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COMMENTARY

Life After Lear

An estoppel is a remedy at equity, that is to say, in looking at a situation as a whole an estoppel brings about a result that is "fair." This concept has a long history which survives, for the most part, today. The exception to the survival of various forms of estoppel is the doctrine of licensee estoppel in patent cases.

Originally the doctrine of licensee estoppel operated under the concept that a person who bargains for a license should be estopped from denying that the licensor had valid title to the object of the license. In developing this concept, one early court analogized the doctrine of licensee estoppel to the doctrine of lessee estoppel, another property concept. In lessee estoppel, a lessee "... is bound to pay rent as long as he continues to enjoy quietly the premises leased to him, though by one who's title may be invalid.... So a lessee cannot dispute the title of his landlord." *Wilder v. Adams*, 29 F.Cas. 1216 (C.C.D. Mass. 1846). In 1805 the English case of *Taylor v. Hare*, 127 Eng. Rep. 461 (1805), addressed the issue of licensee estoppel based upon the concept of sanctity of contract when it stated, "[t]he Plaintiff has had the enjoyment of what he stipulated for, and in this action the Court ought not to interfere..." *Id.*

This deep rooted concept of fundamental fairness was plucked up by the Supreme Court in the case of *Lear v. Adkins*, 395 U.S. 653, 89 S.Ct. 1902, 23 L.Ed.2d 610 (1969). The Court, without citing any specific authority, struck down the doctrine of licensee estoppel, basing its decision upon the rationale that according to federal law, "... all ideas in general circulation be dedicated to the common good unless they are protected by a valid patent." *Id.* This ruling effectively encouraged patent litigation, as well as the unmasking of invalid patents, and making ideas developed by people, which happened to appear in an invalidated patent, available free to everyone.

Ever since it was first decided in 1969, the *Lear* case has caused confusion to reign supreme. The California Court of Appeals was under the impression that *Lear* signaled the demise of licensee estoppel in more than just the patent field, as it attempted to draw an analogy in the copyright field. *Golden West Melodies v. Capitol Records*, 79 Cal. Rptr. 442, 274 Cal. App.2d 713 (1969).

There is also confusion in how to treat the parties in an action where a licensee denies the validity of the patent licensed. According to some courts, a licensor may not terminate a license because of failure to pay royalties once the licensee has challenged the validity of the licensed patent. *Lee v. Lee Engraving*, 476 F.Supp. 361 (E.D. Wisc. 1979); *Warner-Jenkinsees v. Allied Chemical*, 567 F.2d 184 (2d Cir. 1977). At least one court has held that if a licensee fails to pay royalties, the licensor may elect either to: 1) treat the license as terminated and sue for damages; or, 2) sue on the agreement for royalties thus waiving the right to terminate. *Skil v. Lucerne*, 206 U.S.P.Q. 792 (N.D. Ohio 1980).

At least three different positions exist with regard to what should be done about continuing royalty payments during pendency of a suit wherein a licensee has challenged the validity of a patent. One court has ruled that a licensee need not make any payments during litigation. *Qume v. Xerox*, 207 U.S.P.Q. 621 (N.D. Cal. 1979). Another court held that a licensee may prevent a licensor from terminating the license by paying royalties into escrow during pendency of an action for declaratory judgment. *Atlas Chemical v. Moraine Products*, 509 F.2d 1 (6th Cir. 1974). However, most courts refuse to order payments into escrow, holding that if one wants to continue the licensing agreement, one must continue to pay. *Nebraska Engineering v. Shivvers*, 557 F.2d 1257 (8th Cir. 1977); *Warner-Jenkinson v. Allied Chemical*, *supra*; *Milton Roy v. Bausch & Lomb*, 418 F.Supp. 975 (D. De. 1976); *National Patent Development v. Bausch & Lomb*, 191 U.S.P.Q. 629 (N.Y. Sup. N.Y.C. 1976).

Recently introduced in the Senate, in bill S.1535, is a provision to amend the patent laws by adding to 35 U.S.C. a new section 295 dealing with licensee estoppel. The provision is an attempt to codify the decision of the Supreme Court in the *Lear* case. As has been stated earlier, the demise of licensee estoppel is contrary to long tradition and public policy based upon the sanctity of contract. In the parallel theory of lessee estoppel, as set forth in §4.3 of the *Restatement of Property, Second*, the following has been given as the rationale for the doctrine, and is equally valid for the doctrine of licensee estoppel:

- a. Rationale. Once the tenant has entered into possession of the leased property and has begun to enjoy its use, he is assumed to have accepted the state of the landlord's title as adequate to satisfy his expectations as to the possession and use of the property for the term. As long as the tenant remains undisturbed in his contemplated use of the leased property by a paramount title, his expectations have not been frustrated and the landlord is not in default.

The one redeeming feature of the proposed §295 also suffers from lack of attentiveness to contract theory. On the one hand, the section properly permits a licensor to terminate the license upon an assertion of invalidity by the licensee in a judicial action. On the other hand, the provision provides a unilateral escape from a license agreement by a licensee, wherein a licensee may terminate the agreement by its own assertion of invalidity in a judicial action. This second proposition flies in the face of public policy and should be removed from the proposal.

Finally, there may be great discrepancy in determinations of patent validity depending upon the form of the action involving the patent. In a declaratory judgment action, or an infringement action, the case may be appealed eventually to the Court of Appeals for the Federal Circuit ("CAFC"), thus providing for consistent determination of a patent's validity, no matter where a suit is brought. However, if a licensor brings an action for nonpayment of royalties, it is a contract action governed by state law (*Erie Railroad v. Tompkins*, 304 U.S. 64, 58 S.Ct. 817 (1938)), and the assertion of invalidity as a defense by a licensee will not bring the case within the ambit of review of the CAFC. This in turn fosters inconsistent rulings on patent validity.

As a last, but very important, note, the proposed legislation does not address the problem of inconsistent rulings of patent validity by state courts in suits for nonpayment of royalties. The Federal Court's Improvement Act was supposed to address this issue, but the enactment of the proposed 35 U.S.C. §295, as it stands, would defeat that purpose. There must be consistency in determinations of patent validity to *promote* the advance of the useful arts. United States Constitution, Art. 1, Clause 8.

Steven Krantz
Juris Doctor
Franklin Pierce Law Center, 1984

BOOK REVIEW

Bibliographic Information

CASEY, Wm. L. Jr., *et al.*, **ENTREPRENEURSHIP, PRODUCTIVITY, AND THE FREEDOM OF INFORMATION ACT**. 255 pp. Index. Bibliography. Notes. (D.C. Heath and Co., Lexington Books, 1983. Hardbound. \$24.95)

ISBN 0-669-06349-5; L.C. 82-48609

Review

Aside from an introduction and summary/conclusions chapters, the book reviews the history of the FOIA as well as its general impact on businesses and government agencies. It also presents an in-depth examination of the chemical and the pharmaceutical industries.

The book, written by three economists, appears to have been aimed at policy makers rather than economists. Lawyers attempting to influence policy makers (whether legislator, administrator, or judge) to read the trade secret exemption more broadly may find useful grist for their mill. In many ways, chapter 5, entitled "Entrepreneurship and the Case for Protecting Circumstantially Relevant Business Information," is the heart of the book. Also, those who are unfamiliar with FOIA and its background will find the book to provide a brief, although comprehensive, discussion.

The major potential criticism of the book by lawyers, and it is for the most part not a serious one, is the lack of editorial attention to legal citations. In some cases they are inaccurate; in others, they are incomplete; and, generally, they are inconsistent in style.

Reviewed by
Thomas G. Field, Jr.
Professor of Law
Franklin Pierce Law Center

PTC Research Report A Survey Regarding The Lear Decision

In COMMENTARY in this issue of IDEA we present a writing entitled "Life After Lear," which, of course, is about *Lear v. Adkins*, 395 U.S. 653 (1969).

Late last year we conducted a survey among corporate patent counsel and patent attorneys to learn their present thoughts regarding the *Lear* decision and to learn, in particular, what if any changes they would suggest in the law. A copy of the survey papers appear in the Appendix at pages 7 and 8. The second page of the Appendix is a copy of the questionnaire sent; we have added the returns from the survey.

We sent out 250 questionnaires and received 36 returns, mostly from corporate counsel. In the returns, as can be noted, most respondents favored some sort of legislation rendering a change in the *Lear* doctrine to make the licensee more responsible; several said no change is needed; and one said maybe. In general, the respondents favored Senate Bill S. 1535 or something like it. A few of the comments under "C" and "D" in the returns are included below.

Comments

Lear has had little or no impact on our licensing.

It is hard to tell where one stands. Ambiguity and indefiniteness, particularly to rights of licensor.

Licensees feel they may take a license and await challenge until it is economically feasible to do so.

Licensing terms which were previously standard have been revised to comply with the *Lear* doctrine.

Makes licensing easier, because a licensee need not feel locked into payments forever.

It makes a decision to take a license easier and it requires the inclusion in the license of agreements to deal with the effect of invalidity and challenges to validity.

It has given a licensee a substantial advantage over the licensor because the licensee is not bound to his contract with the licensor. The licensor can make one contract and then in effect renegotiate it to obtain

a better financial arrangement by challenging the patent without the threat of an injunction.

The licensing process has been simplified. One of the key issues prior to *Lear*, especially for the licensee, was being satisfied that patent was valid *before* entering into a license. The risk of entering into a bad bargain has been reduced by *Lear*, and the transfer and use of technology through licensing has been made easier.

Licensees more readily agree to a license, without thoroughly questioning validity since they know they can always challenge later if the economic situation warrants. This has been my outlook. (Note that this is a reverse effect from the policy upon which *Lear* is based, i.e., facilitating the challenge of bad patents!

October 4, 1983

Dear Respondent:

We are writing on behalf of the PTC Research Foundation, a nonprofit organization presently engaged in researching the impact of *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969).

This session Congress will be addressing, under S.1535, the doctrine of licensee estoppel emanating from *Lear* by the following proposed amendment to 35 U.S.C.

(a) A licensee shall not be estopped from asserting in judicial action the invalidity of any patent to which it is licensed. Any agreement between the parties to a patent license agreement which purports to bar the licensee from asserting the invalidity of any licensed patent shall be unenforceable as to that provision.

(b) In the event of an assertion of invalidity by the licensee in a judicial action, licensee and licensor shall each have the right to terminate the license at any time after such assertion. Until so terminated by either party, the licensee shall pay and the licensor shall receive the consideration set in the license agreement.

In order for the PTC to represent and assess the impact of *Lear* on businesses such as yours, we ask you to fill out the enclosed one-page questionnaire. Please feel free to expand upon the issues. Your individual response will be kept in confidence, but it will be compiled with others to be presented to the Congress.

Your cooperation is appreciated.

Research Group,
Steven A. Donato
Dawn M. Levandoski
Sedra F. Michaelson
Leslie A. Roff
Patrice A. Seitz

PTC RESEARCH FOUNDATION QUESTIONNAIRE

- A. Has your company/client challenged the validity of a patent that it had licensed under the *Lear* doctrine? (If so, was the challenge successful? Court decision or settlement?)
- 30 No
6 Yes
0 Blank
- B. Has your company/client, as a licensor, been challenged by a licensee as to patent validity under the *Lear* doctrine? (If so, was the challenge successful? Court decision or settlement?)
- 19 No
2 Yes
0 Blank
- C. Has *Lear* had any significant practical impact, in your experience, upon the licensing process? (If so, please explain briefly.)
- 19 No
15 Yes
2 Blank
- D. Do you favor:
- a. Repeal of *Lear, Inc. v. Adkins* by legislation?
- 17 No
5 Yes
14 Blank
- b. Legislation to require license payments until a decision adverse to the patent?
- 10 No
18 Yes
8 Blank
- c. Any other legislation? (Briefly delineate.)
- 6 No
11 Yes
19 Blank

THE FRANCHISE AGREEMENT AND COVENANTS NOT TO COMPETE: ANTITRUST IMPLICATIONS

Philip R. Evans*
Lanny Streeter**

Introduction

The past several years have witnessed a tremendous boom within the franchising industry. Its impact on the economy can hardly be underestimated when retail sales from franchised establishments comprise about one-third of all retail sales in the United States.¹ In 1983, sales by about 465,000 franchised outlets are expected to exceed \$435 billion.²

Considering the extensive use of franchising, its effect upon traditional competition within the marketplace should not be underestimated. Accordingly, the time has come to reevaluate the validity of restrictive covenants commonly contained in franchise agreements in light of the broad social and economic goals of the Federal antitrust laws.

As a condition to obtaining a franchise, franchisors customarily bind their franchisees to a one sided franchise agreement which contains covenants not to compete. These broadly worded covenants, in effect, restrain the franchisee from being associated with any business which is similar to the franchisor's during the term of the franchise agreement. Commonly referred to as an "in-term" restriction, the covenants often have no geographic limitations. Secondly, the agreement contains a post-term restriction which prohibits the franchisee from engaging in any such business within a certain geographic area for a specific length of time at the conclusion of the franchise relationship. Thirdly, most agreements restrict the franchisee from utilizing any of the confidential information acquired from the franchisor in any other business. This

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¹ *U.S. Department of Commerce, Franchising in the Economy 1978-1980*, - 003-009-00329-6 (1981).

² *Id.* at 5.

third restriction has no time or geographic limitations whatsoever. It purports to be perpetual and all encompassing.

The purpose of this article is to review the development of common law rules governing covenants not to compete and the applicability of those rules to covenants contained in franchise agreements. It will then discuss the question of need for deeper involvement of the federal anti-trust laws in face of the apparent failing of common law rules to adequately protect franchisees and the public.

Traditional Common Law Analysis

Under early common law, covenants not to compete were held to be contracts in restraint of trade and therefore deemed unenforceable. In the landmark 1711 case of *Mitchell v. Reynolds*,³ Chief Justice Parker reviewed the validity of a restrictive covenant contained in a contract for the transfer of a bakery business. The covenant restricted the transferor from engaging in the bakery business within the parish for a period of five years. Although Chief Justice Parker acknowledged that such a covenant was presumed to be invalid, he held that the covenantee had overcome that presumption by a showing of the covenant's reasonableness under the circumstances of that particular case. Building upon this decision, subsequent courts have advanced a rule of reason test which provides, in essence, that a covenant is reasonable and therefore valid if (i) it is ancillary to the otherwise legitimate contractual interest of the party in whose favor it is imposed, (ii) it affords no greater protection to the party who will benefit from its existence than is necessary to protect that interest, and (iii) it is limited in duration of time and geographical scope.⁴ In addition of this three-step analysis, the courts may proceed to next examine the covenant's effect on public interests. That is, if reasonable, is the covenant consistent with public policy.⁵

In applying this test, American courts have differentiated between covenants not to compete which are ancillary to a contract for the sale of a business and those which are ancillary to an employment

³ 1 P. Wms. 181, 24 Eng. Rep. 347 (Q.B. 1711).

⁴ See, e.g., *H & R Block Inc. v. Lovelace*, 208 Kan. 538, 493 P.2d 205 (1972); see also *Interstate Automatic Transmission Co. v. W.R. McAlpine Co., Business Franchise Guide* (CCH) Para. 7674 (N.D. Ohio 1981). Cf. *Budget Rent-A-Car Corporation of America v. Fein*, 342 F.2d 509, 515 (1965). See generally *Restatement of Contracts* §514 (1932). Compare *H & R Block Inc.*, 493 P.2d at 215 (on a court of equity's ability to reduce the territorial limitations so that the contract falls within a reasonable limitation).

⁵ *H & R Block Inc.*, 493 P.2d at 210. *Budget Rent-A-Car*, 342 F.2d at 514, 515. See generally, *Heckard v. Park*, 164 Kan. 216, 188 P.2d 926, 930 (1948).

contract.⁶ Restraints which are incidental to a legitimate business transfer have generally been dealt with in a more lenient manner.⁷ This policy is in recognition of the fact that often the most valuable asset to the purchaser of a business is its goodwill. Indeed, a business which relies heavily upon its established goodwill for its continued success could not, in many instances, be sold for an amount greater than the value of its tangible assets if the possibility existed that the seller would, shortly after the sale, begin direct competition in the same market area. Obviously, a seller and buyer are interested in capitalizing on that asset. Its value to both parties would be greatly diminished if the seller could not, in some reasonable manner, be constrained from competing with the purchaser of his business.

A stricter criterion, however, is viewed to be necessary for the enforcement of restrictive covenants which are ancillary to an employment agreement.⁸ Such covenants often unduly prohibit an employee from engaging in an occupation and often produces harsh results to the employee who entered into the contract from a less than equal bargaining position. Moreover, this resulting hardship may be imposed for the sole purpose of benefiting the employer by eliminating a potential competitor.

In short, the test to determine the reasonableness of restrictive employment covenants requires the same analysis described above. However, an additional element must be met. That is, the facts of the case must demonstrate that either the employer has imparted upon the employee confidential business information which is worthy of protection or that the employee had the type of relationship with the employer's customers which would result in substantial harm to the employer if the employee had the unfettered right to solicit those cus-

⁶ *Samuel Stores, Inc. v. Abrams*, 94 Conn. 248, 108 A. 541 (1919). *Original Vincent & Joseph, Inc. v. Schiavone*, 36 Del. Ch. 548, 134 A.2d 843 (1957). *Orkin Exterminating Co. of South Georgia v. Dewberry*, 204 Ga. 794, 51 S.E.2d 669 (1949).

⁷ *H & R Block Inc.*, 493 P.2d at 211. See also *Arthur Murray Dance Studios of Cleveland v. Witter*, 62 Ohio Law Abs. 17, 105 N.E.2d 685, 703-05 (1952) (for rationale supporting the lenient treatment for restrictive covenants included in sales of business).

⁸ See e.g., *Orkin Exterminating Co. of South Georgia v. Dewberry*, 204 Ga. 794, 51 S.E.2d 669, 675 (1949). See generally, 54 Am. Jur. 2d *Monopolies, Restraints of Trade, and Unfair Trade Practices* §543 (1971).

tomers for his own purposes.⁹ It is only when all of these elements are found to exist that the courts have upheld restrictive employment covenants with any consistency.¹⁰

Applicability To Franchise Agreements

The courts have grappled with the question of which test should be utilized to determine the validity of restrictive covenants contained in franchise agreements. Although it is difficult to categorize the typical franchise agreement as an agreement for the sale of a business or as an employment agreement, a majority of those courts deciding the issue have concluded that a franchise is more akin to an employment agreement and thus the rule of strict construction will prevail.¹¹ Concededly, a franchise agreement has elements of both but it is most difficult to place it into the sale of business category since the franchisor retains a substantial measure of control over most aspects of the franchisee's endeavors via the terms of the franchise agreement.¹²

This is a correct conclusion since a franchise agreement does, in fact, more closely approximate an employment agreement. Although franchisors traditionally attempt to label a franchisee as an independent businessman,¹³ the form franchise agreement which franchisees are required to execute typically remove most of the indecia of independent decision making.¹⁴ For example, in "business format"¹⁵ franchising, the franchisee is required to adhere, in every detail, to the

⁹ *Deurling v. City Baking Co.*, 155 Md. 280, 141 A. 542 (1928). See also *H & R Block Inc.*, 493 P.2d at 211 (delineates relative position of prospective employee in the contracting stage).

¹⁰ *Restatement of Contracts* §380.1 (1932).

¹¹ See, e.g., *Mansfield v. B. & W. Gas, Inc.*, 222 Ga. 259, 149 S.E.2d 482 (1966); *H & R Block Inc.*, 30 Wash. App. 538, 635 P.2d 1114 (1981); Compare *Budget Rent-A-Car Corporation of America v. Fein*, 342 F.2d at 516 (here the court acknowledges differentiation between an employment contract and a contract for the sale of a business, but indicates that a particular franchise agreement may be put realistically in *neither* the category of a contract for the sale of a business *nor* an employment contract).

¹² *Singleton v. International Dairy Queen, Inc.*, 332 A.2d 160, 161-163 (1975); *Gizzi v. Texaco, Inc.*, 437 F.2d 308 (C.A. 3d Cir.) reh. den (March 8, 1971) 404 US 829 (1971).

¹³ *Singleton*, 332 A.2d at 162-63.

¹⁴ *Id.* at 161, 162.

¹⁵ *U.S. Department of Commerce, Franchising in the Economy 1978-1980*, 003-009-00329-6, (1981) ("In business format franchising a franchisor establishes a fully integrated relationship [with the franchisee] which includes not only product, service, and trademark but also marketing strategy and plan, operating manuals and standards of quality control...").

franchisor's standards, specifications and methods in all aspects of his day-to-day operations. Furthermore, a franchisee customarily does not have the right to sell, transfer, assign or encumber any of his interest in the franchised business, even upon death, without the consent of the franchisor.¹⁶ Withholding of the required consent is generally not contractually predicated upon the reasonableness of the franchisor's decision. Indeed, consent is often withheld on the basis of subjective interviews with the prospective transferee or upon the franchisor's displeasure with the terms contained in the relevant purchase and sale agreement.¹⁷ Lastly, a review of the standard default provisions contained in franchise agreements indicate that the franchisor can terminate the agreement for a host of reasons.¹⁸ Many of these enumerated grounds for termination are again subjective and require a discretionary evaluation of the alleged discrepancy by the franchisor.¹⁹ In considering these extensive powers which are granted to the franchisor, it should be kept in mind that the majority of judicial decisions on the subject have pronounced the opinion that the franchisor does not have a corresponding fiduciary relationship to the franchisee.²⁰

From a literal reading of a standard franchise agreement, it resembles an employment at will contract which unduly restricts the employee's ability to engage in any trade which competes, either directly or indirectly, with the employer's business. Thus, the courts should be less reluctant to invalidate overly broad restrictions.

¹⁶ Franchise agreements often contain provisions which grant the franchisor the right to approve or disapprove a decedent franchisee's heir as successor to those franchise rights.

¹⁷ *Kastenbaum v. Falstaff Brewing Corp.*, 514 F.2d 690, 697 (5th Cir. 1975) cert. denied 424 U.S. 943 (1976). See also *Bertram Walner v. Baskin-Robbins Ice Cream Co., et al. Business Franchise Guide* (CCH) Para. 7723 (N.D. Texas May 14, 1981) (Both cases indicated that the franchisor possessed the right to disapprove the sale of a franchise if it felt that the sales price was excessive).

¹⁸ A review of the most current standard form franchise agreements utilized by the majority of fast food franchisors in this country indicates that the default provisions contained in those agreements are extensive and covers every possible contingency from failure to service standards to failure to maintain a responsible credit rating.

¹⁹ For example, it is not uncommon for a franchise agreement to contain a provision which provides that conduct by the franchisee which reflects unfavorably on the franchisor would be grounds for default.

²⁰ *Picture Lake Campground v. Holiday Inns, Inc.*, 497 F. Supp. 858, 869 (E.D. Va. 1980). See *Newark Motor Inn Corp. v. Holiday Inns, Inc.*, 472 F. Supp. 1143, 1151-53 (D.N.J. 1979); *Weight Watchers of Quebec Ltd. v. Weight Watchers International, Inc.*, 398 F. Supp. 1047, 1053-54 (E.D.N.Y. 1975); *Accord Amoco Oil Co. v. Cardinal Oil Co., Inc.*, 535 F. Supp. 661 (E.D. Wis. 1982).

Inadequacy Of The Common Law Approach

A franchise agreement customarily has, as indicated in the introduction, several restrictive covenants found in different paragraphs. Accordingly, it is necessary to view their reasonableness, not in the context of each independent covenant but in the totality of their combined effect. Ignoring this, courts, using the traditional common law approach, have been reluctant to declare the individual covenant in controversy to be unreasonable. Also, the larger question of the aggregate effect on the public arising from the existence of numerous similar franchises issued to other franchisees has not adequately been addressed.

Regardless of whether the courts review these covenants on an individual or aggregate basis, they erroneously place an over emphasis upon the concept of freedom of contract and misapply trade secret law.²¹ This failure stems from a fundamental misunderstanding as to the nature of the franchise relationship. Freedom of contract although a doctrine which has been diluted in recent years is still a fundamental concept. However, the courts should be cognizant of the fact that the negotiations preceding the execution of a franchise agreement are often not on an "arms length" basis wherein two sophisticated business people bargain and arrive at terms on an equal footing. Franchising, from its inception, has sought out people who were not experienced in business. It is this ignorant versus all knowing dichotomy which franchise sales are predicated. Accordingly, a franchisee may reasonably be expected to place a great deal of trust and reliance upon the dominant franchisor. Additionally, the terms of the franchise agreements are typically contained in a standard, non-negotiable, form contract. The franchisee is instructed that he must execute that agreement without making any changes to it if he is to become a member of the franchisor's system and become privy to the mysterious secrets which may never be divulged upon penalty of expulsion. It was in recognition of this unique relationship that the Federal Trade Commission passed in 1979, its Rule requiring franchisors make full disclosure to prospective franchisees at "the first meeting."²² Presumably, the F.T.C. felt that the franchisee may not have been fully converted at the time of the first meeting and therefore would proceed in a rational manner.

Granted, there are valid justifications for a franchisor to be able to protect its trade secrets. But, the question which must be addressed is

²¹ *The Antitrust Implications of Employee Noncomete Agreements: A Labor Market Analysis*, 66 Min. L. Rev. 519, 537 (1982).

²² 44 Fed. Reg. 49,977 (1979).

what type of so-called confidential business information is worthy of the legal protection afforded to a trade secret. For example, the following language is similar in form and context to the "Unfair Competition" paragraph currently contained in major fast food franchisors' franchise agreements:

FRANCHISEE acknowledges the uniqueness of the FRANCHISOR'S system, procedures, menu, strategies and materials, and the FRANCHISOR is making its knowledge, know-how and expertise available to him only for the purpose of operating the Restaurant. FRANCHISEE agrees that it would be an unfair method of competition to use or duplicate any of the knowledge, know-how and expertise received from FRANCHISOR for any use other than for the operation of FRANCHISOR'S restaurants.

This language purports to extend legal protection to "all" knowledge, know-how and expertise acquired by a person while serving as a franchisee. A mere recital such as is set forth above however, is not conclusive that the information the franchisee receives is of the type or nature which warrants protection.²³

A trade secret has been defined as "any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it."²⁴ Clearly, not every aspect of the operation of a particular fast food restaurant be a protectable trade secret. In retort to this, a franchisor would argue that trade secret protection arises from the combining of those many pieces of information, which standing alone are not protectable, into a "system."²⁵

However, assuming that a franchisee does not intend to duplicate the franchisor's system in some other business venture, he or she still faces the dilemma of not being able to ascertain what activity would amount to violation of the covenant. Would the order or manner which catsup, mustard and pickle are applied to a hamburg sandwich, or the location where one should place a bun rack for convenient access be considered knowledge worthy of protection? The above representative covenant says that it is.

Although a review of trade secret laws is beyond the scope of this article, a few observations should be made. First, it is widely recognized that training which leads to knowledge or skill generally

²³ *Board of Trade v. Hammond Elevator Co.*, 198 U.S. 424 (1904); *Singleton*, 332 A.2d at 163; *Pritchard v. Smith*, 289 F.2d 153 (8th Cir. 1961); *McCarty v. King County Medical Service Corp.*, 26 Wash.2d 660, 175 P.2d 653 (1946); *Francis v. Pan American Trinidad Oil Company*, 59 F.R.D. 631 (D.C. Del. 1973).

²⁴ *Restatement of Torts* §757.5 comment b (1939).

²⁵ *McDonald's System, Inc. v. Sandy's Inc.*, 45 Ill. App.2d 22 (1963).

known in the industry, does not alone form the basis of a protectable interest. Although a franchisee is trained in skills and techniques which he did not know prior to the affiliation with the franchisor, a franchisor does not have a protectable interest in that knowledge if it is commonly known, or obtainable, within the industry. Further, mere trivial differences in methods and processes are not sufficient to remove the information from the realm of general knowledge.²⁶ As one commentator on this subject has observed:

Merely equipping an employee to be a potentially more dangerous competitor is not, in itself, enough to support a restraint."²⁷

Therefore, one can readily see that in trade secret litigation involving a franchise often the plaintiff's:

"ultimate success is threatened by the serious doubt as to whether the 'know-how' which is the subject matter of the restriction sought . . . is entitled to protection by way of enforcement of a covenant in restraint of trade."²⁸

Additionally, if certain information is claimed to be confidential information, the franchisor should be required to show that he has taken all reasonable measures to protect its secrecy.²⁹ For example, a showing that a franchisor issued franchise agreements not containing protective restrictive covenants to certain franchisees contemporaneously with the agreement in which the contested language was found, could be taken as persuasive evidence that the franchisor himself did not view the information to be worthy of protection. Thus, evidence of this nature would tend to indicate that the restrictive covenants existed only for the improper purpose of restraining legitimate competition.

Despite the question of enforceability of these restraints, a franchisee may choose not to contest an otherwise unenforceable restriction out of fear of having his or her existing franchise agreement(s) terminated or facing onerous litigation. Additionally, countless franchisees do adhere to the restrictions out of an honest desire to abide by their contractual obligations. The following statement, though referring to employee restraints, emphasizes this situation:

²⁶ See generally, *Kaunagraph Co. v. Stampagraph Co.*, 235 N.Y. 1, 138 N.E. 485 (1923); *Vulcan Detinning Co. v. American Can Co.*, 72 N.J. Eq. 387, 67 Atl. 339 (Ct. Err. & App. 1907); *Roy v. Bolduc*, 140 Me. 103, 34 A.2d 479 (1943).

²⁷ Blake, *Employee Agreements Not to Compete*, 73 Harv. L. Rev. 625, 652 (fin. 85) (1960).

²⁸ *Schneider, Hill & Spangler, Inc. v. H.B. Cudmore*, 325 F. Supp. 173, 178 (1971).

²⁹ *Arthur Murray Dance Studios, Inc. v. Witter*, 105 N.E.2d at 709-11.

For every covenant that finds its way to court, there are thousands which exercise an *in terrorem* effect on employees who respect their contractual obligations and on competitors who fear legal complications if they employ a covenantor. . . . [T]he mobility of untold numbers of employees is restricted by the intimidation of restrictions whose severity no court would sanction. If severance is generally applied, employers can fashion truly ominous covenants with confidence that they will be pared down and enforced when the facts of a particular case are not unreasonable.³⁰

APPLICABILITY OF FEDERAL ANTITRUST LAW

Section 1 of the Sherman Act provides:

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several states . . . is hereby declared to be illegal.³¹

Apart from any "combination" or "conspiracy" theories which might apply to a case of unreasonable restraints of trade in franchise agreements, restrictive covenants can well be construed as "contracts" within the meaning of the Sherman Act.³² This statute is not interpreted as meaning that every contract which restrains trade is illegal.³³ Contracts challenged under the statute fall into one of two categories. In the first category, contracts are illegal "per se" if they are agreements "whose nature and necessary effect are so plainly anti-competitive that no elaborate study of the industry is needed to establish their illegality."³⁴ Thus, they are illegal without any showing of unreasonable effects.

Restrictive covenants ancillary to franchise agreements come within the second category,³⁵ which requires a "rule of reason" analysis to determine their validity. The inquiry mandated by this analysis "is whether the challenged agreement is one that promotes competition

³⁰ Blake, *Employee Agreements Not to Compete*, 73 Harv. L. Rev. 625, 682-83 (1960). See also *Richard P. Rita Personnel Serv. Int'l, Inc. v. Kot*, 299 Ga. 314, 191 S.E.2d 79 (1972).

³¹ Sherman Antitrust Act, 15 U.S.C. §1 (1970).

³² *Ungar v. Dunkin' Donuts of America, Inc.*, 68 F.R.D. 65, 119 (1975); *American Motor Inns, Inc. v. Holiday Inns, Inc.*, 365 F. Supp. 1073 (D.N.S. 1973). See generally, Goldschmid, *Antitrust's Neglected Stepchild: A Proposal for Dealing with Restrictive Covenants under Federal Law*, 73 Colum. L. Rev. 1193 (1973).

³³ *National Society of Professional Engineers v. United States*, 435 U.S. 679 (1978).

³⁴ *Id.* at 690; *American Motor Inns, Inc. v. Holiday Inns, Inc.*, 521 F.2d 1230 (3d Cir. 1975).

³⁵ *Ungar* 68 F.R.D. at 121; *Lektro-Vend Corp. v. Vendo Co.*, 660 F.2d 255 (7th Cir. 1981) cert. denied, 455 U.S. 921 (1982); *American Motor Inns*; *Bradford v. New York Times Co.*, 501 F.2d 51 (2d Cir. 1974); *Interstate Automatic Transmission Co.*

or one that suppresses competition.”³⁶ Although the courts are guided by common law precedent to determine the reasonableness of a restrictive covenant, the main purpose of the court’s antitrust analysis described above is “to form a judgment about the competitive significance of the restraint.”³⁷

Notwithstanding the above, the federal antitrust laws, with rare exceptions, have not been applied to restrictive covenants.³⁸ There seems to be little basis for this reluctance. Especially in light of the broad purpose of the Sherman Act, which Justice Black in *Northern Pacific Ry. Co. v. United States* held, “[It] was designed to be a comprehensive charter of economic liberty aimed at preserving free and unfettered competition as the rule of trade.”³⁹

In breaking with this traditional reluctance, the Court of Appeals, Third Circuit, in *American Motor Inns Inc. v. Holiday Inns, Inc.*⁴⁰ found that §1 of the Sherman Act was indeed applicable to in-term restrictive covenants contained in Holiday Inns’ franchise agreements at the time of the District Court trial. The plaintiff’s hotels were operated pursuant to franchise agreements issued by the defendant, Holiday Inns. After applying for the right to construct and operate an additional franchised hotel to be located at a site near the Newark Airport, Holiday Inn informed the plaintiff that its request was denied. The denial was based upon objections received by Holiday Inns’ from other franchisees located within the competitive market area of the proposed site. As an alternative plaintiff then sought to have Holiday Inns waive its “non-Holiday Inn” clause which was contained in plaintiff’s existing franchise agreements so that it could build a Sheraton Inn at the site. This clause provided that the franchisee may not directly or indirectly own any hotel, motel or motor inn which is not a Holiday Inn. The District Court held that the clause violated §1 of the statute and took into consideration that “the effect of the . . . clause is the intended one of reducing and preventing competition among Holiday Inns franchisees and between franchised inns and company-owned inns.”⁴¹

³⁶ *Chicago Board of Trade v. U.S.*, 246 U.S. 23, 38 (1918); *American Motor Inns, Inc.*, 521 F.2d at 1247.

³⁷ *National Society of Professional Engineers*, 435 U.S. at 690.

³⁸ *Ungar*, 68 F.R.D. at 119. See also, Blake, *supra* note 5, at 628; Goldschmid, *supra* note 22, at 1206.

³⁹ *Northern Pacific Railway Co. v. United States* 356 U.S. 1, 4 (1958).

⁴⁰ *American Motor Inns, Inc. v. Holiday Inns, Inc.*, 521 F.2d 1230 (1975).

⁴¹ *American Motor Inns, Inc. v. Holiday Inns, Inc.*, 365 F. Supp. (D.N.J., 1973).

On remanding the case for a reevaluation of that portion of the District Court's opinion regarding the unreasonability of the non-Holiday Inn clause, the Court of Appeals found the District Court's conclusion erroneous in that the trial judge's grounds for his conclusion

"does not reflect any exploration into one of the major determinants under the rule-of-reason test . . . the impact of the restraint on competition within the relevant market. In *Schwinn*, the Supreme Court said, 'Our inquiry is whether . . . the effect upon competition in the market place is substantially adverse.' It is only if the impact of the restriction is to unreasonably restrain competition that it is illegal."⁴²

Whether or not a restraint is unreasonable depends upon the effect such a restraint has upon the competitive structure of the industry effected.⁴³

Similarly, in *Ungar v. Dunkin Donuts of America Inc.*,⁴⁴ the District Court held that the in-term restraint found in Dunkin Donuts' franchise agreement was a valid antitrust issue in applying federal antitrust law.

The court in Holiday Inn recited the established principle that a restraint which would otherwise be reasonable would nonetheless contravene the Sherman Act if it was intended to accomplish a forbidden restraint.⁴⁵ Thus, the real issue may frequently be the franchisor's real motive in establishing the restraints.

However, in the absence of a showing that the restraint in question was intentionally designed to achieve a forbidden restraint, a franchisee must demonstrate the effect which the existence of such restrictive covenants has upon the relevant market in order to show that §1 of the Sherman Act has been violated. In determining that effect, the courts should not limit their inquiry to the particular agreement in controversy, but should focus on the totality of the impact to competition which arises out of the defendant's use of such restraints. There is existing authority to support this proposition.⁴⁶ In light of the fact that it is not uncommon for a franchisor to have in

⁴² *American Motor Inns, Inc.*, 521 F.2d at 1247.

⁴³ *Id.* at 1247; *Associated Press v. United States*, 326 U.S. 1, 27 (1945).

⁴⁴ *Ungar*, 68 F.R.D., 65 (1975).

⁴⁵ *American Motor Inns, Inc.* 521 F.2d at 1248. *United States v. Columbia Street Co.*, 334 U.S. 495, 522.

⁴⁶ See, *Fortner Enterprises, Inc. v. United States Steel Corp.*, 394 U.S. 495, 502 (1969) (the Court noted that in determining whether a "not insubstantial" amount of interstate commerce was affected by a tying arrangement the determining factor would be the total volume of sales affected by the practice and not the portion accounted for by the particular plaintiff who brings the suit).

excess of one thousand franchised units, this approach would definitely be relevant to a determination of market effect.

Market Analysis

Restrictive covenants in franchise agreements result in substantial anti-competitive effects in the relevant market in several ways, all of which are interrelated. First, they reduce competition in the input markets which pertain to the franchise relationship by impeding the mobility of the franchisee's resources among alternative occupational and investment opportunities. Second, it can be expected that these covenants will help limit the number of franchisors competing with one another. And third, such covenants tend to reduce the number of competing firms in the retail product market in which the franchisee directly operates. Each of these needs to be examined in more detail.

1. Input Markets

The most direct impact of restrictive covenants is in the input markets in which the franchisee's resources are bought and sold. The franchisee typically provides both capital and labor resources to the franchisor, and at any particular time presumably has opportunities to employ those resources in alternatives other than additional franchised outlets. Restrictive covenants, both in term and post-term, reduce the potential choices open to the franchisee. This possibility is enhanced because the franchisee is likely to have a relative preference for investing any future capital in similar ventures. Although it would be difficult to substantiate with empirical data, one can recognize that business people experienced in certain types of business enterprise would naturally desire to invest in like businesses. For example, an experienced fast food operator would be more likely to expand within the food industry than to open a shoe manufacturing plant.⁴⁷ Since the franchisee is contractually prohibited from expanding in any business which is same or similar to the franchisor's, or

⁴⁷ A franchisee's predilection to expand in a like or similar business can be explained in terms of relative costs. Before entering a new occupation or business, an individual will typically find it necessary to go through a period of training to acquire information and knowledge relevant to that work. On-the-job experience rounds out this necessary educational process. Economists usually refer to these activities as 'investment in human capital'. Like any investment activity, however, this involves costs to the individual, both possible out-of-pocket expenses as well as the implicit cost of one's time. The franchisee who branches out into an entirely different field will necessarily incur additional 'start-up' costs which would not be present with expansion in a similar endeavor. As a result such movement is likely to occur only if the new enterprise offers the prospect of a significantly higher return than the current type of business.

from utilizing any of the knowledge gained as a result of the franchise relationship, there is a strong incentive for the constrained franchisee to channel its resources only into the franchisor's system.

The franchisee's dilemma can obviously be capitalized upon by the franchisor. The franchisor can raise capital not only through new franchisees coming into the system but by offering franchises to its present captive franchise community who possess additional investable capital. If these existing franchisees have agreed to previously instituted restrictive covenants, the franchisor can now unreasonably exploit these limitations by offering new franchises at lower rates of return.⁴⁸ Indeed, the threat of being disapproved for expansion within the franchisor's system further diminishes, either explicitly or implicitly, the franchisees ability to bargain at arms length and may result in the franchisee agreeing to business or contractual terms which may not have been acceptable in the first instance. For example, the franchisee whose business expansion options have been greatly restricted both within and without the franchisor's system may have little real alternative but to refrain from any business expansion or to request the right to establish an additional franchised unit. The franchisor may take advantage of the situation and grant this request only in exchange for the franchisee accepting a less desirable location or possibly executing a more onerous franchise agreement for that additional unit or giving some other concession.

