had to rely on the right to enforce the patent against contributory infringers without the fear of patent misuse counterclaims in order to have any practical hope of exploiting the claimed invention. However, Rich realized that any attempt to extend the right of patentees to bring contributory infringement action against those making articles other than articles "especially made or adapted for use in connection with such patent and which are not suitable for actual, commercial, non-infringing use" (see 35 USC Sec. 271(c)) would not withstand the test of time. Such extension would be analogous to allowing those subjected to torts which involved a car the right to sue the car manufacturer as a joint tortfeasor.

41 See note 32 supra.

42 Id., at 161–162.

43 *Dawson Chemical Co. v. Rohm and Hass Co.*, 448 U.S. 176 (1980).

44 Although the case does not deal specifically with a genetically engineered product or pharmaceutical the importance of the case was clearly recognized by the pharmaceutical industry in that the PMA (Pharmaceutical Manufacturers Association) submitted an amicus curiae brief to the court urging affirmance.

45 This writer has found no cases involving the enforcement of a method of use patent wherein the patented method involves a compound produced by the use of molecular genetics. However, See *Ciba-Geigy Corp. v. Bolar Pharmaceuticals Co.*, 212 USPQ 712 (E.D.N.Y. 1981) on issue of patent misuse change for limiting scope of license to exclude a combination with an off patent drug. See also *Dr. Salsbury's Laboratories v. I.D. Ressell Co.*, 101 USPQ 137 (8th Cir. 1954) re a poultry treatment composition.

enforcement of method of use patents provide the best guidelines on how such patents might be enforced or defended against.

Prior to *Dawson* the compound 3,4,-dichloropronionilide (hereinafter propanil) was patented by Monsanto Co. with compound per se claims. However, Rohm & Hass successfully had the patent declared invalid[46] and thereafter Rohm & Hass patented a method for using the propanil. The Rohm & Hass method was the application of propanil to rice crops in order to selectively kill weeds without destroying the rice. This was the only known use for propanil. (By analogy it is not difficult to imagine a scenario whereby one biotech company develops a means of making a spectrum of biological compounds and obtains a generic claim to those compounds. Another company then has the claims invalidated as to a species of the claim and then patents a method of using that species compound.)

A number of companies[47] began making and selling propanil with instructions on how to use the compound and Rohm & Hass sued for infringement.[48] Rohm & Hass lost the suit when the District Court held that they had misused their method patent by failing to grant licenses (which were requested) to makers of the unpatented propanil. The Fifth Circuit Court of Appeals[49] reversed the District Court and held that the defendants were contributory infringers and that their was no patent misuse. In *Dawson*, the Supreme Court affirmed the Fifth Circuit in a 5—4 decision.

Rohm & Hass had alleged contributory infringement under Sec. 271(c) for the sale of the propanil to farmers and under Sec. 271(b) due to the instructions on use provided along with the propanil.[50] The patentee presented evidence to show Sec. 271(b) and (c) infringement. More specifically the evidence presented showed that the propanil was a non-staple, and was useful only in the patented method: thus establishing Sec. 271(c) infringement. The evidence also showed the propanil was sold with instructions on how to use the compound in accordance with the claimed method of use thus providing evidence of Sec. 271(b) active inducement. Specifically, the defendants sold the

46 *Monsanto Co. v. Rohm and Hass Co.*, 312 F. Supp. 778 164 USPQ 556 (E.D. Pa. 1970), aff'd 456 F.2d 592 (3d Cir.) Cert. denied 407 U.S. 934, 172 USPQ 324 (1972)

47 The defendants included Helena Chemical Company, Dawson Chemical Company, Crystal Manufacturing Corporation, and Crystal Chemical Company.

48 *Rohm and Hass Co. v. Dawson Chemical Co.*, 191 USPQ 691, S.D.Tx. (1978).

49 *Rohm and Hass Co. v. Dawson Chemical Co.*, 203 USPQ 1, (5th Cir 1979).

50 *Rohm and Hass Co. v. Dawson Chemical Co.*, 448 U.S. 176, 183 (1979).

propanil with instructions on how to use it in a manner which infringed the patented method claims.