2. Reduction in the Number of Competing Franchisors.

The second area in which the anti-competitive effects of restrictive covenants are likely to surface is in the market for licensing franchisees, that is, in the competition among franchisors to sell their franchises to potential franchisees. These sales consist largely of the granting a bundle of intangible assets such as trademarks, service marks, training, on-going managerial advice, recipes, and the like — which the franchisee employs in the production and marketing of his goods and services. The market value of these assets will depend upon

⁴⁸ The underlying reason for this is that restrictive covenants give the franchisor, as purchaser of the franchisee's inputs, an enhanced degree of monopoly power, a phenomenon known as 'monopsony'. When monopsony power is vested in a buyer, it can be expected that the buyer will attempt to exploit this advantage by lowering the price which is paid for the thing being purchased. By limiting the scope of possible expansion for a franchisee, restrictive covenants reduce the number of potential buyers of the franchisee's inputs. The parent franchisor becomes the only potential outlet for the franchisee who wants to expand within a similar line of business, thus creating the possibility for monopsonistic exploitation. For a readable analysis of monopsony power see E. Mansfield, *Microeconomics: Theory and Applications*, New York: W. W. Norton & Company, 392-400 (4th ed. 1982).

the profitability of the franchises in the system, which in turn will tend to be affected by the number of competing franchisors in a given market. The entry of new franchisors into the market can be expected to lower the selling price of the assets of existing franchisors.

However, restrictive covenants will tend to limit entry of new franchisors in two ways. On the one hand, potential franchisors find the supply of qualified franchisee candidates reduced and thus the cost of licensing franchisees higher because of existing restrictions on currently employed franchisees.⁴⁹ But in addition, successful franchisees who may have the desire and the means to establish their own franchise systems will be thwarted. This could be a potentially more important source of competition, for in the course of operating a franchise outlet or outlets, the franchisee not only accumulates experience pertinent to the retail level of the enterprise, but also will gain knowledge relevant to the operation and organization of general franchising system. Restrictive covenants effectively squelch potential competition for this course.

3. *Product market impact*

These input market restrictions discussed above in turn spill over and affect the production and sale of the final output of the franchise system, i.e., in the retail market in which franchisees sell their products or services. Restrictive covenants, by impeding resource mobility, directly limit the number of competing firms at the retail level. This serves the interest of the franchisor in that royalties collected from sales will be higher and the potential for larger initial franchise fees will be enhanced. Overall, it can be expected that consumers will pay higher prices for the output of any franchise system as a result of artificial market barriers.⁵⁰

⁴⁹ It should be noted that even without the restricted supply of potential franchisees it is likely that the costs of entering a market for new franchisors will be of an increasing nature; i.e., the cost of entry into the market tends to increase as more and more franchisors attempt to become established. There are several reasons for this to occur, but one of the more important ones will be the increased scarcity of desirable site locations, a factor which is often very important to the eventual profitability of a franchise. See R. Caves and W. Murphy II, *Southern Economic Journal*, 584 (1979).

⁵⁰ A rigorous analysis of this conclusion is beyond the scope of this paper, but it can be seen rather easily in intuitive terms. When entry of new firms into a market is restricted, existing firms will enjoy larger market demands for their output. Furthermore, as we have noted, restrictive covenants will tend to increase certain resource prices for franchisors. In combination each of these factors contributes to higher product cost for final consumers. For more details the interested reader may consult E. Mansfield, *supra* 311-26.

It would be wrong to leave the impression here, however, that the interests of franchisor and franchisee are entirely consonant with regard to competition at the retail level. Each party perceives benefits from restricting competition from firms outside their mutual system, but only the franchisee may want to limit competition from all sources, including intrabrand competition. Since the franchisor derives income from royalty, payments which are based on a percentage of gross sales of its franchisees, and from its initial franchise fee, it may well find it profitable to establish additional franchises to compete in the market of an existing franchise. Total sales of all franchise units may expand, to the benefit of the franchisor, while diluting the sales and profits of the respective retail outlets, to the detriment of the franchisees. Franchise agreements may or may not provide franchisees protection from this type of franchisor behavior.⁵¹

It should be noted that the anticompetitive affects of restrictive covenants add to existing "natural" barriers to competition in the various markets. In some cases, the initial size of the investment may limit entry into the market. Many times successful competition may require the establishment of a widely known and respected brand image in the minds of consumers, a process which is time consuming and expensive. In other instances, site location may be critical to the success of potential competitors, and such sites may be unavailable or extremely costly. Restrictive covenants thus reinforce barriers to

⁵¹ Franchisor behavior in this regard can be expected to vary depending upon the prevalence of company owned or operated outlets in an area. Where such outlets dominate, the franchisor will tend to limit the number of outlets in order to try to preserve or maximize the profits of these establishments, since in this case the profits of the outlets directly contribute to the profits of the franchisor. Where independent franchisees dominate, the franchisor may be prone to increase the number of outlets in order to increase overall sales, since in this instance the profits of the franchisor are more dependent upon the gross sales of its outlets and not the profitability of the establishments.

competition and promote monopolistic tendencies which are more or less a common feature of the retail markets pertinent to franchise systems.⁵²

Conclusion

The traditional state contract law analysis of overly broad covenants not to compete does not, in the franchising context, adequately protect the franchisee or the public. A viable remedy to this situation can be found in §1 of the Sherman Act. The federal courts, when considering the antitrust implications of these restraints should evaluate the cumulative effect of their widespread use in the franchising industry. Additionally, the purpose and end sought by a franchisor in adopting such restraints are relevant antitrust factors which should be examined.

We have advocated an antitrust approach in this article which is consistent with the broad goals of the antitrust laws and with the established rule of reason analysis.

⁵² These inherent barriers to entry differ in degree, of course, depending upon the particular product or service involved. In some instances these barriers arise in association with the process of 'product differentiation' which is prevalent in these types of markets. Product differentiation occurs when goods or services tend to be close substitutes for one another, but firms engage in activities to make their products appear different than those of their competitors. There are many ways to try to accomplish this, including advertising, new product development, site location, packaging, and the like. These activities are undertaken not only to stimulate demand for their output, but also to try to insulate the firm from actions by its competitors. One result of this process is that entry is made more difficult and costly simply because any new competitor will necessarily have to engage in similar activities in order to become established and to compete effectively. Another potential source of inherent entry barriers may be associated with so-called 'economies of scale'. That is, at some stage or stage of the total production and distribution system, there may be cost advantages which accrue to the large firm. New competitors find it difficult to compete due to their initial disadvantage of small size.

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COMMENTARY

Computer Software In Europe And The United States: Is It Patentable Subject Matter?

Abstract

In Europe, as in the United States, government and industry have been struggling with the problem of protecting computer software. The methods of protection available can roughly be divided into three areas: patent, trade secret and copyright. In this commentary I shall not be debating the relative merits of each area but will be concentrating on the use of the new European patent system to protect computer software in Europe.

It is central to my thesis that the U.S. practice in this area is quite influential in the development of statutory and decisional law in European Economic Community (EEC) member nations. Given that the national laws of the EEC member nations will in large measure determine the substantive law of the patentability of computer software, U.S. practice in this area, by implication, will help shape Community law upon the adoption of the Community Patent Convention.

I. The New Patent Scheme In Europe

The new European system of patent protection consists of three main elements or subsystems:

1. The European patent system created by the European Patent Convention, adopted at Munich in 1973 (The European Convention);
2. The Common Market patent system created by the Community Patent Convention, adopted at Luxembourg in 1975 (The Community Convention); and
3. The harmonization of the national patent systems in Europe.

The European patent leads to a bundle of national patents with effects and rights having their substantive legal basis in the national laws of the individual contracting states. The European Convention aims at granting "European Patents" which are issued by the European Patent Office in Munich and valid for the territory of all the contracting states. The contracting states include some European nations which are not members of the EEC. This Convention regulates in principle only the conditions for obtaining rights in patents having such a supranational European validity. The European Convention does not restrict the possibility for the contracting states to have their own patent office issuing national patents under the conditions set out in national law.

The coming into effect of the Community Convention has been delayed due to constitutional difficulties in Denmark and Ireland. When the Community Convention is ratified by all members of the EEC, the result will be a unitary system for patent protection in the EEC. As one commentator has stated:

"The rules of the Luxembourg (Community) Convention take over where the rules of the Munich (European) Convention leave off, after the grant of the European patent. Its objective is to prevent the dismemberment of the European bundle patent granted in Munich for the Common Market. Accordingly, it transforms a part of that bundle into a unitary, so-called Community patent for the EEC countries. This patent enjoys uniform protection in all EEC countries and cannot be used to split up the Common Market. It can only be filed, granted, transferred, and cancelled for the whole territory of all the member states of the Common Market.

Bier, *The European Patent System*, 14 Vand. J. Transnat'l L. 1, 6 (Winter 1981).

The third element has been undertaken, without any legal compulsion to do so, in an effort to adapt member nations national patent legislations to the main rules of the European Convention, and, to a large extent, to the rules of the Community Convention. The recently amended patent laws of Denmark, France, the Federal Republic of Germany, Italy and the United Kingdom are in this vein. G. Kolle, *The Legal Protection of Computer Software* 30-64 (Hugh Brett ed. 1981). In many cases the legislation in EEC member nations has adopted the provisions of these two Conventions word for word.

II. Patent Protection Of Computer Software In Europe

In Europe the patent protection afforded computer software depends first on whether it is statutory subject matter, and secondly on how the claims are drafted if computer software is involved in an invention.

Article 52 of the European Convention defines patentable inventions as follows:

- (1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step;
- (2) The following in particular shall not be regarded as inventions within the meaning of §1:

...

- (c) schemes, rules and methods of performing mental acts, playing games or doing business, and programs for computers;
- (3) The provisions of §2 shall exclude patentability of the subject matter or activities referred to in those provisions only to the extent to which a European patent application or European patent relates to such subject matter or activities as such.

The provisions of Art. 52(1) include three preconditions to the grant of a patent: 'susceptible of industrial application', 'new' and 'inventive step'. It is the precondition of 'industrial application' which, like the U.S. practice under 35 U.S.C. §101, determines what is patentable subject matter. For the purposes of the European Convention, 'industrial application' is found if the invention can be manufactured or used in any kind of industry, including agriculture. Ramey, *Patentability of Software and Firmware*, 78 Pat. and T.M. Rev. 99 (1980).

It should be noted that Art. 52(2) (c) specifically provides that computer programs are not patentable subject matter. The effect of the 'as such' language in Art. 52(3), however, is to make it possible to refer to computer software in a patent application without automatically rendering it unpatentable subject matter. I will examine this problem in more detail in my discussion of national laws, below.

The signatories to the European Convention are taking legislative steps to ensure their laws conform to the provisions of that convention without the compulsion to do so. For instance, Article 6 of the French law of patents, according to the bill which was put before the National Assembly by M. Foyer and of which the law promulgated on July 13, 1978 was born, has borrowed from the European Convention the very terms of its Art. 52. Ramey, *supra* at 106. This brings into substantial alignment the substantive laws of patentability in the

French and European patent systems.

The national laws in other EEC member nations are, and will continue to be, brought into alignment with Art. 52 of the European Convention.

Guidelines have been developed for substantive examination of patent applications under the European convention. [1978] Guidelines for Examination in the European Patent Office, adopted by the President of the EPO with effect from 1 June 1978 (looseleaf edition). Despite the guidelines it remains speculative as to what the practice in the EPO will be with respect to computer software. It is likely that the EPO will look to the practice in the member states of the European Convention for guidance. See Kolle, *supra* at 43-44. Accordingly, I will examine the state of the law in this area in several member nations.

United Kingdom

As under the European Convention, computer programs, as such, are specifically excluded from patent protection. Section 1(2) (c) of the 1977 Patents Act.

Up to the enactment of the 1977 Patents Act, The United Kingdom had the most liberal practice with respect to the patentability of computer software. It is unclear, however, whether the Patent Court will continue this practice.

Under the 1949 Patents Act the UK Patent Office decided *Slee and Harris's Application*, [1966] RPC 194, [1966] FSR 51, in which a computer programmed in such a way as to solve a specific problem and the programming means for controlling the computer so that it effected the desired process were patentable subject matter. The specific holding was that a programmed computer could be regarded as a claim to a machine modified in a particular way.

Recent decisions have allowed claims to methods involving the use of a programmed computer and to computer programs having the effect of controlling computers to operate in a particular way, where such programs are embodied in physical form. See *Burroughs' Application*, [1974] RPC 147, [1973] FSR 439. These cases are arguably consistent with the 'as such' language in Section 1 (2)(c) of the 1977 Patents Act in that what is being claimed is not a computer program *per se*.

France

In contrast to the practice in the UK, the test for the patentability of computer software in France is quite a rigid one as laid down by the French Supreme court. *Mobil Oil Corporation v. I.N.P.I.*, Supreme

Court, Commercial Division, 28-5-1975, Judgment No. 380; PIBD 1975, 155, III, at 349. The subject matter of that case referred to both a process and an apparatus for selecting the proper pigments to go into a mix to reach the desired color. The court found that the subject matter of the patent, a computer program which made the pigment selection, was lacking in technical character. The Supreme Court distinguished between claims which relate to a data processing method applied to or implemented by a computer and claims which read exclusively on a program proper. If the latter is the case, there is no patentable subject matter.

As discussed above, the statutory scheme for the substantive laws of patentability is the same in France and the European Patent Office.

Netherlands

Computer software is not patentable, nor is a combination of a computer with a computer program per a decision of the Netherlands Patent office Board of Appeals reported at [1971] BIE 54, [1971] 2 IIC 308. The technology involved was telephone switching equipment. The invention was to be carried out by programming a computer to make telephone connections on a selective basis between a plurality of lines. The Board took a rather pragmatic, although not very useful approach. They said that a reprogrammed computer does not create a new, patentable, device. A hardware embodiment of the same program would, however, be patentable subject matter.

The result is that a process claim is not patentable subject matter when the process does no more than control known computer equipment. Likewise a product claim is not patentable subject matter if it is no more than known computer hardware programmed in a new way.

Italy

As with pharmaceuticals, computer software is not considered patentable subject matter.

Federal Republic of Germany

Per §1 of the Patents Act which came into force on 1 January 1978, computer programs are not patentable *per se*.

It is interesting to note from the outset that the invention held by the U.S. Supreme Court to be not patentable in *Gottschalk v. Benson* (see *infra*, section III) was held patentable by the German Federal Patent Court. [1973] Mitt 171, [1974] 5 IIC 211. An excerpt of the

decision reads in translation as follows:

1. A teaching for planned activity is patentable if governable forces of nature, viz. the physical properties of the employed circuits of a data processing system, are used and a causally predictable success is achieved. . . . It is not important whether the circuit is permanently wired or whether the circuit connections are established respectively when necessary by means of a control mechanism.
2. No objections are engendered with respect to the statement of the sequence of the run of individual steps in the data processing system within the scope of a process claim, since a change of the physical states of the objects treated, viz. the structural groups of the data processing system, occurs sequentially when doing so.

Patent Law and Practice of the Major European Countries, Vol. I, d16-d17 (Seminar Services, S.A. 1976) [hereinafter cited as *European Patent Law*]

This, more than the U.S. Supreme Court decision in *Benson* and unlike the practice in the Netherlands, recognizes the reality that each time a computer program is run it "re-engineers" the circuit connections within the CPU as readily as if the hard wiring of the CPU were changed each time. The effect of this holding is to grant patentability to computer programs with industrial application, even if their only application is in connection with digital computers.

Notwithstanding its appreciation for the realities of computer software design and application, the decision has been somewhat narrowed by subsequent case law. See Ramey at 118-119; Kolle at 51-55. These more recent holdings have limited the patentability of software, holding that patentable subject matter does not exist where the use of software leads to the ordinary use of computers known in structure and design. See Kolle, *supra* at 53.

A recent case reported at [1981] GRUR 39-41, [1981] 7 EIPR D-135 is instructive. The application related to a method of measuring rolled rods behind continuously working rolling sheets. The main claim related to such measuring where results were fed to a known computer. The computer was programmed so that the desired lengths of rods were obtained. The Federal Supreme Court found that the claim was not patentable subject matter as it was for a computer pro-

gram to be used in connection with a known computer. Such was the holding despite the fact that the computer had immediate feedback to the process so as to control it and to obtain the desired lengths of rod.

The result of these decisions of the Federal Supreme Court has been that "computer programs . . . constitute patentable subject matter only if they require and disclose a new, inventive structure of data processing equipment, or if they convey the instruction how to use such equipment in a new, previously not customary and non-obvious way." Kolle, *supra* at 54.

III. Patent Protection Of Computer Software In The United States

An excellent discussion of this topic can be found in Davidson *Protecting Computer Software: A Comprehensive Analysis*, 23 *Jurimetrics* 337 (Summer 1983).

The starting point for a determination of the patentability of computer software in the United States is the question of whether it is patentable subject matter under the patent laws. 35 U.S.C. §101 states that patentable inventions must relate to a "process, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . ." The term process is further defined as a "process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." 35 U.S.C. §100 (b). The critical cases dealing with the patentability of software involve an interpretation of these provisions.

The seminal cases interpreting 35 U.S.C. §101 for computer software are the Supreme Court decisions in *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Parker v. Flook*, 437 U.S. 584 (1978); and *Diamond v. Diehr*, 450 U.S. 175 (1981) and the Court of Customs and Patent Appeals (CCPA) cases of *In re Freeman*, 573 F.2d 1237 (CCPA 1978) and *In re Walter*, 618 F.2d 758 (CCPA 1980). These cases, and their holdings, are reviewed below.

The invention in *Benson* related to a conversion method allowing a numeral represented in binary-coded decimal form to be converted into pure binary form. The Supreme Court held this invention to be outside the purview of 35 U.S.C. §101, largely on the basis that the invention could be performed by hand or even mentally by a competent person without the aid of a computer. As what was claimed was the algorithm or formula to perform the transformation, there was no patentable subject matter.

The Supreme Court in *Flook* reiterated this position in finding that

a process, having its sole novel element a mathematical formula, was not statutory subject matter. The process was for refining hydrocarbons. The invention itself was a mathematical formula and the application of the solution of that formula to the up-dating of the limit values of certain process parameters. There was, in the Court's language, some "insignificant post-solution activity" in that the operator was to shut down the process when the parameter limit was reached. The Court found that this activity did not make an unpatentable algorithm claim patentable.

Just before the decision in *Flook*, the CCPA, in *In re Freeman* upheld claims relating to computerized control of typesetting based upon a two-step test:

First, it must be determined whether the claim directly or indirectly recites an "algorithm" in the *Benson* sense of that term, for a claim which fails even to recite an algorithm clearly cannot wholly preempt an algorithm. Second, the claim must be further analyzed to ascertain whether in its entirety it wholly preempts that algorithm.

In re Freeman, 573 F.2d at 1245.

After *Flook* the CCPA broadened and clarified the second step in the *Freeman* test in the case of *In re Walter* as follows:

If it appears that the mathematical algorithm is implemented in a specific manner to define structural relationships between the physical elements of the claim (in apparatus claims) or to refine or limit claim steps (in process claims), the claim being otherwise statutory, the claim passes muster under § 101. If, however, the mathematical algorithm is merely presented and solved by the claimed invention, as was the case in *Benson* and *Flook*, and is not applied in any manner to physical elements or process steps, no amount of post-solution activity will render the claim statutory; nor is it saved by a preamble merely reciting the field of use of the mathematical algorithm.

In Re Walter, 618 F2d at 767.

The Supreme Court followed this approach in *Diamond v. Diehr*. The computer program in *Diehr* was used to monitor, time and interrupt the curing process for rubber. Another notable aspect of this case was the narrow definition given to the word "algorithm". The majority interpreted it to mean a procedure for solving a given type of prob-

lem, not following the minority approach of defining algorithm to be synonymous with computer program.

The U.S. Patent and Trademark Office has issued guidelines for determining when mathematical algorithms or computer programs are patentable subject matter. [1981] Manual of Patent Examining Procedures, §2110. These guidelines follow the Freeman-Walter two-step approach as described above.

IV. Conclusion

From the liberal practice in the UK to the more restrictive attitudes that seem to prevail on the continent, the answer to the question of whether software constitutes patentable subject matter lies on a spectrum within the EEC. I believe that the Freeman-Walter approach in U.S. practice would provide a workable compromise.

What is required to accomplish this goal is the final step in the harmonization of the patent laws among the various nations within the EEC. The patent statutes in the EEC member nations now, or soon will, conform with each other and with the European Convention. In addition the 'as such' language in these laws makes them consistent with the Freeman-Walter approach. These statutes, however, have gone as far as they can toward establishing harmony. The courts must now complete the process.

By way of example consider the *Diehr* case which was found to contain patentable subject matter by the U.S. Supreme Court.

The practice in Germany would likely find the invention in *Diehr* to be unpatentable based on the notion that the claimed process brought about no structural adjustments to the computer nor was the computer used in a new, non-obvious way. At the other extreme is the practice in the UK which could, based on the case law, find the computer programmed with the algorithm in the *Diehr* case to be patentable subject matter, were such program to be embodied in physical form.

The practice in the United States provides a useful tool in this judicial process of creating harmony for three reasons. First, the statutory scheme in the U.S.A., as interpreted by the U.S. Supreme Court and the CCPA, is consistent with the statutory scheme under the European Convention with respect to patentability of software. Second, there is a great body of case law built up in the United States which can provide a guidance to national courts in the EEC looking to implement Art. 52 of the European Convention when considering computer software. Third, the U.S. approach seems to provide a middle ground in the European practice in this area.

The entry into force of the Community Convention will provide a unitary patent system to EEC member nations. One component of this system will be the patentability of computer software. It is important to the strength of such a system that before it comes into being there be some unanimity in the approach towards computer software. US practice in this area provides some useful and appropriate guidance.

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Juris Doctor
Franklin Pierce Law Center, 1984

BOOK REVIEW

Bibliographic Information

WHALE, R.F. and PHILLIPS, Jeremy J., *WHALE ON COPYRIGHT*. 3d ed. 291 pp. Index (ESC Pub. Ltd., Oxford, 1983).

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Contents

Primarily a discussion of the evolution of copyright and related law in the United Kingdom. However, there are a number of chapters dealing with other topics, *e.g.*, the theory of the authors' right, international copyright, and copyright in the Republic of Ireland. There is also a chapter on the U.S. law.

Review

Notwithstanding an occasional convoluted sentence, the book is generally well written. One would not have to be a lawyer, much less a copyright expert, to find it useful. Americans knowledgeable about U.S. copyright law will find much of interest. Because the book tracks not only the historical development of copyright in Great Britain (from 1496), but also that of international conventions, a thoughtful reader will get more than an occasional insight into the U.S. law.¹ Moreover, one can learn about topics which are likely to arise in the future, *e.g.*, the authors' "moral" right² or the U.K. law affording authors' compensation based on the frequency with which their books are borrowed from public libraries (the *source* of the compensation, however, is not clear).³

It should be mentioned, however, that the discussion of U.S. law, not surprisingly, leaves a bit to be desired. For experts, there will be no problem, but others should be on the alert. For example, the authors failed to catch the 1980 amendment to §117 (dealing with computer programs).⁴ Also, the discussion of the "notorious" manufacturing clause fails to point out why it would cause problems, *e.g.*, for British authors.⁵ Consequently, its extension to 1986 would not

¹ Not only is the early English law the antecedent of our law, but also the international situation has affected and will continue to affect its direction.

² *WHALE, e.g.*, at 21-28; 239-240.

³ *Id.*, at 241-243.

⁴ *Id.*, at 224. Compare Pub L. 96-517 §10(b), 94 Stat. 3028.

⁵ *Id.*, at 221-222. See 17 U.S.C. §601(b)(1); indeed, even U.S. nationals who have been out of the country more than a year are exempted from having to publish in the U.S.A. or Canada.

seem to be as egregious as the authors suggest.⁶ Finally, while one could quarrel with their discussion of “formalities” under the U.S. law,⁷ their ultimate conclusion is sound. It is better to register promptly than to wait.⁸

Nitpicking aside, the book is *highly recommended*. Even if the reader is not interested in U.K. or other foreign copyright law, as such, he or she will nevertheless find themselves with an enhanced understanding of copyright in general.

Reviewer

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⁶ *Id.*, the extension appears in Pub. L. 97-215, 96 Stat. 178 (1982).

⁷ Especially at 9, but misimpressions are corrected at 214-215.

⁸ As they point out, §412 (*not* §112) works a forfeiture of *statutory* damages (*not* damages) and attorney’s fees unless a work is registered within three months of first publication. Also, under §411 (*not* 114), registration (or at least *attempted* registration) is necessary to bringing an infringement action. These provisions make the language of §408(a) [*“Registration Permissive (except when notice is omitted) . . . such registration is not a condition of copyright protection.”*] misleading at best. *See also* §407; while subsection (a) appears to make deposit obligatory, no sanctions attach until failure to respond to a demand under subsection (d). Moreover, persons concerned about hardships should note that, under §407(c), the Register has the power to exempt two categories of work from deposit; perhaps that section should be expanded to allow exemption for works of foreign nationals.

TOWARD ECONOMIC RECOVERY: University/Industry Cooperation*

JOHN E. MAURER**

Let me first say, Bob (Robert H. Rines, President of Franklin Pierce Law Center), that I'm pleased to be with this group today. What I would call the meeting of minds about the relationships between industry and academia. When Bob Shaw first called me and asked me to be on the program and to talk about Monsanto's relationship with academia, I did some thinking about my relationship with universities. As a lawyer for Monsanto, I have certainly had dealings with many universities, both directly and indirectly.

As a father, my three children have led me into a different kind of association with universities, certainly from a completely different perspective. And of course, years ago I was a student.

As I thought about these various roles that I've been involved in over the years, I noted to myself that there was a common thread. In each case the relationship was based on the mutual trust that both parties had something to offer, and certainly that both parties had something to gain from the association. That is critical to what we are talking about today.

Furthermore, two of my children found out after they graduated from college that there was something else that they were seeking that they did not quite find from their first round of education. So they went back to school. Many of you, most of you, have done the same thing.

That is not very different from what Monsanto is trying to do. It is really the motivation in a sense for forming collaborative relationships

*There are four articles in this issue taken from talks at a conference held at the Massachusetts Institute of Technology in April 1983, dealing with university/industry interaction.

**General Patent Counsel, Monsanto Company.

with excellent universities around the country. We have discovered that there is something that we need to know in order to do our job better. As simple as that may sound, however, it was not nearly as easy for us to do it as you might think.

We have all read and heard a great deal about the internal problems with which universities have struggled in the last few years and the threat to academic freedom. However, there has not been very much emphasis on the "price" which companies must pay in order to "go back to school." At Monsanto, we had to do a great deal of soul searching before we could seriously consider collaboration with an academic institution on the levels that we're going to talk about.

We had three main problems, or hurdles, as I'll call them. One was the Patent Department, the second was the Board of Directors, and the third was our Research and Development staff.

First, let me talk about the Patent Department. Certainly I can speak first hand. The whole issue of secrecy is essential to whether a collaboration can work. From the university's point of view, the secrecy issue appears in a need for publication. The scientist needs to be able to attend meetings and to talk about his (or her) work. That is where he gets his recognition, and where he gets some of his reward.

From the perspective of the Patent Department, and our financial managers as well, however, the issue is threatening. When a breakthrough occurs, and is publicized before we have time to secure an adequate patent position, any advantage is lost. If Monsanto invests a great deal of money financing a breakthrough, such disclosure will give other companies an immediate access to the discovery. The invention, after all, is the least expensive part of the innovation process. For every dollar invested in an invention, many hundreds of dollars will be spent before that invention ever becomes a marketplace item. Therefore, the big risk for a company like Monsanto, and I am sure all other companies, is not in supporting research.

The risk is when we, as a company, decide to pour concrete and build manufacturing plants to produce a new material. Without adequate patent protection, no company can afford, in my judgment, to invest the additional funds which are required to bring an invention to commercialization. However, we were not sure that we could get the kind of protection we thought we needed from an academic collaboration.

Let me turn to the next hurdle, the Board of Directors. The big question still is, and always will be with regard to research, can we guarantee the shareholders a program that will be worthwhile in terms of their investment in the corporation. The risk is high for any

new research, but it certainly is higher with outside collaboration for reasons of which we all are aware.

Thus, we have to make a strong justification for major research expenditures. If we cannot prove the potential value in such an investment, the Board simply will not authorize us to expend the money. This policy certainly applies for research inside the corporation, as well as for that conducted outside.

Finally, we have to face the question of internal problems with our own R and D staff. This is a point that is often overlooked. Industrial scientists work for a salary regardless of their contribution to the company. Inventiveness is rewarded with various incentives; promotion, higher salary, and, occasionally, a prize. Nonetheless, the company scientist is generally not likely to become rich. In many academic institutions, on the other hand, an individual scientist is entitled to royalties on any inventions he or she discovers. It does not take too much imagination to see that in a collaboration, a significantly different reward for the various scientists could lead to major morale problems within the company.

Moreover, the very existence of an outside research project has the potential for causing problems. Some R&D projects may be turned down, and money put into an institution outside of the company. Because of the limited amount of resources available, a certain amount of persuasiveness will be required to convince the company scientist that that is the right thing to do.

So, we have three things that we are constantly struggling with; secrecy, investment value, and morale. Certainly, if one of those gets off the track, the whole project would be off the track.

What encouraged us to go ahead? In the first place academic institutions often possess skills that industry sees as extremely valuable. Skills too valuable to wait the many years it takes to build our own internal expertise. Secondly, at Monsanto we had already had experience in small collaborative programs which gave us some idea of new arrangements that could work and where problems might arise. We knew we had to have partners with whom we could place our trust. We wanted a real collaboration, not just someone hired to do a job.

In the early 1970's, Monsanto scientists began to see the value of building up an expertise in the biological sciences beyond what we had already developed on our own in the agricultural chemical field. Also it became apparent to our senior research management that we wanted to know even more about bio-technology and that we should accelerate the process of learning. The result was the 1974 agreement

with Harvard Medical School through which Monsanto opened a window on biology. The agreement, which runs for twelve years, is concerned generally with seeking the molecular basis for organ development. The principal investigator had been a Monsanto consultant. The program involves collaborative work in Monsanto laboratories as well as in Harvard's laboratories.

As time progressed, we acknowledged that Monsanto still wanted to play a bigger role in developing the commercial aspects of biotechnology. In 1979 we announced the formation of a molecular biology staff. We also entered into a joint program at Genentech to develop animal growth hormones. Then we began to investigate ways we might use bio-technology as a vehicle to enter the health care field.

As a result, in May of 1982 we announced our five year \$23,500,000 agreement with Washington University Medical School for biotechnology research. The purpose of that agreement is to fund basic research and to make discoveries which we hope will ultimately lead to new therapeutic materials useful in the health care field.

Based on that background, a discussion of the development of the Washington University agreement illustrates a very important point. In order to create the framework for this collaboration with Washington University, Monsanto drew on its past experience and another agreement with that particular university dating back to the 1960's. Back then Monsanto scientists collaborated with Washington University on a program that was funded by the Office of Naval Research in the area of high performance composite materials. Through that early pioneering collaboration, we developed an organizational confidence and trust that this arrangement could work for the mutual advantage of the parties.

And yet, with all of that background, the Washington University agreement was only developed after two years of extensive discussions and negotiations, including, before it was signed, a two and a half day science retreat for the University and Monsanto scientists who would be involved in the proposed project. Although I can not stand here today and tell you that we are positive the program will work, I can tell you that we have done everything we could think of, at this point, to make sure that it works.

Building on those experiences over time, we have developed some broad guidelines that may be helpful in creating a truly cooperative relationship. The guidelines are based on a fairly good understanding of the two cultures that are involved, corporate and academic, and the steps taken to preserve those particular cultures. The guiding prin-

ciples for formalizing a relationship is that it must serve our own needs at Monsanto, but cannot alter the culture of the university. I offer a recommendation at this point.

There is no best way to arrange a relationship between industry and the university. I can only describe guidelines which seem to work for us.

The most obvious issue, and one requiring great sensitivity on both sides, is the tradeoff between security for patent purposes and the right to publish. In my judgment, this is not an area where an iron-clad rule is appropriate. Most people would agree that there seems to be some initial period, many choose 30 days, within which the sponsor has an opportunity to review a proposed publication for patentable subject matter. But, there also needs to be some reasonable mechanism for delaying publication when necessary.

Second, the arrangement should be between institutions, rather than individuals, whenever possible. This is the way it is between Monsanto and Washington University. It prevents the kind of distortion that happens when one individual receives large sums of money which are not available to his colleagues. Beneficial to that particular relationship is the fact that the Washington University Medical School faculty do not receive personal gain from patents or individual effort. With our arrangement, if major royalties should accrue to the University as a result of the work, one third of the royalties will go to Washington University, one third to the medical school, and one third to the individual principal investigators laboratory, but not to an investigator as such.

This situation has an obvious advantage for Monsanto as well as for the University where faculty members remain on a par whether they are working on Monsanto funded programs, or in other areas. They will also remain on an equal level with Monsanto scientists with whom they are collaborating. The morale problem I mentioned earlier would be a real issue, in our judgment, if individual Monsanto scientists were expected to collaborate on work which might make their associates rich, but would only be business as usual for them.

As a further guideline, I would urge any of you who are contemplating such an arrangement to make sure that it is a real partnership to which both parties contribute. Neither party will be happy with such an arrangement unless the industry sponsor has in-house skills in the particular area of the agreement. And I might add at this point, that this is one way of minimizing what might appear to be a harsh type of thing, setting short time periods in which you have to review publications for protectable inventions. When the people from the corporate

sponsor are involved with the people from the university and are aware of current activity, they should be able to anticipate developments which offer patentable possibilities. A publication should not be the first time such activity is disclosed. This lead time assures that the agreement is working properly.

As another guideline, we favor the concept of an oversight committee which administers the funds for the individual research projects. In the case of Monsanto's agreement with Washington University, the committee is made up of four representatives from Monsanto, and four representatives from the University. By agreement, a specific research project will not go forward unless both Monsanto and the University endorse it. Washington University, under this arrangement, defines the kind of research projects in which it wishes to engage. Monsanto selects from that list of options the projects in which it has an interest. By this procedure, Monsanto does not advise the University of research topics, but rather which aspects of those topics seem worthwhile to Monsanto's needs.

Last, to assure scientific credibility of a program, Monsanto recognizes the need for scientific review. A strong commitment to peer review by outside scientific experts insures both parties that a program is progressing as planned. The science, which is the whole aim of the program, should be addressed by objective, informed, outsiders at regular intervals. Such review provides assurance to university officials that their efforts are of proper quality. Further, they reassure a board of directors that the work is progressing as it should, since the central purpose of the program is to increase the flow of novel ideas to institutions such as Monsanto.

In the case of our agreement with Washington University, the driving force for the collaboration is the biological revolution. The fact that changes are occurring faster in bio-technology than a company like ours can keep up with during the normal year-to-year recruiting schedule, results in the necessity for retooling of older technologies and skills in companies like Monsanto. Relationships with academic institutions and departments speed the corporate ability to effect this retooling. By "piggybacking" on university skills as we build our own skills, we increase our ability to bring important new products to people of the world.

If Monsanto's relationships with universities work the way we believe they will, and if we at Monsanto are able to mingle our knowledge with that of a university in a truly synergistic way, it will not just be Monsanto and the university which benefit from this relationship, but certainly society as a whole. A successful collaboration can

not only bring new products to consumers but have another desired effect as well. America's technological advantage is being challenged as we find ourselves competing in the international arena with countries such as Japan, where research is an industry-wide cooperative effort. We need to counterbalance that source of competition.

In the United States, such cooperation is difficult because of the various legal restraints on companies to collaborate. However, by combining the skill bases of universities and industry, given the enormous scientific skills of the university, American companies can be more competitive in the international arena. Obviously, although we cannot have and, certainly from our standpoint, do not want to have a West German or Japanese type of formal relationship, we can have one that is uniquely American. Under the proper circumstances, universities and industry are natural partners. The result of such partnership holds significant promise for both of us.

What I have said today is an advocacy for self-interest for both sides. Unless a relationship brings something to both parties, it certainly will not flourish and probably not survive. Both institutions have a very selfish reason for wanting this relationship to work. The universities need funding and need an outlet for key research ideas. Industry, on the other hand, needs to catch up with new scientific advances and, more than that, wants to be the beneficiary of other emerging ideas, techniques and technologies in the future.

Universities and industry have a common goal to serve as mutual catalysts for scientific advancement. While a university has available many skills, a company like Monsanto also has a formidable array of scientific talent, special skills and facilities. If you remember that a catalyst is something which alters the rate of reaction but is not itself degraded or consumed in the process, it is clear that mutual catalysis is the ultimate purpose behind any collaboration between industry and academia. Thank you.

THOMAS I. O'BRIEN*

First of all I want to thank Bob Shaw for inviting me here today and, even more so, I want to thank him for setting up the schedule as he did by putting us at the end of the schedule.

Although the subject today is toward economic recovery, a much broader subject of the interface between academia and industry was addressed. This interface involves all sorts of cooperation, objectives and sizes of funding. Cooperation between academia and industry is not something new. As stated by Jim Morrison (Professor James D. Morrison, University of New Hampshire), the cycle may be repeating itself today. Endowments, grants, support from foundations funded by industry, and sponsorships are examples of cooperation over the years. Other examples are consulting arrangements and, more recently, a number of institutes have been formed through the joint efforts of academia and industry support, such as the Whitehead Institute at MIT for bio-medical research.

Furthermore, the making of inventions by academic researchers is not new. Many of these inventions have been commercialized, and many of the scientists have benefited from those inventions and have become entrepreneurs in their own right within the last generation. Certainly, invention is not new with the university. What is truly new is innovation as the exploitation and commercialization of invention. Innovation is entrepreneurial in nature. Such activity, as currently being undertaken by the academic community, is something that is new, although some universities have been involved in entrepreneurial activities for at least 20-25 years. For those universities pursuing entrepreneurship, such activity is fundamentally driven by the current economic situation. By looking for additional funding, universities are trying to realize some of the benefits of their own research through greater return on their investment.

Today, however, the problem is the basic lack of infrastructure on the campuses to coordinate entrepreneurial activity. First, a university must decide whether it really wants to enter this activity. At a colloquium held for the New York City Bar Association last year, Dr. Steven Muller, President of Johns Hopkins University,** indicated

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that as far as Johns Hopkins was concerned, he did not want to tamper with the basic function of the university as a teaching institution. He felt that once entrepreneurial associations and affiliations entered as part of the university, the basic teaching function would be undermined. He was against direct university participation.

However, the infrastructure that is available in industry is certainly prepared to handle the types of problems that come up once the innovation process is entered. Based on my own personal experience and those of most of the people in this business, industry does not really have a problem in dealing with a university. In contrast, the universities, because of a lack of infrastructure, have had a fundamental problem in dealing with industry. In trying to deal with new concepts and new problems that they were not previously aware of, universities have had the perception that such problems are antithetical to their own basic philosophy. They are not really. Dealing with these problems is something new to the university and, without having the assistance offered by industry, they find it very difficult to reach a solution. This is particularly true in the area of patents.

For some reason, patents seem to be construed as a very esoteric area familiar only to people who become involved with them, but distant and unattainable to people who are outside the field. Perhaps patents are not only unattainable but also lacking in glamour. Further, patents seem to smack of being a monopoly, and nobody likes a monopoly or wants to deal with a monopoly. But, the role of patents in the innovative process is an extremely important driving force, inducing people to invest the money that is necessary to make the innovative process work.