The four dissenting justices[51] in *Dawson* reasoned that Rohm & Hass had committed patent misuse. Sec. 271(d) notwithstanding, by refusing to grant a license to all but purchasers of the unpatented propanil. The dissent correctly pointed out that a strict interpretation of Sec. 271(d) only immunized Rohm & Hass from misuse charges for (1) deriving revenue from the sale of unpatented propanil. (2) licensing others to sell propanil. and (3) suing unauthorized sellers of propanil. Nothing within Sec. 271 specifically states that the patentee may refuse to grant licenses. The dissent felt the majority opinion allowed Rohm & Hass to extend the scope of their patent rights beyond the granted claims to the extent of allowing Rohm & Hass monopoly control over the unpatented and unpatentable propanil. The dissent also correctly pointed out that Rohm & Hass only granted licenses under its method patent to those who purchased the unpatented propanil.

The majority in *Dawson* held that Sec. 271(d) could be interpreted to mean that the patentee could license the sale of propanil or refuse to license its sale and not commit patent misuse. The court recognized that Rohm & Hass would have no real patent rights if they were required to license others to sell the propanil. Rohm & Hass undoubtedly would grant such licenses if a sufficiently high royalty were paid. If Rohm & Hass were required to grant licenses at some low rate their patent rights would be restricted and they would not be provided with an exclusive market.

The biotech industry can look to *Dawson* for some guidelines on the enforceability of method of use patents. The holding would allow the patentee of a method of use patent to sell an unpatented DNA probe needed in a patented method of detecting a particular DNA sequence.[52] The patentee could refuse to license others to sell the DNA probe and sue them as contributing infringers for selling the DNA probe provided the probe (1) had *no non-infringing uses;* (2) was a *non-staple:* and (3) was *sold with instructions* on how to use the probe in accordance with the method covered by the patent.

Dawson has however left many questions unanswered. For example, *propanil had no other uses* making it unnecessary for the court to interpret the meaning of "*substantial non-infringing use.*" Further,

51 Justice White wrote the dissent in which Brennan, Marshall and Stevens joined.

52 See PCT Publication 8404758 on using restriction fragment length polymorphisms, published also as Canadian 1.224.391 on 7/21/87.

Dawson did not require the term "staple" to be interpreted. In addition, there was no discussion of whether the propanil itself or the propanil in an inert carrier was the non-staple.

The patentees in *Dawson* were presented facts allowing them to claim infringement under Sec. 271(b) and (c), i.e. active inducement (b) and contributory infringement (c). Accordingly, no consideration needed to be given to a situation wherein only (b) or only (c) might apply. In view of this, distinction between (b) and (c)[53] and the degree of intent required under (b) to prove active inducement was not addressed.[54] Perhaps more importantly the 5–4 decision of the court might have been decided in favor of a patent misuse holding in a purely Sec. 271(b) situation, i.e. if propanil had substantial non-infringing uses, was a staple, but was sold with instruction which induced infringement. In such a (b) type situation it remains undetermined as to whether the court would apply the patent misuse immunity of (d) where the patentee refused to license others to sell an unpatented product used in the patented method.[55]

Vectors[56] are an essential part of recombinant DNA procedures and molecular biologists might well invent a new recombinant procedure using an old and unpatentable vector. Having obtained a patent on a method of using a "staple" vector it is uncertain if the patentee could sue another who sold the vector with instructions on how to use it in the patented method.[57]

---

53 Federico. *Commentary on the New Patent Law*. 35 U.S.C.A. Sec. 1-110 (hereinafter cited as Federico). Distinctions and similarities are discussed in detail.

54 "Paragraph (b) is a broad statement and enactment of the principal that one who actively induces infringement of a patent is likewise liable for infringement. The Committee Report in several places refers to this paragraph as relating to contributory infringement. There is apparently some looseness in the use of the terms "infringement" and "contributory infringement" which ought to be considered immaterial in construing the section. Paragraphs (b) and (c) are independent as written but, in connection with the sale of such things as staple articles and commodities of commerce suitable for substantial non-infringing use, which fall within the specific exception of paragraph (c), clearly something more than mere knowledge of an intended infringing use would have to be shown to make out a case of active inducement under paragraph (b)." Id. at 53.