The universities with infrastructure have the ability to deal with industry without difficulties. While the role of the patent lawyer in this infrastructure is only one role of many, it is worth briefly mentioning. Basically, the first role of the lawyer in the innovative process is to decide what he or she should do to try to protect an invention. Regardless of approach, there are only two ways of protecting invention, as a trade secret or as a patent. Interestingly, Dwight Bauman (Professor, Carnegie-Mellon University) suggested new types of government grants other than patents or quasi-patents that were not directly awarded on the basis of invention, but rather on the basis of improvements in marketing, or improvements in reducing costs and products. Although it is an interesting concept, I do not think it is entirely new, based on the history of classical grants by governments of the kinds of patents later abolished by the monopoly statutes passed in England in the sixteenth century. Nonetheless,

the role of the lawyer in the innovative process is to determine how to protect the property of his or her client.

Fundamentally, the patent is the better form of protection because it is a legally stronger right. The grant of a patent permits the patentee to exclude others from using his invention. The trade secret, however, is only good as long as it is secret. If somebody else develops it, they can use it freely. Another problem that arises, and is not readily recognized, is the problem of protecting an invention in a country other than the one in which the invention was made. Thus, the question becomes: what can be done with an invention in order to maintain the availability of legal protection? This is where a common misunderstanding arises with academic investigators. Such individuals do not realize the implications on patent protection of publication. Industry is not against publication, for it recognizes and accepts the fundamental essence of the patent system as a system of publication. Patents are indeed themselves publications. In fact there is not only publication of what was invented but the law of the United States also requires a description of the best way to practice the invention. That is a requirement far beyond what is needed, and usually included in, an academic paper. The patent must describe to the public the best way of performing the invention. As Bob Rines (President, Franklin Pierce Law Center) said earlier, the perceived conflict between publication by the academic community and patenting by the industrial community really does not exist as a fundamental problem. Of course, it exists as a time problem. What is to be published, when can it be published, and why must publication ever be delayed in order to file a patent application are all pertinent questions to an analysis of this time problem. The answer simply lies in the requirements of the laws governing the filing of a patent application. The laws in some countries bar the patenting of inventions published prior to the filing of a patent application. The patent law also requires complete information on the invention with adequate experimental data to support what is claimed as the invention. It is not industry that is against early publication; it is the patent laws of various countries that mandate against it, if patent protection is to be sought.

Apart from the patenting role the patent lawyer plays in innovation, his or her participation also extends into the licensing area. In the licensing area, it is the lawyer who performs the function of safeguarding the interest of his clients and of working out agreements with the party with whom the technology is either being transferred to, or transferred from. Another interest of the lawyer in the innova-

tion process is in the anti-trust area, referred to several times today. Basically, the principal issue in the anti-trust area in contracts between industry and academia is the nature of the collaboration on the commercial side. Currently, the attitude of the courts on anti-trust violation in this area is easing considerably. The Department of Justice in particular is easing considerably its views on the applicability of the anti-trust laws in respect to collaborative efforts in the United States in research and development.

Another recent development of interest in the law is in the area referred to by Alex Schwarzkopf (NSF); that is, the area is government funding of research. The development is the important change in the law relative to government funded research. This change should be one of the great stimulants to encouraging industry to work with academia in research. Part of the motivation for greater industry collaboration with academia is the effective reductions in R&D that have been made by the major industries in the United States over the last ten years. The amount of inflation-adjusted money that is being directed to R&D by industry is not growing at the same rate it grew in the 1950s and 60s. It is being reduced. Industry's attitude toward research has changed for various reasons. Over the same period of time, there has been great growth in government funded research, and the government has become a competitor to industry in research and development. But government-funded research has been notoriously unsuccessful in leading to much commercial innovation in technology in the United States, because industry has not had much interest in undertaking the financial risks of innovation without the assurance and security of exclusive proprietary positions on the new technology. Such positions have heretofore been unavailable under government owned patents and technology. The federal law has now been changed to permit universities and small businesses to retain title to inventions made under government funded research. This change in the law should be a tremendous boom to the university in respect to collaborations with industry, because, fundamentally, it provides that the university can secure exclusive proprietary positions on inventions made under government contracts.

Collaborations between academia and industry require that each situation be taken on its own merits. All factors that come into play cannot be reduced to a common denominator requiring all agreements arranged between industrial organizations and academic organizations to be the same. Agreements on joint research that are worked out between industrial organizations themselves are never the same or standard. The academic community is entering into the

same game of negotiating contracts with others, where each of those contracts is negotiated on its own merit. The question of what can be given and what can be taken is certainly going to be determined by the values or considerations given and taken. Certainly, the smaller the amount given, the more flexible industry will be. As the amount of money involved grows, so does industry inflexibility. This is just straight-forward negotiation.

The one last item that I'll mention is that Union Carbide does not have any major funding arrangements or affiliations with academia at this present time. We certainly have had over the years numerous small programs, sponsorships and grants, and I do not think we have ever had a problem in working out any of these arrangements with any university. However, since such collaborations were on a relatively small scale, there was considerable flexibility on our part. Basically, as far as the lawyer's role is concerned, industry is always looking for the same goals. Industry wants to make sure that there is enough time to try to obtain patents, and that its own proprietary information is protected if it is to be disclosed to the academic investigator.

PAULINE NEWMAN*

As one of the last persons on the program I have the opportunity to mention some issues that were not discussed this afternoon or this morning. Part of the reason they were not discussed is that we are an audience of the converted. While we have considered many forms of cooperation and collaboration involving government as well as industry with the academic world, we have not really discussed the accompanying problems. It has been my observation that the situation that prevails at Oxford, as Mr. Brett (Hugh Brett) mentioned, prevails very much in the academic world. At least, it is something that we in industry must be aware of, understand, and respect.

The primary role of the university, as I understand it, is to educate. This has traditionally included education in scientific methodology, which term I use in its broadest sense, to include the scientific information the research universities add to the nation's and the world's store of knowledge. Thus, education in scientific methodology encompasses the search for scientific and philosophical truth as part of and as the core of the educational process.

There are today many educators who are concerned about what they consider an unfortunate tilt in the education obligation of the university, away from the purity of the process. Educators in science draw a distinction between what they call basic and applied science. They argue that only basic, pure, science is the province of the university. This is not my personal view, and I believe that this narrow attitude is not supported by the history of science.

Historically, important scientific discoveries were often "applied" science, and were rendered immediately useful for human benefit. Many great scientific advances were made in the course of seeking solutions to practical problems — and there was no hesitancy at all about entering into the patent system. Pasteur, Lavoisier, Faraday, Edison, Benjamin Franklin saw, or sought, the practical value of their work, and acted for commercial as well as scientific gain. Thus, it seems to me that the purported conflict between the so-called purity of scientific achievement, and the taint of occupational profit that accompanies the kinds of industry/academic relationships we are dis-

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cussing today, represent artificial and misplaced values.

It is essential that the university face these questions, for as stated by Jack Maurer (see earlier Maurer remarks), this is a problem that the university must solve for itself. In the business world, we are doing what we have always done and must do: we are seeking to produce goods and services for which there is a need and a market, and we are seeking and must provide a sufficient return to justify the risk that goes with the commitment. By so doing, it is expected that industry will contribute to the wealth of the nation, and to technological growth — not only of this nation but throughout the world.

With this background, some questions require either solution or accommodation if we are to develop a beneficial relationship between industry and the academy. First, is industrial support of targeted academic research the best use of our industrial resources and academic resources? Are we diverting academic talent too far from the search for fundamental truth? If they do not search for it, who will? Could the work that we are talking about doing at the university have been funded from traditional non-industrial sources? Most administrations and agencies of the federal government have accepted the obligation to direct adequately large sums of money to the basic research process. What about the encumbrances on the results of industry-sponsored academic research? Should there, for instance, be favored industrial licensees? We understand that if there were not industrial funding of certain projects, research support would not otherwise be available; nevertheless, the academy argues that it is not fair to encumber the results. The other side of the coin is whether it is fair to encourage sponsors to support research without expecting some favoritism in their direction.

There are other equities in this issue which combine in a complex way with the education process. Consider for example the viewpoint of the graduate student, or even the undergraduate student: is that person getting the best possible scientific or technological training, or is there subtle pressure to work on commercializable results? We have heard today that many universities are seeking and welcoming ties to industry of the variety that we have been discussing. What will happen to the spontaneous generation of ideas within the university for fascinating research to do? How much does the relationship with sponsors or with potential sponsors limit that value of the enormous intellect which resides in the university environment? If a person is not free to pursue one's wild ideas, what happens to those ideas? This issue is made more complex by the alternative which is or was available to the university researcher, to seek research support

from the government or government agencies. I have felt that accommodation to agency interests has had a negative effect on the spontaneous search for truth, on investigation for the sake of investigation. We are all aware that the great and growing commercial value that we now see in biotechnology is the fruit of 20 or 30 or 40 years of undirected pure research.

A related question is that of the societal obligation of industry to fill some of the voids left by withdrawal of government research support. This is an important philosophical question. Also, what are the implications if the university becomes a stockholder and participant in a profit-making industry which flows from its own research efforts? Some universities have taken a strong position against such collaborative relationships. Others have taken just the opposite viewpoint. It is too soon to know how this issue may be resolved, but we must be aware that there is the potential for conflicting demands on our nation's intellectual resources.

How, then, does one balance the academic responsibility to add to the store of human knowledge against the academic wish to share in the profits of its own research? And what if that research was publicly supported or endowed? Funding not only from industry but also from public and private sources has probably contributed to the evolution of all the scientific advances which are now of commercial interest. Is there not an obligation on the part of the corporation, of the user, the entrepreneur, to pay the university for the science and the technology it is using for profit? If that science and technology is in the public domain, are there still obligations?

The patent aspects, which Tom O'Brien (see earlier comments) has discussed quite thoroughly are involved here. As a matter of law, basic scientific principles are not patented. They are not patented, and not patentable. A fine legal line is being drawn in some of the most fascinating areas of science and technology. By establishing patent rights at the forefront of technological/scientific boundaries, is damage being done to the future development of that research — or are socially more important benefits accrued by providing the patent rights that are essential to support the innovative process? The costs of innovation and commercialization amount to many hundreds or thousands of dollars for every dollar of research costs, which without patent rights may not be incurred at all. This is one of the most difficult combinations of practical and theoretical issues which must be faced. There is no easy answer, and we must be concerned that we do not adopt an easy answer resulting in more long-term damage than the short-term benefits might support. An overriding concern must be

how all of this affects the educational process. The educational process is our long-term and short-term investment in our future and in our national security.

Other peripheral issues arise from this debate: for example, questions of priority of invention in active fields of research, and differences in the way priority is decided. The academic community has occasionally confronted questions of priority of relatively concurrent discoveries, and tends to recognize contributions from various sources. The patent law in its present form does not accommodate relatively concurrent contributions to the solution of a complex problem. Rather, the law decides and recognizes only the person who was there first. I predict that some of the fields of science which are very active today will provide some entertaining exercises in that area.

Scientific collaboration between industries, as mentioned earlier in this program, is generally inhibited by the antitrust laws. It may be just a matter of time before antitrust practitioners decide that there are reasons to intervene in some of the industry-academic relationships that are being developed. The guidelines which are in this booklet distributed by Mr. Alex Schwarzkopf of NSF (an earlier speaker), are interesting. They do not discuss most of the kinds of industry-academic arrangements which are being developed. Again, I think we will observe some interesting legal developments very soon.

There is no question in my mind — and not just because of its historical justification — that this revived interdependence of academic science and its industrial users is a healthy relationship. It encourages scientists to accept new obligations to society; to foresee and to look for the practical consequences of their actions, as they did in the early days of science. There are important ways that the university and industry can help meet each others' needs. We have heard many such valuable contributions described today. The importance and the potential of these relationships encourage us to face the accompanying problems.

DONALD M. ALSTADT*

First of all, I would like to thank all of the participants who have contributed so immeasurably to the completeness of the discussion this morning, this afternoon, and early evening. I have a few brief matters to mention before I adjourn the meeting.

My first brief subject involves asking another as yet unanswered question. We have heard a great deal of discussion today about the transition that is occurring within the universities, and whether these transitions are good or bad. Is a pursuit of things other than academic excellence (such as financial return on its research) satisfactory and good, or otherwise?

I would also like to ask — is the American corporation changing? Is it moving outside of its first historical perspectives and dimensions? The historical concept of the role of stockholders, and the obligation a corporation owes to society to support academic institutions, has been frequently mentioned. These discussions have not, however, mentioned a new concept — stakeholders — as suggested by the Stanford Research Institute a number of years ago. Such a group includes the stockholders, employees, society, the customer, and all those people who have interest in the success of that corporation. Are the parameters under which the corporation will operate in the future in terms of who it must satisfy changing? It was not, incidentally, the stockholders wellbeing that was significant in the Chrysler financing or the Lockheed bailout. Some other stakeholder whose wellbeing was in question was the source of government action. Clearly, the corporate world perspective in society's eyes is changing.

In closing, I would like to refer to the New York conference mentioned a number of times today. I would like to emphasize the challenge put forth by Ed David of Exxon at that meeting of the law profession (see 24 IDEA). It is clear that powerful influences are combining to bring industrial and academic researchers together. To get the most advantage, however, from cooperative agreements, industry and academia will have to find ways to accommodate their historical cultural differences. Members of the Bar who are wise in the ways of science and technology, including those of the Franklin Pierce Law Center, can serve both parties by acting as mediators dedicated not to

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win-lose scenarios, but to win-win agreements. Agreements will and should take a variety of new forms of cooperation reflecting the extraordinary diversity of the nation's industrial and academic institutions. As suggested reading supporting the need for win-win programming, I would like to refer quickly to four books that I have encountered in the last year or so. One is "The Nature of the Cell" by Lewis Thomas of Sloan Kettering. The second is called "Reconciliations" by Rubin, the celebrated New York psychiatrist. The third is "A Naturalistic View of Man" by George Crile of the Cleveland Clinic. The fourth is a book called "The Turning Point" by Fitz Capra, a Berkeley based theoretical physicist. All of these authors suggest that man has evolved to the point of his progress that he now enjoys, in spite of the adversarial relationships that so seemingly interest the American society. Historically, man has survived not so much because of adversarial relationships which have their basis and groundwork in man's early biological evolution, but because of symbiotic relationships that take place within the evolution of the species. These authors include a biologist who is concerned with the nature of the cell, a physician, one concerned with theoretical physics, and another with psychiatric problems at home in society. All suggest that it is time that we stop dwelling so much on an adversarial point of view and on win-lose scenarios in our society. We must begin to realize that much of our progress may be due to cooperation not competition. Much progress has come about because of symbiotic cooperation which, perhaps even against our will, produced subtle types of win-win viewpoints. Cooperation is our challenge. How do we restructure our society with more win-win games and less negative conflict effort? Both our university and corporate world will profit if we so do. Thank you.

COMBINING A VARIETY OF PRIOR ART REFERENCES TO INVALIDATE A PATENT UNDER 35 U.S.C. §103

GUY McCLUNG*

Prior to the creation of the new Court of Appeals for the Federal Circuit, a decision of a federal district court involving patent issues was appealed to the district court's respective circuit court of appeals.¹ The Court of Appeals for the Federal Circuit is an Article III court created by the Federal Courts Improvement Act of 1981² The Act provides that the new court will be the only forum for appeals in patent cases.³

The Court of Appeals for the Federal Circuit ("CAFC") held its first session on October 1, 1982. In its first published opinion, *South Corp. v. U.S.*,⁴ the new court stated that precedents from the old Court of Claims and from the old Court of Customs and Patent Appeals ("CCPA") announced before the close of business on September 30, 1982 would serve as precedents for the Court of Appeals for the Federal Circuit.

By implication, the new court was excluding as precedents the cases decided by the various courts of appeal. Over the years numerous conflicts had developed between the various courts of appeal concerning particular points of patent law. Also, many interpretations of patent law by the circuit courts of appeal were subject to question.

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¹ 28 U.S.C. §1291 (1958).

² The Federal Courts Improvement Act was signed by President Reagan on April 2, 1982. Public Law 97-164, 97th Cong., 2d Sess., 96 Stat. 25 (1982).

³ The new court is the result of the merger of the Court of Claims and the Court of Customs and Patent Appeals both of which are now abolished. The new court's jurisdiction is based on subject matter — patents and government claims — rather than on geography. See 28 U.S.C. §1295 (1982).

⁴ 690 F.2d 1368 (Fed. Cir. 1982).

This article will focus on the new court's treatment of one particularly important patent law issue: When is it proper under 35 U.S.C. §103⁵ to combine the teachings of more than one prior art reference to invalidate a patent?

Combination Patents

Under the judicially created doctrine of so-called "combination patents" courts have looked with a jaundiced eye on patents for combinations of old elements.⁶ Often, combinations of old mechanical elements used to form some new type of machine, rather than chemical or electrical subject matter, were brought within the patent-defeating ambit of the doctrine.

In one form or another the United States Supreme Court and each of the circuit courts of appeal have held that combination patents deserve special scrutiny or must meet a very strict standard for patentability⁷. As recently as 1976, the U.S. Supreme Court in

⁵ 35 U.S.C. §103 reads as follows:

§103. Conditions for patentability; non-obvious subject matter

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

⁶ 2 CHISUM, PATENTS, §5.04[4] (1983).

⁷ *U.S. Supreme Court:*
Hicks v. Kelsey, 85 U.S. 670 (1874).

First Circuit:

Sylvania Elec. Prods. Inc. v. Brainerd, 499 F.2d 111 (1st Cir. 1974).

Second Circuit:

Supreme Equip. & Sys. Corp. v. Lear Siegler, Inc., 495 F.2d 860 (2d Cir. 1974).

Third Circuit:

Henkels & McCoy, Inc. v. Elkin, 455 F.2d 936 (3d Cir. 1972).

Fourth Circuit:

Blohm & Voss AG v. Prudential-Grace Lines, Inc., 489 F.2d 231 (4th Cir. 1973).

Fifth Circuit:

Sterner Lighting, Inc. v. Allied Elec. Supply, Inc., 431 F.2d 539 (5th Cir. 1970).

Sixth Circuit:

Shatterproof Glass Corp. v. Guardian Glass Co., 462 F.2d 1115 (6th Cir. 1972).

Seventh Circuit:

Henry Mfg. Co. v. Commercial Filters Corp., 489 F.2d 1008 (7th Cir. 1972).

Sakraida v. Ag Pro, Inc., has stated that a patent directed to a combination of old elements did not exhibit a "synergistic" result or a new and different function⁸. In *Sakraida*, the Court cited with approval one of its previous decisions, *Great Atlantic & Pacific T. Co. v. Supermarket Corp.*,⁹ in which it asserted that courts must "scrutinize combination patent claims with a care proportionate to the difficulty and improbability of finding invention in an assembly of old elements."¹⁰

The CAFC has explicitly rejected the judicially-created doctrine of combination patents. In *Environmental Designs, Ltd. v. Union Oil Co.*,¹¹ Chief Judge Markey declared: "Virtually all inventions are combinations and virtually are all combinations of old elements. A court must consider what the prior art as a whole would have suggested to one skilled in the art . . ." ¹² On the same day as the *Environmental Designs* decision, in *Richdel, Inc. v. Sunspool Corp.*¹³, Chief Judge Markey presented a detailed rejection of the doctrine of combination patents:

It was error for the district court to derogate the likelihood of finding patentable invention in a combination of old elements. No species of invention is more suspect as a matter of law than any other. Attempted categorization for the purpose of determining varying "rules" detracts from what should be the sole question: whether the *claimed invention* would have been obvious within the meaning of §103. Most, if not all, inventions are combinations and mostly of old elements.¹⁴

Eighth Circuit:

John Blue Co. v. Dempster Mill Mfg. Co., 275 F.2d 668 (8th Cir. 1960).

Ninth Circuit:

Hewlett-Packard Co. v. Tel-Design, Inc., 460 F.2d 625 (9th Cir. 1972).

Tenth Circuit:

Scaramucci v. Dresser Indus., Inc., 427 F.2d 1309 (10th Cir. 1970).

D.C. Circuit:

Blair v. Dowd's, Inc., 438 F.2d 136 (D.C. Cir. 1970).

⁸ 425 U.S. 273 (1976).

⁹ 340 U.S. 147 (1950).

¹⁰ 340 U.S. at 152.

¹¹ 713 F.2d 693 (Fed. Cir. 1983).

¹² 713 F.2d at 698.

¹³ 714 F.2d 1573 (Fed. Cir. 1983).

¹⁴ 714 F.2d at 1579-80;

See also: *Stratoflex v. Aeroquip Corp.*, 713 F.2d 1530 (Fed. Cir. 1983); *Fromson v. Advance Offset Plate, Inc.*, 219 U.S.P.Q. 1137 (Fed. Cir. 1983); and *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563 (Fed. Cir. 1983).

Proper Combination of References

To fill the void created by its rejection of the strict scrutiny test for combination patents, the CAFC has proposed clarifying criteria for determining whether references can be combined under 35 U.S.C. §103 to invalidate a patent. In *In Re Sernaker*¹⁵ the Court posited a test in the form of two questions to be asked when a combination of a variety of prior art references is attempted:

- (1) Whether a combination of the teachings of all or any of the references would have suggested (expressly or by implication) the possibility of achieving further improvement by combining such teachings along the line of the invention in suit and
- (2) Whether the claimed invention achieved more than a combination which any or all of the prior art references suggested, expressly or by reasonable implication.¹⁶

The Court sought to answer these two questions only after it had been determined that all the prior art references under consideration were in a common or related art and that the knowledge of a person of ordinary skill in the pertinent art included knowledge of these references. The crucial concept in each of the two tests is suggestion, either express or implied.

In *Sernaker* the invention sought to be patented was a type of embroidered emblem and a method of making it. By using thread of only one color, usually white, and then dying that thread with different colors using one transfer print, the difficulties associated with prior art methods involving the use of multiple different colored threads were avoided. The Board of Patent Appeals (the "Board") had rejected the application for obviousness under 35 U.S.C. §103. In applying test number (1) above to the Board's reasoning, the Court found that the reference made "no mention" nor did they even "hint at" the mating of a transfer print with a lace pattern as taught and claimed by the applicant's invention¹⁷. The Court stated: "Without some express or implied suggestion, we cannot assume that one of ordinary skill in the art would have found it obvious to mate the transfer print with this pattern"¹⁸.

¹⁵ 702 F.2d 989.

¹⁶ 702 F.2d at 994.

¹⁷ 702 F.2d at 995.

¹⁸ *Id.*

In applying test number (2) above, the Court stated:

The conclusion is the same under test (b) as it is under test (a). Under test (b), the person who considered merely combining the teachings of prior art references would not expect from the references or any implication to be drawn therefrom that the great advance made by appellants' invention could be attained. The Board never showed how the teachings of the prior art could be combined to make the invention.¹⁹

In addition to its analysis of the two tests in *Sernaker*, the CAFC mentioned six previously-decided cases of the CCPA which in the CAFC's view provided illustrative examples of the application of the two tests and which, under the ruling in *South Corp v. U.S.*,²⁰ are precedents to be followed by the CAFC. A brief review of these six cases serves to explain the application of the two tests proposed in the *Sernaker* opinion. The six cases are: *In Re Rinehart*, *In Re Imperato*, *In Re Adams*, *In Re McLaughlin*, *In Re Conrad* and *In Re Sernaker*.²¹ In the first three listed cases, the invention was found not to be obvious and in the second three listed cases the invention was found to be obvious.

In *Rinehart*²², the CCPA reversed the Board's rejection of claims for a chemical method. The rejection, which was based on the combination of two references, was held to be incorrect since the references were devoid of "any suggestion . . . that features of the process of one should be combined with features of the other to achieve the commercial scale production of which neither is capable . . ." ²³ The court also asserted that "the view that success [resulting from the combination of references] would have been 'inherent' cannot, in this case, substitute for a showing of reasonable expectation of success. Inherency and obviousness are entirely different concepts."²⁴

In *Imperato*²⁵, although combining the references' teachings yielded

¹⁹ Id.

²⁰ 690 F.2d 1368 (Fed. Cir. 1983).

²¹ *In Re Rinehart*, 531 F.2d 1048 (CCPA 1976).

In Re Imperato, 486 F.2d 585 (CCPA 1973).

In Re Adams, 356 F.2d 998 (CCPA 1966).

In Re McLaughlin, 443 F.2d 1392 (CCPA 1971).

In Re Conrad, 439 F.2d 201 (CCPA 1971).

In Re Sheckler, 438 F.2d 999 (CCPA 1971).

²² 531 F.2d 1048 (CCPA 1976).

²³ 531 F.2d at 1054.

²⁴ Id.

²⁵ 486 F.2d 585 (CCPA 1973).

the result claimed, the CCPA held that the combination was not obvious "unless the art also contains something to suggest the desirability of the combination."²⁶ The references contained no such suggestion. In *Sernaker*, the CAFC interpreted *Imperato* to mean that "prior art references in combination do not make an invention obvious unless something in the prior art references would suggest the advantage to be derived from combining their teachings."²⁷ In *Adams*,²⁸ the Board was reversed because "neither reference contains the slightest suggestion to use what it discloses in combination with what is disclosed in the other."²⁹

Neither *Rinehart*, *Imperato*, nor *Adams* deals with the question of *implicit suggestion*. In each of these three decisions, the Court did not have to deal with the question of whether or not there was implicit suggestion since it found that there was *no* suggestion in any of the references under consideration to make the combination.

The remaining three cases mentioned by the CAFC in *Sernaker* do serve to explain what the CAFC means by "implicit suggestion." In *McLaughlin*,³⁰ the patent applicant sought to patent a new railroad boxcar for carrying palletized loads. Two features stressed by the applicant were: (1) the alleged novel use of side filler panels and bulkheads to keep loads on the pallets in place and to prevent shifting of the loads; and (2) the offsetting of the doors on either side of the car. One cited reference showed that it was well-known to use offset doors in boxcars. Another cited reference showed that it was well-known to use side filler panels and bulkheads to confine palletized loads. Since the purpose of the use of the panels and bulkheads in the reference was the same as the purpose of the use in the subject matter sought to be patented, the CCPA found that it would be obvious to combine the teachings of the references to achieve the claimed subject matter.³¹

In *Conrad*³² the CCPA explicitly stated that "express suggestion" is not necessary to invalidate claims for obviousness:

²⁶ 486 F.2d at 587.

²⁷ 702 F.2d at 995-96.

²⁸ 356 F.2d 998 (CCPA 1966).

²⁹ 356 F.2d at 1002.

³⁰ 443 F.2d 1392 (CCPA 1971).

³¹ 443 F.2d at 1395.

³² 439 F.2d 201 (CCPA 1971).

In substance, appellants main contention is that the prior art falls short of suggesting his particular simplification. The examiner and the Board rejected his contention and so do we The law does not require express suggestion. As was said by this Court in *In Re Rosselet*, 347 F.2d 847, 52 CCPA 1533 (1965):

... The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art *presumed* to be familiar with them.³³

The *Sheckler*³⁴ decision stands for the proposition that if the knowledge used by a patent applicant is knowledge clearly present in the prior art, that that clear presence is sufficient to show implicit suggestion to combine references: "... it was not necessary that the prior art suggest expressly or in so many words, the 'changes or possible improvements' the inventor made. It is only necessary that he apply '*knowledge clearly present in the prior art.*'"³⁵

When the prior art relied on to invalidate a patent or to render an invention obvious contains no suggestion to combine the teachings of the references, such combination may be the result of improper hindsight reconstruction of the prior art. As the CAFC stated in *W.L. Gore & Assoc. Inc. v. Garlock, Inc.*:

In concluding that obviousness was established by the teachings in various pairs of references, the district court lost sight of the principle that there must have been something present in those teachings to suggest to one skilled in the art that the claimed invention before the court would have been obvious . . .

* * *

To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.³⁶

Additional Considerations Indicating Noncombinability

In recent decisions the CAFC has provided further fleshing-out of the criteria for the proper combination of invalidating references. When the references to be combined contain express statements that the components of one are not interchangeable with the components of another, this indicates that it would not be obvious to combine the

³³ 439 F.2d at 205.

³⁴ 438 F.2d 999 (CCPA 1971).

³⁵ 438 F.2d at 1001.

³⁶ 721 F.2d 1540, 1551, 1553 (Fed. Cir. 1983).

two references and that a person who, nevertheless, successfully combines such teachings is entitled to a patent.³⁷ The CAFC has held that mere "conjectural modifications" of the disclosure of a prior art reference are not justified.³⁸ The Court has also indicated that when there is a "technological incompatibility" that prevents those of ordinary skill in the pertinent art from making the combination, and yet this incompatibility is overcome, this would indicate nonobviousness.³⁹

Conclusion

The new Court of Appeals for the Federal Circuit has rejected the judicially created doctrine of the strict scrutiny of so-called combination patents. In order to provide a methodology for determining whether or not the combination of two or more references to invalidate a patent is proper, the court has proposed the "express or implied suggestion" criteria. Decisions both of the predecessor court, the Court of Customs and Patent Appeals, and recent decisions of the CAFC itself indicate the manner in which these tests are to be applied.

³⁷ *In Re Graselli*, 713 F. 2d 731 (Fed. Cir. 1983).

³⁸ *Schenck v. Norton Corp.*, 713 F.2d 782 (Fed. Cir. 1983).

³⁹ *In Re Farrankopf*, 713 F.2d 714 (Fed. Cir. 1983).

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COMMENTARY

Ruckelshaus v. Monsanto

I. Introduction

The Supreme Court recently decided a case that may have far reaching effects for industries that submit trade secret data to the federal government. The Court in *Ruckelshaus v. Monsanto*, 104 S. Ct. 2862, (June 26, 1984) was confronted with two basic issues concerning government use and disclosure of information classified as trade secret by its submitter. First, to what extent can a trade secret be extinguished by legislation enacted subsequent to its submission to the government? Second, assuming, at least in some circumstances, that compensation is appropriate in such cases of subsequent extinguishment, what are the minimum process requirements for compensating owners of extinguished trade secrets?

Insofar as the issues directly involved the Federal Insecticide Fungicide Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, a brief overview of pertinent provisions is warranted. Following the overview, there will be discussion of the District Court decision, the Supreme Court decision and an analysis of the Supreme Court opinion.

II. Overview of FIFRA

FIFRA was first enacted in 1947 (61 Stat. 163) primarily as a labeling law for pesticides. Pesticides, as used in this article, include herbicides, fungicides and other chemical entities regulated by FIFRA. In 1970, Reorganization Plan No. 3 transferred the administration of FIFRA from the Department of Agriculture to the EPA.

In 1972, FIFRA was amended (86 Stat. 973) to require certain test data to be submitted to the EPA to support registration. Without prior registration, a pesticide could no longer be shipped or marketed. Also, a section allowing for public disclosure of portions of the submitted data not designated "trade secrets or commercial or financial information" was added. The EPA was also now allowed to consider data submitted by one applicant in support of another application, provided the subsequent applicant offered compensation to the data submitter. The amount of compensation was to be negotiated by the parties, or, if that failed, the amount was to be determined by the EPA, subject to judicial review.

The effective date of the 1972 provisions, however, was omitted from the 1972 Act. Thus, not until 1975 legislation was it clear that

all data submitted after January 1, 1970 was to be included in the disclosure and compensation provisions.

In 1978, Congress amended FIFRA (92 Stat. 819) to include new public disclosure and data consideration provisions. Under the 1978 Act, applicants for registration were granted exclusive use of data submitted for pesticides initially *registered* after September 30, 1978 for a period of 10 years, followed by a five year compensation period. All other data submitted after December 31, 1969 could be cited and used in support of another application for a period of 15 years, subject to compensation being negotiated or arbitrated. Further, these amendments provided that in the event that a data submitter refused to submit to binding arbitration he forfeits "the right to compensation for use of the data in support of the application." Data not qualifying for exclusive use or compensation may be considered by the EPA without limitation.

The 1978 amendments effectively *extinguished all trade secret status for data submitted prior to 1970* by allowing EPA to consider such data without limitation. Also, the trade secret status of all other data submitted prior to 1978 was extinguished following the period of compensation. This was done *after* such data was submitted with the good faith expectation that the data would remain secret unless the parties involved agreed otherwise. Further, *judicial review on the merits* of the arbitration process was *expressly eliminated* by the 1978 Act.

Moreover, the 1978 amendments provided for disclosure of all health, safety and environmental data to qualified requestors, notwithstanding the prohibition against disclosure of trade secrets. This provision was limited only in that it did not authorize disclosure of information that would reveal "manufacturing or quality control processes" or information concerning deliberately added inert ingredients unless the EPA first determined that disclosure was necessary to protect against an unreasonable risk of injury to health or the environment. While an arbitration award may not be reviewable on the merits, this is almost sure to be; *c.f.*, *Chrysler Corp. v. Brown*, 441 U.S. 281 (1979).

III. District Court Decision

In *Monsanto Co. v. E.P.A.*, 564 F. Supp. 552 (E.D. Mo. 1983), Monsanto challenged the constitutionality of the 1978 statute. Monsanto also asked the Court to enjoin the EPA from disclosing all trade secret data under the 1978 amendments to FIFRA.

The Court held the amendments to be unconstitutional, finding

that they were beyond the power conferred to Congress by Article I Section 8 clause 3 of the Constitution (regulation of commerce), and in violation of the Fifth Amendment (due process and taking). The Court enjoined EPA from any disclosure, use or consideration in support of another person's application without the express consent of the submitter of the trade secret data.

Helpful to understanding the magnitude of the impact created by the 1978 amendments are certain findings of fact by the Court. No specific pesticide data seemed to be at issue, but the Court found *in general* that Monsanto had incurred costs of more than \$23.6 million in developing the data it had submitted to the EPA under FIFRA and that the development process may take between 14 and 22 years, 564 F. Supp at 560 and 555. During this time it is unlikely that the company developing the data will realize any return on its investment. Moreover, a company must expend \$5 million to \$15 million annually for several years to develop a *potential* commercial pesticide candidate, *id.* at 555 (emphasis added). Of these potential candidates only a fraction are actually marketed.

Specifically, the Court found that Monsanto had proprietary rights arising under state law in the data submitted to the EPA and that the use of the data by the EPA for the benefit of others was never a risk stated or understood to be inherent in submitting it. The court's analysis of the constitutionality of the taking followed the test set forth by the Supreme Court in *Penn. Central Transportation Co. v. New York*, 438 U.S., 104, 124-128, (1978). A significant factor in determining what constitutes a taking is the owner's "investment backed expectations." The Court here found that Monsanto had a reasonable "investment backed expectation" that data it submitted would be kept secret and that the government effected a "taking" by interfering with those expectations. Since this gave Monsanto's competitors a free ride, the Court held that this provision destroyed Monsanto's property rights, 564 F. Supp. at 566. Those, of course, consist of the ability to exclude others from use of the data. The Court also found that the public disclosure provision was beyond the power of valid regulation of commerce, *id.* at 567.

Moreover, the Court stated that eminent domain power must be exercised in light of the due process clause of the Fifth Amendment. It held that the binding arbitration provision, without guidelines or judicial review on the merits, did not satisfy this requirement. The Court also found that the scheme improperly delegated judicial power to determine property disputes without the necessary Article 3 prerequisites, *id.* at 567.

The government argued that the Tucker Act, 28 U.S.C. §1491, applied. This Act gives the United States Claims Court jurisdiction to render a judgment for damages against the United States from claims not sounding in tort. However, analyzing the legislative history of the 1978 amendments, the Court found the Tucker Act to be unavailable as a remedy to Monsanto. It found the key factor to be the lack of any appropriations by Congress under FIFRA to compensate for such claims, 564 F. Supp. at 568.

IV. *Supreme Court Decision*

The Supreme Court disagreed, vacating and remanding the decision. First, it found that, prior to the 1972 amendments Monsanto could have had *no* "reasonable investment backed expectation that its information would remain inviolate in the hands of the EPA," 104 S. Ct. at 2876. Moreover, even "the Trade Secrets Act, 18 U.S.C. §1905, was found not to be a guarantee of confidentiality to submitters of data," *id.* Thus, there could be no "taking of this data," *id.*

The Court then held that, as to post-1978 submitted data:

as long as Monsanto is aware of the conditions under which the data are submitted, and the conditions are rationally related to a legitimate government interest, a voluntary submission in exchange for the economic advantages of a registration can hardly be called a taking (*id.*).

However, data submissions between 1972 and 1978 were found to be submitted *with* a "reasonable investment backed expectation" of secrecy since Congress had, in effect, "guaranteed" non-disclosure or non-use by the 1972 amendments. Thus, any data submitted during this period, subsequently used or disclosed, would be deemed "taken" by the government and, therefore, subject to compensation.

Moreover, the Court found that not only was arbitration available to Monsanto, but the Tucker Act was as well. However, since Monsanto had yet to enter into the arbitration process or make a Tucker Act claim, the Court found the taking issue not yet ripe for adjudication. It held that compensation "did not depend solely on the validity of the statutory scheme," 104 S. Ct. at 2882.

V. *Conclusion*

In conclusion, it appears that while the Supreme Court clearly recognized that property rights do exist in trade secrets, it also succinctly stated that Congress could validly extinguish those rights over time by defining periods of exclusivity and compensation for data submitted *with notice* of such periods. However, because it was not until 1975 that Congress established the effective date of the 1972 amendments as

being 1970, notice apparently need not be *advance* notice! It also declared an action under the Tucker Act was not precluded by FIFRA where there was a taking.

That was helpful, but the Court failed to adequately explain how data submitted prior to January 1, 1970 could be, consistent with the Fifth Amendment, placed in the public domain, without *any* compensation or advance notice! The court *extinguished* the trade secret protection, originally afforded this data, with a few short lines. Neither it nor Congress gave any indication why this data was to be no longer considered valuable in as short a time as nine years.

It was on this issue that Justice O'Connor registered a lone dissent. Arguing that the Trade Secrets Act flatly forbade disclosure, she felt that Monsanto's expectation that pre-1972 submitted data would not be publicly disclosed or used to benefit others was reasonable. As to EPA use of this data to support subsequent applications without the data submitter's express consent, she strongly objected to the majority's "fact finding" and skimpy rationale, stating that, at the least, the appropriate disposition of the issue would be to remand to the district court for further fact finding, 104 S. Ct. 2884.

Because of this dissent, the majority's extinguishment without notice or compensation can not be passed over. It is unfortunate that there was no record discussion relating to the cost and time involved for the development of data for any *specific* product — and especially any indication of the present value of still useful data falling into the public domain. Perhaps, with specific examples before the Court, the majority would not have been so quick to find that no taking had occurred. It is to be hoped that, when provided with such data, the Court will, in the future, narrow and explain its holdings. While the limits may not be entirely clear, it presently appears that Congress can nevertheless determine the useful life of trade secrets, as long as they have not "guaranteed" *specifically* that they will not be disclosed.

Before stopping, a brief discussion of the second issue is also warranted. Little can be said for the Court's unwillingness to guide Congress by setting process limitations. Rather, it chose to leave undecided the basic issue of whether the power to determine "just compensation" can be delegated to a private party, particularly where guidelines and the possibility of judicial review on the merits are absent.

Thus, only after entering into an arbitration process and exhausting his remedies thereunder, will a FIFRA registrant be able to challenge the Constitutionality of the 1972-1978 data compensation process. Yet, failure to decide this issue, coupled with the availability of the Tucker Act, may nevertheless cause Congress or the EPA to es-

tablish reasonable guidelines to avoid time consuming and costly litigation in the Court of Claims.

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*This paper was done in partial fulfillment of the requirements for the J.D. (1985) at Franklin Pierce Law Center. This work, supervised by Professor Thomas G. Field, Jr., is the foundation for ongoing research which the author is conducting as a 1984-1985 Food and Drug Law Institute scholar. Copyright 1984 Vincent Youmatz.

A Step Beyond Novelty, Utility and Non-Obviousness*

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Whether dull or exciting, the file history of a patent issued by the United States Patent and Trademark Office (PTO) can serve as an educational tool. Let us consider an application which matured into United States Patent No. 4,381,301.