55 The Commentary of Federico does provide support for applying the immunity of (d) to (b). "Paragraphs (b) and (c) define and limit contributory infringement of a patent and paragraph (d) is ancillary to those paragraphs." Id. at 52.

56 Vector referred to a number of different DNA molecules such as pBR322 described in note 23. Vectors are generally plasmids or bacteriophage DNA into which fragments of DNA may be inserted or cloned. The vector DNA should be capable of autonomous replication in a host organism e.g. an E. coli microorganism.

57 Fisher. *The Misuse Doctrine and Post Expiration Discriminatory and Exorbitant Patent Royalties*. 51 JPOS 215, 216 (1969).

Bringing such an action might result in a holding of patent misuse which denies the patentee the right to sue for infringement or collect royalties until the effects of the improper activity are purged. Further, without (d) type immunity a court could hold that the misuse reached antitrust proportions, subjecting the patentee to treble damages[58] in a counterclaim.

Economically important patents exist which claim methods of use wherein the method involves the administration of an unpatented and unpatentable drug to patients.[59] Makers of compounds used in such methods would not be liable as direct infringers under Sec. 271(a). If the compound had no other use than in the claimed method a maker of the compound would, under *Dawson*, be enjoined from further contributory infringement. Many compounds produced by molecular genetics are pharmaceuticals and federal law[60] (as enforced by the FDA) requires the seller of a pharmaceutical to describe indications (uses) in detail on drug labelling. Accordingly, active inducement might also exist in that the labelling might teach the patented method of use. Labelling might not effect a finding of infringement for 271(b) active inducement if the patented method of use was for a non-FDA approved use.[61]

Substantial Non-Infringing Use

In *Sims, et al. v. Mack Trucks, Inc.*[62] *(hereinafter Sims)* the court held that the maker of a chassis used in making a patented concrete mixer actively induced infringement of the patent. The defendant presented evidence that the chassis had non-infringing uses and the court held that the plaintiff had not met its burden of proving the chassis had no substantial non-infringing use.[63] Notwithstanding their holding the court held that the promotional marketing and sales methods carried out in connection with the chassis constituted inducement

58 35 USC Section 284.

59 See for example USP 3,987,200 assigned Lilly which covers a method of treating cardiac contractility with the commercially successful Dobutamine (1984 sales about $45 million).

60 21 USC Sec. 355.

61 Id. Required FDA labeling would describe the second use only if the efficacy of the drug had been established for that use. However, the second use could be patented as the Patent Office and Title 35 of the U.S.A. merely require the invention be "useful" (see USC Sec. 101) a burden much easier to establish than that of efficacy under 21 USC Sec. 355.

62 *Sims et al v. Mack Trucks, Inc.*, 199 USPQ 668 E.D. Penn. (1978) revs. on other grounds at 203 USPQ 961 (reversal based on obviousness).

63 Id at 687. See also *Plastering Development Center v. Perma Glas-Mesh Corp.*, 179 USPQ 838 (N.D. Ohio 1973).

of infringement where the chassis was sold and later used to construct an infringing mixer.[64] However, if the mixer was constructed after the expiration of the patent there would be no direct infringement;[65] and there can be no infringement under Sec. 271(b) or (c) unless there is a Sec. 271(a) direct infringement.[66] As explained below, the *Sims* holding is potentially very significant to a biotech company wishing to market a compound after the expiration of a competitors use patent.

The present Patent Laws[67] allow a company to carry out testing of a drug to obtain FDA approval during the life of the patent and be immune from infringement provided all testing was done "solely" to obtain FDA approval. Just prior to the expiration of this use patent the drug could be shipped to wholesalers and pharmacists with instruction that would (if coupled with latter infringing use) constitute inducement to infringe. This action could coincide with extensive marketing and advertising. On the day the use patent expired the drug could be sold and used. This would provide invaluable market lead time over others attempting to begin the marketing of the same drug.

Biotech companies might attempt to further increase market lead time by actually selling a compound covered only by a use patent by arguing a second use for the compound, i.e. capable of "substantial non-infringing use." Such might be possible if no active inducement was shown and the second use was a "substantial" use. However, a biotech company attempting to avoid infringement of a method of use patent by claiming a second "substantial" use should review *Erie Resistor Corp. v. Solar Mfg. Corp. (hereinafter Erie)*[68] wherein the defendant argued that certain piezoelectric ceramics were capable of a substantial non-infringing use as a nontransducers. In *Erie* the court held that any use as a nontransducer was "purely in the experimental stage." Since there was no "substantial non-infringing use" the defendant was held to be a contributory infringer.[69]

64 See *Sims* at 686–687.

65 Id. at 686.

66 *Deepsouth Packing Co. Inc. v. Laitram Corp.*, 173 USPQ 769 (S. Ct. 1972). See also *Stukenborg v. Teledyne, Inc.*, 169 USPQ 584 (9th Cir. 1971).

67 Senator Hatch and Congressman Waxman were the primary sponsors of the bill which came to be known as the "Drug Price Competition and Patent Term Restoration Act of 1984." This legislation made substantial amendments to several areas of federal law effecting the pharmaceutical industry including amendments to 35 USC Sec. 271 relating to infringement. (See PL 98-417 enacted September 24, 1984).

68 *Erie Resistor Corp. v. Solar Mfg. Corp.*, 138 USPQ 496 (S.O. Cal. 1963).

69 Id. at 497.

The potential strength of a method of use patent is substantiated by *Erie* which would appear to provide precedent for a holding of Sec. 271(c) contributory infringement where a drug sold had only one FDA approved use (such as being covered by a method of use patent). Any unapproved use could be argued as not a "substantial non-infringing" use in that such use was only experimental.

Further elaboration of "substantial non-infringing" use is provided by *Reynolds Metal Co. v. Aluminum Co. of American*[70] (hereinafter *Reynolds*). In *Reynolds* the court held that the alternate uses proposed were clearly less efficient than the end use for which the material was particularly adapted and that "proposed less efficient alternative uses are not sufficient to avoid contributory infringement under 35 U.S.C. Sec. 271(c)."[71]

Reynolds as applied to biotech/pharmaceutical type method of use patents could be read as an expansion of *Erie* and as such have significant implications. Many drugs are far less efficient or useful in treating one disorder than another. In a situation where only the method of use and not the compound is patentable a strict reading of *Reynolds* would provide that a patented less efficient use of a compound would infringe a method patent on a more efficient use. It might also provide that a second patent on a more efficient use of a compound would be infringed by a first patented less efficient use of the compound.[72]

Applying the general holding of *Reynolds* to a factual situation in the biotech industry demonstrates that what a "substantial non-infringing" use is may be definable only on a case by case basis. Let's assume that a researcher discovers a naturally occurring compound "X" or DNA sequence "X" and uses well known genetic engineering technology to produce X. It might well be that neither X or its method of manufacture are patentable. However, Inventor A could invent and patent a method of treating a disorder using the unpatented compound

70 *Reynolds Metal Co. v. Aluminum Co. of America*. 198 USPQ 529. (N.D. In 1978).

71 Id at 554. See also *Parson Non-Skid Co. v. Atlas Chain Co.*. 198 F. 399 (2nd Cir. 1912) which held that when one sells a device, the natural, usual and preferential use of which constitutes infringement, it is not a defense to infringement that it is possible to limit the device's efficiency to so use the device not to infringe or that instructions were given to so use the device.

72 Overlapping patent claims is not a new concept. A genus of compounds can be patented and thereafter a species of that genus with improved unexpected results over other members of the genus could be patented. In such a situation, the genus patent would dominate and be infringed by any making of the species.

X or detecting the disorder using the unpatented DNA sequence X. In connection with the method of treatment it could be that massive amounts of compound X are needed to treat the disorder (in connection with the method of detection it could be that many copies of sequence X are needed to detect the disorder). Inventor B thereafter invents and patents a method for treating another disorder by the application of relatively small amounts of compound X (or in connection with the method of detection B invents a new method of detecting another disorder in a different organism which method requires only small amounts of sequence X). It would appear (under the *Reynolds* holding) that B could enjoin A's manufacture of X by claiming A was a Sec. 271(c) contributory infringer in that X had no substantial non-infringing use: i.e. only a far less efficient use than that patented by B.