The application was filed under the International Convention [cf. 35 U.S.C. 119 — Appendix I]. A prior art statement [cf. 37 C.F.R. § 1.97 — Appendix II] was submitted several months thereafter. About a year later an Official Action (Paper No. 4) issued. An interview [cf. 37 C.F.R. § 1.133 — Appendix II] was conducted with the Examiner, and a response [cf. 35 U.S.C. § 132 — Appendix I] was duly filed with appropriate amendments to the specification and claims [cf. Appendix IV — Amended Claims]. The issues raised in the Official Action and the response thereto are reflected in the following:

Paper No. 4

1. The specification is objected to as being indefinite or incomplete. The use of the symbols "I*", "I**" and "Ia" at pages 7-14 is confusing since they are not clearly defined. For example, it appears that the symbol I** represents more than one embodiment of the compounds of formula I and includes compounds not reading on formula I. Note particularly pages 8 and 9 and the paragraph bridging pages 12 and 13. Correction is required.

Response to Paper No. 4

1. *Sufficiency of Disclosure* — The objection to the specification "as being indefinite or incomplete" is respectfully traversed. Applicant submits that he is entitled to be his own lexicographer. This is regularly pointed out in court opinions. In this regard, e.g., please note the opinion for *Maclaren v. B-I-W Group Inc.*, 187 USPQ 345, 351 (N.Y. 1975):

... and it has been said that an inventor may be his own lexicographer. E.g., *Bela Seating Company v. Poloron Products Inc.*, 297 F. Supp. 489, 506, 160 USPQ 646, 659-660 (N.D. Ill. 1968). Aff'd. 438 F.2d 733, 168 USPQ 548 (7th Cir. 1971), cert. denied, 403 U.S. 922, 170 USPQ 646 (1971).

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In its opinion in *H.K. Porter Company, Inc. v. The Gates Rubber Company*, 187 USPQ 692, 711 (Colorado 1975), the Court cited *Chicago Steel Foundry Co. v. Burnside Steel Foundry Co.*, 132 F.2d 812, 56 USPQ 537 (7th Cir. 1943); *Barrett v. United States*, 405 F.2d 502, 156 USPQ 565 (Ct. Cl. 1968) with reference to "the familiar doctrine that the patentee is entitled to be his own lexicographer so long as he makes his invention clear." Applicant respectfully submits that the invention is clear whether formulae are designated by letters, numbers, asterisks or any other available designations; the designations themselves have little to do with defining the substance of the invention. Compounds Ia are clearly defined on pages 14 and 15 of the specification; they are compounds of formula I wherein each of the variants is as defined on page 14 and the first eight lines on page 15. This is made ultimately clear by the express reference to the noted designation at line 2 on page 14. These compounds are pharmacologically-active embodiments of the substituted thienobenzodiazepinones of formula I.

Substituted thienobenzodiazepinones of formula I wherein R³ is halo (let us name them compounds Ib) are intermediates for the preparation of compounds Ia. Compounds I* (cf. lines 1 to 14 on page 7) are in this category. The sum of compounds Ia and compounds Ib make up compounds of formula I.

Compounds I* constitute a selected group of compounds Ib. Compounds I** are presented in the paragraph bridging pages 7 and 8 of the specification; they comprise a selected group of compounds of formula Ia. All compounds of formula I** read on formula I. Issue is respectfully taken with the unsupported allegation that compounds of

formula I** "include compounds not reading or the formula I." No inconsistency is found in any of the cited text. If this objection is maintained, the PTO is respectfully requested to point out the specific disclosure (by page, line and limitation) which is regarded to exclude an embodiment of formula I** from compounds of formula I.

2. The specification is objected to for the recitation of human use. There is no adequate showing that the compounds of the instant claims can be used effectively in humans. There is no showing of any of the claimed compounds in treating or the prophylaxis of stomach and intestinal disorders. Note M.P.E.P. 608.01 (p) [Appendix III]. Applicant is required to cancel all references to treating humans from the specification.

3. The references cited and supplied by applicant have been made of record in the file. The additional references are cited to further show the state of the art.

4. Claims 1-12 [Appendix IV - Original Claims] are in this case.

2. *Utility - Human Use* - The objection to the specification (for the recitation of human use) is also respectfully traversed. There is an extensive presentation of guidelines for considering disclosures of utility in drug cases provided by MPEP 608.01 (p), which explicitly points out:

If the asserted utility of a compound is believable on its face to persons skilled in the art in view of the contemporary knowledge in the art, then the burden is upon the examiner to give adequate support for rejections for lack of utility under this section . . .

. . . Proof of utility will be required for other members of the claimed genus only in those cases where adequate reasons can be advanced by the examiner for believing that the genus as a whole does not possess the asserted utility . . .

The paragraph bridging pages 12 and 13 of the specification and the first complete paragraph on page 13 clearly show that the pharmacologically-active compounds of this invention are useful in humans. Particular conditions are specified; they are not limited to animals. No basis or authority is provided for requiring cancellation of "all reference to treating humans from the specification."

Reference is respectfully made to the pharmacology section (pages 37 to 40) of the specification. In many cases animal data are regarded as more than adequate to support utility in warm-blooded animals (including humans). The record does not provide any basis whatsoever for a more stringent requirement in the subject case.

5. Claims 1-7 are rejected as being directed to improper Markush groups. The claims read on both intermediates and final products; this is improper in a Markush claim. *In re Ruzicka*, 66 USPQ 226 (C.C.P.A. 1945); *In re Winnek*, 73 USPQ 225 (C.C.P.A. 1947).

5. *Markush Claims* – The rejection of Claims 1 to 7 “as being directed to improper Markush groups” is respectfully traversed. This ground of rejection was considered in some detail by the C.C.P.A. in its opinion for *In re Harnisch*, 206 USPQ 300 (C.C.P.A. 1980). With regard to an “improper Markush grouping” this opinion states:

We were and are aware that it does not have a specific statutory basis, as we are aware of an applicant's right to define what he regards as his invention as he chooses, so long as his definition is distinct, as required by the second paragraph of § 112, and supported by enabling disclosure, as required by the first paragraph of § 112

. . . It found the claims before it to cover compounds all belonging to a genus of tetralyl compounds having a substituted methyl group at position 6 and ruled that they had a community of properties justifying their grouping which was not repugnant to principles of scientific classification.

. . . Clearly, they are all coumarin compounds which the board admitted to be ‘a single structural similarity.’ We hold, therefore, that the claimed compounds all belong to a subgenus, as defined by appellant, which is not repugnant to scientific classification. Under these circumstances we consider the claimed compounds to be part of a single invention so that there is unity of invention as was held to be the case in *Ex parte Brouard*, supra, 201 USPQ at 540. The Markush groupings of claim 1 and 3-8 are therefore proper.

All of the compounds of formula I belong to a genus of thienobenzodiazepinones having a substituted alkanoyl group in the 4-position of the tricyclic moiety. This is the structural similarity considered essential in the *Harnisch* case. That there is a clear established relationship between intermediate and final products, particularly those intermediates which lend to the final products the structure responsible for their utility, is established, e.g., by the opinion of the C.C.P.A. for *In re Magerlein*, 202 USPQ 473 (1979), wherein the Court gave special recognition to this point.

All of the compounds of Claim 1 may be regarded as intermediates for other compounds of Claim 1. All of the free bases are intermediates for the preparation of acid-addition salts, and each acid-addition salt is an intermediate for the preparation of either the corresponding free base or a different acid-addition salt. All of the compounds of Claim 1 thus have a common utility as an intermediate for pharmacologically-active and physiologically useful compounds also encompassed by that claim.

6. Therefore, tentative restriction is required under 35 USC 121 [Appendix I] as follows.

I. The final-product compounds, composition and method of use of claims 1-12, classified in 424-250.

II. The intermediate compounds of claims 1-7, classified in 260-240.3.

The above inventions are distinct one from the other since each has acquired separate status in the art, and the use of one is not dependent on the use of the other. Further, each of the inventions is patentable over the other under 35 USC 103 [Appendix I].

Applicant is advised that, to be complete, the response must include a provisional election consonant with the above requirement even though the requirement be traversed.

7. Applicant is further advised that the response should include limiting the claims to read only on the elected invention.

6. *Restriction* – The “tentative restriction” is thus respectfully traversed. Reconsideration and withdrawal of this requirement are solicited. To assure a complete response, a provisional election is made to Group I, the final product compounds, compositions and methods of use. Claims 1 and 3 through 13 read on this election. If it is regarded essential to elect an ultimate species in order to assure a complete response, a provisional election is made to the compound of Claim 8.

The fact that compounds may have acquired a separate status in the art does not establish patentable distinction. Classification schedules are created for ease of examination without regard to any criteria for patentable distinctness. That all of the compounds have a common utility has already been pointed out. Again, reconsideration and withdrawal of the restriction requirement are solicited.

7. *Limiting Claimed Invention* – Issue is also respectfully taken with the advice regarding limiting claims “to read on the elected invention only.” Should such suggestion be retained, authority for any requirement in this regard is respectfully re-

8. Claims 1, 3, 4, 7 and 9-12 are rejected under 35 USC 112 [Appendix I], second paragraph as indefinite. In the definition of R⁵ the recitation of the phrase "together with R⁴ ..." is redundant since the definition of R⁴ and R⁵ together has been previously recited. The term "an acid-addition salt thereof" renders the claims indefinite since the nature of the acid is not recited.

quested. The statute makes it ultimately clear that Applicant is entitled to define in his claims what he regards as his invention, and he regards the entire subject matter instantaneously claimed as his invention.

8. *Definiteness* – The rejection of Claims 1, 3, 4, 7 and 9 to 12, "under 35 U.S.C. 112, second paragraph, as indefinite" is also respectfully traversed. Applicant respectfully submits that that which is alleged to be redundant is not truly so and that anyone of ordinary skill in the art would have absolutely no difficulty whatsoever in understanding precisely what is intended. In order to overcome the issue completely, however, the designated claims have been amended.

Issue is respectfully taken with the allegation that the term "an acid-addition salt thereof" renders the claims indefinite. The cited expression reflects standard accepted usage in the involved art. This is reflected, e.g., by Claim 1 in each of the following patents: 3,951,979; 3,951,980; 3,951,981; 3,951,982; 3,953,430; 4,168,269; 4,168,272; 3,660,380; 3,743,734; 4,021,557; 4,115,574; 4,310,461; 4,310,533; and 4,310,534. Many more claims of issued patents can be cited in support of this proposition. The specific nature of the acid is not the essence of the invention nor is it that which is relied upon to establish patentability. Cf. *In re Fuetterer*, 138 USPQ 217, 223 (C.C.P.A. 1963). Should this ground of rejection be retained, authority for such retention is respectfully solicited.

Attention is respectfully directed to the final paragraph on page 6 of the specification which clearly and unequivocally states:

All the acid-addition salts are contemplated. The pharmacologically-acceptable salts of the inorganic and organic acids customarily used

galenically are of particular importance. Pharmacologically-unacceptable salts are readily converted into pharmacologically-acceptable salts by conventional and well-established processes...

The first complete paragraph on page 26 of the specification completes the teaching of the utility of all possible acid-addition salts. Those which are not pharmacologically acceptable can readily be converted either to others which are or to the corresponding free base. This knowledge is sufficiently well known to anyone of ordinary skill in the art that it should be beyond challenge by a qualified Examiner.

9. Claims 1, 3 and 12 are rejected under 35 USC 112 [Appendix I], first paragraph, as being based on an insufficient disclosure. There is no adequate support in the disclosure for all acid-addition salts reading on the instantly claimed compound, nor is there an adequate showing that all would be used. There is no adequate teaching that the compounds of the instant claims can be used effectively in the prophylaxis of all stomach and intestinal disorders in mammals as the claims presently read. Are cancers of the stomach and/or intestines included? There is no adequate data in the specification to support the treatment of humans which clearly read on claim 15.

9. *Sufficiency of Disclosure* – The rejection of Claims 1, 3 and 12 “under 35 U.S.C. 112, first paragraph, as being based on an insufficient disclosure” is also respectfully traversed in the same manner and for the same reasons as presented in the immediately-preceding discussion. With all due respect to the unsupported allegations to the contrary, the disclosure does provide adequate support for all acid-addition salts and for establishing that they would be useful. No authority is known to require Applicant to teach “that the compounds of the instant claims can be used effectively in the prophylaxis of all stomach and intestinal disorders in mammals” in order to warrant their presentation. The statute requires Applicant to teach how to use his claimed invention; he has done this. The specification does not teach the use of the claimed invention for “cancers of the stomach and/or intestine”. Cf. *In re Sichert*, 196 USPQ 209, 211-213 (C.C.P.A. 1977). The specific reference to Claim 15 is not understood, as there is not yet any Claim 15 in the instant case.

As previously mentioned, an interview was conducted (after issuance of Paper No. 4 and prior to filing a response thereto) with the Examiner. His SPE (Supervisory Primary Examiner) also attended the latter part of the interview. Since the Examiner did not have citations of decisions referred to by the SPE at the time of the interview, he agreed to obtain the citations and provide an Examiner Interview Summary Record promptly thereafter. The latter (Paper No. 5) was mailed without the citation of the *Graver Tank* case, *infra*.

Immediately following the interview a report was dispatched to the principal party in interest. This report reflected that, during the interview, the Examiner indicated that the point raised in paragraph 1 of Paper No. 4 might be dropped. With regard to paragraph 2, the Examiner took the position that the utility claimed should be limited to that which was disclosed. With reference to page 13 of the specification, "disorders of the stomach or intestine and illnesses directly related thereto" was regarded as too broad, since such disorders were alleged to include cancer. Limiting the illnesses to those specifically enumerated at lines 14 to 16 on page 13 was suggested for the method-of-use claim.

With regard to the restriction requirement, the SPE appeared to limit his interpretation of the cited *Harnisch* opinion to a situation wherein all encompassed compounds have the same ultimate utility, i.e., utility beyond that of an intermediate.

With regard to acid-addition salts, the SPE took the position that the phosphotungstate salt would be so insoluble that it would not be readily converted into pharmacologically-acceptable salts or into the corresponding free base by conventional and well-established processes. It was pointed out that: a) no specific mention was made in either the specification or claims to any phosphotungstate salt; b) no basis is known and no authority is found for total insolubility of even the phosphotungstate salt in all available solvents, much less in water; c) even were the solubility of the phosphotungstate salt severely limited, it could be sufficiently dispersed in available media to obtain either the corresponding free base or a pharmacologically-acceptable salt.

[Subsequent checking of the solubility of acid-addition salts with phosphotungstate acid revealed that the acid is soluble in water, ethanol and diethyl ether and is used as a reagent for alkaloids and nitrogen bases (Rompps Chemie Lexikon, 7th edition, page 2655). Reference is made therein to Kirk-Othmer 22:357. An interesting paragraph (Chapter 30.C Molybdenum and Tungsten) about "heteropoly acids and their salts" in a translation of "Advanced Inorganic Chemistry" (F. Albert Cotton-Geoffrey Wilkinson, 2nd edition, 1967) says that

the free acids and most of the salts of the heteropoly acids are soluble in water and in organic solvents (containing oxygen atoms, e.g., ethers, alcohols, ketones). They are degraded (decomposed) by strong bases. Only the salts of alkaloids have low solubility.]

The SPE took the position that claims including even one inoperative embodiment are invalid. In support of this position he cited an opinion of the United States Supreme Court [*Graver Tank & Mfg. Co., Inc., v. The Linde Air Products Company*, 80 USPQ 451 (S. Ct. 1949)]. Pertinent text (page 453, right column) of *Graver Tank* provides:

While the cases more often have dealt with efforts to resort to specifications to expand claims, it is clear that the latter fail equally to perform their function as a measure of the grant when they overclaim the invention. When they do so to the point of invalidity and are free from ambiguity which might justify resort to specification, we agree with the District Court that they are not to be saved because the latter are less inclusive.

The clear inference from this language is not that inclusion of an inoperative embodiment invalidates a claim but that inclusion of a significant proportion may constitute overclaiming "to the point of invalidity".

Comments on this opinion by the Supreme Court are found in the opinion for *Hercules Inc. v. Exxon Corp.*, 207 USPQ at 1106:

The trial court refused to enforce these claims because "The evidence is clear and convincing that many silicates, even many metallic silicates, are inoperative as major constituents in a welding composition having for its objectives those stated in the patent."

A recent opinion, *Studiengesellschaft Kohle mbH v. Eastman Kodak Company*, 206 USPQ 577 (5th Cir. 1980), clearly takes the view (at page 599, right column) that inclusion of inoperative embodiments does not preclude validity of a claim.

With regard to the *Graver Tank* case, the SPE readily admitted that there were a number of subsequent C.C.P.A. cases which made it clear that inclusion of inoperative embodiments does not negate the patentability of asserted claims, but he took the position that no weight could be accorded these cases in view of the noted holding of the Supreme Court. The Examiner recognized the position of the C.C.P.A. with regard to the propriety of including inoperative embodiments in a generic claim. Support is provided, e.g., by *Ex parte Janin*, 209 USPQ 761 (PTO Bd. App. 1979) at 763:

It is not the function of claims or the specification to exclude all inoperative substances. *In re Dinh-Nguyen and Stenhagen*, 492 F.2d 856, 181 USPQ 46 (C.C.P.A. 1974), and as stated in *In re Geerdes*, 491 F.2d 1260, 180 USPQ 789 (C.C.P.A. 1974) at page 793 . . .

A careful reading of the Supreme Court opinion relied upon reveals that it fails to stand for the proposition for which it is cited. The opinion of the Supreme Court states:

... The trial court looked at claims 24 and 26 alone and declined to interpret the terms "silicates" and "metallic silicates" therein as being limited or qualified by specifications to mean only the nine metallic silicates which had been proved operative. The District Court considered that the claims therefore were too broad and comprehended more than the invention....

Resort to the opinion of the District Court [*The Linde Air Products Co. v. Graver Tank & Mfg. Co., Inc.*, 75 USPQ 231 (D.C. Ind. 1947)] for that case reveals the following:

Neither claim 24 nor claim 26 is limited to alkaline-earth-metal silicates. The one claims a new fluxing material comprising "Metallic silicate and calcium fluoride" and the other claims an electric welding composition consisting chiefly of "silicates." The evidence is clear and convincing that many silicates, even many metallic silicates, are inoperative as major constituents in a welding composition having for its objective those stated in the patent. The central fact renders these broad claims invalid.

As is readily appreciated by a review of the actual facts, a vast majority of encompassed embodiments were apparently inoperative, and that is what led the Supreme Court to the conclusion that the claims failed to perform their function as a measure of the grant to such an extent that they reached the point of invalidity. This is not a holding that the inclusion of an inoperative embodiment by a claim might render the claim invalid. Such issue was not before the Supreme Court; it was not considered by the Supreme Court; and it was not decided by the Supreme Court in the *Graver Tank* case.

During the interview the stated PTO position was that, subsequent to the noted Supreme Court decision, the only holdings that valid claims might encompass inoperative embodiments were those of the C.C.P.A., and such holdings were inadequate to overturn or to reverse a decision by the highest court in the land. That such is contrary to fact is confirmed by the opinion for *Studiengesellschaft Kohle mbH v. Eastman Kodak Company*, 206 USPQ 577, 599 (5th Cir. 1980), in which the following text appears:

Eastman complains that the great majority of the catalysts described in the examples, including many of the "preferred" systems, were shown to be inoperative for polymerizing propylene. Even assuming the truth of this assertion, it does not necessarily follow that the patent is invalid. Such claims encompassing myriad operative combinations are not invalid but are merely construed to exclude those inoperative combinations. *Noll v. O. M. Cott & Sons Co.*, 467 F.2d 295, 300 175 USPQ 392, 396-397 (6th Cir. 1972); *Ansul Co. v. Uniroyal, Inc.*, 301 F. Supp. 273, 288-289, 162 USPQ 525, 537-539 (S.D.N.Y. 1969), affirmed, 488 F.2d 872, 876, 878, 169 USPQ 759, 760-763 (2d Cir. 1971). See also *Application of Bowen*, 492 F.2d 859, 181 USPQ 48 (Cust. & Pat. App. 1974).

The foregoing provides clear authority beyond cases of the C.C.P.A. for the proposition that inclusion of inoperative embodiments does not invalidate or negate the patentability of a claim. The courts involved, including the C.C.P.A., must be regarded as being aware of the cited holding of the Supreme Court.

As pointed out to the Examiner and to his Supervisory Primary Examiner during the interview, even "insoluble" acid-addition salts are conventionally converted to corresponding free bases by forming a dispersion in a suitable carrier and adding an appropriate base to the resulting dispersion. No compounds are completely insoluble. No matter how limited solubility might be, to that extent the acid-addition salt is converted to its corresponding free base, and that free base has the noted utility. According to the specification all acid-addition salts are contemplated. Every possible acid-addition salt does not have to be a commercially-acceptable source of a useful pharmaceutical in order to satisfy utility requirements of the prevailing statute. There is no express mention in the specification of any insoluble acid-addition salt.

The Examiner Interview Summary Record states: "Applicant's counsel was asked to cite court decision(s) to support the inclusion of toxic salts in claims." Applicant's counsel has no recollection whatsoever of any such request. Reference is also made to *In re Gardner*, 166 USPQ 138 (C.C.P.A. 1970) and *Ex parte Reed*, 135 USPQ 34 (PTO Bd. App. 1961); however, no indication whatsoever is found of the proposition for which either of these cases was cited or how it applies to the facts at hand.

With regard to the several issues before the Court in *In re Gardner*, the C.C.P.A. stated:

... We do not find any indefiniteness in any of the claims by reason of their failure to name a host. They are merely broad in this respect and cover the composition and the method when administered or applied to *any* host capable of enjoying the benefits of an antidepressant drug. Breadth is not indefiniteness.

A similar situation obtains with respect to the dosage limitations of the claims. ... Where the invention resides in finding the activity rather than discovering some critical range or the like, we have approved of such broad definitions of quantity or dosage. ... They are enormously wide ranges but there is nothing indefinite about them. ...

... Now, it is observed that all of the pharmacological, posological (dosage) theory is before us only in the form of unsupported statements by appellants' counsel in their brief. There is nothing of the sort in appellants' specification, which contains neither the theory, the animal data, nor the information about the existence or the properties of the alleged standard antidepressant, imipramine There has been no disclosure of any "usual dose" of the claimed compounds or of the antidepressant effect of any *specific* dose on a human being or other animal.

The only adverse holding by the C.C.P.A. concerned the disclosure of utility in the specification. In this regard, attention was directed to Applicant's specification, pages 15 to 20, Examples 12 to 14 and pages 37 to 40. With regard to the second decision cited in the Examiner Interview Summary Record, Applicant noted that *Ex parte Reed*, supra, was decided almost twenty years prior to the previously cited *Studiengesellschaft Kohle* case.

The holding in the *Reed* case actually provides firm support for Applicant's position. In the paragraph of the opinion bridging pages 36 and 37 the PTO Board of Appeals states:

The examiner has also rejected claim 12 as "unduly broad in salts," as including toxic as well as non-toxic materials and as being unsupported by the specification. Claim 17 has been rejected as unpatentable over the acid, the examiner stating that no invention is involved in preparing simple salts of any acid, as this is a well-known chemical principle. We are not convinced of any error in these objections. In fact appellants in their brief concede that the salts are prepared by the conventional procedure of neutralization. Accordingly, the salts would be readily apparent and thus obvious to one skilled in the art, particularly as there is nothing patentable in the broad idea of forming the salts. Furthermore, appellants have specifically disclosed only the simple salts as giving the desired results and this affords insufficient basis for assuming that all metals of the periodic system will be suitable for the same intended purpose. . . .

The Applicant's disclosure is readily distinguishable from that before the Board of Appeals in the *Reed* case. Page 6 of Applicant's specification states:

All the acid-addition salts are contemplated. The pharmacologically-acceptable salts of the inorganic and organic acids customarily used galenically are of particular importance. Pharmacologically-unacceptable salts are readily converted into pharmacologically-acceptable salts by conventional and well-established processes.

How acid-addition salts are obtained and how they are converted into the corresponding free base or into other acid-addition salts is disclosed in the two complete paragraphs on page 26 of the specification. Toxic and non-toxic salts are clearly contemplated and expressly supported by Applicant's disclosure.

Since the salts are patentably indistinct from the free base in the situation at hand and since support is provided for "toxic as well as non-toxic materials", there is no reason to restrict Applicant's claims. Applicant's disclosure makes it ultimately clear that the salts are conventionally prepared and conventionally converted to either the corresponding free base or to pharmacologically-acceptable acid-addition salts. This is not an instance (as in the *Reed* decision) wherein any claim has been rejected "as unpatentable over the acid".

Although it is generally accepted that claims are read in the light of the specification upon which they are based, the PTO view of the *Graver Tank* holding also colored the PTO holding with regard to the disclosure required to support a claim to prophylaxis for and treatment of stomach and intestinal disorders in mammals. The Office Action questioned whether all such disorders were thus effectively treated, including cancers of the stomach and/or intestines. There was no mention in the specification of use in treating cancer. Related issues were considered prior to reaching a decision for *In re Sichert*, 196 USPQ 209, 211-213 (C.C.P.A. 1977):

The specification discloses the intended use of the compositions to be the removal of "lymphatic congestions." The sections 101 and 112 rejections are based upon the construction of this term by the P.T.O. Although the specification does not set forth a specific definition of the term, it does disclose using the compositions for treating a symptom or condition in which the lymphatic vessels are clogged, or the lymph flow is otherwise retarded. Appellant argues that the words "lymphatic congestion" are common and well known and should be given their ordinary meaning, that the term, as used in the specification, is limited to simple lymphatic congestion (clogged lymph vessels) and does not extend to the causes or results of lymphatic congestion (various therapy resistant diseases).

The board in the *Sichert* case found "that the term is intended to include lymphatic edemas resulting from various trauma including postoperative trauma and any number of disease states, including various forms of cancer"; further, that "the totality of the evidence of record strongly suggests that it [cancer] must be at least implicitly included within the disclosure of 'lymphatic congestion.'"

Nevertheless, the C.C.P.A. concluded that appellant's compositions were intended only for treatment of congestions or stoppages in the lymph system. The specification contained fifteen examples of such treatment. There was no mention of use in treating cancer. Appellant's brief set forth the following explanation, which was entirely consistent with the specification and the dictionary definitions, *supra* note 3:

As a result of the clogging, lymph may not flow beyond the point of clogging but lymph continues to flow toward that point, thereby filling to excess with lymph the space in the tubes upstream of the point of stoppage. As this overfilling continues, the pressure it exerts on the walls of the tubes increases and the lymph passes through those walls, which are porous, and into the space between the cells in the surrounding flesh, thereby producing edemas and the like.

Sichert's record clearly showed that the compositions were developed for the "activation and regeneration of the lymphatic vessels and of the lymph nodes associated with them"; that one of the criteria for determining the effectiveness of the composition was the "tendency of the

swellings of the tissues to decrease on account of the treatment"; that these compounds were "suited to diminish inflammatory changes of the lymphatic system and to remove congestions as well as products deposited in the lymph"; and that the result of treatment was "the effective drainage of the entire lymphatic system."

The (*Sichert*) board's finding that appellant's compositions were intended for treatment of diseases that cause or result from lymphatic congestions apparently rested on a semantical interpretation of the word "covers" in the board's statement that appellant "acknowledged" in Paper No. 8 (amendment of January 14, 1975, in response to office action of August 12, 1974) "that the term lymphatic congestion covers all the various diseases listed by the examiner in his rejection as well as others." Since the portion of Paper No. 8 containing this "acknowledgment" had not been included in the record, the C.C.P.A. accepted the finding as true. *Tiffany & Co. v. National Gypsum Co.*, 59 CCPA 1063, 459 F.2d 527, 173 USPQ 793 (1972). However, the C.C.P.A. did not accept the board's interpretation of "covers" to mean that appellant's compositions were intended for treatment of such diseases when the specification and the record as a whole did not support such an interpretation. Also, the C.C.P.A. noted that appellant's affidavit, which accompanied Paper No. 8 contained no such "acknowledgment."

As previously related, the examiner and the board in *Sichert* found that "the utility disclosed is inherently incredible." However, this finding was premised on an overly broad interpretation of "lymphatic congestion," discussed above. Construing the term more narrowly, as appellant has persuasively argued, the claimed utility was clearly not "incredible" and the C.C.P.A. so held.

Applicant's case is reminiscent of *In re Gazave*, 54 CCPA 1524, 379 F.2d 973, 154 USPQ 92 (1967), in which the claimed invention was directed to the treatment of "vascular disorders." The court held that the utility was not speculative, unbelievable, incredible, or factually misleading and said that where the assertion of usefulness appears to be believable on its face, the disclosed utility will be accepted as accurate.

Support provided by Applicant's disclosure clearly parallels those considered by the C.C.P.A. Specific illnesses:

Such illnesses include acute and chronic ulcer ventriculi and ulcer duodeni, gastritis and hyperacid gastric irritation in humans and other mammals

are explicitly set forth in the specification. The treatment is defined as being characterized "by administering a therapeutically-effective and pharmacologically-acceptable amount of one or more compounds of the

invention to a sick mammal afflicted with such an illness. The specification further points out that the pharmacologically-acceptable compound of the invention provides an excellent protective action on the stomach, as is demonstrated by comparative animal test data included in the application.

All of the preceding arguments were presented in a paper filed at the PTO two weeks prior to the issuance of the second Office Action (Paper No. 7) on the merits. This Office Action was made final [cf. 37 CFR § 1.113 - Appendix II].

[In view of the nature of the PTO operation a period of time elapses between the drafting of an Official Action by an Examiner and the typing, processing and mailing of the Official Action. When a paper is filed by an applicant during that period, the PTO has been unable to find a satisfactory way to consider the paper and to revise the Official Action draft to reflect such consideration.]

The substance of Paper No. 7 and of the response thereto is reflected in the following:

Response to Paper No. 7

Favorable reconsideration and withdrawal [cf. M.P.E.P. 706.07(c), (d) and (e) — Appendix III] of the finality of Paper No. 7 are respectfully requested in view of the preceding amendments and the following representations.

The instant amendments [cf. Appendix IV — Twice-Amended Claims] are substantially editorial in nature and are well supported by originally-asserted claims. Newly-submitted claim 14 is identical to original claim 1 except for the restriction of R³ to one of the two alternative meanings and the restriction of the acid-addition salt to one which is pharmacologically acceptable.

Withdrawal of the finality of Paper No. 7 is in order to provide Applicant record consideration of the paper filed on April 13, 1982, as directed to the attention of the PTO in a letter filed on July 16, 1982. Applicant submits that he is entitled to record consideration of a paper filed two weeks prior to

the issuance of Paper No. 7. Moreover, he should be entitled to full record consideration of all arguments and evidence submitted to the PTO prior to the issuance of an Office Action which was made final.

The instant paper was not previously presented because Applicant could not have known prior to the issuance of Paper No. 7 that such a paper would be issued [cf. Appendix II — 37 CFR § 1.116] without due consideration of the arguments and authorities presented in a paper filed at the PTO on April 13, 1982.

Applicant respectfully notes that the Examiner Interview Summary Record (Paper No. 5) was mailed on March 25, 1982. The arguments and authorities presented on April 13th were in response to Paper No. 5.

This matter was discussed with the Examiner on July 19, 1982. It is understood from that discussion that there is a reasonable prospect of having the finality of Paper No. 7 withdrawn.

Paper No. 7

1'. The specification is again rejected as being indefinite for the recitation of the symbols "I*", "I**" and "Ia" at pages 7-15 of the specification for the reasons given in paper No. 4, paragraph 1.

The arguments advanced and decisions cited have been considered but are not found to be persuasive that objection is improper. It is not seen where either of the decisions relied on by applicant would support applicant's position since the issues in each of the cases are different from those in the instant case. Although an applicant may be his (her) own lexicographer, he (she) may not use

1'. Applicant is unaware of any basis for rejecting a specification. The rejection of the specification "as being indefinite" is respectfully traversed. Applicant has considered the entire position presented on pages 2 and 3 of Paper No. 7 and is still unable to find any justification for the adverse holding.

Applicant's disclosure defines embodiments of formula I in the specification from line 9 on page 4 to line 22 on page 5. Embodiments I* are defined at lines 1 to 8 on page 7. Embodiments I** are defined in the text from line 15 on page 7 to line 18 on page 8. Embodiments Ia are defined in the text from line 2 on page 14 to line 8 on page 15. The respective embodiments are so defined that their meaning would be ultimately clear to anyone of ordinary skill in

a single symbol to represent more than one part of a given invention. Note particularly M.P.E.P. 608.01 (g) [Appendix III], the second complete paragraph at page 93. For example, at page 7, line 10, the sentence which begins with "Preferred representatives of embodiment I* . . .", the phrase, "Embodiment I*" has not been defined or identified. Note also line 15 of page 7 where the symbol "I**" is similarly used. At lines 20-23 on page 8 of the specification, it is not clear that the phrase "... R² . . . has one of the meanings of R¹" is referring to R¹ as defined at lines 16-17 of page 7 or as defined at page 4, lines 12-13. Applicant should note that at pages 7-15, each of the symbols "I*", "I**" and "Ia" are independently defined as being more than one embodiment of the compounds of Formula I, which is clearly improper as is set forth as page 93, column 2, second complete paragraph of M.P.E.P. 608.01(g). Correction is required.

the art and to many of far less skill.

Issue is respectfully taken with any allegation that one or more of these subgenera are not adequately defined in the specification. The definitions are readily found in the text cited in the preceding paragraph.

At lines 20 to 23 on page 8 of the specification Applicant respectfully submits that the normal reading of the cited text would be that R¹ at line 23 clearly refers to the definition of R¹ at line 21. At line 20 reference is made to representatives of embodiment I**; the definition of these embodiments expressly limits R² to a chlorine atom or one of the meanings of R¹ set forth at lines 16 and 17 on page 7. Even a cursory reading of the specification would confirm that all of the provided meanings are clear and unequivocal and would offer no difficulty to any artisan.

The cited section of the M.P.E.P. has been reviewed with interest. M.P.E.P. 608.01(f) [Appendix III] concerns drawings and cautions that "the detailed description of the invention shall refer to . . . the different parts by use of reference letters or numerals . . .". M.P.E.P. 608.01(g) relates back to the preceding section when it states:

The reference characters must be properly applied, no single reference character being used for two different parts or for a given part and a modification of such part. . . .

The cited text of the M.P.E.P. makes reference to elements of a drawing designated by a single reference character. That is not involved in the present text. Applicant is entitled to have selected subgenera and to identify them by any means he selects. Nothing is found in the M.P.E.P. which precludes this, and no authority outside of the M.P.E.P. is known which denies Applicant this right.

2'. The specification is again objected to for the recitation of human use at page 13, lines 18 and 22. There is no showing of any data in the specification to support the use of the compounds of the instant claims in the treatment or prophylaxis of any stomach and intestinal disorders. The arguments advanced by applicants have been considered but are not found to be persuasive that human use is adequately supported by the instant specification, especially within the guidelines set forth in M.P.E.P. 608.01(p). There is no showing that the compounds of the instant claims will in fact "inhibit the development of gastric ulcers" or can be "used for the treatment and *prophylaxis* (emphasis added) of disorders in the stomach or intestine and illnesses directly related thereto", as is recited at pages 12 and 13 of the specification. Are the compounds of the instant claims useful in the prophylaxis of cancers of the large intestines, as discussed in the reference to Carter, et al., "Chemotherapy of Cancer", second edition, 1981, J. Wiley & Sons, N.Y., pages 169-172? The cancers discussed therein are clearly "disorders of the intestines". There is no showing at pages 12 and 13 of the specification that the compounds of the instant claims are "useful in humans", as is urged by applicant. The data at pages 37-40 is not deemed to be sufficient to establish human use, as is

2'. The objection to the specification "for the recitation of human use" is also respectfully traversed. What the cited section of the M.P.E.P. states with regard to human use is:

If the asserted utility of a compound is believable on its face to persons skilled in the art in view of the contemporary knowledge in the art, then the burden is upon the examiner to give adequate support for rejections for lack of utility under this section. . . . On the other hand, incredible statements . . . or statements deemed unlikely to be correct by one skilled in the art will require adequate proof on the part of applicants for patents.

Proof of utility under this section may be established by clinical or *in vivo* or *in vitro* data, or combinations of these, which would be convincing to those skilled in the art More particularly, if the utility relied on is directed *solely* to the treatment of humans, evidence of utility, if required, must generally be clinical evidence, although animal tests may be adequate where the art would accept these as appropriately correlated with human utility . . .

From the preceding it is clear that there is no need for a showing or any data in the specification "to support the use of the compounds of the instant claims in the treatment or prophylaxis of any stomach and intestinal disorders." There is also no need for showing that the compounds of the instant claims will in fact "inhibit the development of gastric ulcers" or can be "used for the treatment and *prophylaxis* (emphasis added) of disorders in the stomach or intestine and illness directly related thereto."

In the absence of any clear and cogent reason to disbelieve the disclosed use of Applicant's claimed compounds, no showing and no data are required either in the specification or any other way. The PTO has failed to provide any possible basis for questioning Applicant's disclosed utility. Under the circumstances the objection to the specification is without any viable support; its withdrawal is in order and is respectfully

urged by applicant, since there is no showing of any data to correlate the test data in rats to humans.

Applicant is therefore required to cancel all reference to human use from the specification or to present some data, either direct or indirect, to support human use. This requirement is herein made *FINAL*.

4'. Claims 1-13 [cf. Appendix IV — Amended Claims] remain in this case.

5'. Claims 1 and 3-7 are again rejected as being directed to an improper Markush group for the reasons given in paper No. 5, page 3, fourth complete paragraph. The arguments advanced and the decisions cited by applicant have been considered

solicited.

Applicant respectfully submits that the data on pages 37 to 40 of the specification clearly support utility in humans. Carbenoxolon is an ethical drug commercially sold in Germany under the trademarks, Biogastrone® and Ulcus-Tablinen®. The test employed is an established method in the field for evaluating drugs for humans. This is confirmed, e.g., from texts of other United States patents, such as USP 4,243,678 (column 63, Table IX), USP 4,311,700 (columns 29 and 30), USP 4,317,823 (columns 36 and 37). Reference is further made to USP 3,275,634 (column 1, lines 31 through 33), USP 3,235,554, USP 3,660,380 (columns 12 and 13) and USP 3,743,734 (columns 12 and 13).

The practice set forth in the cited section of the M.P.E.P. does not require clinical data. The utility disclosed in this application is not *solely* directed to the treatment of humans, but to that of animals as well. Use of data on standard test animals, such as rats, is adequate for patent purposes. According to the M.P.E.P. human use does not have to be supported by an application or by proof unless there is good and sufficient reason to disbelieve what is disclosed. Reconsideration and withdrawal of the requirement "to cancel all reference to human use from the specification or to present some data . . . to support human use" are respectfully requested.

5'. The rejection of claims 1 and 3 to 7 "as being directed to an improper Markush group" is respectfully traversed. Claims to subject matter which is part of a single invention are properly included and examined in a single application. The intermediates and final products included in claim 1 are very closely related structurally; all of the

but are not found to be persuasive that the rejection is improper. Unlike in the *In re Harnisch*, supra, case where in all of the compounds possessed a single known utility as dyestuffs, the compounds of the instant application have more than one use, as is acknowledged by applicant. Therefore, the *Harnisch* case is not seen to support applicant's position. It is also not seen where the decision to *In re Magerlein*, supra, supports applicant's position since the issue and fact situation in the instant case are not the same as in the *Magerlein* case. Applicant's attention is again directed to *In re Ruzicka*, supra, and *In re Winnek*, supra, which are directly in point. The two classes of compounds of the instant claims are deemed to be patentable over each other under 35 U.S.C. 103 and are therefore capable of supporting separate patents under 35 U.S.C. 121.

compounds are useful in making medication compositions, such as those called for by claims 9 to 11. The major and significant structural relationship of all compounds is defined by the structure presented at line 2 of claim 1. This is submitted to be of sufficient structural similarity to warrant inclusion of all claimed compounds in a single application and in a single patent. The *Harnisch* case emphasizes the significance of structural similarity in determining the propriety of including compounds in a single claim. The structural similarity between all embodiments of Applicant's claimed compounds is regarded as substantially greater than that present in the *Harnisch* case. The *Magerlein* case acknowledges the fact that intermediates can be regarded as closely related to final products produced therefrom when critical structure is present in the intermediates. In the instant case the critical structure is clearly included in all claimed compounds. Applicant further notes the decision of February 26, 1982, for *Ex Parte Holt*, 214 USPQ 381 (PTO Bd. App. 1982), which indicates that the PTO Board of Appeals concluded that the Examiner's rejection for an improper Markush group was improper because the claimed compounds possessed a structural similarity, i.e., they were all piperidine derivatives.