In such a situation it would appear as though a court would have to consider factors such as the means and purpose of administration or use. Such a situation would also be avoided if the method of use claims of B specifically claimed what they were used for. e.g. a method of improving heart function and not merely a method of treating a patient. The above cases show how the enforceability of method of use patents depend on a court's interpretation of terms such as "substantial non-infringing use." "experimental use" and "less efficient use." The market exclusivity obtainable by a biotech company will depend on how courts interpret these terms. The importance of such interpretations becomes apparent when recognizing that molecular genetics will provide a means for producing larger amounts and types of naturally occuring biologically active compounds. Thereafter researchers will discover and patent ways of using these compounds to treat humans and case law will develop interpreting those terms.

KNOWLEDGE UNDER SECTION 271(C) INTENT UNDER SECTION 271(B)

There is little case law on the meaning of the word "knowledge" used in Sec. 271 (c) and/or the word "intent" based in Sec. 271 (b)[73] and the cases and commentary[74] that do exist are confusing and at

73 See *Sims* supra at 686. See also *Dennison Manf. Co. v. Ben Clements and Sons. Inc.*, 203 USPQ 895 (S.D. N.Y. 1979).

74 See note 53 supra.

times contradictory.[75] Judges,[76] commentators[77] and expert witnesses[78] alike have expressed their difficulty in dealing with these issues. However, some guidance on interpretation can be found in the commentary of Federico[79] and the holding of *Nordberg Mfg. Co. v. Jackson Vibrators, Inc.* (hereinafter *Nordberg*).[80]

Plaintiff Nordberg Mfg. Co. was the licensee of McCormick who held a patent[81] on an apparatus and method of correcting and aligning railroad tracks. Nordberg Mfg. Co. sued the defendant Jackson Vibrators, Inc. for infringement under Sec. 271(a) and (b) for making the patented apparatus and advertising and selling same with instructions for their use in the patented method.[82] The court held that there was no direct infringement of the apparatus claims under Sec. 271(a)[83] but

75 See note 54 supra.

76 See Judge Gee's Comments at note 7 supra.

77 Oddi. *Contributory Infringement/Patent Misuse: Metaphysics and Metamorphosis*. 44 U of Pitt L.R. 73 (1982).

78 Patent Law Codification and Revision, 1951: Hearings on H.R. 3760 Before Subcomm. No. 3 of the House Committee on the Judiciary, 82d Cong., 1st Serr. 153 (1951) Giles S. Rich Says "It is meta metaphysics, beyond the beyond, you might say."

79 Federico has indicated that establishment of a valid case for contributory infringement under (c) requires the presence of the following factors:

1. The thing sold must be "a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process. The thing sold is presumably not itself patented since if it were patented the question of contributory infringement, as distinguished from direct infringement, would scarcely arise and the paragraph would have little or no apparent purposes.
2. The thing sold must constitute a material part of the invention, that is, of the patented invention.
3. The thing sold must be especially made or especially adapted for use in an infringement of the patent.
4. The seller must have knowledge of factor 3.
5. In addition, the thing sold must not be "a staple article or commodity of commerce suitable for substantial non-infringing use."

Proof of compliance with all of the foregoing factors would be necessary to establish liability under paragraph (c).

With respect to providing a case for active inducement under (b), Federico has indicated the following:

in connection with the sale of such things as staple articles and commodities of commerce suitable for substantial non-infringing use, which fall within the specific exception of paragraph (c), clearly something more than mere knowledge of an intended infringing use would have to be shown to make out a case of active inducement under paragraph (b) (underlining added).

80 *Nordberg Mfg. C. v. Jackson Vibrators, Inc.* 153 USPQ 777 (N.D. Ill 1967) reversed on other grounds at 393 Fed. 2nd 192 (7th Cir. 1968). See also Moseley, D. *The Knowledge Requirement of Contributory Infringement and the ARO Case*. 47 JPOS 98 (1965).

81 United States Patent 2,962,979.

82 Note 80 supra at 779.

83 Id. at 786.

that there was direct infringement of the method claims by those using defendant's machines. The court also held that the defendant actively induced infringement under Sec. 271(b). This holding was made even though the machines sold by the defendant (Jackson Vibrators, Inc.) were more advanced than those sold by plaintiff Nordberg (or patented by licensor McCormick) and could be operated in either infringing or non-infringing manners.[84] In order to be operated in an infringing manner the machine had to be used with a reel and cable present on the machine. Detailed instructions on the operation of the machine with the reel and cable in an infringing manner were given in the "Operating and Maintenance Manual"[85] provided by defendant Jackson Vibrators, Inc.

When Judge Decker recognized that Sec. 271(b) was "rarely litigated"[86] he referred to a Senate Report[87] and the commentary of Federico and held:

> Paragraphs (b) and (c) define the limits of contributory infringement of a patent. They must be read together, as allied expressions of the basic underlying doctrine of contributory infringement. Since subsections (b) and (c) spring from the same basic doctrine, it is necessary to include the direct infringement requirement in (b).[88]

Nordberg is significant for its recognition of the interrelationship between paragraphs (b) and (c) of Sec. 271. Both sections were apparently enacted with the intent of codifying the case law of contributory infringement. As pointed out by Federico "There is apparently some looseness in the use of the terms "infringement" and "contributory infringement" which ought to be considered immaterial in construing the section."[89] Paragraphs (b) and (c) require that there be a showing of actual or Sec. 271(a) direct infringement and both require that the alleged contributory infringer knew that the combination for which his component was especially designed was both patented and infringing.[90] *Nordberg* holds that the "knowing" requirement which is explicitly incorporated in (c) is "at least a threshold requirement under

84 Id. at 782.
85 Id. at 782–783.
86 Id. at 783. See also *In re Certain Surveying Devices*, 208 USPQ 36 (Intern. T. Comm. 1980) on 271(b) intent and same case at 214 USPQ 900.
87 Senate Report 1979 (82nd Cong. 2nd Session).
88 Note 80 supra at 783.
89 See notes 53 and 54.
90 See note 80 supra at 784.

(b)''[91] and goes on to hold that ''[a] showing of sufficient knowledge to meet the requirement of Sec. 271(c) as established by Aro II is sufficient to impose liability under Sec. 271(b). The unitary nature of these two subsections require this result.''[92]

While emphasizing the nexus between (b) and (c) *Nordberg* recognizes that factual situations may well exist where only (b) or (c) apply.[93] The Machines sold by Jackson were capable of substantial non-infringing use thus eliminating liability under Sec. 271(c). However, active inducement under (b) clearly existed in that the machines were sold with the reel, cable and instructions for use in an infringing manner. Analogizing to the biotech industry, the maker of a non-staple DNA probe with no substantial non-infringing use could be liable for Sec. 271(c) infringement under *Dawson*. Under *Nordberg* there could be liability under (b) even if a substantial non-infringing use existed provided the probe were sold with instructions to use the probe in an infringing manner.

Defendant Jackson argued that there was patent misuse in that the patentee was attempting to extend the patent grant beyond its inherent limitations, and that Sec. 271(d)(3) did not provide immunity in that the suit was for inducement under Sec. 271(b) and Sec. 271(d) only referred to the contributory infringement of Sec. 271(c). The court held that there was no patent misuse and that (d) applied to both (b) and (c).[94] Presumably, a method of use patentee would be afforded the same immunity from patent misuse charges under Sec. 271(d) when attempting to enforce his patent against the maker of a DNA probe with a substantial non-infringing use if the probe were sold with instructions on how to use it in a manner which would (and in at least some cases did) infringe the method of use claims.

The FDA might well require that the drug or medical detection kit using a DNA probe be labeled so as to show indications, effects and method of use which could be covered by a method patent. If the FDA required the ''inducing activity'' a court might be reluctant to enjoin the ''inducing activity'' and by doing such prevent further sales of the properly labelled drug or detection kit.

91 Ibid.
92 Id. at 785.
93 Ibid.
94 Id. at 786.

The Meaning of "Not a Staple"

In *Robintech, Inc. v. Chemidus Ltd.*[95] the court states that: "'[s]taple' products mean a commodity or product with substantial uses apart from the patented invention."[96] Using such a definition is of course somewhat redundant when one considers the other language in 271(c). More specifically if a product or commodity is capable of "substantial non-infringing use" then it is a "staple." If it is not capable of such it is "not a staple." As redundant as such a definition might seem neither the legislative history or the case law appear to offer a different interpretation for the term.