The case law cited on Applicant's behalf is 1980 vintage, not the 1947 or earlier vintage of the *Ruzicka* or *Winnek* cases. There have been many changes in practice over the last thirty years and the rejection relating to the propriety of the Markush group, as applied, is not in accord with current practice. No current case law supports this rejection. Moreover, the rejection is not supported by any statute or other authority. In the ab-

sence of clear and unequivocal support of current vintage, withdrawal of this ground of rejection is also respectfully requested.

6'. The restriction requirement as made in paper No. 5 is herein maintained and is made *FINAL*.

The arguments advanced by applicant are not found persuasive that the restriction is improper. Applicant's arguments at page 7, last complete paragraph relative to "classification schedules" are noted but are not found to be pertinent since the restriction requirement is not based on a "classification schedule". Applicant's attention is directed to M.P.E.P. 808.02(2) [Appendix III] relative to the argument concerning "separate status in the art."

7'. Applicant is advised that any further response *MUST* include the cancellation of the claims to the non-elected invention or the taking of other appropriate action, M.P.E.P. 821.01 [Appendix III]; 37 C.F.R. 1.144 [Appendix II].

Claim 2 stands withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) [Appendix II], as being for a nonelected invention, the requirement having been traversed in paper No. 6.

8'. Claims 1 and 3 are rejected under 35 USC 112, second paragraph, as being indefinite. The phrase "an acid-addition salt thereof" continues to render the

6'. For the same reasons, the restriction requirement is unwarranted. Reconsideration and withdrawal of that requirement are also respectfully solicited for the given reasons. The intermediates and final products are all part of one invention and should be included in claims for a single patent.

7'. Applicant has effectively cancelled claim 2. Claim 1, however, has been retained.

8'. The rejection of claims 1 and 3 "under 35 USC 112, second paragraph, as being indefinite" is also respectfully traversed. The phrase "an acid-addition salt thereof" clearly does not render any claim indefinite.

claims indefinite since there is no recitation of the nature of the acid. The fact that the phrase may appear in the claims of other patents is no basis for urging that the phrase "reflects standard accepted usage in the involved art". Each patent must be examined on its own merits. In the instant case, the phrase renders the claims indefinite.

The meaning of the cited expression is clear and is well known to anyone of ordinary skill in the art. No artisan has any difficulty whatsoever in understanding completely what is included by that expression. The term may be broad, but it certainly is not indefinite at all. No basis has been provided for considering the expression indefinite, and the rejection on that basis is completely unjustified.

The fact the phrase appears in literally hundreds of patents regularly issued by qualified Examiners is certainly good and sufficient reason to believe that the phrase "reflects standard accepted usage in the involved art". Although each patent must be examined on its own merits, there are certain criteria which are standards which are continually repeated and clearly reflect established practice. Merely alleging that a phrase "renders the claims indefinite" does not make it so.

Virtually every compound known to man is soluble in some solvent. There is no reason to believe that an acid-addition salt exists that cannot be converted to a free base or to a pharmacologically-acceptable acid-addition salt in a conventional manner. Even (purely arguendo) were such an embodiment to exist, such would not be sufficient to preclude the patentability of Applicant's asserted claims.

9'. Claims 1, 3 and 12 are rejected under 35 USC 112, first paragraph, as being based on a non-enabling disclosure. The phrase "an acid-addition salt thereof" renders the claims readable on compounds not finding adequate support in the disclosure, not adequately shown how to be prepared and not adequately shown to

9'. The rejection of claims 1, 3 and 12 "under 35 USC 112, first paragraph, as being based on a non-enabling disclosure" is also respectfully traversed. The phrase "an acid-addition salt thereof" clearly does not read on compounds "not finding adequate support in the disclosure, not adequately shown how to be prepared and not adequately shown to possess the disclosed utility." There is no viable basis for such a

possess the disclosed utility. Applicant urges that "no authority is known to require applicant to teach that the compounds of the instant claims can be used effectively in the prophylaxis of all stomach and intestinal disorders in mammals in order to warrant their presentation." Applicant is advised that no authority is known that permits the claiming of substances not shown to be useful. The objected to claim terminology is so broad as to read on substances which would clearly be toxic if administered to animals or humans, compare *In re Gardner*, supra; *Graver Tank v. Linde Air Products Co.*, 1949 CD 527, 531. Although there is no specific teaching in the specification of the use of the claimed compounds for "cancers of the stomach and/or intestines", the broad statement as page 13, lines 8-16, clearly reads on "cancer of the stomach or intestines", as is shown in the reference to Carter, et al., cited supra. There is no adequate showing that the compounds of claim 7 can be used in the prophylaxis of the stomach or intestinal disorders of all mammals as claim 12 presently reads. The erroneous reference to claim 15 in paper No. 5 is regretted.

statement and such a holding. The PTO is hereby challenged to support each and every one of these statements or to withdraw them from the record. In the absence of proof that any acid-addition salt (which is not pharmaceutically acceptable) is completely insoluble in all solvents and cannot possibly be converted by conventional means to either the corresponding free base or to a pharmacologically-acceptable acid-addition salt, the allegations are unsupportable. How to convert acid-addition salts to corresponding free bases and to pharmacologically-acceptable acid-addition salts is known to those of ordinary skill in the art. That which was known prior to Applicant's filing date need not be written out expressly in the specification.

With all due respect to the allegation to the contrary, if, by chance, any of Applicant's generic claims actually happen to encompass one or two substances which were subsequently proved to be non-useful, there is no reason to believe that such would provide a valid basis for precluding the patentability of Applicant's claims. The fact is that the PTO has been unable to come up with any possible embodiment that can be established to be non-useful.

Any encompassed substance "which would clearly be toxic if administered to animals or humans" could readily be converted by conventional means to a corresponding free base or pharmacologically-acceptable acid-addition salt.

Reference is made to claim 12. This claim is limited to the treatment "of a stomach or intestinal disorder of the type of acute and chronic ulcer ventriculi and ulcer duodeni, gastritis and hyperacid gastric irritation". No basis for questioning this utility in mammals afflicted with the stated type of

10'. Claims 8-11 and 13 are objected to for depending from a rejected parent claim. These claims are considered to contain allowable subject matter and would be considered allowable if rewritten in independent form.

disorder is presented.

10'. The objection to claims 8 to 11 and 13 "for depending from a rejected parent claim" will be clearly resolved by the allowance of the corresponding parent claims. Such allowance is supported by the preceding comments and is respectfully solicited.

Concurrently with the previously-presented principal response to Paper No. 7 a supplemental response was filed at the PTO. The supplemental response deleted from the specification each cited recitation of human use and requested the addition of a further claim [cf. Appendix IV — Claim 15]. If an attempt had been made in the principal response to add a claim, such response could have been refused consideration. Increasing the number of asserted claims is regarded by many Examiners as necessarily increasing issues and thus prohibited after an application is under final rejection. By presenting separate papers to the PTO, the Examiner could decide whether either or both were appropriately enterable.

The Examiner actually found claim 13 objectionable and rewrote it [cf. Appendix IV — Claim 16] by Examiner's Amendment [cf. M.P.E.P. 1302.4 — Appendix III] at the time the application was allowed. After the formal Notice of Allowance issued, this application was subjected to quality review [cf. M.P.E.P. 1308.03 — Appendix III] and the consequent discovery that Claims 7 and 14 were identical in scope. With Applicant's oral approval an Examiner's Amendment deleted "pharmacologically-acceptable" from Claim 4.

The prosecution of this application was noteworthy in several respects:

1. No ground of rejection was based on any prior art.
2. A restriction requirement was made, traversed, made final and was not subsequently withdrawn. Generic claim 1 was subsequently allowed, however.
3. A basic issue involved the propriety of a Markush group defining both intermediates and final products.
4. Another basic issue was whether claims have to exclude possibly-inoperative embodiments or whether claimed acid-addition salts (of a compound disclosed as having pharmacological utility) have to be limited to those which are physiologically acceptable and, possibly, those

which are readily convertible to physiologically-acceptable acid-addition salts.

5. A third, perhaps less significant, issue concerned the objection to or rejection of the specification as indefinite in the use of cited symbols.

The resolution of each of these noted issues is reported with the hope that other applicants will not be harassed by these and similar issues.

APPENDIX I PATENT LAWS

§103 Conditions for patentability; non-obvious subject matter

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

§112 Specification

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.

Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

§119 Benefit of earlier filing date in foreign country; right of priority

An application for patent for an invention filed in this country by any person who has, or whose legal representatives or assigns have, previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed; but no patent shall be granted on any application for patent for an invention which had been patented or described in a printed publication in any country more than one year before the date of the actual filing of the application in this country, or which had been in public use or on sale in this country more than one year prior to such filing.

No application for patent shall be entitled to this right of priority unless a claim therefor and a certified copy of the original foreign application, specification and drawings upon which it is based are filed in the Patent and Trademark Office before the patent is granted, or at such time during the pendency of the application as required by the Commissioner not earlier than six months after the filing of the application in this country. Such certification shall be made by the patent office of the foreign country in which filed and show the date of the application and of the filing of the specification and other papers. The Commissioner may require a translation of the papers filed if not in the English language and such other information as he deems necessary.

In like manner and subject to the same conditions and requirements, the right provided in this section may be based upon a subsequent regularly filed application in the same foreign country instead of the first filed foreign application, provided that any foreign application filed prior to such subsequent application has been withdrawn, abandoned, or otherwise disposed of, without having been laid open to public inspection and without leaving any rights outstanding, and has not served, nor thereafter shall serve, as a basis for claiming a right of priority.

Applications for inventors' certificates filed in a foreign country in which applicants have a right to apply, at their discretion, either for a patent or for an inventor's certificate shall be treated in this country in

the same manner and have the same effect for purpose of the right of priority under this section as applications for patents, subject to the same conditions and requirements of this section as apply to applications for patents, provided such applicants are entitled to the benefits of the Stockholm Revision of the Paris Convention at the time of such filing.

§121 Divisional applications

If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application. If a divisional application is directed solely to subject matter described and claimed in the original application as filed, the Commissioner may dispense with signing and execution by the inventor. The validity of a patent shall not be questioned for failure of the Commissioner to require the application to be restricted to one invention.

§132 Notice of rejection; reexamination

Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Commissioner shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. No amendment shall introduce new matter into the disclosure of the invention.

APPENDIX II

RULES OF PRACTICE

§1.97 Filing of prior art statement.

(a) As a means of complying with the duty of disclosure set forth in §1.56, applicants are encouraged to file a prior art statement at the time of filing the application or within three months thereafter. The statement may either be separate from the specification or may be incorporated therein.

(b) The statement shall serve as a representation that the prior art listed therein includes, in the opinion of the person filing it, the closest prior art of which that person is aware; the statement shall not be construed as a representation that a search has been made or that no better art exists.

§1.113 Final rejection or action.

(a) On the second or any subsequent examination or consideration the rejection or other action may be made final, whereupon applicant's or patent owner's response is limited to appeal in the case of rejection of any claim (§1.191), or to amendment as specified in §1.116. Petition may be taken to the Commissioner in the case of objections or requirements not involved in the rejection of any claim (§1.181). Response to a final rejection or action must include cancellation of, or appeal from the rejection of, each rejected claim. If any claim stands allowed, the response to a final rejection or action must comply with any requirements or objection as to form.

(b) In making such final rejection, the examiner shall repeat or state all grounds of rejection then considered applicable to the claims in the case, clearly stating the reasons therefor.

§1.116 Amendments after final action.

(a) After final rejection or action (§1.113) amendments may be made cancelling claims or complying with any requirement of form which has been made. Amendments presenting rejected claims in better form for consideration on appeal may be admitted. The admission of, or refusal to admit, any amendment after final rejection, and any proceedings relative thereto, shall not operate to relieve the application or patent under reexamination from its condition as subject to appeal or to save the application from abandonment under §1.135.

(b) If amendments touching the merits of the application or patent under reexamination are presented after final rejection, or after appeal has been taken, or when such amendment might not otherwise be

proper, they may be admitted upon a showing of good and sufficient reasons why they are necessary and were not earlier presented.

(c) No amendment can be made as a matter of right in appealed cases. After decision on appeal, amendments can only be made as provided in §1.198, or to carry into effect a recommendation under §1.196.

§1.133 Interviews.

(a) Interviews with examiners concerning applications and other matters pending before the Office must be had in the examiners' rooms at such times, within office hours, as the respective examiners may designate. Interviews will not be permitted at any other time or place without the authority of the Commissioner. Interviews for the discussion of the patentability of pending applications will not be had before the first official action thereon. Interviews should be arranged for in advance.

(b) In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for response to Office actions as specified in §§1.111, 1.135.

§1.142. Requirement for restriction.

(a) If two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant in his response to that action to elect that invention to which his claim shall be restricted, this official action being called a requirement for restriction (also known as a requirement for division). If the distinctness and independence of the inventions be clear, such requirement will be made before any action on the merits; however, it may be made at any time before final action in the case at the discretion of the examiner.

(b) Claims to the invention or inventions not elected, if not canceled, are nevertheless withdrawn from further consideration by the examiner by the election, subject however to reinstatement in the event the requirement for restriction is withdrawn or overruled.

§1.144. Petition from requirement for restriction.

After a final requirement for restriction, the applicant, in addition to making any response due on the remainder of the action, may petition the Commissioner to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention

elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested. (See §1.181.)

APPENDIX III

MANUAL OF PATENT EXAMINING PROCEDURES

608.01(f) Brief Description of Drawings

37 CFR 1.74. Reference to drawings. When there are drawings, there shall be a brief description of the several views of the drawings and the detailed description of the invention shall refer to the different views by specifying the numbers of the figures, and to the different parts by use of reference letters or numerals (preferably the latter).

The examiner should see to it that the figures are correctly described in the brief description of the drawing, that all section lines used are referred to, and that all needed section lines are used.

608.01(g) Detailed Description of Invention

A detailed description of the invention and drawings follows the general statement of invention and brief description of the drawings. This detailed description, required by 37 CFR 1.71, § 608.01, must be in such particularity as to enable any person skilled in the pertinent art or science to make and use the invention without involving extensive experimentation. An applicant is ordinarily permitted to use his own terminology, as long as it can be understood. Necessary grammatical corrections, however, should be required by the examiner, but it must be remembered that an examination is not made for the purpose of securing grammatical perfection.

The reference characters must be properly applied, no single reference character being used for two different parts or for a given part and a modification of such part. In the latter case, the reference character, applied to the "given part", with a prime affixed may advantageously be applied to the modification. Every feature specified in the claims must be illustrated, but there should be no superfluous illustrations.

The description is a dictionary for the claims and should provide clear support or antecedent basis for all terms used in the claims. See 37 CFR 1.75, §§ 608.01 (i), 608.01(o), and 1302.01.

608.01(p) Completeness [R-5]

Newly filed applications obviously failing to disclose an invention with the clarity required are discussed in § 702.01.

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which the invention pertains to make and use the invention as of its filing date, *In re Glass*, 181 USPQ 31; 492 F.2d 1228 (CCPA 1974).

While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details, including proportions and techniques where necessary, as to enable those persons skilled in the art to make and utilize the invention.

Specific operative embodiments or examples of the invention must be set forth. Examples and description should be of sufficient scope as to justify the scope of the claims. Markush claims must be provided with support in the disclosure for each member of the Markush group. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula.

A complete disclosure should include a statement of utility. This usually represents no problem in mechanical cases. In chemical cases, varying degrees of specificity are required.

A disclosure involving a new chemical compound or composition must teach persons skilled in the art how to make the compound or composition. Incomplete teachings may not be completed by reference to subsequently filed applications.

A. Guidelines for Considering Disclosures of Utility in Drug Cases

General

These guidelines are set down to provide uniform handling of applications disclosing drug or pharmaceutical utility. They are intended to guide patent examiners and patent applicants as to criteria for utility statements. They deal with fundamental questions and are subject to revision and amendment if future case law indicates this to be necessary.

The following two basic principles shall be followed in considering matters relating to the adequacy of disclosure of utility in drug cases:

(1) The same basic principles of patent law which apply in the field of chemical arts shall be applicable to drugs, and

(2) The Patent and Trademark Office shall confine its examination of disclosure of utility to the application of patent law principles, recognizing that other agencies of the Government have been assigned the responsibility of assuring conformance to the standards established by statute for the advertisement, use, sale or distribution of drugs. *In re Krimmel*, 48 CCPA 1116, 292 F.2d 948, 130 USPQ 215 (1961); *In re Hartop et al.*, 50 CCPA 780, 311 F.2d 249, 135 USPQ 419 (1962).

A drug is defined by 21 U.S.C. 321 (g)

The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (c) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C); but does not include devices or their components, parts or accessories.

In addition, compositions adapted to be applied to or used by human beings, e.g., cosmetics, dentifrices, mouthwashes, etc., may be treated in the same manner as drugs subject to the conditions stated.

Any proof of a stated utility or safety required pursuant to these guidelines may be incorporated in the application as filed, or may be subsequently submitted by affidavit if and when required. The Patent and Trademark Office, in reaching its own independent decisions on questions of utility and how to use under 35 U.S.C. 101 and 112, will continue to avail itself of assistance and information from the Secretary of Health, Education, and Welfare as authorized by 21 U.S.C. 372(b), when necessary.

In accordance with the basic principles set forth above, the following procedures shall be followed in examining patent applications in the drug field with regard to disclosure relating to utility.

35 U.S.C. 101

Utility must be definite and in currently available form; (*Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689) not merely for further investigation or research but commercial availability is not necessary. Mere assertions such as "therapeutic agents," (*In re Lorenz et al.*, 49 CCPA 1227, 305 F.2d 875, 134 USPQ 312; cf. *Ex parte Brockmann et al.*, 127 USPQ 57) "for pharmaceutical purposes," (*In re Diedrich*, 50 CCPA 1355, 318 F.2d 946, 138 USPQ 128) "biological activity," *In re Kirk et al.*, 54 CCPA 1119, 153 USPQ 48; *Ex parte Lanham*, 135 USPQ 106) "intermediate," (*In re Joly et al.*, 54 CCPA 1159, 153 USPQ 45; *In re Kirk et al.*, 54 CCPA 1119; 153 USPQ 48) and for making further unspecified preparations are regarded as insufficient.

If the asserted utility of a compound is believable in its face to persons skilled in the art in view of the contemporary knowledge in the art, then the burden is upon the examiner to give adequate support for rejections for lack of utility under this section (*In re Gazave*, 54 CCPA 1524, 154 USPQ 92). On the other hand, incredible statements (*In re Citron*, 51 CCPA 852, 325 F.2d 248, 139 USPQ 516; *In re Oberweger*, 28 CCPA 749, 115 F.2d 826, 47 USPQ 455; *Ex parte Moore et al.*, 128 USPQ 8) or statements deemed unlikely to be correct by one skilled in the art (*In re Ruskin*, 53 CCPA 872, 354 F.2d 395, 148 USPQ 221; *In re Pottier*, 54 CCPA 1293, 153 USPQ 407; *In re Novak et al.*, 49 CCPA 1283, 306 F.2d 924, 134 USPQ 335. See also, *In re Irons*, 52 CCPA 938, 340 F.2d 974, 144 USPQ 351) in view of the contemporary knowledge in the art will require adequate proof on the part of applicants for patents.

Proof of utility under this section may be established by clinical or *in vivo* or *in vitro* data, or combinations of these, which would be convincing to those skilled in the art (*In re Irons*, 51 CCPA 938, 340 F.2d 924, 144 USPQ 351; *Ex parte Paschall*, 88 USPQ 131; *Ex parte Pennell et al.*, 99 USPQ 56; *Ex parte Ferguson*, 117 USPQ 229; *Ex parte Timmis*, 123 USPQ 581). More particularly, if the utility relied on is directed solely to the treatment of humans, evidence of utility, if required, must generally be clinical evidence, (*Ex parte Timmis*, 123 USPQ 581) although animal tests may be adequate where the art would accept these as appropriately correlated with human utility (*In re Hartop et al.*, 50 CCPA 780, 311 F.2d 249, 135 USPQ 419; *Ex parte Murphy*, 134 USPQ 134). If there is no assertion of human utility, (*Blicke v. Treves*, 44 CCPA 753, 241 F.2d 718, 112 USPQ 472; *In re Krimmel*, 48 CCPA 1116, 292 F.2d 948, 130 USPQ 215; *In re Dodson*, 48 CCPA 1125, 292 F.2d 943, 140 USPQ 224; *In re Hitchings*, 52 CCPA 1141, 342 F.2d 80, 14 USPQ 637) or if there is an assertion of animal utility, (*In re Bergel et al.*, 48 CCPA 1102, 292 F.2d 955, 130 USPQ 206; *Ex parte Melvin*, 155 USPQ 47) operativeness for use on standard test animals is adequate for patent purposes.

Exceptions exist with respect to the general rule relating to the treatment of humans. For example, compositions whose properties are generally predictable from a knowledge of their components, such as laxatives, antacids and certain topical preparations, require little or no clinical proof (*Ex parte Harrison et al.*, 129 USPQ 172; *Ex parte Lewin*, 140 USPQ 70).

Although absolute safety is not necessary to meet the utility requirement under this section, a drug which is not sufficiently safe under the conditions of use for which it is said to be effective will not

satisfy the utility requirement (*In re Hartop et al.*, 50 CCPA 780, 311 F.2d 249, 135 USPQ 419). Proof of safety shall be required only in those cases where adequate reasons can be advanced by the examiner for believing that the drug is unsafe, and shall be accepted if it establishes a reasonable probability of safety.

35 U.S.C. 112

A mere statement of utility for pharmacological or chemotherapeutic purposes may raise a question of compliance with section 112, particularly "... as to enable any person skilled in the art to which it pertains ... to use the same." If the statement of utility contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are contemplated, section 112 is satisfied (*In re Johnson*, 48 CCPA 733, 282 F.2d 370, 127 USPQ 216; *In re Hitchings et al.*, 52 CCPA 1141, 342 F.2d 80, 144 USPQ 637). If the use disclosed is of such nature that the art is unaware of successful treatments with chemically analogous compounds, a more complete statement of how to use must be supplied than if such analogy were not present (*In re Moureu et al.*, 52 CCPA 1363, 345 F.2d 595, 145 USPQ 452; *In re Schmidt et al.*, 54 CCPA 1577, 153 USPQ 640). It is not necessary to specify the dosage or method of use if it is obvious to one skilled in the art that such information could be obtained without undue experimentation.

With respect to the adequacy of disclosure that a claimed genus possesses an asserted utility representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if it would be deemed likely by one skilled in the art, in view of contemporary knowledge in the art, that the claimed genus would possess the asserted utility (*In re Oppenauer*, 31 CCPA 1248, 143 F.2d 974, 62 USPQ 297; *In re Cavallito et al.*, 48 CCPA 711, 282 F.2d 357, 127 USPQ 202; *In re Cavallito et al.*, 48 CCPA 720, 282 F.2d 363, 127 USPQ 206; *In re Schmidt*, 48 CCPA 1140, 293 F.2d 274, 130 USPQ 404; *In re Cavallito*, 49 CCPA 1335, 306 F.2d 505, 134 USPQ 370; *In re Surrey*, 54 CCPA 855, 370 F.2d 349, 151 USPQ 724; *In re Lund et al.*, 54 CCPA 1361, 153 USPQ 625). Proof of utility will be required for other members of the claimed genus only in those cases where adequate reasons can be advanced by the examiner for believing that the genus as a whole does not possess the asserted utility. Conversely, a sufficient number of representative examples, if disclosed in the prior art will constitute a disclosure of the genus to which they belong.

In the case of mixtures including a drug as an ingredient, or mixtures which are drugs, or methods of treating a specific condition with a drug, whether old or new, a specific example should ordinarily be set forth, which should include the organism treated. In appropriate cases, such an example may be inferred from the disclosure taken as a whole and/or the knowledge in the art (e.g., gargle).

Where the claimed compounds are capable of several different utilities and one use is adequately described in accordance with these guidelines, additional utilities will be investigated for compliance with sections 101 and 112 only if not believable on their face to those of ordinary skill in the art in view of the contemporary knowledge of the art. Failure to meet these standards may result in a requirement to cancel such additional utilities (*Ex parte Lanham*, 121 USPQ 223; *Ex parte Moore et al.*, 128 USPQ 8; *In re Citron*, 51 CCPA 852, 325 F.2d 248, 139 USPQ 516; *In re Gottlieb et al.*, 51 CCPA 1114, 328 F.2d 1016, 140 USPQ 665).

706.07(c) Final Rejection, Premature

Any question as to prematurity of a final rejection should be raised, if at all, while the case is still pending before the primary examiner. This is purely a question of practice, wholly distinct from the tenability of the rejection. It may therefore not be advanced as a ground for appeal, or made the basis of complaint before the Board of Appeals. It is reviewable by petition.

706.07(d) Final Rejection, Withdrawal of, Premature

If, on request by applicant for reconsideration, the primary examiner finds the final rejection to have been premature, he should withdraw the finality of the rejection.

706.07(e) Withdrawal of Final Rejection, General [G-6]

See §§ 714.12 and 714.13, Amendments after final rejection.

Once a final rejection that is not premature has been entered in a case, it should not be withdrawn at the applicant's or patent owner's request except on a showing under 37 CFR 1.116(b). Further amendment or argument will be considered in certain instances. An amendment that will place the case either in condition for allowance or in better form for appeal may be admitted. Also, amendments complying with objections or requirements as to form are to be permitted after final action in accordance with 37 CFR 1.116(a).

The examiner may withdraw the rejection of finally rejected claims. If new facts or reasons are presented such as to convince the examiner that the previously rejected claims are in fact allowable or

patentable in the case of reexamination, then the final rejection should be withdrawn. Occasionally, the finality of a rejection may be withdrawn in order to apply a new ground of rejection.

Although it is permissible to withdraw a final rejection for the purpose of entering a new ground of rejection, this practice is to be limited to situations where a new reference either fully meets at least one claim or meets it except for differences which are shown to be completely obvious. Normally, the previous rejection should be withdrawn with respect to the claim or claims involved.

The practice should not be used for application of subsidiary references, or of cumulative references, or of references which are merely considered to be better than those of record. Furthermore, the practice should not be used for entering new non-reference or so-called "formal" grounds of rejection such as those under 35 U.S.C. 112.

When a final rejection is withdrawn, all amendments filed after the final rejection are ordinarily entered.

New grounds of rejection made in an Office action reopening prosecution after the filing of an appeal brief require the approval of the supervisory primary examiner. See § 1002.02(d).

808.02 Related Inventions

Where, as disclosed in the application, the several inventions claimed are related, and such related inventions are not patentably distinct as claimed, restriction under 35 U.S.C. 121 is never proper (§ 806.05). If applicant optionally restricts, double patenting may be held.

Where the related inventions as claimed are shown to be distinct under the criteria of §§ 806.05(c-i), the examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following:

- (1) Separate classification thereof:

This shows that each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification.

- (2) A separate status in the art when they are classifiable together;

Even though they are classified together, as shown by the appropriate explanation each subject can be shown to have formed a separate subject for inventive effort when an explanation indicates a recognition of separate inventive effort by inventors. Separate status in

the art may be shown by citing patents which are evidence of such separate status.

(3) A different field of search:

Where it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists, a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims. Patents need not be cited to show different fields of search.

Where, however, the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among related inventions.

821.01 After Election With Traverse

Where the initial requirement is traversed, it should be reconsidered. If, upon reconsideration, the examiner is still of the opinion that restriction is proper, it should be repeated and made final the requirement in the next Office action. (See § 803.01). In doing so, the examiner should reply to the reasons or argument advanced by applicant in the traverse.

If the examiner, upon reconsideration, is of the opinion that the requirement for restriction is improper, he or she should state in the next Office Action that the requirement for restriction is withdrawn and give an action on all the claims.

If the requirement is repeated and made final, in that and in each subsequent action, the claims to the nonelected invention should be treated by using Form Paragraph 8.05

This will show that applicant has retained the right to petition from the requirement under 37 CFR 1.144. (See § 818.03(c).)

When the case is otherwise ready for issue, and has not received a final action, the examiner should treat the case by using Form Paragraph 8.03. See §809.02(c).

When preparing a final action in an application where there has been a traversal of a requirement for restriction, the examiner should indicate in his action that a complete response must include cancellation of the claims drawn to the non-elected invention, or other appropriate action (37 CFR 1.144). See Form Paragraph 8.24

Where a response to a final action has otherwise placed the application in condition for allowance, the failure to cancel claims drawn to the non-

elected invention or to take appropriate action will be construed as authorization to cancel these claims by examiner's amendments and pass the case to issue after the expiration of the period for response.

Note that the petition under 37 CFR 1.144 must be filed "not later than appeal". This is construed to mean appeal to the Board of Appeals. If the case is ready for allowance *after* appeal and no petition has been filed, the examiner should simply cancel the non-elected claims by examiner's amendment, calling attention to the provisions of 37 CFR 1.144.

1302.04 Examiner's Amendments and Changes

Except by formal amendment duly signed or as hereinafter provided, no corrections, erasures, or interlineations may be made in the body of written portions of the specifications or any other paper filed in the application for patent. (See 37 CFR 1.121.)

Correction of the following obvious errors and omissions only may be made with pen by the examiner of the case who will then initial the sheet margin and assume full responsibility for the change. When correcting *originally filed* papers, clean red ink *must* be used (not blue or black ink).

1. Misspelled words.
2. Disagreement of a noun with its verb.
3. Inconsistent "case" of a pronoun.
4. Disagreement between a reference character as used in the description and on the drawing. The character may be corrected in the description but only when the examiner is certain of the propriety of the change.
5. Entry of "Patent No.____" to identify a patent which has been granted on a U.S. application referred to by serial number in the specification.
6. Entry of "abandoned", if a U.S. patent application referred to by serial number in the specification has become abandoned.
7. Entry of "now Defensive Publication No. T____," following the filing date if a patent application referred to in the specification by serial number has been published as a Defensive Publication.
8. Other obvious minor grammatical errors such as misplaced or omitted commas, improper parentheses, quotation marks, etc.

9. Obvious informalities in the application, other than the ones noted above, or of purely grammatical nature.

The fact that applicant is entitled under 35 U.S.C. 120 to an earlier U.S. effective filing date is sometimes overlooked. To minimize this possibility, the statement that, "This is a division (continuation, continuation-in-part) of Application Serial No.____, filed____." should appear as the first sentence after the abstract except in the case of design applications where it should appear as set forth in § 1503.01. Any such statements appearing elsewhere in the specification should be relocated. The clerk indicates the change for the printer in the appropriate margin when checking new applications for matters of form.

Other obvious informalities in the application may be corrected by the examiner, but such corrections must be by a formal examiner's amendment, signed by the primary examiner, placed in the file, and a copy sent to the applicant. The changes specified in the amendment are entered by the clerk in the regular way.

The amendment or cancellation of claims by formal examiner's amendment is permitted when passing an application to issue where these changes have been authorized by applicant (or his attorney or agent) in a telephone or personal interview. The examiner's amendment should indicate that the changes were authorized, the date and type (personal or telephone) of interview, and with whom it was held.

The examiner's amendment practice may be used to make charges against deposit accounts under special conditions. Such charges must not exceed \$50.00 for any one patent application.

An examiner's amendment can be used to make a charge against a deposit account, provided prior approval is obtained from the applicant, attorney or agent, in order to expedite the issuance of a patent on an application otherwise ready for allowance. When such an examiner's amendment is prepared the prior approval is indicated by identification of the name of the authorizing party, the date and type (personal or telephone) of authorization, the purpose for which the charge is made (drawing correction, additional claims, etc.), and the deposit account number. Further identifying data, if deemed necessary and requested by the attorney, should also be included in the examiner's amendment.

A change in the abstract may be made by examiner's amendment.

Where a reference to the parent application in an otherwise allowable § 1.60 case has inadvertently been omitted by the applicant, the examiner should insert the required reference by examiner's amend-

ment (see § 201.11).

References cited as being of interest by examiners when passing an application to issue will not be supplied to applicant. The references will be cited as usual on form PTO-892, a copy of which will be attached to examiner's amendment form PTOL-37.

Where an application is ready for issue except for a slight defect in the drawing not involving change in structure, the examiner will note in pencil on the drawing the addition or alteration to be made. The examiner will also prepare an examiner's amendment indicating the changes made and send the drawing to the Draftsman for the required correction.

See also § 608.02(w).

No other changes may be made by any person in any record of the Patent and Trademark Office without the written approval of the Commissioner of Patents and Trademarks.

In reviewing the application all errors should be carefully noted. It is not necessary that the language be the best; it is, however, essential that it be clear in meaning, and free from errors in syntax. Any necessary examiner's amendment is usually made at the time a case is being prepared for issue by the examiner. However, the need for such may not be noted until after the proof of the patent is read and the case is sent up to the examiner with a "printer waiting" slip (Form PTO-97). A copy of any formal examiner's amendment is sent to applicant even if the application is already in the printer's hands. See § 1309.01.

Examiners will not cancel claims on the basis of an amendment which argues for certain claims and, alternatively, purports to authorize their cancellation by the examiner if other claims are allowed. In re Willingham, 127 USPQ 211 (CCPA 1960).

In all instances, both before and after final rejection, in which an application is placed in condition for allowance as by an interview or amendment, applicant should be notified promptly of this fact by means of form letter PTOL-327 or an examiner's amendment.

If after reviewing, screening or surveying an allowed application in the Office of Quality Review, an error or omission of the type noted in items 1 through 9 under the second paragraph above is noted, the error or omission may be corrected by the Patentability Review Examiner in the same manner as set forth in the second paragraph. Since all other obvious informalities may only be corrected by a formal examiner's amendment, if the office of Quality Review discovers any such informality, the Patentability Review Examiner will return the application to the Group examining personnel via the Group Di-

rector suggesting, as appropriate, specific changes for approval and correction by the Examiner through the use of an Examiner's amendment. [R-5]

1308.03 Quality Review Program for Examined Patent Applications [R-9]

The Office of Quality Review administers a program for reviewing the quality of the examination of patent applications. The general purpose of the program is to improve patent quality and increase the likelihood of patents being found to be valid.

The quality review is conducted by Patentability Review Examiners on a randomly selected sample of allowed applications from each Art Unit. The sample is computer generated under the office-wide computer system (PALM III), which selects a predetermined number of allowed applications from each Art Unit per year for review only, and which selects from each Art Unit's sample a sub-sample of allowed applications for both review and full re-search. The only applications excluded from the sample are those in which there has been a decision by the Board of Appeals, by the Board of Patent Interferences, or by a Court.

The Patentability Review Examiner independently reviews each sampled application assigned to his or her docket to determine whether any claims may be unpatentable. This Review Examiner may consult with, discuss or review an application with any other reviewer or professional in the examining corps, except the professional who acted on the application. The review will, with or without additional search, provide the examining corps personnel with information which will assist in improving the quality of issued applications. The program shall be used as an educational tool to aid in identifying problem areas in the Examining Groups.

Reviewed applications may be returned to the Examining Groups for consideration of the Reviewer's question(s) as to adequacy of the search and/or patentability of a claim(s). The Group Director determines the appropriateness of the field of search and also has the authority to decide questions of patentability raised by the Reviewers. The Group Director may present the question of patentability to a panel including:

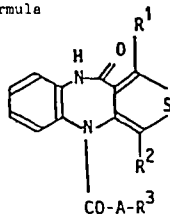
1. Reviewer
2. Examiner
3. SPE
4. Group Director
5. Director of Quality Review

The purpose of the panel is to elicit a full discussion of all patentability questions and to serve as a learning experience for all interested and involved professionals. The Group Director will make the final decision on all patentability questions.

APPENDIX IV
CLAIMS

Original Claims

1. A substituted thienobenzodiazepinone of the formula



wherein

R¹ denotes a hydrogen atom (-H) or alkyl with from 1 to 4 carbon atoms,

R² represents halo or has one of the meanings of R¹,

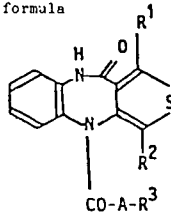
R³ denotes halo or -N(R⁴)R⁵,

R⁴ denotes alkyl with from 1 to 4 carbon atoms, alkenyl with from 3 to 5 carbon atoms or, together with R⁵ and the nitrogen atom to which both are bound, morpholino, pyrrolidino, piperidino, hexahydroazepin-1-yl, piperazin-1-yl which is optionally substituted in the 4-position by methyl, ethyl or benzyl, 2,4-dimethylpiperazin-1-yl or hexahydro-1H-1,4-diazepin-1-yl which is substituted in the 4-position by methyl or ethyl,

R⁵ denotes one of the meanings of R⁴, -(CH₂)_m-N(R⁶)R⁷ or, together with R⁴ and the nitrogen atom to which both are bound, morpholino, pyrrolidino, piperidino, hexahydroazepin-1-yl, piperazin-1-yl which is optionally substituted in the 4-position by methyl, ethyl or benzyl, 2,4-dimethylpiperazin-1-yl or hexahydro-1H-1,4-diazepin-1-yl which is substituted in the 4-position by methyl or ethyl,

Amended Claims

1. A substituted thienobenzodiazepinone of the formula



wherein

R¹ denotes a hydrogen atom (-H) or alkyl with from 1 to 4 carbon atoms,

R² represents halo or has one of the meanings of R¹,

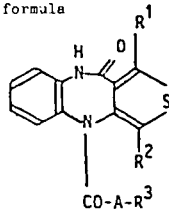
R³ denotes halo or -N(R⁴)R⁵,

R⁴ denotes alkyl with from 1 to 4 carbon atoms or alkenyl with from 3 to 5 carbon atoms,

R⁵ denotes one of the meanings of R⁴ or -(CH₂)_m-N(R⁶)R⁷ or -N(R⁴)R⁵ denotes morpholino, pyrrolidino, piperidino, hexahydroazepin-1-yl, piperazin-1-yl which is optionally substituted in the 4-position by methyl, ethyl or benzyl, 2,4-dimethylpiperazin-1-yl or hexahydro-1H-1,4-diazepin-1-yl which is substituted in the 4-position by methyl or ethyl,

Twice-Amended Claims

1. A substituted thienobenzodiazepinone of the formula



wherein

R¹ denotes a hydrogen atom (-H) or alkyl with from 1 to 4 carbon atoms,

R² represents halo or has one of the meanings of R¹,

R³ denotes halo or -N(R⁴)R⁵,

R⁴ denotes alkyl with from 1 to 4 carbon atoms or alkenyl with from 3 to 5 carbon atoms,

R⁵ denotes one of the meanings of R⁴ or -(CH₂)_m-N(R⁶)R⁷ or -N(R⁴)R⁵ denotes

morpholino, pyrrolidino, piperidino, hexahydroazepin-1-yl, piperazin-1-yl which is optionally substituted in the 4-position by methyl, ethyl or benzyl, 2,4-dimethylpiperazin-1-yl or hexahydro-1H-1,4-diazepin-1-yl which is substituted in the 4-position by methyl or ethyl,

Original Claims	Amended Claims	Twice-Amended Claims
<p>R⁶ denotes alkyl with from 1 to 4 carbon atoms, R⁷ denotes alkyl with from 1 to 4 carbon atoms, A denotes straight-chain or branched alkylene with from 1 to 5 carbon atoms and m denotes 2 or 3, or an acid-addition salt thereof.</p> <p>2. A substituted thienobenzodiazepinone according to claim 1</p> <p>wherein R¹ denotes a hydrogen atom, methyl or ethyl, R² represents chloro or has one of the meanings of R¹, R³ denotes chloro and A denotes straight-chain or branched alkylene with 1 or 2 carbon atoms.</p> <p>3. A substituted thienobenzodiazepinone according to claim 1</p> <p>wherein R¹ denotes a hydrogen atom, methyl or ethyl, R² represents chloro or one of the meanings of R¹, R³ denotes -N(R⁴)R⁵, R⁴ denotes alkyl with from 1 to 4 carbon atoms, alkenyl with from 3 to 4 carbon atoms or, together with R⁵ and the nitrogen atom to which both are bound, morpholino, pyrrolidino, piperidino, hexahydroazepin-1-yl, piperazin-1-yl which is substituted in the 4-position by methyl, ethyl or benzyl, 2,4-dimethylpiperazin-1-yl or hexahydro-1H-1,4-diazepin-1-yl which is substituted in the 4-position by methyl or ethyl,</p>	<p>R⁶ denotes alkyl with from 1 to 4 carbon atoms, R⁷ denotes alkyl with from 1 to 4 carbon atoms, A denotes straight-chain or branched alkylene with from 1 to 5 carbon atoms and m denotes 2 or 3, or an acid-addition salt thereof.</p> <p>2. A substituted thienobenzodiazepinone according to claim 1</p> <p>wherein R¹ denotes a hydrogen atom, methyl or ethyl, R² represents chloro or has one of the meanings of R¹, R³ denotes chloro and A denotes straight-chain or branched alkylene with 1 or 2 carbon atoms.</p> <p>3. A substituted thienobenzodiazepinone according to claim 1</p> <p>wherein R¹ denotes a hydrogen atom, methyl or ethyl, R² represents chloro or one of the meanings of R¹, R³ denotes -N(R⁴)R⁵, R⁴ denotes alkyl with from 1 to 4 carbon atoms or alkenyl with from 3 to 4 carbon atoms,</p>	<p>R⁶ denotes alkyl with from 1 to 4 carbon atoms, R⁷ denotes alkyl with from 1 to 4 carbon atoms, A denotes straight-chain or branched alkylene with from 1 to 5 carbon atoms and m denotes 2 or 3, or an acid-addition salt thereof.</p> <p>2. A substituted thienobenzodiazepinone according to claim 1</p> <p>wherein R¹ denotes a hydrogen atom, methyl or ethyl, R² represents chloro or has one of the meanings of R¹, R³ denotes chloro and A denotes straight-chain or branched alkylene with 1 or 2 carbon atoms.</p> <p>3. A substituted thienobenzodiazepinone according to claim 7</p> <p>wherein R¹ denotes a hydrogen atom, methyl or ethyl, R² represents chloro or one of the meanings of R¹, R³ denotes -N(R⁴)R⁵, R⁴ denotes alkyl with from 1 to 4 carbon atoms or alkenyl with from 3 or 4 carbon atoms,</p>

Original Claims

R⁵ has the meaning of R⁴, represents $-(CH_2)_m-N(R^6)R^7$ or, together with R⁴ and the nitrogen atom to which both are bound, denotes morpholino, pyrrolidino, piperidino, hexahydroazepin-1-yl, piperazin-1-yl which is substituted in the 4-position by methyl, ethyl or benzyl, 2,4-dimethylpiperazin-1-yl or hexahydro-1H-1,4-diazepin-1-yl which is substituted in the 4-position by methyl or ethyl,

R⁶ denotes methyl or ethyl, R⁷ denotes methyl or ethyl, m denotes 2 or 3 and A denotes straight-chain or branched alkylene with 1 or 2 carbon atoms or an acid-addition salt thereof.