Accordingly, it would appear as though "staple" compounds are those capable of "substantial non-infringing use" and those not capable of "substantial non-infringing use" are not staples. Again the issue becomes the interpretation of "substantial" which as pointed out above must be decided on a case by case basis.

Recent Developments

Although there have been a number of published decisions involving biotechnology[97] the decisions have not involved the issue of contributory infringement and the biotech industry may have a uniquely urgent need for elaboration of this area of law.[98] As different company's seek to develop and market the same biomolecules.[99] efforts are

---

95 *Robintech, Inc. v. Chemidus Wavin Ltd.*, 205 USPQ 873 (Dist. Col. App. 1980). See also *Rohm and Hass Co. v. Owens-Corning Fiberglass Corp.*, 196 USPQ 726 (N.D. Al. 1977) holding a resin useful only in the claimed invention was not a stable: See Federico at 53: Miller, C. *Some views on the Law of Patent Infringement by Inducement*, 53 J.P.O.S. 86 (Feb. 1971): *Bless & Laughlin Ind. Inc. v. Bel-Jax, Inc.*, 176 USPQ 119, 122 (N.D. Ohio 1972). The court refers to Webster's Dictionary definition of "Stable": *Fromberg, Inc. v. Thornhill*, 137 USPQ 84, 90 (5th Cir 1963) to make a showing that article was not a stable court required showing that the "suitability for such non-infringing use was actual and substantial."

96 Id. at 874.

97 *M.I.T. v. AB Fortia et al.* 227 USPQ 428 (1985 CAFC) discusses whether presenting oral teaching of cell culture techniques to 50–500 cell culturists along with a paper is a "printed publication" under 35 USC Section 102. *Hybritech Inc. v. Monoclonal Antibodies, Inc.* 231 USPQ 81 (1986) discusses the unobviousness of a biotech invention and the definiteness requirements of claims. *In re Lundak*, 227 USPQ 90, (1985 CAFC) discussed the use of an independent depository to make a deposit and satisfy the requirements of 35 USC Section 112. *Scripps Clinic v. Genentech, Inc.* 231 USPQ 978 (N.D. Ca DC. 1986) discusses infringement exemption under 271 (e) (1).

98 See text accompanying notes 10–11 supra.

99 Wall Street Journal, *Chic Disease—Venture Capitalists See Ways to Make Money In Combating AIDS* Sept. 28, 1987, discusses numerous companies seeking AIDS vaccines and methods of detecting AIDS virus. In addition numerous companies are attempting to develop products with alpha interferon (Hoffman-La Roche sued Burroughs Wellcome Co.) Factor VIII: C (Scripps and Revlon sued Genentech) Interleukin 2 (Cetus sued Amgen).

made to find new uses and means of administration for the same active ingredients. For example, human growth hormone (hGH)[100] is sold for use on children to promote growth but researchers have found that if hGH is applied in a different manner it speeds wound healing.[101] This example is not an unusual one in that many naturally occuring biologically active substances perform more than one function.[102] The same active ingredient, used for different purposes, would very likely be sold in different forms, i.e. in combination with different inactive components (pharmaceutically acceptable carriers) useful with a particular means of administration.

Hodosh[103] is a recent decision which addresses the issue of whether the "staple" is the active ingredient alone or that active ingredient in a carrier, i.e. the actual final product sold which is used in the patented method. In *Hodosh* the defendant Block Drug Co. Inc. had asked for and was refused a license to make toothpaste which included a particular active ingredient.[104] The license was refused by plaintiff Hodosh who held a patent[105] on a method of desensitizing teeth by applying to teeth a toothpaste which included potassium nitrate as the active ingredient. Hodosh had been refused patent claims on the combination of the paste and active ingredient.[106]

The CAFC held that in addressing the issue of what was a "staple," attention should be directed to the combination of paste and active ingredient (i.e. the product actually sold) not the active ingredient alone.[107] Such a holding would appear to add strength to the enforceability of method of use patents. A patent generically claiming a carrier component (useful in a claimed method of use) in combination with an active ingredient needed for a claimed method, could well be enforceable against a wide range of contributory infringers.