4. A compound according to claim 3 in which R¹ denotes -H, methyl or ethyl; R² represents chloro or has one of the meanings of R¹; R⁴ denotes methyl, ethyl or, together with R⁵ and the nitrogen atom to which both are bound, pyrrolidino, piperidino or hexahydroazepin-1-yl; R⁵ has the meaning of R⁴, represents $-(CH_2)_m-N(R^6)R^7$ or, together with R⁴ and the nitrogen atom to which both are bound, denotes pyrrolidino, piperidino or hexahydroazepin-1-yl; each of R⁶ and R⁷ denotes methyl or ethyl; m denotes 2; and A denotes methylene; or a pharmacologically-acceptable acid-addition salt thereof.

5. A compound according to claim 3 in which R¹ denotes -H, methyl or ethyl; R² represents chloro or has one of the meanings of R¹; R⁴ and R⁵, together with the nitrogen

Amended Claims

R⁵ has the meaning of R⁴ or represents $-(CH_2)_m-N(R^6)R^7$ or $-N(R^4)R^5$ denotes morpholino, pyrrolidino, piperidino, hexahydroazepin-1-yl, piperazin-1-yl which is substituted in the 4-position by methyl, ethyl or benzyl, 2,4-dimethylpiperazin-1-yl or hexahydro-1H-1,4-diazepin-1-yl which is substituted in the 4-position by methyl or ethyl,

R⁶ denotes methyl or ethyl, R⁷ denotes methyl or ethyl, m denotes 2 or 3 and A denotes straight-chain or branched alkylene with 1 or 2 carbon atoms or an acid-addition salt thereof.

4. A compound according to claim 3 in which R¹ denotes -H, methyl or ethyl; R² represents chloro or has one of the meanings of R¹; R⁴ denotes methyl or ethyl, R⁵ has the meaning of R⁴ or represents $-(CH_2)_m-N(R^6)R^7$, or $-N(R^4)R^5$ denotes pyrrolidino, piperidino or hexahydroazepin-1-yl; each of R⁶ and R⁷ denotes methyl or ethyl; m denotes 2; and A denotes methylene; or a pharmacologically-acceptable acid-addition salt thereof.

5. A compound according to claim 3 in which R¹ denotes -H, methyl or ethyl; R² represents chloro or has one of the meanings of R¹; R⁴ and R⁵, together with the nitrogen

Twice-Amended Claims

R⁵ has the meaning of R⁴ or $-N(R^4)R^5$ denotes morpholino, pyrrolidino, piperidino, hexahydroazepin-1-yl, piperazin-1-yl which is substituted in the 4-position by methyl, ethyl or benzyl, 2,4-dimethylpiperazin-1-yl or hexahydro-1H-1,4-diazepin-1-yl which is substituted in the 4-position by methyl or ethyl,

R⁶ denotes methyl or ethyl, R⁷ denotes methyl or ethyl, m denotes 2 or 3 and A denotes straight-chain or branched alkylene with 1 or 2 carbon atoms or an acid-addition salt thereof.

4. A compound according to claim 7 in which R¹ denotes -H, methyl or ethyl; R² represents chloro or has one of the meanings of R¹; R⁴ denotes methyl or ethyl, R⁵ has the meaning of R⁴ or represents $-(CH_2)_m-N(R^6)R^7$, or $-N(R^4)R^5$ denotes pyrrolidino, piperidino or hexahydroazepin-1-yl; each of R⁶ and R⁷ denotes methyl or ethyl; m denotes 2; and A denotes methylene; or a pharmacologically-acceptable acid-addition salt thereof.

5. A compound according to claim 7 in which R¹ denotes -H, methyl or ethyl; R² represents chloro or has one of the meanings of R¹; R⁴ and R⁵, together with the nitrogen

Original Claims

atom to which both are bound, denote piperazin-1-yl which is substituted in the 4-position by methyl, ethyl or benzyl, 2,4-dimethylpiperazin-1-yl or hexahydro-1H-1,4-diazepin-1-yl which is substituted in the 4-position by methyl or ethyl; and A denotes methylene; or a pharmacologically-acceptable acid-addition salt thereof.

6. A compound according to claim 3 in which R¹ denotes -H or methyl; R² denotes -H or methyl; R⁴ and R⁵, together with the nitrogen atom to which both are bound, denote piperazin-1-yl which is substituted in the 4-position by methyl; and A denotes methylene; or a pharmacologically-acceptable acid-addition salt thereof.

7. A thienobenzo-diazepinone of the formula according to claim 1 wherein R¹ denotes -H or alkyl with from 1 to 4 carbon atoms, R² represents halo or has one of the meanings of R¹, R³ denotes -N(R⁴)R⁵, R⁴ denotes alkyl with from 1 to 4 carbon atoms, alkenyl with from 3 to 5 carbon atoms or, together with R⁵ and the nitrogen atom to which both are bound, morpholino, pyrrolidino, piperidino, hexahydroazepin-1-yl, piperazin-1-yl which is optionally substituted in the 4-position by methyl, ethyl or benzyl, 2,4-dimethylpiperazin-1-yl or hexahydro-1H-1,4-diazepin-1-yl which is substituted in the 4-position by methyl or ethyl, R⁵ has one of the meanings of R⁴, represents -(CH₂)_m-N(R⁶)R⁷ or, together with R⁴ and the nitrogen atom to which both

Amended Claims

atom to which both are bound, denote piperazin-1-yl which is substituted in the 4-position by methyl, ethyl or benzyl, 2,4-dimethylpiperazin-1-yl or hexahydro-1H-1,4-diazepin-1-yl which is substituted in the 4-position by methyl or ethyl; and A denotes methylene; or a pharmacologically-acceptable acid-addition salt thereof.

6. A compound according to claim 3 in which R¹ denotes -H or methyl; R² denotes -H or methyl; R⁴ and R⁵, together with the nitrogen atom to which both are bound, denote piperazin-1-yl which is substituted in the 4-position by methyl; and A denotes methylene; or a pharmacologically-acceptable acid-addition salt thereof.

7. A thienobenzo-diazepinone of the formula according to claim 1 wherein R¹ denotes -H or alkyl with from 1 to 4 carbon atoms, R² represents halo or has one of the meanings of R¹, R³ denotes -N(R⁴)R⁵, R⁴ denotes alkyl with from 1 to 4 carbon atoms or alkenyl with from 3 to 5 carbon atoms,

R⁵ has one of the meanings of R⁴ or represents -(CH₂)_m-N(R⁶)R⁷, or -N(R⁴)R⁵ denotes morpholino,

Twice-Amended Claims

atom to which both are bound, denote piperazin-1-yl which is substituted in the 4-position by methyl or ethyl; and A denotes methylene; or a pharmacologically-acceptable acid-addition salt thereof.

6. A compound according to claim 7 in which R¹ denotes -H or methyl; R² denotes -H or methyl; R⁴ and R⁵, together with the nitrogen atom to which both are bound, denote piperazin-1-yl which is substituted in the 4-position by methyl; and A denotes methylene; or a pharmacologically-acceptable acid-addition salt thereof.

7. A thienobenzo-diazepinone according to claim 1 wherein R¹ denotes -H or alkyl with from 1 to 4 carbon atoms, R² represents halo or has one of the meanings of R¹, R³ denotes -N(R⁴)R⁵, R⁴ denotes alkyl with from 1 to 4 carbon atoms or alkenyl with from 3 to 5 carbon atoms,

R⁵ has one of the meanings of R⁴ or represents -(CH₂)_m-N(R⁶)R⁷, or -N(R⁴)R⁵ denotes morpholino,

Original Claims

are bound, denotes morpholino, pyrrolidino, piperidino, hexahydroazepin-1-yl, piperazin-1-yl which is optionally substituted in the 4-position by methyl, ethyl or benzyl, 2,4-dimethylpiperazin-1-yl or hexahydro-1H-1,4-diazepin-1-yl which is substituted in the 4-position by methyl or ethyl, R⁶ denotes alkyl with from 1 to 4 carbon atoms, R⁷ denotes alkyl with from 1 to 4 carbon atoms, A denotes straight-chain or branched alkylene with from 1 to 5 carbon atoms and m denotes 2 or 3, or a pharmacologically-acceptable acid-addition salt thereof.

8. A compound according to claim 7 which is 9,10-dihydro-4-[(4-methylpiperazin-1-yl)-acetyl]-4H-thieno[3,4-b]-[1,5]benzodiazepin-10-one or a pharmacologically-acceptable acid-addition salt thereof.

9. A medicament composition in which a pharmaceutical excipient is combined with a compound according to claim 7, the amount of the latter being from 0.5 to 95 percent by weight of the composition.

10. A medicament composition having a pharmaceutical excipient and a sufficient amount, per unit dose, of a compound according to claim 7 to prevent or reduce the effects of stomach or intestinal disorders.

11. A medicament composition having, per unit dose, a pharmaceutical excipient and from 0.1 to 500 mg of a compound according to claim 7.

Amended Claims

pyrrolidino, piperidino, hexahydroazepin-1-yl, piperazin-1-yl which is optionally substituted in the 4-position by methyl, ethyl or benzyl, 2,4-dimethylpiperazin-1-yl or hexahydro-1H-1,4-diazepin-1-yl which is substituted in the 4-position by methyl or ethyl,

R⁶ denotes alkyl with from 1 to 4 carbon atoms, R⁷ denotes alkyl with from 1 to 4 carbon atoms, A denotes straight-chain or branched alkylene with from 1 to 5 carbon atoms and m denotes 2 or 3, or a pharmacologically-acceptable acid-addition salt thereof.

8. A compound according to claim 7 which is 9,10-dihydro-4-[(4-methylpiperazin-1-yl)-acetyl]-4H-thieno[3,4-b]-[1,5]benzodiazepin-10-one or a pharmacologically-acceptable acid-addition salt thereof.

9. A medicament composition in which a pharmaceutical excipient is combined with a compound according to claim 7, the amount of the latter being from 0.5 to 95 percent by weight of the composition.

10. A medicament composition having a pharmaceutical excipient and a sufficient amount, per unit dose, of a compound according to claim 7 to prevent or reduce the effects of stomach or intestinal disorders.

11. A medicament composition having, per unit dose, a pharmaceutical excipient and from 0.1 to 500 mg of a compound according to claim 7.

Twice-Amended Claims

pyrrolidino, piperidino, hexahydroazepin-1-yl, piperazin-1-yl which is optionally substituted in the 4-position by methyl, ethyl or benzyl, 2,4-dimethylpiperazin-1-yl or hexahydro-1H-1,4-diazepin-1-yl which is substituted in the 4-position by methyl or ethyl,

R⁶ denotes alkyl with from 1 to 4 carbon atoms, R⁷ denotes alkyl with from 1 to 4 carbon atoms, A denotes straight-chain or branched alkylene with from 1 to 5 carbon atoms and m denotes 2 or 3, or a pharmacologically-acceptable acid-addition salt thereof.

8. A compound according to claim 7 which is 9,10-dihydro-4-[(4-methylpiperazin-1-yl)-acetyl]-4H-thieno[3,4-b]-[1,5]benzodiazepin-10-one or a pharmacologically-acceptable acid-addition salt thereof.

9. A medicament composition in which a pharmaceutical excipient is combined with a compound according to claim 7, the amount of the latter being from 0.5 to 95 percent by weight of the composition.

10. A medicament composition having a pharmaceutical excipient and a sufficient amount, per unit dose, of a compound according to claim 7 to prevent or reduce the effects of stomach or intestinal disorders.

11. A medicament composition having, per unit dose, a pharmaceutical excipient and from 0.1 to 500 mg of a compound according to claim 7.

Original Claims

12. A method for the prophylaxis or treatment of stomach or intestinal disorders which comprises administering to a mammal subject to or afflicted with such disorders an effective amount of a compound according to claim 7.

Amended Claims

12. A method for the prophylaxis or treatment of a stomach or intestinal disorder of the type of acute and chronic ulcer ventriculi and ulcer duodeni, gastritis and hyperacid gastric irritation which comprises administering to a mammal subject to or afflicted with such a disorder an effective amount of a compound according to claim 7.

Twice-Amended Claims

12. A method for the prophylaxis or treatment of a stomach or intestinal disorder of the type of acute and chronic ulcer ventriculi and ulcer duodeni, gastritis and hyperacid gastric irritation which comprises administering to a mammal subject to or afflicted with such a disorder an effective amount of a compound according to claim 7.

13. A compound according to Claim 7 which is 9,10-dihydro-3-methyl-4-[(4-methylpiperazin-1-yl)acetyl]-4H- thieno[3,4-b][1,5]benzodiazepin-10-one or a pharmacologically-acceptable acid-addition salt thereof.

14. A substituted thienobenzodiazepinone according to claim 1 wherein R³ denotes -N(R⁴)R⁵, or a pharmacologically-acceptable acid-addition salt thereof.

15. A method for the prophylaxis or treatment of acute and chronic ulcer ventriculi and ulcer duodeni, gastritis and hyperacid gastric irritation which comprises administering to a mammal subject to or afflicted with such a disorder an effective amount of a compound according to claim 7.

Computer Aided Litigation Support In Patent Litigation*

WILLIAM S. FEILER**

Much has been written about the need for modern and efficient methods of handling documents and information with computers in large scale litigations. Many patent litigations—some may say all—fall into the large scale litigation category. Unfortunately, little has been written about actual experience with computers in such cases. This paper reports on some actual experiences with computer aided systems including some statistics regarding costs, time, results achieved, and some recommendations to those considering computer aided systems.

Before starting the discussion, one extremely important point must be made. Computer systems are not the cure for large scale litigations. A computer system will do things faster, more accurately, and more efficiently, but the first thing that is necessary is a system—not a computer. If the attorney does not have a system for controlling documents and information that will work manually, the system will not be adaptable to a computer. The failure to have a system in the first instance will foreclose or needlessly delay computer implementation. System planning is the key element.

To give the discussion a framework, Table 1 gives a profile of a patent case. This profile is illustrative of the problems to be overcome. With 15 years of research and some 2,500 files of documents, each containing from 5 - 1,000 pages of paper, the amount of information is awesome. Large cases will be engaged in more than one jurisdiction, sometimes around the world, and involve many parties.

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Thus, the law firm and client should as soon as possible determine the jurisdictions, the likely areas of controversy and the parties so that the system can be properly planned for full utilization. A decision should also be made as to who is to maintain the data base and service the needs of all the law firms representing the client.

The mountain of information in a large litigation requires planning and the rules of discovery have to be carefully considered.

COMPLYING WITH THE FEDERAL RULES

Several recent changes in the Federal Rules of Civil Procedure have a dramatic effect on the production of documents in large document cases and show the need for early planning in a case. In 1970, subdivision (c) was added to Fed.R.Civ.P.33 to shift the burden of discovery to its potential beneficiary by allowing the production of documents in lieu of answers. This shift of the burden apparently went too far. In 1980, Fed.R.Civ.P.33(c) was again amended to further define the specification of documents that is required from the responding party:

A specification shall be in sufficient detail to permit the interrogating party to locate and to identify, as readily as can the party served, the records from which the answer may be ascertained. Fed.R.Civ.P. 33(c).

Comparable rules exist in many states, e.g. New Jersey, N.J. Civ.P.R. 4:17-4(d).

A similar change was also made to Fed.R.Civ.P. 34 in 1980 to control the production of documents.

A party who produces documents for inspection shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the request Fed.R.Civ.P. 34(b).

The 1980 Notes of the Advisory Committee indicate that the change in Fed.R.Civ.P. 34(b) was based upon a report* that "It is apparently not rare for parties deliberately to mix critical documents with others in the hope of obscuring significance."

In a litigation, where thousands of documents will be involved, the ability to comply with these changes and to verify the adversary's compliance is important. It is not unusual for a discovering party to couple both interrogatories and requests for production, i.e., ask hundreds of interrogatories including sub-parts and then ask for all the documents relating to the answers. Complying in good faith with such requests in large scale cases is burdensome and costly.

*Report on the Special Committee for the Study of Discovery Abuse, Section of Litigation of the American Bar Association (1977) 22.

There are several approaches which may be used to handle large document requests in accordance with both Fed.R.Civ.P. 33 and 34. An approach, frequently used in small cases, is to assign staff to find and review the documents, segregate them by classification based upon the requests and provide the documents to the requesting party. This is a high labor intensive approach and can become unfeasible if several waves of discovery are used in one case or if there are different discovery requests in different but related cases. There are also problems of repetitive document reviews, potential for misplacing or losing documents and disruption of the client's business records.

THE INVENTORY APPROACH

A better approach is the inventory approach. In this method, all the pertinent files of the client are surveyed for potential relevance. It should not be an in-depth document by document review. It is a survey at the file level only. This review should be broad so that all files that are even peripherally related to the subject matter of the litigation are reviewed. Remember that the areas of relevancy may change during a litigation and from one litigation to the next litigation.

In the inventory approach, each file is specifically identified by number, the location and name of the file is recorded and a general description of its contents is captured. In most instances, the name of the file itself will be sufficiently explanatory for review, but other information may also be collected as to the potential importance of the contents of the file. All of this information is then assembled to form an inventory list.

The advantage of the inventory file approach is clear. Responsible attorneys can select those files from the inventory list which correspond to the discovery requests. In the example of Table 1, the inventory list would contain 2,500 entries for review. Using the individual document approach, hundreds of thousands, if not millions, of documents would have to be reviewed. Furthermore, the inventory list is a permanent record of potential information so that, if additional requests are received, the list can again be reviewed and the pertinent files identified without having to repeat inspection.

The inventory list can be used to comply with both changes in Rules 33 and 34. Suppose an adversary has requested all research and development records and all sales records. Under Rule 33, the files from the R&D facility and the sales department can be identified in the inventory list from their location and specified by file number and file title. When production for inspection takes place, the appro-

priate files can be produced as they are normally kept in the course of business. Prior to production for inspection, these files would be reviewed to remove privileged documents and any irrelevant materials as necessary.

The inventory approach may be used with a manual system. However, once the number of inventory records becomes large, e.g. 500 - 1,000, it is more efficient to use a computer data base for searching the inventory files. This type of file system is easily computerized and quite cost effective, particularly where the computer is used initially since the data input operator replaces secretarial typing. Furthermore, each time the system is used, the computer will print out an accurate and reliable list or portion thereof which can be used for the specification required by Fed.R.Civ.P. 33(c).

Once the strategy of specifying and producing documents for inspection has been developed, the attorney should plan for the handling of the documents his adversaries will actually request and the documents he will be receiving from the adversaries and third parties. Remember that the profile in Table 1 is for only one side of the case. Similar production may be received from each adversary. Therefore, do not base the decision to use computerized support in litigation just on your clients' document collection. Otherwise, you may be surprised by receiving five times that amount from the other parties. So, let's examine how *all* documents can be handled.

IMPLEMENTING A DOCUMENT SYSTEM

There are nine major operations to be performed in large scale discovery. These areas are listed in Table 2. All operations will be performed for your clients' documents but operations 5,6,8, and 9 will have to be performed by you on the adversary's documents. The sequence of execution of these operations generally vary with the type of case and the particular practice of the law firm involved.

When large document collections are involved, every pass through the documents or portions of them is burdensome and costly. For this reason, each step requires coordination with the entire project.

When computer supported litigation of a document collection is considered, cost/benefit analysis is critical. The record that will be created in the computer system is a document record. Therefore, one should not confuse pages with documents. A ten page report is only one document. A document record may be the same as a document but it can be defined differently. Take for example, a 200 page laboratory notebook or a file of 200 pages of laboratory log sheets. Each can be treated as a single document record, or each page can be

treated as a document record with substantial cost difference. Therefore, the attorney must decide early how a document record will be defined.

The time and expense required to generate a computer supported system depends on the degree of sophistication and depth of the coding operation that creates the document records. Broadly, coding is the operation by which information is extracted from the individual documents and transferred to individual records. In a computer system, the information is placed in particular categories, called fields, in the record.

Various possible levels of sophistication are possible, and the expenses associated with each level vary substantially. For example, a coding operation with only document numbers being captured is the least expensive and least informative. Bibliographic coding may cost more, in the range of \$2.00 - \$4.50 per document, but yields substantially more useful information.

An interesting cost/benefit problem arises when considering coding beyond the bibliographic level to include abstracts or keywords. To code beyond merely bibliographic information requires coders to read and digest the information in the text of each document. This is extremely time consuming and can drive the coding cost up by a factor of 2-5 times the cost of mere bibliographic coding. The benefit of coding beyond the bibliographic level, at least on the full collection of documents, is highly questionable. This type of coding is subjective and is often geared to the legal issues that were initially anticipated. As most litigators are aware, the legal issues have a nasty habit of changing, sometimes quite dramatically during the course of a litigation. For these reasons, coding for keywords, abstracting, and other text analyses should not be done initially. The initial coding effort should be factual only, i.e. bibliographic information. As the case progresses and documents take on significance, the records for important documents can be upgraded to add more information.

The full text document computer system sounds great, but on closer examination, it is not justified for an entire document collection. The full text costs in terms of coding time and expense are comparable to the cost of the Bibliographic/Abstract/Keyword coding, and surprisingly may be somewhat cheaper, which is another reason to avoid the latter at the initial stage. The main drawback of full text coding of all documents is that too much information is available without a corresponding increase in benefit. Full text coding of all documents results in mountains of information and increased storage costs and search time. Full text coding has its place, but it must be used with discretion and judgment. It should be reserved for important docu-

ments, such as documents used as deposition exhibits.

The most cost effective route for coding is a careful selection of bibliographic information as a first round of coding coupled with selective updating of important document records as the case progresses. Table 3 lists some of the possible types of fields of information that can be designed into the data base. From a careful survey analysis of the documents and a knowledge of the litigation, fields suitable to the particular case may be selected.

DOCUMENT DATA BASE CREATION

Labor costs for data input are high. Table 4 provides a percentage breakdown of the cost of setting up a computerized litigation support system. This breakdown shows that at least 65% of the cost of the system is for labor—the cost of coding the documents. The usage fee for the computer system would run about 15-25% of the total creation cost. The breakdown in Table 4 does not include the cost of handling, numbering, or copying of documents.

Table 5 shows some of the statistics associated with coding of documents. The time spent by coders varies widely with the type of document and the coder's experience with handling them. The "learning curve" associated with each coder is shown by the 30 - 100 documents/day range of documents. Twelve to fifteen fields of information represent a typical effort at comprehensive bibliographic coding, but the type of field can affect coding time. Abbreviations, authority lists, and other short cuts should be used to maintain cost control. Some applications can use computer-generated data, for example, information from the inventory list may be merged into the document records.

PATENT DOCUMENT PROFILE

Table 6 is a characterization breakdown of the types of documents that appeared in four document collections from patent litigations. The breakdown is in percent occurrence. For example, letter characterized 16.7%, 16.2%, 13.07%, and 16.98% of collections 1 through 4, respectively. The relative size of each collection is also indicated as a percent of the Collection No. 4, the largest collection. This list gives an idea of the types of documents and their frequency of appearance in patent cases.

A statistical review of the amount of masking that was done to documents is presented in Table 7. Table 8 shows the ratio of documents withheld from production to documents actually produced. Weighted averages based upon the four collections are also listed.

Based upon the weighted averages, these statistics indicate that for every 1,000 documents produced, 136 will be masked and 116 additional documents will have been withheld from production. It is interesting to note that Collection No. 1 has the lowest masking rate and the greatest rate for listing of privileged documents which may suggest comprehensive production. On the other hand, Collection No. 3 had the highest masking rate and lowest identification of privileged documents rate. These statistics may suggest that production in Collection No. 3 was much more tightly controlled with the outflow of information very restricted. While it is noted that the size of Collection No. 3 is the smallest, its character and the issues involved were similar to the other collections. An analysis of this type may prove useful in obtaining complete discovery from an adversary if sufficient data for comparison exists.

BENEFITS AND USES

Despite the cost of creating a comprehensive data base, the computer litigation support does save money and benefit the client. Savings are realized in the lower staffing requirements and in the lower overall time requirements for the staff. The attorneys staffing the case are better able to retrieve, analyze, and use discovery if the information is computerized. The mere act of assembling documents and the selection process is greatly expedited. With a typical system, documents in a particular time span, documents relating to a particular subject, documents authored by certain individuals, and other types of searches can be made in an extremely short time.

The identification of potential deponents can be ascertained quickly by analyzing the data base in terms of the persons who write and receive documents.

Correlation of documents and a history of the facts can be created by suitable search requests through the production records and sorting the results by date. For example, where a case involves several parties and third party production, all of which have produced documents that have moved among the parties, the computer can survey the entire collection, select the relevant documents and sort them. A typical application may involve a purchaser who has been involved with four suppliers, some of whom may be independents and some who are sub-contractors for a particular project. If documents have been produced from each, the computer can search through the data, select all the documents produced by each which relate to the project, then sort by date. The result of the search will be a chronological history of documents showing each party's involvement. If a com-

puterized listing of documents withheld from production is made, the search can include these as well thereby providing a complete chronological history. Doing such analysis by hand could easily take days or weeks but with the computer it can be done in minutes.

Updates on the results of document analysis can be generated routinely. The data base should be periodically updated by the staff in terms of digesting or commentary on the documents to provide greater insight into the case. Where several attorneys or law firms are involved, these reports permit everyone to be briefed on the facts in an orderly and consistent manner.

Verification of documents and dates may be completed in a short time. For example, several times an adversary has attempted to establish a statutory defense based upon publications. Using the computer to verify the date by other evidence has proven to be invaluable. In one situation, where the same adversary law firm was involved in several cases, one attorney tried for several hours to prove a report date that would have been a statutory bar defense. Apparently unknown to that lawyer, one of his colleagues in another related case had submitted documents which showed clearly that the report in fact had not been published. A five minute computer search at a break resulted in a devastating cross examination.

Generating lists of documents withheld from production on the basis of attorney-client privilege is an important asset. In many complex cases, these lists will vary depending on the issues and parties. Using the computer with planning can permit a single computer list of all privileged documents to be maintained. Then as each case may require, an appropriate list of withheld documents may be generated. For example, where a computer system is used to support several litigations involving Patents A, B, C, and D, a privileged list for litigation 1 involving Patent A and C is prepared; litigation 2 has a list based on Patents B, C, and D and so on. A typical list of withheld documents may include several thousand documents from each party. The computerization of a privileged list of all parties in the cases also permits a more comprehensive search as indicated above.

The computer listings can be used offensively in a litigation depending on the creativity of the attorneys. For instance, in one series of cases where the same parties were involved in common patent litigation in the United States and Canada, the adversary had attempted to limit its production in Canada to some several hundred documents. In the United States, the adversary had been forced to produce thousands of documents. A motion to compel production was brought in Canada based upon a computer printout of the adversary's United

States production. The Canadian Court ordered the adversary to produce all of the documents in Canada. This case is apparently the first case in Canada where the Courts accepted computerized lists. The computerized data base was also used by one client to generate its document list and/or privileged document list in several foreign actions based upon the comprehensive data base for its United States Actions.

The computer system may be used to facilitate trial preparation. The system can be used to generate proposed trial exhibit lists, deposition transcript page designations, and cross-examination document lists.

Conclusion

Computer aided litigation support is a viable tool for patent litigation. Lower costs for computer charges will make such systems even more attractive. As attorneys become more familiar with such systems and their benefits, wider usage will follow. The speed afforded by such systems should reduce some of the time consumed in discovery and contribute to even more thorough preparation of cases.

TABLE 1
A Case Profile

Years Span of Documents:	15 years
Number of Files of Documents Reviewed:	2,500
Number of Pages in Each File:	5-1,000
Anticipated Number of Litigations:	5
Anticipated Years of Litigation:	5 years
Number of Parties:	7

TABLE 2
Document Operations

1. Document Assembly
2. Numbering and Confidential Stamping of Documents
3. Screening/Masking of Irrelevant Material
4. Screening for Privilege
5. Inspection of Produced Documents
6. Analysis of Contents
7. Copying
8. Coding
9. Updating Analysis

TABLE 3
Possible Fields

— Abstract	— Dollars
— Addressee	— Exhibit No.
— Addressee — Organization	— Events
— Attached Documents	— Key Words
— Attorney Comments	— Legal Issues
— Author	— Marginalia
— Author — Organization	— Masking
— Batch No.	— Micro. No.
— Confidentiality Claimed	— Misc. Flag Codes
— Computer No.	— Names Mentioned
— Copies Recipient	— Pages in Document
— Copied To	— Privilege Claim
— Date	— Source
— Dates Mentioned	— Subject Area
— Description	— Text
— Document No.	— Value
— Document Title	— Witnesses Testified
— Document Type	

TABLE 4
Document Data Base Creation Cost Summary

Set-Up Charges	5.0%
Labor	65.0%
Direct Expenses	1.5%
Special System Work	11.5%
Fixed Costs	17.0%
Total	100%

TABLE 5
Coding Statistics

Average coding Time	10.4 min./doc.
Average Documents Coded per coder	46 doc./day
Range	30 - 100 doc./day
Number of Fields Coded	13
Average Document Size	10 pages

TABLE 6
Document Collection Profile Frequency

Type	Collection No. 1 (Percent)	Collection No. 2 (Percent)	Collection No. 3 (Percent)	Collection No. 4 (Percent)
Affidavit	0.16	1.95	0	0.96
Agreement	2.48	5.24	4.96	3.75
Article	3.18	4.11	0.57	3.41
Call Report	0.42	2.82	6.01	1.72
Catalogue	1.47	1.01	1.04	1.24
Drawing	4.37	0.51	3.24	2.77
File History	1.26	0	0	0.60
Graph/Table	13.0	6.69	18.7	10.7
Lab Notebook	0.87	1.29	0	1.01
Letter	16.7	16.2	13.07	16.98
Manual	0.86	0.03	0.85	0.12
Memo	34.7	33.7	27.86	33.6
Patent	5.66	0.21	0.76	3.07
Proposal	1.31	0.21	0.47	0.82
Presentation	0.48	1.88	0	1.03
Report	8.20	15.22	20.7	11.75
Sales Doc.	1.39	8.50	1.62	4.26
Telegrams	3.85	0.39	0.09	2.21
Weight %	53.2	36.6	6.2	100

TABLE 7
Masking Statistics

Collection	Weight Size	Per Cent Masked
No. 1	53.2	2.6%
No. 2	36.6	25.2%
No. 3	6.2	39.2%
No. 4	100	13.0%
Weighted Average		13.6%

TABLE 8
Privileged Documents

Collection	Weight Size	Ratio of Priv./Produced
1	53.2	14.2%
2	36.6	9.4%
3	6.2	5.97%
4	100	11.4%
Weighted Average		11.6%

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COMPILED BY JUDITH GIRE NORCROSS*

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COMMENTARY

New Legislation: Copyright Protection for Semiconductor Chip Masks

Introduction: The Semiconductor Chip Protection Act of 1984 was signed into law on November 8, 1984. The law is designed to protect "mask works fixed in a semiconductor chip product," 17 U.S.C. §902(a)(1) (enacted November 8, 1984). A "semiconductor chip product" includes semiconductor material containing multiple layers of metallic, insulating, or semiconductor deposits in a given pattern so as to create an electronic circuit. *Id.* at §901(a)(1). The "mask work" consists of "a series of related images" which are fixed and show the three-dimensional pattern of layers in the semiconductor chip product. *Id.* at §901(a)(2). The "mask work" is considered "fixed in a semiconductor chip product when its embodiment is sufficiently permanent or stable to permit the mask work to be perceived or reproduced . . ." *Id.* at §901(a)(3). What follows is a summary of those portions of the bill relating to subject matter, registration, exclusive rights and other information pertinent to American high-tech businesses.

Subject Matter and Duration: A "mask work" is eligible for protection if,

- (1) on the date the work is registered or first commercially exploited anywhere in the world, the owner is a national or domiciliary of this country, a national, domiciliary, or sovereign authority of a foreign nation that has signed a treaty with the United States pertaining to the protection of "mask works" or is a "stateless person";
- (2) the work is first exploited commercially in this country;
or
- (3) the work is contained within the scope of a Presidential proclamation pertaining to the "mask works" of foreign nationals, as detailed in the law. *Id.* at §902(a)(1).

Protection will be denied if the "mask work" is not original or "consists of designs that are staple, commonplace or familiar in the semiconductor industry or variations of such designs, combined in a way that, considered as a whole, is not original." *Id.* at §902(b). Some guidance as to the interpretation of such language is provided by Senator

Mathias's Senate Report. H.R. 6163, 98th Cong., 2d Sess. (1984). The Senator stated that the degree of originality is not as great as is required for patent protection by 35 U.S.C. §103(1982), however, "mere insubstantial or trivial variations on prior mask works" would not meet the statutory requirement. H.R. 6163, 98th Cong., 2d Sess. (1984). He further stated that §103 is "instructive" in ascertaining the standard to be applied to a "mask work" because "[i]t warns us not to dissect old elements away from a new combination," but, to view the work as a whole "lest we run the danger of failing to recognize . . . novelty and intellectual creativity . . ." *Id.*

The protection applies to any "mask work" once it has been commercially exploited or registered with the Copyright Office or both, after the enactment of the law, 17 U.S.C. §913(c)(enacted November 8, 1984), as well as to any work first commercially exploited between July 1, 1983 and the date of enactment, November 8, 1984. *Id.* at §913(d)(1).

The duration of the protection commences on the date when the work is registered or is first commercially exploited anywhere in the world, whichever come first. *Id.* at §904(a). The date of registration is the date on which the application, deposit material, and fee are submitted to the Copyright Office. *Id.* at §908(e). The term lasts for ten years from the date of commencement, *Id.* at §904(b), and expires at the end of the calendar year in which it is scheduled to terminate. *Id.* at §904(c).

The filing fee, as of this date, is \$20 per "mask work." Circular R100 Federal Statutory Protection for Mask Works, Copyright Office, Library of Congress (December 1984). The deposit requirement for a commercially exploited work involves delivery of four chips as originally "exploited" and one complete set of "visually perceptible reproductions of each layer" of the chip. *Id.* The latter of the two need only be deposited for those works that have not been commercially utilized. *Id.* The reproductions may consist of "plastic color overlays, composite plots," or, in the case of commercially available chips, photographs. *Id.* Each layer should be reproduced to between twenty and thirty times actual size. *Id.*

Registration and Deposit: The Copyright Office will make available a form "MW" specifically for "mask works" to be filed by the owner. No applications will be accepted until January 7, 1985, 60 days after enactment of the bill. *Id.* at §913(a). Protection is afforded only to those "mask works" that are registered within two years of the date the work is first commercially exploited anywhere in the world, *Id.* at §908(a), or by July 1, 1985 for those works first exploited between July 1, 1983 and the protection bill's enactment. *Id.* at §913(d)(1).

If the Register of Copyrights refuses to grant a certificate and the owner feels that such action was unjustified, he or she may seek review in a United States District Court of appropriate jurisdiction no later than sixty days after refusal. *Id.* at §908(g). A failure by the Copyright Office to issue a certificate of registration within four months of the application date is deemed a refusal.

An action for infringement, however, may still be commenced if notice of the action along with a copy of the complaint is served on the Register of Copyrights, who may, if he or she so chooses, become a party to the action by entering an appearance within sixty days of service. *Id.* at §910(b)(2).

Notice: The owner should place the notice on the "mask work," the mask, or the "semiconductor chip product" embodying said "mask work." *Id.* at §909(a). The actual notice consists of affixing:

- (1) one of the following: "mask work", *M*, or "M" in a circle; and
- (2) the name of the owner or owners or a recognized abbreviation thereof. *Id.* at §909(b).

Exclusive Rights: The owner of the "mask work" has exclusive rights regarding reproductions of the work, importation or distribution of any semiconductor chip product which has the "mask work" incorporated into it and the licensing of another party to reproduce, import or distribute the protected work. *Id.* at §905.

There are, however, certain limitations on the owner's exclusive rights. Unauthorized reproduction of the work is permitted if it is involved with teaching or evaluating techniques, "circuitry, logic flow, or organization" embodied in the "mask work." *Id.* at §906(a)(1). A similar evaluation is also allowed if the results of the process are to be incorporated into an original "mask work" to be distributed. *Id.* at §906(a)(2). The latter permits what Senator Mathias refers to as "reverse engineering." H.R. 6163, 98th Cong., 2d Sess. (1984). The Senator stated, "[i]f the resulting semiconductor chip product is not substantially identical to the original, and its design involved significant toil and investment so that it is not a mere plagiarism, it does not infringe the original chip." *Id.* It is believed by the Senator that reverse engineering "will ordinarily leave a 'paper trail' " and, therefore, can be distinguished by the courts from mere infringement. *Id.*

There are also special provisions regarding innocent infringement. A purchaser is not liable for the importation or distribution of an infringing semiconductor chip product if it had no notice of the

copyright prior to purchase. 17 U.S.C. §907(a)(1)(enacted November 8, 1984). Any subsequent purchaser who, similarly without notice, obtains the infringing chip product is also shielded from liability. *Id.* at §907(c), (d). The amount of damages assessable against the "innocent purchaser" is limited to "a reasonable royalty on each unit" imported or distributed after he has notice of the copyright. *Id.* at §907(a)(2).

Another limitation relates to infringing products manufactured before the law's enactment. These products are not liable for damages when imported into or distributed in this country until two years after the date of registration, if the importer or distributor pays or offers to pay a "reasonable royalty," previously referred to regarding "innocent purchasers." *Id.* at §913(d)(2). If such an offer or payment is not forthcoming from the infringer, the "mask work" owner is not limited in the amount of damages he may seek. *Id.* at §913(d)(3).

Infringement, Injunctions, and Damages: Infringement is defined as the making, importation or distribution of any semiconductor chip product that interferes with the exclusive rights of the "mask work's" owner. *Id.* at §901(a)(9). Any action must be brought "within three years after the claim accrues." *Id.* at §911(d). Court orders can include temporary restraining orders, preliminary injunctions, or permanent injunctions used to reasonably prevent infringement. *Id.* at §911(a). Importation of infringing articles can also be enjoined through an order of the International Trade Commission under Section 337 of the Tariff Act of 1930. *Id.* at §910(c)(1)(A). An infringer may be liable for one of the following:

- (1) actual damages suffered by the owner (infringer's profits can be included as part of the award), *Id.* at §911(b);
- (2) statutory damages, *Id.* at §911(c) (where there is no evidence submitted regarding actual damages or that which is submitted is insufficient to justify such an award, M. Nimmer, Nimmer on Copyright §1404[A] (1984); the amount is left up to the court's discretion and can not exceed \$250,000), 17 U.S.C. §911(c)(enacted November 8, 1984); or
- (3) "reasonable royalty" (awarded against "innocent purchasers" and importers and distributors of infringing products manufactured before the law's enactment). *Id.* at §907(a)(2), 913(d)(2).

Recording of Documents and Licenses: All documents relating to "mask works" can be recorded in the Copyright Office. *Id.* at §903(c)(1). A license transferring rights of the owner should be recorded within three months of its execution so as to establish priority over subsequent transferees who purchase identical rights in the same work for valuable consideration and without notice of the prior transfer. *Id.* at §903(c)(2).

"Mask Work" Protection for Companies in Foreign Countries: Businesses in foreign countries have two avenues when seeking protection for "mask works." The first involves petitioning the Secretary of Commerce and the second relates to the granting of a Presidential proclamation. *Id.* at §914(a). An order from the Secretary of Commerce will be granted upon finding:

- (1) that the foreign nation in question is "making good faith efforts and reasonable progress" towards entering into a treaty with the United States regarding "mask work" protection or passing legislation which extends similar protection to American companies;
- (2) that "nationals, domicilliaries, and sovereign authorities of the foreign nation" are not involved in pirating American "mask works"; and
- (3) that such protection "would promote the purposes of this chapter and international comity." *Id.* at §914(a).

An order from the Secretary of Commerce terminates upon the occurrence one of three events. *Id.* at §914(d)(1). The first is the issuing of a Presidential proclamation granting "mask work" protection to the companies of a given foreign nation. *Id.* at §914(d)(1)(B). A finding by the Secretary that the foreign nation no longer meets the previously stated criteria would also lead to a retraction of such an order. *Id.* at §914(d)(1)(A). The final mode of termination occurs three years after the law's enactment when the powers of the Secretary of Commerce come to an end under the statute. *Id.* at §914(c). Those "mask works" issued under a viable order, however, will remain in effect for the entire statutory period of ten years. *Id.* at §914(d)(2).

A Presidential proclamation is the second method under which foreign companies can qualify for "mask work" protection. It is granted whenever the President finds that a foreign nation extends protection

to American companies based on “mask work” protection laws that are similar to our own. *Id.* at §902(a)(2).

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THE PERIL OF ELECTION UNDER 37 C.F.R. 1.78(C)*

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Two commonly-assigned applications for letters patent (Serial No. 387,454 and Serial No. 387,456) were filed at the PTO June 11, 1982. The claimed subject matter was invented abroad by foreign nationals. One application (A) had five applicants, all of whom were included among the six applicants for the other application (B). Both applications were examined by the same Examiner. A was based on an earlier foreign filing than was B; convention rights were claimed for both applications.

Corresponding claims in the respective applications read as follows:

A

8. (Amended) An electrical contact material having high wear, adhesion and arc resistance comprising a matrix of copper alloyed or diffused with nickel having a surface portion within said matrix defining an electrical contact surface, said surface portion having a depth of from 0.01 to 0.2 mm and including a diffusion structure in which boron is diffused into said matrix to combine with said nickel and to form fine nickel boride particles uniformly dispersed in said surface portion, the surface portion containing a greater proportion of said nickel boride particles toward the surface of said electrical contact material, said fine nickel boride particles having an average of diameter of from 0.1 to 20 microns and said surface portion comprising from about 5 to 80 percent by volume of said fine nickel boride particles, the balance being copper or an alloy thereof.

B

1. (Amended) An electrical contact material comprising a copper or copper alloy matrix having a surface portion within said matrix defining an electrical contact surface, said surface portion having a depth of from 0.01 to 1 mm and including a diffusion structure of fine boride particles of at least one element selected from the group consisting of aluminum, arsenic, cadmium, cobalt, gallium, manganese, chromium, tantalum, tungsten, zirconium, iron, molybdenum, niobium, vanadium, magnesium and platinum uniformly dispersed in said surface portion, said fine boride particles having an average diameter of from 0.1 to 20 microns and said surface portion comprising from 1 to 50% by volume of said fine boride particles, the balance being copper or an alloy thereof.

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The claims of both applications are directed to electrical contact material comprising a matrix of copper or copper alloy, the surface of which has finely-divided metal boride particles uniformly diffused therein. In the earlier work (abroad) of A the metal boride was limited to nickel boride, whereas B's metal boride was that of aluminum, arsenic, cadmium, cobalt, gallium, manganese, chromium, tantalum, tungsten, zirconium, iron, molybdenum, niobium, vanadium, magnesium or platinum, but not of nickel. There was thus a clear line of distinction between the subject matter defined by the sets of claims in the respective applications.

With respect to the several applications, significant portions of respective Office Actions reflect the following positions:

A

a) This application is considered to claim an invention not patentably distinct from the invention claimed in commonly assigned (when assignment recorded) S.N. 387,456. Where different inventive entities are involved only one patent should issue for inventions that are not patentably distinct from each other, *Aelony et al. vs. Arni et al.*, 192 U.S.P.Q. 486. *Bull, et al.* discloses the fungibility of Ni boride and the boride species of S.N. 387,456, hence the inventions are considered obvious over each other.

b) A terminal disclaimer can have no effect in this situation, since the basis for refusing more than one patent for one invention is 35 U.S.C. 102 or 103 or estoppel, and is not connected with any extension of monopoly. In accordance with 37 C.F.R. 1.78(c), the assignee is called upon to state which entity is entitled to priority of the following invention: Diffused boride particle surface layer electrical contact material of any of the species found in *Bull, et al.*

c) Failure to comply will result in abandonment of this application.

d) If the other inventive entity is named the prior inventor, claims 1 to 8 are rejected as unpatentable over the invention of said entity for reasons stated above.

e) Claims 7 and 8 are rejected under 35 U.S.C. 103 as being unpatentable over

B

1) This application is considered to claim an invention not patentably distinct from the invention claimed in commonly assigned (when assignment recorded) S.N. 387,454. Where different inventive entities are involved only one patent should issue for inventions that are not patentably distinct from each other, *Aelony et al. vs. Arni et al.*, 192 U.S.P.Q. 486. *Bull, et al.* discloses the fungibility of the various species of S.N. 387,454 and the instant case, hence the inventions are considered obvious over each other.

2) A terminal disclaimer can have no effect in this situation, since the basis for refusing more than one patent for one invention is 35 U.S.C. 102 or 103 or estoppel, and is not connected with any extension of monopoly. In accordance with 37 C.F.R. 1.78(c), the assignee is called upon to state which entity is entitled to priority of the following invention: Diffused boride particle surface layer electrical contact material of any of the species found in *Bull, et al.*

3) Failure to comply will result in abandonment of this application.

4) If the other inventive entity is named the prior inventor, claims 1 to 8 are rejected as unpatentable over the invention of said entity for reasons stated above.

5) Claims 1, 3, 6 to 13, 15 to 18, 21 and 22 are rejected under 35 U.S.C. 103 as be-

Bull, et al and Schaefer, et al.

f) Applicants' arguments filed November 15, 1983, have been fully considered but they are not deemed to be persuasive.

g) Applicants' attention is directed to Ex parte Andresen, 212 U.S.P.Q. 100, and the application of 35 U.S.C. 102(f). This is believed to distinguish Ex parte Conner, 119 U.S.P.Q. 182, and Margolis vs. Banner, 202 U.S.P.Q. 365.

h) Since Applicants urge that they cannot determine the earliest inventor, they are requested under 37 C.F.R. 1.56 to furnish the information as to which work was done first, this application or S.N. 387,456, so the Examiner can determine same as outlined in Margolis vs. Banner.

i) While it is urged that the prior art is not directed to the same problem as Applicants' motivation, there is no such requirement for obviousness. There is no indication that Bull, et al. and Schaefer, et al. are otherwise uncombinable.

ing unpatentable over Bull, et al. in view of Shaefer, et al.

6) Claims 14, 19 and 20 are rejected under 35 U.S.C. 103 as being unpatentable over Bull and Schaefer, et al. as applied to claim 1 above, and Caule, et al. or Powell who discloses the fungibility of Cu alloys of Ga, Pt or Cd, including those of the dependent claims, which include the other adducts as alloys of Cu in the whole piece which includes the surface.

7) The use of the other alloys in Bull would be obvious in view of the fungibility suggested by the other patentees.

8) While it is urged that the prior art is not directed to the same problem as Applicants' motivation, there is no such requirement for obviousness. There is no indication that Bull, et al. and Schaefer, et al. are otherwise uncombinable.

The Examiner acknowledged that somewhat related facts were considered in a previously-rendered opinion [*Margolis, Rushmore, Liu, and Anderson v. Banner, Commissioner of Patents and Trademarks*, 202 USPQ 365 (CCPA 1979)]. In that case, the Examiner had also requested (under threat of abandonment of the application) that petitioners state which inventive entity, petitioners or Pagliaro et al., "is the prior inventor of the subject matter [of allegedly conflicting claims]," and that petitioners' assignee limit the claims of the other application accordingly. The Court observed that, although the regulations do not define "conflicting claims," MPEP 804.03 uses this term to describe "a single inventive concept [claimed by different inventive entities], including variations of the same concept each of which would be obvious in view of the other." Since the Examiner's request was based upon MPEP 804.03, the Court accepted this as a definition of "conflicting claims" for purposes of the appeal. However, the Court found it unnecessary to decide whether, in fact, there were conflicting claims.

The Court further observed that the Examiner did not specify the "subject matter" (nor did he specify which petitioners' claims conflicted with the claims of the Pagliaro et al. application) for which petitioners

were to name the prior inventor. The Court took the position that it was incumbent upon an Examiner in making a request pursuant to 37 C.F.R. 1.78(c) to specify the "subject matter" so that an Applicant *can* name the prior inventor thereof.

According to the Court's opinion, 37 C.F.R. 1.78(c) sets forth the requirement that petitioners state "which named inventor [as between Pagliaro et al. and petitioners] is the prior inventor". The regulation does not provide that, upon threat of abandonment of their application, petitioners may be required to state which inventive entity is the prior inventor of the subject matter of conflicting claims, MPEP 804.03 to the contrary notwithstanding. If petitioners did not believe there were conflicting claims, their only available response was to state who was the prior inventor of the respective inventions. Indeed, 37 C.F.R. 1.78(c) clearly provides that petitioners have the right to explain "that no conflict exists in fact." In the case before the Court, petitioners exercised this right by traversing the Examiner's assertion of the applicability of MPEP 804.03.

The Court confirmed that it was persuaded that the Examiner improperly required, under threat of abandonment per MPEP 804.03, that petitioners' assignee limit the claims of the Pagliaro et al. application. Although 37 C.F.R. 1.78(b) provides for "elimination" of conflicting claims from all but one application of the same applicant, 37 C.F.R. 1.78(c) provides no such authority when the applications are from different inventors and are owned by a common assignee, and to the extent that MPEP 804.03 undertakes to authorize such action, the Court held it to be invalid.

Any ameliorating effect the Court's opinion may have had on the prosecution of the applications which form the subject matter of this paper or on the propriety of the threat of abandonment was not sufficient to resolve a number of outstanding issues.

In the file histories being reviewed, the Examiner did specify the "subject matter" for which respective Applicants were to name the prior inventor. The designated "subject matter", however, was that which the Examiner wished to regard as the invention rather than what the inventive entities regarded as their respective inventions. The Examiner defined a broad enough genus to encompass the separate inventions of both inventive entities. Although this may be a convenient ploy, it tends to frustrate the very promotion of progress which is an objective of the patent system.

Although the Examiner failed to provide any explanation whatsoever, he did provide some insight [cf. paragraph (g) in the prosecution of A] as to the basis for his adverse holding. The opinion for the

Andresen Case (PTO Bd App 1981) indicated:

The fact that the events concerning the invention and derivation occurred abroad is not here fatal to the rejection [based on 35 U.S.C. 102(f)/103]. Despite the reference to locus of invention in 35 U.S.C. 102(g) and 104, the site of derivation need not be in this country to bar a deriver from patenting that subject matter. See *Hedgewick v. Akero*, 497 F.2d 905, 182 USPQ 167 (CCPA 1974).

In the first Official Action (Paper No. 3) issued in the prosecution of B, the following appeared:

Claims 1 to 6 are rejected under 35 U.S.C. 102(a) or (f) as being anticipated by S.N. 387,454 in the interim to expedite prosecution.

No further reference whatsoever is found to 35 U.S.C. 102(f) in the entire prosecution of B.

In the prosecution of A the only reference to 35 U.S.C. 102(f) was in paragraph (g), which appeared for the first time in the Office Action which was made final. Although reference is made to that section of the statute, it certainly is not clear that any ground of rejection is based on 35 U.S.C. 102(f).

No rejection based on derivation was formally made in the prosecution of A, and that issue was clearly dropped subsequent to the first Office Action in the prosecution of B. When the respective Applicants have a common assignee and an appropriate terminal disclaimer is filed at the PTO, no justification is seen for prolonging prosecution on the basis of issues or practices reflected in the prosecution of these applications.

As a result of an interview with the Examiner, further reconsideration and what was understood to be a policy decision at a level higher than that of the Examiner, an Office Action (issued in B on May 15, 1984) stated:

Claims 3, and 6 to 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7 and 8 of applicant's copending application S.N. 387,456 in view of Bull. At the time the invention was made, it would have been obvious to employ the fungible metals of Bull for Ni.

Although the inventive entities are not identical this ground of rejection is still proper, see *In re Rogers*, 157 USPQ 69.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of monopoly by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619. A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321(b) would overcome a rejection on this ground. See MPEP 804.02 and 1490.

A similar Office Action issued on the same date in the prosecution of A.

Accordingly, it now appears that at least in the case of overlapping inventive entities, commonly-assigned applications with a line of distinction between respectively-claimed subject matter (irrespective of the proximity of such claimed subject matter) can issue as separate patents if the effective lives of the patents terminate on the same date. Even without overlapping inventive entities, an appropriate terminal disclaimer should enable the assignee of commonly-assigned applications to overcome virtually all significant problems based on the relationship between the subject matter claimed in the respective applications.

One further issue is raised by paragraph (i) in the prosecution of A. For the teachings of a reference to be prior art under 35 U.S.C. 103, there must be some basis for concluding that the reference would have been considered by one skilled in the particular art working on the pertinent problem to which the invention pertains. For no matter what a reference teaches, it could not have rendered obvious anything "at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains" unless said hypothetical person would have considered it [*In re Horn, Horn, Horn and Horn*, 203 USPQ 969, 971 (CCPA 1979)].

The reported prosecution took place well before the signing on November 8, 1984 of Public Law 98-622 which significantly helps to avoid the recurrence of many of the problems encountered in the prosecution of the subject applications. Even though the PTO eventually relented, it was not until after an unduly heavy burden was placed on applicants. If the purpose of the patent system is to advance progress, the PTO must be vigilant in its sensitivity to formal impediments to issuing patents. Unnecessary abandonments deter rather than promote progress.

COPYRIGHTING TRADE SECRETS UNDER THE 1976 COPYRIGHT ACT

BY *THOMAS F. MARSTELLER, JR. AND **ROBERT L. TUCKER

This paper seeks to explore the advantages of using federal copyright law (Title 17 of the U.S. Code) to provide additional protection to specific types of common law trade secrets. At the outset, it is important to stress that copyright laws protect only the "expression" of ideas and not actual "ideas" themselves. For example, copyright will protect a specific textile pattern of flowers, incorporating roses, carnations and daisies. But this does not foreclose anyone from designing and producing another floral print comprising roses, carnations and daisies. The nature of copyright will severely limit the types of trade secrets to which copyright can give expanded protection. However, in many instances, especially with proprietary computer software, copyright can serve to provide additional valuable protection.

The impetus for this paper stems from a recent addition to the Milgrim Treatise on trade secrets, entitled "Trade Secrets and Copyright"¹.

While the concept of copyright protection for trade secrets has not been tested in the courts, there is every indication, based on relevant statutes, regulations, conversations with the Copyright Office and peripheral case law, that it can provide increased protection for a minimum amount of expense and effort.

THE STATE LAW OF TRADE SECRETS

As defined by the Committee on Torts of the American Law Institute in comment b of section 757 of the Restatement of Torts (1939),

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¹ 12 R. Milgrim, *Business Organizations, Trade Secrets* 2-72.1 (1981).

A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers. It differs from other secret information in a business . . . in that it is not simply information as to single or ephemeral events in the conduct of the business, as, for example, the amount or other terms of a secret bid for a contract or the salary of certain employees, or the security investments made or contemplated or the date fixed for the announcement of a new policy or for bringing out a new model or the like. A trade secret is a process or device for continuous use in the operation of a business. Generally it relates to the production of goods, as, for example, a machine or formula for the production of an article. It may, however, relate to the sale of goods or to other operations in the business, such as a code for determining discounts, rebates or other concessions in a price list or catalogue, or a list of specialized customers, or a method of bookkeeping or other office management.

Trade secrets protect much of the same subject matter as that of patents: machines, processes, compounds, and so forth. Many companies seek to protect unpatentable inventions and ideas with trade secrets. This practice was explicitly acknowledged by the Supreme Court in *Kewanee Oil v. Bicron*,² where the Court stated that: "trade secret law will encourage invention in areas where patent law does not reach, and prompt the independent innovator to proceed with the discovery and exploitation of his invention."³ However, the *Kewanee* type of trade secret, concerned with potentially patentable inventions, is not the type of trade secret to which this paper is directed because copyright will not protect ideas.⁴ The type of trade secret that interests us here is one where the expression itself is the property which needs to be protected, such as codes, price lists, computer programs, customer lists or internal informational books to facilitate business operation.

An example of this last type of trade secret was the basis for a lawsuit filed in a state district court of Texas.⁵ The suit was between two international companies engaged in building deep sea oil production equipment. The plaintiff, a manufacturer, brought suit for misappropriation of trade secrets (consisting of a set of eight 300-page

² 416 U.S. 470 at 485 (1974).

³ See also: Arnold, Durkee and Aspelund, "Trial Tactics and Trade Secret Cases" in *Protecting Trade Secrets* (1981).

⁴ *Mazer v. Stein*, 347 U.S. 201 at 217; *Sid & Marty Krofft Television v. McDonald's Corp.*, 562 F.2d 1157 at 1163 (9th Cir. 1977); *Universal Athletic Sales Co. v. Salkeld*, 511 F.2d 904 at 906 (3rd Cir. 1975), *cert. denied*, 423 U.S. 863 (1975).

⁵ *Koomey, Inc. v. William Michael Koen, d/b/a ODSO, and NL Industries, Inc. v. Koomey, Inc., et al*, C.A. No. 8780, In the District Court of Waller County, Ninth Judicial District, State of Texas.

internal catalogs of all of plaintiff's repair parts, arranged by part number, description, original vendor and vendor part number⁶) which allegedly allowed the defendant to rapidly set up a parts department and enjoy substantial sales in the first year of existence.

While trade secrets provide protection against unlawful misappropriation, they do not protect an owner from independent invention, reverse engineering or development after observation in public or in published literature. Many states provide criminal penalties for the theft of trade secrets.⁷ Other states make their larceny or theft statutes applicable to the taking of trade secrets.⁸ While civil remedies vary by jurisdiction, most include injunctive relief and a variety of damages.⁹

On August 9, 1979, the Uniform Trade Secret Act was approved by the National Conference of Commissioners on Uniform State Laws and recommended for enactment in all the states, although thus far there have been reported decisions under the Act in three states.¹⁰ The Act provides for damages for actual loss caused by misappropriation, as well as any unjust enrichment as a result of the misappropriation that was not taken into account in computing the actual loss damages. Exemplary damages may also be awarded in an amount not exceeding twice the amount recovered by actual loss in unjust enrichment.¹¹

THE COPYRIGHT PREEMPTION PROBLEM

The basis for copyright protection is the expression of an idea contained in a work. The extent of the protection is limited to only the

⁶ Plaintiff's parts catalog is an important informational source for its multi-million dollar parts supply business.

⁷ Arkansas, California, Colorado, Florida, Georgia, Michigan, Nebraska, New Mexico, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Tennessee, Texas, Virgin Islands and Wisconsin.

⁸ See: M.A. Epstein, "Criminal Liability for the Misappropriation of Trade Secrets" in 12A R. Milgrim, *Business Organizations, Trade Secrets* 85-1 (1981).

⁹ Loss of profits, start-up expenses and additional overhead, loss of goodwill and punitive damages. See Browne, "Remedies and Recoveries and Trade Secret Cases" in *Protecting Trade Secrets* at 119 (1981).

¹⁰ Minnesota. See *Jostens, Inc. v. National Computer Systems, Inc.*, 318 N.W.2d 691 (1982).

Indiana. *Steenhover v. The College Life Insurance Co. of America*, No. 2-783 A 254, slip op. (ct. App. Ind., 2d Dist., Jan. 16, 1984).

Louisiana. *Tubular Threading, Inc. v. Scondaliante*, No. 82-CA-165, slip op. (Ct. App. La., 5th Cir., Dec. 8, 1983).

¹¹ Reasonable attorney's fees may be awarded to the prevailing party if a claim of misappropriation is made in bad faith, a motion to terminate an injunction is made or resisted in bad faith, or willful and malicious misappropriation exists.

form of an expression, not an underlying idea.¹²

The U.S. Supreme Court in its landmark decision of *Baker v. Selden*, 101 U.S. 99, 103 (1880), held that:

The copyright of a work on mathematical science cannot give to the author an exclusive right to the methods of operation which he propounds, or to the diagrams which he employs to explain them, so as to prevent an engineer from using them whenever occasion requires. The very object of publishing a book on science or the useful arts is to communicate to the world the useful knowledge which it contains. But this object would be frustrated if the knowledge could not be used without incurring the guilt of piracy of the book. And where the art it teaches cannot be used without employing the methods and diagrams used to illustrate the book, or such as are similar to them, such methods and diagrams are to be considered as necessary incidents to the art, and given therewith to the public; not given for the purpose of publication in other works explanatory of the art, but for the purpose of practical application.

The Third Circuit in *Apple Computer*¹³ adopted the idea/expression dichotomy in its analysis of whether a computer program was subject to copyright protection. The defendant alleged that the computer program was an "idea" and as such was not subject to copyright protection. The court held that

If other programs can be written or created which perform the same function as an Apple's operating system program, then the program is an expression of the idea and hence copyrightable. In essence, this inquiry is no different than that made to determine whether the expression and idea have merged, which has been stated to occur where there are no or few other ways of expressing a particular idea.¹⁴

Since copyright protects the form of the expression, trade secrets are then another form of intellectual property.

Trade secret law protects contents irrespective of form of expression . . .

* * *

Trade secret law prohibits unauthorized disclosure or use of protected ideas only by persons who are privy to the trade secret by reason of some relationship to the owner which legally limits use or disclosure by them. Copyright law prohibits unauthorized copying by anyone of the form of expression in which the ideas are fixed by the author."¹⁵

The dichotomy between the idea and the expression which carries over to the differences between trade secret law and copyright law would be of no benefit if federal laws preempted state trade secret law.

¹² *M. Bryce & Associates, Inc. v. Gladstone*, 319 N.W.2d 907, 915 (Wis. 1982), cert. denied, U.S. , 103 S.Ct. 258 (1982).

¹³ *Apple Computer, Inc. v. Franklin Computer Corp.*, 714 F.2d 1240 (3d Cir. 1983).

¹⁴ *Apple Computer*, 714 F.2d at 1253

¹⁵ *Bryce*, 319 N.W.2d at 915-916 citing *Baker v. Selden*, 101 U.S. 99 at 105.

The cases under both the 1909 and the 1976 Copyright Acts¹⁶ as well as the legislative history of the 1976 Act indicate that federal copyright law does not act to preempt state trade secret law.¹⁷ Using the federal form of pleading alternative causes of action permitted by Rule 8(a) of the Federal Rules of Civil Procedure, a plaintiff would be able to alternatively plead both state trade secret claims and federal copyright claims.

A work may be generally published, be of a limited publication or remain unpublished and still be entitled to copyright protection under the 1976 Act.¹⁸

In *SmokEnders*¹⁹ the federal district court found that a trade secret owner did not lose his state common law rights by communicating the trade secret to persons who were either in a confidential relationship with the plaintiff or were under a contract not to make the disclosure public. As long as a disclosure is made under the cloak of secrecy and was not publicly available in its specific form, a trade secret owner is free to disclose the secret to others.²⁰

Under the 1909 Act, one could have a common law copyright as long as there was no general publication. Since there was no general publica-

¹⁶ *Warrington Associates v. Real-Time Eng. Systems*, 522 F.Supp 367, 368 (N.D. Ill. 1981); *Technicon Medical Information v. Green Bay Packaging*, 211 U.S.P.Q. 343, 347 (E.D. Wis. 1980), *ctfd. ques. ans.*, 687 F.2d 1032, 215 U.S.P.Q. 1001, (7th Cir. 1982), *cert. denied*, U.S. , 103 S. Ct. 732 (1983). *Data General Corp. v. Digital Computer Controls, Inc.*, A.2d , 188 U.S.P.Q. 276, 281 (Del. ch. 1975), *M. Bryce & Assoc., Inc., v. Gladstone*, 319 N.W.2d. at 915 (Wis. 1982).

¹⁷ *But see: Avco Corp. v. Precision Air Parts, Inc.*, F.Supp. , 210 U.S.P.Q. 894 (M.D. Ala. 1980), *aff'd* 676 F.2d 494 (11th Cir. 1982), *cert. denied*, U.S. , 103 S.Ct. 450 (1982) and, *Videotronics, Inc. v. Bend Electronics*, 564 F.Supp. 1471 (D.Nev., 1983) where the courts without precedent held that the Copyright Act of 1976 preempted state trade secret protection through both misappropriation and unfair competition causes of action. However, in neither case was there any contract between the parties requiring secrecy nor other factual elements showing a breach of trust, confidentiality or privacy to support either state action. Further, the Videotronics court did not cite Avco to support its holding. *Compare with Synercom Technology, Inc. v. University Computing Co.*, 474 F.Supp. 37 (N.D. Tex. 1979) in which the Court found that the Copyright Act preempted misappropriation where "there was no theft of trade secrets . . . , no breach of contract, and no breach of a confidential relationship.; *id.* at 43, but did not preempt a claim of unfair competition.

¹⁸ Under the 1976 Copyright Act, a limited publication is equivalent to a work being unpublished. See 17 U.S.C. §101.

¹⁹ *SmokEnders, Inc. v. Smoke No More, Inc.* 184 U.S.P.Q. 309 (S.D. Fla. 1974).

²⁰ *SmokEnders*, 184 U.S.P.Q. at 317

tion with a common law copyright, a plaintiff could also enforce state trade secret rights.

A limited publication does not destroy common law copyright protection in that such form of publication only communicates the knowledge therein contained under express or implied conditions precluding its disclosure to the public.²¹

A limited publication which is a publication that "communicates the contents of a manuscript to a definitely selected group and for a limited purpose, and without the right of diffusion, reproduction, distribution or sale"²² does not divest an author of a common law copyright under the 1909 Copyright Act or under state common law rights. Only a general publication acted to destroy common law copyrights.²³ In *Bryce*, the court found that there was a general publication of the document, yet found that the copyright protection extended only to the expression of the idea. Since the plaintiff conveyed the trade secret which was the methodology during an oral presentation held in confidence, the plaintiff might have lost copyright protection in the published manual and forms, but did not lose trade secret protection in the methodology.²⁴

The 1976 Copyright Act eliminated common law copyright (17 U.S.C. §301). In other words, the 1976 Act equally includes unpublished works under its protective umbrella as well as published works. The earlier distinction under the 1909 Act between a published work and an unpublished work no longer applies. The 1976 Act, however, does not preempt state trade secret actions. The legislative history of the 1976 Act indicates that: "The evolving common law rights of 'privacy,' 'publicity' and trade secrets and the general laws of defamation and fraud, would remain unaffected as long as the causes of action contain elements, such as an invasion of personal rights or a breach of trust or confidentiality, that are different in kind from copyright infringement."²⁵

The crux of the issue differentiating trade secrets and copyrights is the additional factual elements of confidentiality or contract accompanying a trade secret that are not found with copyrights. An action for misappropriation of a trade secret under the Restatement of Torts §757

²¹ Data General, 188 U.S.P.Q. at 282.

²² *White v. Kimmell*, 193 F.2d 744, 746-47 (9th Cir. 1952).

²³ *Bryce*, 319 N.W.2d at 913.

²⁴ *Bryce*, 319 N.W.2d at 916.

²⁵ H.R. Rep. No. 1476, 94th Cong., 2d Sess. 132 (1976). U.S. Code Cong. & Admins. News, pp. 5659, 5748.

requires the elements of an invasion of privacy, a trespass, a breach of trust or a breach of confidentiality.²⁶

Section 301 of the 1976 Act provides that the Federal Act preempts all state law, both common and statutory, which grant rights equivalent to any of the exclusive rights provided for within the general scope of copyright law as specified by section 106 for a qualifying work fixed in a tangible medium.²⁷ This created some confusion insofar as the possible preemption of common law trade secrets by the new federal copyright. But trade secrets do not always give protection equivalent to the "ex-

²⁶ Compare *Avco*, 210 U.S.P.Q. at 898, where the court found that the Copyright Act preempted unfair competition, but not the misappropriation cause of action, with *Synercom*, 474 F.Supp. at 43 and *Videotronics*, 564 F.Supp. at 1477, in which those courts found the Copyright Act to preempt the misappropriation cause of action. In *Videotronics* the court further blurred the issues by requiring a confidential relationship for an unfair competition cause of action.

²⁷ Section 301 of the Copyright Act provides:

(a) On and after January 1, 1978, all legal or equitable rights that are equivalent to any of the exclusive rights within the general scope of copyright as specified by section 106 in works of authorship that are fixed in a tangible medium of expression and come within the subject matter of a copyright as specified by sections 102 and 103, whether created before or after that date and whether published or unpublished, are governed exclusively by this title. Thereafter, no person is entitled to any such right or equivalent right in any such work under the common law or statutes or any State.

(b) Nothing in this title annuls or limits any rights or remedies under the common law or statutes of any State with respect to —

(1) subject matter that does not come within the subject matter of copyright as specified by sections 102 and 103, including works of authorship not fixed in any tangible medium of expression; or (2) any cause of action arising from undertakings commenced before January 1, 1978; or (3) activities violating legal or equitable rights that are not equivalent to any of the exclusive rights within the general scope of copyright as specified by section 106.

Section 106 of the 1976 Copyright Act provides:

Subject to sections 107 through 118, the owner of copyright under this title has the exclusive rights to do and to authorize any of the following:

- (1) to reproduce the copyrighted work in copies or phonorecords;
- (2) to prepare derivative works based upon the copyrighted work;
- (3) to distribute copies or phonorecords of the copyrighted work to the public by sale or other transfer of ownership, or by rental, lease, or lending;
- (4) in the case of literary, musical, dramatic, and choreographic works, pantomimes, and motion pictures and other audiovisual works, to perform the copyrighted work publicly; and
- (5) in the case of literary, musical, dramatic, and choreographic works, pantomimes, and pictorial, graphic, or sculptural works, including the individual images of a motion picture or other audiovisual work, to display the copyrighted work publicly.

clusive rights" within the scope of section 106 and thus do not fall prey to section 301.²⁸

The U.S. Supreme Court recognized the independent existence of trade secrets, separate from that of other statutory protections in *Kewanee Oil v. Bicron*.²⁹

[t]rade secret law and patent law have co-existed in this country for over 100 years. Each has its particular role to play, and the operation of one does not take away from the need of the other . . . Congress, by its silence over the many years, has seen the wisdom of allowing the states to enforce trade secret protection. Until Congress takes affirmative action to the contrary, states should be free to grant protection to the trade secrets.

PROCEDURE FOR COPYRIGHTING TRADE SECRETS

The heart of the problem of copyrighting trade secrets lies in registering a fixed work. It is obviously of paramount importance to maintain the secrecy of a trade secret³⁰ sought to be copyrighted or its value becomes minimal. This seemingly is in conflict with the spirit and intent of the Copyright Act. However, unlike the 1909 Act, superseded by the 1976 Act, copyright protection automatically attaches to original works of authorship when such a work is fixed in a tangible medium.³¹ Publication is not required to obtain federal protection and thus trade secrets can remain so and still receive copyright protection.

The superior benefits of federal copyright protection lie in the statutory remedies to which an author is entitled. To obtain statutory remedies, it is critical to register a work prior to bringing a lawsuit based on a copyright.³²

The deposit requirement of section 408 of the Copyright Act, which requires one complete copy of an unpublished work to be submitted along with the application is the stumbling block in the registration process. Depositing a copy of a trade secret in the Library of Congress would be the death knell to a trade secret. Side-stepping this deposit requirement is the key to registration.

Basically, two statutory sections deal with deposit, section 407 and section 408. Section 407, is a provision aimed at expanding the archives of the Library of Congress. If an author publishes a work with a notice of copyright, she is required to submit to the Copyright Office two copies of

²⁸ Warrington Associates, 522 F.Supp at 368.

²⁹ 416 U.S. 470, 493 (1974).

³⁰ Smith v. Dravo Corp., 203 F.2d 369, 373 (7th Cir. 1953).

³¹ 17 U.S.C. §106

³² 17 U.S.C. §412

the work within three months of publication. Failure to deposit the requisite copies can result in civil fines of \$250 for each work plus the cost of acquiring the work by the Library of Congress. Provision (c) of section 407 allows the Register of Copyrights to exempt, by regulation, certain categories of material. The categories of materials allowed to fall under this exemption are specified in 37 C.F.R. §202.19 as: scientific diagrams and models, greeting cards, individually published lectures, machine readable computer programs, three-dimensional sculptural works and so forth. Section 407, however, does not deal with registration and is required only of "published work". "Publication" is defined in 17 U.S.C. §101 as:

the distribution of copies or phono records of a work to the public by sale or other transfer of ownership, or by rental, lease, or lending. The offering to distribute copies or phono records to a group of persons for purposes of further distribution, public performance, or public display, constitutes publication.

Based on this definition of "publication", a trade secret, although fixed in a tangible medium, would be exempt from the provisions of section 407 since it is not published.³³

Section 408 of the 1976 Copyright Act prescribes the deposit requirement for registration. Although registration is not a condition to copyright protection, sections 411 and 412 make registration a prerequisite to infringement actions and certain other remedies, including statutory damages and attorneys fees. To maximize the benefits of copyrighting trade secrets, it is thus necessary to register the work before an infringement action can be commenced.³⁴ In the case of an unpublished work, section 408(b)(1) requires the depositing of one complete copy with the Copyright Office. However in the regulations, 37 C.F.R. §202.20 provides provisions to avoid the deposit requirement altogether:

For a computer program which is an unpublished work [i.e., a trade secret] or a published work, published only in the form of machine-readable copies [such as a floppy disc used to sell computer software] §202.2(c)(viii)(A) requires the deposit of one copy of identifying portions of

³³ As a practical matter, very few authors are penalized for failing to meet the deposit requirement of section 407, and failure to do so does not prevent the ability to later register the work. Several violations of the deposit requirement have been reported by the Copyright Office to the Department of Justice, but there are no reported opinions or court rulings actually brought under this provision.

³⁴ 17 U.S.C. §412(1)

the program, reproduced in a form visually perceptible without the aid of a machine or device, either on paper or in microform.³⁵

If it is not possible to submit a visually perceptible portion, the object code of the program (computer language, zeros and ones) can be submitted. The Copyright Office will register the program and issue a "Letter of Doubt" which stipulates that the work is not readable, but that the Copyright Office is adopting the owner's assertion that the work comprises copyrightable subject matter.³⁶

³⁵ Identifying portions is defined as meaning "the first and last twenty-five pages or equivalent units of the program if reproduced on paper, or at least the first and last twenty-five pages or equivalent units of the program if reproduced in microform, together with the page or equivalent unit containing the copyright notice, if any." 37 C.F.R. §202.20(c)(vii)(B).

³⁶ The Copyright Office will register a computer program along with the following letter:

We are delaying registration of the claim to copyright in this work because the deposit consists of a printout of a computer program and object code or other non-source code format. The Copyright Office generally requires the best representation of the authorship for which copyright is being claimed. Because copyright examiners are not skilled computer programmers, they have extreme difficulty in examining computer programs in other than source code format to determine whether the deposit contains copyrightable authorship. Deposit copies of works registered for copyright are available only for inspection in the Copyright Office by members of the public and may not be "copied".

The Office believes that the best representation of the authorship in a computer program is a printout of the program in source code format. Where, whenever the applicant is unable or unwilling to deposit a printout in source format, we will proceed with registration under our "rule of doubt," upon receipt of a letter from the applicant assuring us that the work as deposited contains copyrightable authorship.

Please, therefore, forward either a copy of the entire computer program or the first twenty-five and last twenty-five pages of source code format to be used along with the object code format as the deposit. On the other hand, if you wish to pursue registration without depositing the source code format, please forward the letter mentioned above.

In your reply, please return the enclosed carbon referring to our CONTROL NUMBER.

Sincerely yours,

R.L. R-70

Deposit is Computer

Program in non-source

Code format

7/81.

³⁷ R.M. Milgrim, *Protecting and Licensing Software in Technology Licensing* at 437 (1982).

If the materials deposited are in human-perceptible form, it would obviously be important to reorganize the source code such that the first and last twenty-five pages of the deposit contain only irrelevant filler or non-sensitive information so as not to disclose the trade secret.³⁷

If the trade secret consisted of a data base with thousands of pages of information, a deposit requirement of only fifty pages would probably not harmfully disclose enough of the data base to allow misappropriation. However, if the data base consisted of a small amount of pages, the deposit requirement of 37 C.F.R. §202.20 would negate the secrecy of the data base and destroy the advantages of copyrighting the data base.

There are many types of trade secrets that do not consist of computer programs or data banks, which would also be beneficial to copyright. This type of trade secret would most likely fall under the deposit regulations required for a "secure test". This regulation, 37 C.F.R. §202.20(c)(vi), provides for the return of any secure test after examination "provided, that sufficient portions, description, or the like are retained so as to constitute a sufficient archival record of the deposit."³⁸ The Copyright Office, however, recommends personally carrying the trade secret material into the Copyright Office, having the work examined in light of the application and personally carrying the material out of the office.³⁹

Commenting on 37 C.F.R. §202.20(c)(vi), the Court of Appeals for the 7th Circuit upheld the legality of this regulation holding that the "statutory scheme of the Copyright Act demonstrates that the deposit provisions are not for the purpose of disclosure".⁴⁰

It is thus far, uncertain, whether the Copyright Office will allow a trade secret which does not fall under one of the provisions for an alternative deposit to be registered without complying with the full statutory deposit requirements. In drafting the proposed rules, the then Register of Copyrights, Barbara Ringer, recognized that it was not possible to anticipate all the situations that might necessitate exemptions to the deposit requirement.⁴¹ Thus, §§202.19(e) and 202.20(d) were included in the regulations to allow the Register to

³⁸ §202.20(c)(vi).