100 Human growth hormone is sold under the tradename Protropin by Genentech who was sued by Hormone Research Foundation and its licensee Hoffman-La Roche.

101 Bio/technology, Van Brunt et al. *Growth Factors Speed Wound Healing* Volume 6, No. 1, January 1988.

102 Minoxidil, a product sold by Upjohn as Rogaine Topical Solution to promote hair growth, was originally used as a vasodiolated to prevent angina.

103 See note 6 supra.

104 Id.

105 U.S. Patent 3,863,006 to Hodosh for a "Method of Densensitizing Teeth."

106 See note 6 supra and the file history of U.S. Patent 3,863,006.

107 See note 6 supra.

Summary and Conclusion

Having looked at pre-1952 cases,[108] Congressional hearings,[109] cases directly interpreting 271 (b), (c) and (d)[110] and recent developments[111] a fair question remains—"What factors constitute contributory infringement and/or active inducement of a method of use claim?" The answer is important in determining the market exclusivity obtainable for future biotech products.[112] Based on the above review, the following factors are critical in determining infringement under 271 (b) and (c):

1. The product (e.g. XYZ) sold must be a compound, material or device used in practicing the patented methods.[113] The (XYZ) product is presumably not itself patented or paragraph (a) would apply for a finding of direct infringement.
2. Direct infringement under 271 (a) must take place using (XYZ). However, the party selling (XYZ) need not carry out the direct infringement.[114]
3. The product (XYZ) which is sold must constitute a material part of the claimed method.[115]
4. The product (XYZ) must be especially made or adapted for use in connection with the claimed method of use.[116]
5. The party selling (XYZ) must have knowledge of (4). Such knowledge should be relatively easy to establish if (4) is shown, i.e. if it is shown that the product is especially made or adapted for use in the patented method.[117]
6. The product cannot be a staple article or commodity of commerce suitable for substantial non-infringing case.[118]

Establishment of 1–6 would show contributory infringement under 271 (c). However, to show active inducement under 271 (b) the party selling (XYZ) would have to be shown to have more than mere knowledge, i.e. a showing beyond criteria (5).[119] However, establishing some intent to have infringement take place at some point would not necessarily require a higher (and may demand a lesser) degree of proof

108 See text accompanying notes 13–35.
109 See text accompanying notes 36–42 supra.
110 See text accompanying notes 43–96 supra.
111 See text accompanying notes 97–107 supra.
112 See notes 10 and 11 supra.
113 See notes 18 and 46.
114 See note 66 supra.
115 See notes 62 and 68 supra.
116 See note 71 supra.
117 See notes 80 and 88
118 See notes 29 and 46.
119 See note 79 supra.

establishing that the product was especially made or adapted for (criteria 4) infringing use.

There appears to be a relationship between factors (4) and (5) as relates to paragraphs (b) and (c). Establishing contributory infringement under (c) would appear to require a higher degree of proof establishing that the product is especially made for use in the claimed method (factor 4) than is required to show active inducement under (b). Having met that higher burden regarding factor (4), however, contributory infringement can be shown with a lower burden of proof on the issue of knowledge (factor 5) than is required to show active inducement.

Others have listed factors[120] and offered opinions[121] on what is required to establish contributory infringement. As more method of use patents issue each week, disputes will result and courts will decide the ultimate factors to be applied in establishing infringement in this complex area of law. Method of use claims are clearly a valuable tool which can be of great importance in protecting inventions of molecular biologists. If this article aids in protecting those inventions by assisting in the clarification of this area of law then it will have served its purpose toward promoting the progress of the useful arts.

120 Factors 1–6 shown are in part an expansion and modification of those put forth by Federico (see note 79 supra). Consideration has been given to cases since Federico's comments and to the particular situations which might involve the inforcement of method of use claims used to protect the intellectual property of molecular biologists.

121 Rich. *Infringement Under Section 271 of the Patent Act of 1952*. 21 Geo. Wash. L. Rev. 521 (1953).