³⁹ Summarized from a conversation with Ms. Larissa Pastuchiv, Copyright Information Specialist in the Copyright Office on November 1, 1982.

⁴⁰ *National Conference of Bar Examiners v. Multi-State Legal Studies, Inc.*, 692 F.2d 478, 486 (7th Cir. 1982); *cert denied* U.S. , 104 S.Ct. 69 (1983).

⁴¹ Volume 43, No. 182 of the Federal Register, September 19, 1978, page 41975-84.

grant special relief from the deposit requirements of 17 U.S.C. §§407 and 408. The special relief may be to "permit the deposit of one copy . . . , or alternative identifying material."⁴² In the case of a trade secret, it is identifying material that an "author" would wish to deposit. While there is no case law directly on point, any "author" of a trade secret (not comprising a computer program or a computerized data base) who desires copyright protection should seek to comply with the deposit requirement in a manner similar to that of a secure test, i.e., by submitting identifying material, or hand carrying the "fixed" trade secret into the Copyright Office for examination in regard to the application and then personally carrying the trade secret material out of the Copyright Office. It has also been suggested that identifying materials may be created by photographing the trade secret through diagonal slits so that only slices of the secret information would be visible. The original secret, being identifiable by these photographed slits, would reveal no intelligent information so as to disclose the trade secret.⁴³

BENEFITS OF COPYRIGHTING TRADE SECRETS

Usually, claims of trade secret misappropriation or unfair competition are brought in state courts under state common law.⁴⁴ In order to file suit in federal court, it would be necessary to meet the jurisdictional requirements of 28 U.S.C. §1332, diversity jurisdiction, and the minimum statutory amount.

By copyrighting trade secrets, access is gained to federal courts under 28 U.S.C. §1338. The benefits of being in federal court include grants of nationwide injunctions,⁴⁵ and the availability of federal discovery, procedural and evidentiary rules.⁴⁶

The 1976 Copyright Act provides damages for infringement,⁴⁷ which include: the copyright owner's actual damages and additional profits made by the infringer as a result of infringement. A copyright owner may elect to recover statutory damages, which, in a willfully committed case, as in trade secret misappropriation, can be increased by the court to \$50,000 per infringement. The Act also allows reason-

⁴² 37 C.F.R. §202.20(d)(i).

⁴³ D.M. Davidson, *Protecting Computer Software: A Comprehensive Analysis*, 23 *Jurimetrics* 339, 404 (1983).

⁴⁴ Alternatively, under the penal code; note 7, *supra*.

⁴⁵ 17 U.S.C. §502(b).

⁴⁶ 12 R. Milgrim, *Business Organizations, Trade Secrets* 2-72.5 (1981).

⁴⁷ §504.

able attorneys fees to be awarded to the prevailing party.⁴⁸

In addition, §506 of the Act makes it a criminal offense, punishable by not more than one year in jail, \$10,000 in fines, or both, for infringers who, willfully and for purposes of commercial advantage or private financial gain, infringe a copyright. This provision is available even if the trade secret owner does not register.⁴⁹

While statutory remedies are beneficial, they may be unnecessary in states which have adopted the Uniform Trade Secret Act⁵⁰ and have existing criminal penalties for trade secrets misappropriation. However, even in these states, the Copyright Act would still be useful as a means of gaining access to federal court.

CONCLUSION

Trade secrets are becoming evermore important in industry, especially in light of the increasing sales of computer software. While copyright only protects expressions and not actual ideas, copyrighting a trade secret will allow an "author" to obtain both the benefits of trade secret protection of ideas and copyright protection of expression.⁵¹ Although copyright protection attaches at the moment of fixation, the practitioner should be careful to fulfill the statutory requirements of registration prior to an infringement action so that maximum benefit can be derived from the provisions of the 1976 Copyright Act.

⁴⁸ §505.

⁴⁹ See §412 of the Copyright Act.

⁵⁰ See *supra* note 10.

⁵¹ Securing a copyright may also lower the risk when faced with maverick courts such as Avco or Videotronics that treat the Copyright Act as preempting state trade secrets actions. This is all the more important if the "expression" was copied, i.e., the aspect that is covered by copyright principles.

PATENT LAW'S EXPERIMENTAL USE DOCTRINE: AN ANALYSIS OF COURT DECISIONS INCLUDING CASES OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

THOMAS J. CIONE

INTRODUCTION

The United States Constitution confers on Congress the power to grant inventors an "exclusive Right" to any inventions they discover.¹ Before given this "exclusive Right", however, inventors must satisfy the Congressional mandate that their inventions be new,² useful,³ and a nonobvious development over the prior art.⁴

This paper reviews the doctrine of "experimental use" and its effect on one of the aforementioned requirements, i.e., novelty. The doctrine arose out of case law and its significance lies in its application to overcome the statutory bar of 35 U.S.C. §102(b). This statute provides:

A person shall be entitled to a patent unless . . . b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

A finding of "public use" and/or sale of an invention one year before the application date, negates the invention's novelty and will cause a

¹ U.S. Const. art. 1, §8, cl. 8.

² 35 U.S.C. §102 (1982).

³ 35 U.S.C. §101 (1982).

⁴ 35 U.S.C. §103 (1982).

patent application to fail or invalidate an issued patent. The policy behind this statute is to ensure the prompt disclosures of inventions, thereby enlarging the relevant prior art,⁵ and to protect the public by not allowing an inventor to expand his patent monopoly beyond the time period granted him by statute.⁶

The public use and sale bars to patentability can be overcome in situations where an inventor can show that the use or sale of his invention before the "critical date" (e.g., prior to one year before his patent application) was for experimental purposes. This doctrine, known as the "experimental use exception", is really not an exception at all.⁷ The Supreme Court in *City of Elizabeth v. Pavement Co.*,⁸ said that an invention used for experimental purposes is not a "public use" which would work to void a patent within the meaning of the patent statutes. If a use is experimental, public use is negated.

Whether the "experimental use" doctrine should be regarded as an "exception" is really not important, since it is a convenient phrase which acknowledges judicial approval of experiment made to "perfect" one's invention or, as the Court in *Elizabeth* said, to "ascertain whether it will answer the purpose intended."⁹

The "experimental use" exception also applies to sales made prior to the "critical date," providing that the primary purpose of the sale was for experimental reasons.¹⁰

⁵ *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19 (1892).

⁶ See *Pickering v. Holman*, 459 F.2d 403, 406, 173 U.S.P.Q. 583, 585 (9th Cir. 1972).

⁷ *Id.*

⁸ 97 U.S. 126 (1877). In *City of Elizabeth*, the Supreme Court first enunciated the "experimental use" exception, and applied it to save a patent on a wooden pavement which was used by the traveling public on a heavily traveled thoroughfare out of Boston, Massachusetts, for six years prior to the invention's application for a patent. The Court, after considering all of the evidence (e.g., the fact that it was constructed at the inventor's expense; placed in an area where he had the opportunity to inspect it on a daily basis; examined by inventor almost on daily basis; inventor constantly inquired of the toll bridge employees how people reacted to the pavement), concluded that the inventor's intention in putting his invention where he did was to test its "usefulness and durability," and that such a use was experimental and not a public use within Section 7 of the Act of 1839. "The use of an invention by the inventor himself, or of any other person under his direction, by way of experiment, and in order to bring the invention to perfection, has never been regarded as [a public use]." *Id.* at 134.

⁹ *Id.* at 137.

¹⁰ *Robbins Co. v. Lawrence Mfg. Co.*, 482 F.2d 426, 431, 178 U.S.P.Q. 577, 581 (9th Cir. 1973). See also *Kock v. Quaker Oats Co.*, 681 F.2d 649, 653, 215 U.S.P.Q. 200, 204 (9th Cir. 1982), *cert. denied*, 459 U.S. 1147 (1983).

Confusion in patent law with respect to the doctrine, is evident in several areas. It is seen most frequently with questions relating to "reduction to practice" of the patentable idea before, during, and after experimentation, and with issues addressed to an inventor's control (or lack thereof) of his invention during the experimental stage, as well as to the existence of commercial exploitation before the "critical date". The purpose of this paper is to try to clarify the discussion of the doctrine and to analyze the cases the United States Court of Appeals for the Federal Circuit has decided in this area. In order to do this, it is necessary to see how the leading cases answer the topics discussed herein.

QUESTION 1: WHAT SORT OF ACTIVITY FALLS UNDER THE DOCTRINE OF "EXPERIMENTAL USE"?

Discussion:

Before the question can be answered, it must be established at the outset that the courts are strict in invalidating issued patents or upholding the invalidity of patent applications if a public use or sale has taken place before the "critical date" without a showing of experimental use. In *Egbert v. Lippman*,¹¹ a case which was decided by the Supreme Court in 1881, a patent for corset springs worn underneath a woman's dress, was held invalid even though the invention was given to the inventor's fiancée for her personal use and was unseen by the general public. The Court said:

We observe, in the first place, that to constitute the public use of an invention it is not necessary that more than one of the patented articles should be publicly used. The use of a great number may tend to strengthen the proof, but one well-defined case of such use is just as effectual to annul the patent as many

We remark, secondly, that, whether the use of an invention is public or private does not necessarily depend upon the number of persons to whom its use is known.¹²

The Court, after reviewing the facts, invalidated the patent because it saw no evidence of experimental use. This case is illustrative in bringing home the idea that, absent experimental use, the public use of an invention, however innocuous it may seem, will cause the patent to fail under the patent statutes. The same result occurs for a single sale

¹¹ 104 U.S. 333 (1881).

¹² *Id.* at 336.

of the invention before the critical date.¹³ In order to have this patent invalidating effect an actual sale of the invention doesn't necessarily have to occur since "activity by the inventor or his company in attempting to sell the patented idea"¹⁴ including an offer to sell are also sufficient to put an invention on sale.¹⁵

Since the public use or sale of an invention, if made for experimental purposes, will save a patent application, it is now important to inquire as to what sort of activities the court labels "experimental," so as to put them outside the reach of §102(b) and its earlier statutory counterparts.

The beginning point of our inquiry, as with all other questions involving the "experimental use" exception, is to see what the Supreme Court said in *City of Elizabeth*. The Court, in this case, said that an inventor's public use of his invention before the "critical date"

if used . . . for the purpose of enabling him to test the machine, and ascertain whether it will answer the purpose intended, and make such alterations and improvements as experience demonstrates to be necessary, . . . will . . . be a mere experimental use, and not a public use, within the meaning of the statute.¹⁶ (Emphasis added.)

In the *City of Elizabeth*, the invention (a wooden pavement) was used by the traveling public for six years without being modified and yet, an experimental use was found since "durability could not be ascertained without its being subjected to use for a considerable time."¹⁷ The inventor's continuous "bona fide effort to bring his invention to perfection," by checking on its durability, was the only way he could ascertain if his invention "was what he claimed it to be". These efforts, the Court reasoned, will not cause his use of the invention to be a "public use" covered by the patent statutes, since "it is the interest of the public, as well as [the inventor] himself, that the inven-

¹³ See *B.F. Sturtevant Co. v. Massachusetts Hair & Felt Co.*, 124 F.2d 95, 51 U.S.P.Q. 420 (1st Cir. 1941) cert. denied, 315 U.S. 823, 52 U.S.P.Q. 644 (1942), "The putting 'on sale' intended by the statute is more or less analagous to a public use" *Id.* at 97, 51 U.S.P.Q. at 422 (quoting *McCreery Eng'g Co. v. Massachusetts Fan Co.* 195 F. 498, 502 (1st Cir. 1912)). See also *Martin v. Norman Industries, Inc.*, 725 F.2d 990, 221 U.S.P.Q. 1130 (5th Cir. 1984)

¹⁴ *Amphenol Corp. v. General Time Corp.*, 397 F.2d 431, 433, 158 U.S.P.Q. 113, 115 (7th Cir. 1968).

¹⁵ *In re Yarn Processing Patent Validity Litig.*, 498 F.2d 271, 183 U.S.P.Q. 65 (5th Cir. 1974), cert. denied, 419 U.S. 1057, 184 U.S.P.Q. 65 (1974)

¹⁶ 97 U.S. at 135.

¹⁷ *Id.* at 136.

tion should be perfect and properly tested, before a patent is granted for it."¹⁸

City of Elizabeth's determination of what constitutes an experimental use is sometimes neglected by the courts, which often get bogged down in discussions of whether an invention was "reduced to practice" before or after experiments occurred. (See Question Three herein). The focus of inquiry should instead be on whether the inventor conducted his experiments to "ascertain whether it will answer the purpose intended" and whether the inventor intended his use of his invention to be experimental. This will often depend on the degree of control the inventor has over his invention, thereby indicating any abandonment of the patentable idea and any commercial exploitation resulting from its use or sale.

The fact that no modification or change has occurred during the experimental stage does not affect the application of the "experimental use" doctrine to that invention.¹⁹ The Court in *In re Yarn* said, "experiments [made] so as to satisfy [the inventor] that [the invention] needs no further refinement and to prove its fitness for the intended purpose,"²⁰ are covered by the "experimental use" doctrine. And, in the case of a sale of a patentable idea, the Court in *Kock v. Quaker Oats Co.*, said that, where the purpose of the sale "is to determine whether the invention can be improved or reduced to operable, manufacturable, and useful form, a valid experimental purpose exists."²¹ In *Kock*, the inventor was paid one thousand dollars to build and develop a toy watch for the Merry Manufacturing Company. The watch had to tick when running, be accurate, run for an hour per winding, be easily assembled and be marketable for one dollar. Kock came up with a prototype he thought met these standards and sold it to Merry. The contract between the parties stated: "The INVENTOR hereby sells, assigns and transfers all rights to his novelty toy watch movement and any invention embodied therein to the COMPANY."²² The Court, stating that the invention could have undergone "further refinements before reduction to useful and manufacturable form" after the sale to Merry, nevertheless found that the patent was invalid under §102(b), since "there was no basis at all for finding that Merry was required to

¹⁸ *Id.* at 136-37.

¹⁹ *In re Yarn*, 498 F.2d at 277, 183 U.S.P.Q. at 69.

²⁰ *Id.* at 275, 183 U.S.P.Q. at 67.

²¹ *Kock*, 681 F.2d 649, 653, 215 U.S.P.Q. 200, 204 (9th Cir. 1982).

²² *Id.* at 652, 215 U.S.P.Q. at 203.

perform further experiments,” or that the inventor had control over the commercial use of the invention after the sale.²³ (See Question 2.)

QUESTION 2: HOW DOES AN INVENTOR'S CONTROL AND COMMERCIAL EXPLOITATION OF HIS INVENTION AFFECT HIS RIGHTS TO A PATENT?

Discussion:

The policy behind §102(b), as previously stated, addresses the above question. A loss of control of an invention and commercial exploitation conflict with this policy and, if one of these occur, a patent will not be granted for that invention.

Commercial exploitation may occur in many forms, but it is usually associated with sales made for the purpose of developing or promoting a market for the invention.²⁴ The context in which the sale or offer is made will often determine whether commercial exploitation exists. Other important *indicia* are: were profits made on transfers consummated without experimental intent? Did the inventor advertise his invention?²⁵ Did the inventor subject his invention to public demonstrations, consumer or market testing? Questions like these are continuously considered by the courts to ensure that patents are not issued for inventions that were commercially exploited in contravention of the policy behind §102(b).

Where the purpose of a sale is to investigate or stimulate the demand for the product, the object of the transfer is deemed commercial, not experimental, and the exception does not apply. Such a sale is within the bar of Section 102(b). On the other hand, where the purpose of the sale, as revealed by objective circumstances, is to determine whether the invention can be improved, or reduced to operable, manufacturable, and useful form, a valid experimental purpose exists.²⁶

Commercially exploiting one's invention, whether it is by sale or public use, will not allow one to take advantage of the "experimental use" exception, even if the transfer was allegedly made in good faith

²³ *Id.* at 658, 215 U.S.P.Q. at 208.

²⁴ *The Public Use Bar to Patentability: Two New Approaches to the Experimental Use Exception*, 52 Minn. L. Rev. 851, 858 (1968)

²⁵ See *Smith v. Davis Mfg. Co. v. Mellon*, 58 F.705 (8th Cir. 1893) where it was held that advertising implies commercial exploitation.

²⁶ *Kock*, 681 F.2d at 653, 215 U.S.P.Q. at 204.

for experimental purposes.²⁷ A profit made on a transfer is not, by itself, a commercial exploitation of the invention where the profit is incidental to a bona fide experimental use.²⁸ The important thing to remember when determining whether commercial exploitation exists, is to see what the inventor's intention was in his use of the invention. "[T]he use ceases to be experimental when the motivation of the inventor is to exploit the invention and gain a competitive advantage over others."²⁹

The consumer testing of a chain saw in *Omark Industries, Inc. v. Carlton Co.*,³⁰ was considered to be an attempt to gain a competitive advantage and, therefore, not deserving of the "experimental use" exception. The "testing program was undertaken primarily to determine

²⁷ In *George R. Churchill Co. v. American Buff Co.*, 365 F.2d 129, 150 U.S.P.Q. 417 (7th Cir. 1966), the inventor contended that distribution of his invention was for testing purposes and, therefore, entitled to the exception to §102(b). But the court found the evidence showed that the open and unrestricted sales effort, which spoke about product superiority, combined with quotations or maximum prices and a lack of restriction to use or of secrecy, "was commercially tinged" and "an impermissible public use . . . undertaken in an atmosphere of competitive activity." *Id.* at 134, 150 U.S.P.Q. at 421.

In *American Can Co. v. Crown Cork & Seal Co. Inc.*, 693 F.2d 653, 216 U.S.P.Q. 859 (7th Cir. 1982), on a patent for a one piece seamless cup-like steel container, the court, after acknowledging that the invention could have been improved before it could fully satisfy a client's order, held that evidence which showed that the inventor sent thousands of containers to a client; quoted prices; agreed on quantity and sizes; installed machinery to manufacture the cans; offered a warranty; received purchase orders; selected the name; commissioned an outside consumer survey; calculated its rate or return; obtained detailed specifications from its client as to packing; and the fact that it was mentioned in the annual report; all point to sales efforts which seek to "secure a competitive advantage" which outweigh any experimental development that may have existed. *Id.* at 656, 216 U.S.P.Q. at 861.

²⁸ *Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249, 256 (1887).

²⁹ *Solo Cup Co. v. Paper Mach. Corp.*, 240 F. Supp. 126, 131, 144 U.S.P.Q. 729 (E.D. Wis. 1965), modified on other grounds, 359 F.2d 754, 149 U.S.P.Q. 239 (7th Cir. 1966). See also *Dataq, Inc. v. Tokheim Corp.*, 222 U.S.P.Q. 677 (10th Cir. 1984). The court in this case, noted that the test for determining whether an invention is "on sale" is primarily a matter of the inventor's intent which must have been communicated to the prospective purchaser. The court in *National Business Systems, Inc. v. AM International*, 223 U.S.P.Q. 1011 (7th Cir. 1984), held that the intent must be towards a device that embodies the future patentable invention and that a general existing order for similar devices prior to the critical date, without more, is not an attempt to sell or an offer of sale under §102(b).

³⁰ 652 F.2d 783, 212 U.S.P.Q. 413 (9th Cir. 1980).

the merchantability of the chain, rather than to perfect its essential qualities."³¹

If a finding of commercial exploitation is rendered, it is not necessary to determine to what extent the inventor had control of his invention. Conversely, if the inventor did not have control of the invention during the experimental stage, it is not necessary to determine whether he commercially exploited it. However, if the inventor had control of his invention, then it is necessary to see whether he exploited his patent monopoly protection by attempting to gain a commercial advantage.³²

When considering the questions relating to an inventor's control of an invention, look only at those situations where the transfer does not amount to an abandonment of the patentable invention.

Not all transfers from an inventor to a third party trigger the bar of section 102(b). If a transfer is made for the dominant purpose of experimentation, that is, to perfect the invention, and only incidentally for the profit of the inventor, then there is no public use or sale within the meaning of the statute.³³

The transfer may be by sale or by public use. In *City of Elizabeth*, the wooden pavement which constituted the invention, was put in public use for over six years before a patent application was filed. Nevertheless, the patent was held valid, since there existed the necessary amount of control over the invention by the inventor, which is required in every "experimental use" situation.

³¹ *Id.* at 787, 212 U.S.P.Q. at 416.

³² "Public use may be established either by showing a nonsecret, nonexperimental use of the invention prior to the critical date or by establishing that the inventor himself has used the invention primarily for trade and profit prior to the critical date, whether the use is secret or not. Thus, under certain circumstances a single instance of competitive exploitation of the invention by the inventor prior to the critical date can raise both the "on sale" and "in public use" bars to patentability. *In re Yarn*, 49 F.2d at 277, 183 U.S.P.Q. at 69. *See also* *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 7 (1892), *Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249 (1887) and *Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946), *cert. denied*, 328 U.S. 840 (1946).

³³ *Kock*, 681 F.2d at 652, 215 U.S.P.Q. at 203-04.

When the subject of invention is a machine, it may be tested and tried in a building, either with or without closed doors. In either case, such use is not a public use, within the meaning of the statute, so long as the inventor is engaged in good faith, in testing its operation. He may see cause to alter it and improve it, or not. His experiments will reveal the fact whether any and what alterations may be necessary. If durability is one of the qualities to be attained, a long period, perhaps years, may be necessary to enable the inventor to discover whether his purpose is accomplished *So long as he does not voluntarily allow others to make it and use it, and so long as it is not on sale for general use, he keeps the invention under his own control, and does not lose his title to a patent.*³⁴ (Emphasis added)

A transfer of the legal ownership of an invention, in order to have it tested, does not in itself cause a patent to be invalid under §102(b), where the transfer is made to one who has superior testing facilities³⁵ or where the intention of the parties was to further refine the invention.³⁶ In *Kock*, the court found that the transfer was not for experimental purposes, but instead was for the purpose of investigating and stimulating demand for the product.³⁷ The inventor had lost all control over the invention and had effectively placed it on sale, thereby precluding the application of the "experimental use" exception.

In *Egbert v. Lippman*, which involved an inventor's transfer of corset springs to his fiancée six years before the patent application, a public use was found since there was no evidence of an inspection by the inventor of his invention during the period, no obligation of secrecy, nor any condition or restriction on the transferee whatsoever.³⁸

The next area in the doctrine that needs to be addressed is what the courts mean by the phrase "reduction to practice". The concept is important because it signifies a time reference on which the "experimental use" doctrine operates. Unfortunately, this phrase has been interpreted differently by the courts, sometimes confusing a proper understanding of the "experimental use" doctrine.

QUESTION 3: WHAT EFFECT DOES "REDUCTION TO PRACTICE" HAVE ON THE "EXPERIMENTAL USE" DOCTRINE?

³⁴ 97 U.S. at 134-35.

³⁵ *The Public Use Bar to Patentability: Two New Approaches to the Experimental Use Exception*, 52 Minn. L. Rev. 851, 855 (1968).

³⁶ *Kock*, 681 F.2d at 652, 215 U.S.P.Q. at 204.

³⁷ *Id.* at 653, 215 U.S.P.Q. at 204.

³⁸ 104 U.S. at 337.

Discussion:

The Supreme Court in *City of Elizabeth*, was faced with an invention that was complete throughout the experimental stage. The seventy-five-foot length of pavement (which constituted the invention) was laid on a busy thoroughfare out of Boston, and was left intact while the inventor could test its durability. The experimental stage lasted for six years, since it was only by subjecting the pavement to the traffic of Boston for this period, that it could be ascertained "whether it [would] answer the purpose intended."³⁹ The inventor apparently made no modifications of his invention throughout this period. He would check to see how it was holding up by inspecting it almost daily and by asking people (toll-collectors) how they felt about the pavement's durability and performance. The Supreme Court reasoned that the experimental stage ended when the intended purpose for this invention could be ascertained, after all "alterations and improvements as experience demonstrated to be necessary"^{39a} were made.⁴⁰ This then, can be said to be the Supreme Court's definition of "reduction to practice," even though the phrase was not used in the decision. This definition would include all "bona fide" efforts made by the inventor to "bring his invention to perfection." This is the way it should be, since "it is [in] the interest of the public, as well as [the inventor] himself, that the invention should be perfect and properly tested, before a patent is granted for it."⁴¹ The Fifth Circuit in *In re Yarn* succinctly paraphrased the Supreme Court's position in *City of Elizabeth*, thusly:

An invention is "perfected" for purposes of patentability once it has been reduced to practice by sufficient testing and experimentation to demonstrate its utility. At that point, then, further experimentation is not necessary before applying for a patent, and it would seem that the experimental period should end.⁴²

³⁹ See note 16, *supra*.

^{39a} 97 U.S. at 139

⁴⁰ The Court in *In Re Yarn* called this the "American reduction to practice" which "is not achieved until the inventor has sufficiently tested the prototype to prove its utility and to determine that no further refinements are necessary." 498 F.2d at 279, 183 U.S.P.Q. at 70.

⁴¹ *Id.* at 137. See also *Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249 and *In re Smith*, 714 F.2d 1127, 218 U.S.P.Q. 976 (Fed. Cir. 1983) for the determination that the motivation to improve and perfect must be the real purpose and not merely incidental and subsidiary to the inventor's intention regarding such use.

⁴² 498 F.2d at 281, 183 U.S.P.Q. at 71.

Confusion in the area of "reduction to practice" has occurred because of two different definitions given to it by the courts. One view, seen in *In re Yarn*, holds that "'reduction to practice' does not occur until the inventor has had a reasonable time after reduction of the invention to reality [i.e. after constructing a working model that substantially embodies the claims later to be patented]⁴³ to experiment."⁴⁴ The other view, holds that "reduction to practice" occurs when the invention has been reduced to a reality, at which point experimentation may take place afterwards for a reasonable time.⁴⁵

Despite these two different definitions, one thing is clear: Once an invention has been reduced to a reality (i.e., a functional working model), to save it from a §102(b) bar, a public use or sale must be for experimental purposes, that is, to perfect it to a point where it will answer its intended purpose.

QUESTION 4: HOW HAS THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT TREATED THE "EXPERIMENTAL USE" DOCTRINE?

Discussion:

*In re Smith*⁴⁶ is the first case decided by the Federal Circuit that involved the "experimental use" doctrine. It is illustrative and important in our inquiry of how the Court will decide "experimental use" cases in the future, because it has confronted and decided many of the issues inherent in the doctrine. The invention in *In re Smith* was a

⁴³ The Court in *In Re Yarn* follows the development of an invention in three phrases: *Phase 1*: Mental conceptualization by the inventor; *Phase 2*: Ends when inventor has rendered his idea a reality, i.e., a prototype is built; and *Phase 3*: Experimental stage. This phase ends when the inventor satisfies himself that no further refinements are needed on an invention which proved its fitness for the intended purpose. *Id.* at 275, 183 U.S.P.Q. at 67.

⁴⁴ *Id.* at 282, 183 U.S.P.Q. at 73.

⁴⁵ The Court in *Cataphote Corp. v. DeSoto Chemical Coatings, Inc.*, 235 F. Supp. 936, 143 U.S.P.Q. 226 (N.D. Cal. 1964), *aff'd*, 356 F.2d 24, 148 U.S.P.Q. 527 (9th Cir. 1966), said that "the test for establishing a reduction to practice is different than the test for establishing an experimental use. To establish a reduction to practice of the inventor's idea, there must be demonstration that the inventor's idea works; in other words, that the invention will perform in a manner which will accomplish its intended purpose. To establish an experimental use, there must be a demonstration that the use was substantially for the purpose of experiment. Thus, there *may be an experimental use even following reduction to practice where the experiments are part of an attempt to further refine the device.*" (Emphasis added.) 235 F. Supp. at 937, 143 U.S.P.Q. at 228.

⁴⁶ 714 F.2d 1127, 218 U.S.P.Q. 976 (Fed. Cir. 1983).

vacuumable, powdered carpet composition that deodorized and imparted antistatic and antisoil characteristics to the carpet on application. The relevant facts are, that more than one year before applying for a patent, the assignee of the invention (Airwick) conducted a consumer test in St. Louis, involving 76 consumers. The first stage of the test involved a videotape presentation of the product concept, at the end of which the consumers were questioned about the pricing of the product, the believability of the claims made for the product, and their purchase intent. In the second stage of the test, the consumers were given samples of the product which they were allowed to use in their homes for two weeks. The use of the product was without legal restriction and there did not exist any agreement of confidentiality between the consumers and Airwick. At the end of the two week period, 68 of the consumers were personally interviewed regarding their experience with the product.

After the St. Louis test, work continued at Airwick in experimenting with different formulations. In an affidavit, James McLaughlin, one of the co-inventors stated:

Airwick . . . was seeking to technically develop the product while testing consumer reaction to the concept and to various prototype forms This test was during a period of intensive experimental work in the laboratory to define the metes and bounds of the Carpet Fresh product. I did not consider these tests to be a commercial exploitation but an integral part of our development and experimental work.⁴⁷

On appeal to the Board of Appeals, the inventor's claims were declared to be unpatentable since the "factual situation in the appeal . . . is well nigh on all fours with the factual situation before the courts in *Omark Industries*"⁴⁸ Applying the tests in *In re Yarn*, the Board concluded that the market testing in St. Louis was "motivated primarily by the desire for competitive exploitation, not for experimentation."⁴⁹

On appeal to the Federal Circuit, appellants argued that the board's reliance on *Omark Industries* was misplaced, since their test was supervised, the information derived therefrom was reported to Airwick's scientists, and the test was conducted by a market research group. Appellants also argued that the work at developing different

⁴⁷ *Id.* at 1131, 218 U.S.P.Q. at 980.

⁴⁸ *Id.* at 1132, 218 U.S.P.Q. at 981. See note 30, *supra*.

⁴⁹ *Id.* at 1133, 218 U.S.P.Q. at 981.

formulations made after the St. Louis test, indicated that their product was still in the experimental stage.⁵⁰

As we have previously seen, the "experimental use" doctrine foresees efforts at perfecting or improving one's invention, but the inquiry must not stop there. Commercial exploitation, or a loss of control of the invention during the alleged "experimental phase," results in a finding that the use was not experimental. The Court in analyzing appellant's St. Louis activities, summarized the type of objective evidence which indicates an intention that the activities be deemed experimental⁵¹ and said, that "[o]bjective evidence may include, *inter alia*, whether the inventor inspected the invention regularly, whether the inventor retained control over the invention, and whether the commercial exploitation was merely incidental to the primary purpose of experimentation."⁵²

The Court, using these tests, found that the St. Louis tests were not experiments in the technical or legal sense, but were "experiment[s] geared toward marketing and only incidentally toward technological improvement."⁵³ In addition, the Court held that the claims were unpatentable under authority of *Minnesota Mining and Manufacturing Co. v. Kent Industries, Inc.*,⁵⁴ because the "experimental use exception is not applicable to experiments performed with respect to unclaimed features of an invention,"⁵⁵ and, citing *Egbert v. Lippman*,⁵⁶ since "[a]ppellants did not control the actual testing of the composition"⁵⁷ or bind the consumers by a confidentiality agreement.⁵⁸ Such market testing, the Court held, did not fall within the "experimental use" exception.

The United States Court of Appeals for the Federal Circuit had the opportunity to decide another case involving the experimental use doctrine in *D.L. Auld Co. v. Chroma Graphic Co.*⁵⁹ D.L. Auld sued

⁵⁰ *Id.*

⁵¹ An inventor's subjective intent is of minimal value. *Robbins Co. v. Lawrence Mfg. Co.*, 482 F.2d 426, 431, 178 U.S.P.Q. 577, 581 (9th Cir. 1973).

⁵² 714 F.2d at 1135, 218 U.S.P.Q. at 983.

⁵³ *Id. Cf.* *In re Theis*, 610 F.2d 786, 204 U.S.P.Q. 188 (C.C.P.A. 1979).

⁵⁴ 409 F.2d 99, 101, 161 U.S.P.Q. 321, 322-23 (6th Cir. 1969).

⁵⁵ 714 F.2d at 1136, 218 U.S.P.Q. at 984.

⁵⁶ 104 U.S. 333, (1881).

⁵⁷ 714 F.2d at 1136, 218 U.S.P.Q. at 984.

⁵⁸ *Id.* at 1137, 218 U.S.P.Q. at 984.

⁵⁹ 714 F.2d 1144, 219 U.S.P.Q. 13 (Fed. Cir. 1983)

Chroma Graphics, for infringement of its patent, which claimed a method of forming foil-backed inserts in the form of cast decorative decals. Chroma Graphic defended its use alleging that the patent was invalid as a result of plaintiff's sales offering of the claimed invention prior to plaintiff's "critical date." The only issue in this case was whether, as a matter of law, defendant was entitled to summary judgment based on the facts before the Court.⁶⁰ The Court held that summary judgment was justified because plaintiff's argument, that the emblems were made by a "laboratory method" instead of the "patented method," raised no material fact issue, since plaintiff's own witness' "testimony establishes unequivocally that the 'laboratory' method involved each step of the claimed method."⁶¹ The "laboratory method" related to procedures which Auld employed in making samples. It argued that this method was distinct from the "patented method" which lent itself to mass production of the emblems. This distinction, the plaintiff reasoned, entitled them to characterize the process of making the emblems and its offer for sale, as an "experimental use" exception to the statutory bar of 35 U.S.C. §102(b). The Court disagreed, stating "that Auld may have experimented, after the critical date, with means to achieve tooling for mass production bears no relation to whether the method of the claim had earlier been used and the product of that earlier use offered for sale."⁶²

The Court held Chroma's evidence established that offers for sale were made, requiring Auld to submit facts indicating an ability to come forward with evidence that proof of an experimental purpose was possible. This was required to defeat a motion for summary judgment.⁶³ Auld failed to do this.

The next case which involved the experimental use exception in the Court of Appeals for the Federal Circuit is *TP Laboratories v. Professional Positioners, Inc.*⁶⁴ This case involved the question of whether the placing of orthodontal devices in dental patients' mouths before the "critical date", was experimental. The appellant-plaintiff, TP Industries, makes and sells orthodontic supplies and appliances and was the owner of a patent for a molded tooth positioning appliance

⁶⁰ *Id.* at 1147, 219 U.S.P.Q. at 15.

⁶¹ *Id.* at 1149, 219 U.S.P.Q. at 17.

⁶² *Id.* at 1150, 219 U.S.P.Q. at 18.

⁶³ *Id.*

⁶⁴ 724 F.2d 965, 220 U.S.P.Q. 577 (Fed. Cir. 1984)

used to keep patients' teeth in place while the patients were undergoing orthodontal treatment. The use of the device in the treatment of three patients before the "critical date" led to the issues under §102(b). The District Court held that the plaintiff was not entitled to a finding of experimental use, because "these users were 'under no limitation, restriction or obligation or secrecy to the inventor,'" and the patent owner did not prove that the inventor's use was experimental.⁶⁵ The Circuit Court disagreed with the district court's analysis and its holding with regard to a shift in the burden of proof.⁶⁶

Relying on *City of Elizabeth*, the Circuit Court said, that "[t]he fact that the device was not hidden from view may make the use not secret but non-secret use is not *ipso facto* 'public use' activity."⁶⁷ The Court correctly reasoned that in order to conclude that a use is "public", each case must be decided individually by considering the evidence in its entirety. While the patients use was "public," in the sense that it was open to public view, and no confidentiality pledge existed between the parties, a view of the evidence "considered as a whole" proves that the inventor had not made a public use within the meaning of §102(b). The dispositive factors, which lead the Court to this conclusion, were the previously mentioned criteria so important in the doctrine, e.g., lack of commercial exploitation and sufficient *indicia* of control over the claimed invention by the inventor.⁶⁸ Concerning the issues of control and lack of a pledge of confidentiality, the Court said:

In some circumstances, no doubt it would be significant that no pledge of confidentiality was obtained from the user. In the circumstances of use by orthodontal patients, we attach no importance to the fact that the doctor did not ask a patient to swear to secrecy. As in *City of Elizabeth*, testing of the device had to be public to some extent and it is beyond reasonable probability that a patient would show the device to others who would understand the function of the [invention] or would want to duplicate the device . . .

⁶⁵ *Id.* at 969, 220 U.S.P.Q. at 580.

⁶⁶ Citing *Richdel Inc. v. Sunspool Corp.*, 714 F.2d 1573, 219 U.S.P.Q. 8, the Court said "35 USC 282 *permanently* places the burden of proving facts necessary to a conclusion of invalidity on the party asserting such invalidity." *Id.* at 971, 220 U.S.P.Q. at 582.

⁶⁷ *Id.* at 972, 220 U.S.P.Q. 583.

⁶⁸ See Question 2, *supra*.

In any event, a pledge of confidentiality is indicative of the inventor's continued control which here is established inherently by the dentist — patient relationship of the parties. Nothing in the inventor's use of the device on his patients (or the transfer to them) is inconsistent with experimentation.⁶⁹

With regard to the issue of commercial exploitation, the Court said that "the inventor had readily available all of the facilities of TP to commercially exploit the device [and] [y]et, no [devices] were offered competing orthodontists despite the fact this was one facet of the inventor's total business activity."⁷⁰

In *Barmag Barmer Maschinenfabrik Ag v. Murata Machinery, Ltd.*,⁷¹ the Court of Appeals for the Federal Circuit affirmed a grant of summary judgment in a case which invalidated an issued patent on the basis of the "on sale" bar restriction in §102(b). In addition to holding that summary judgment is available in patent cases, the *Barmag* decision is important because of the treatment given by the Court to the issues involving the term "reduction to practice." The Court, relying on precedent, noted that the "on sale" bar of §102(b) applies in cases where a "makeshift" model was actually produced, so long as the "claims read on the embodiment of the device which was in existence prior to the critical date."⁷² Offers of sale made before the critical date which rely on a "makeshift" model, will trigger the "on sale" bar if the invention was found to have been "reduced to practice," i.e., it was "sufficiently tested to demonstrate that it will work for its intended purpose."⁷³ The "experimental use" exception, which protects improvements and refinements on makeshift models, will not be applicable if, as was the case in *Barmag*, commercial exploitation was not merely incidental to the primary purpose of experimentation. Since the claimed invention was embodied in the models offered for sale prior to the critical date, the fact that changes were made thereafter was immaterial.

The *Barmag* Court, ever mindful of the statutory policy of precluding commercial exploitation, refused to establish a standard which would require a physical embodiment of the claimed invention in all cases. The court said, "[i]t is not difficult to conceive of a situation

⁶⁹ 724 F.2d at 972, 220 U.S.P.Q. at 583.

⁷⁰ *Id.* at 972-973, 220 U.S.P.Q. at 583.

⁷¹ 731 F.2d 831, 221 U.S.P.Q. 561 (Fed. Cir. 1984).

⁷² 731 F.2d at 838, 221 U.S.P.Q. at 566 (Fed. Cir. 1984).

⁷³ *Id.*, quoting, *General Electric Co. v. United States*, 654 F.2d 55, 62, 211 U.S.P.Q. 867, 872. (Ct. Cl. 1981).

where, because commercial benefits outside the allowed time have been great, the technical requisite . . . for a physical embodiment, particularly for a simple product, would defeat the statutory policy [behind §102(b)]."⁷⁴ The Court has created a very fertile ground for litigation in not accepting a standard for physical embodiment. This can only cause confusion in the understanding of the term "reduction to practice."

The Court of Appeals for the Federal Circuit in *Hycor Corp. v. Schlueter Co.*,⁷⁵ said "there is no experimental use exception."⁷⁶ Such a statement has been voiced before. (See Introduction). The Court's displeasure with the term is semantic and will not have any effect on the law as it relates to §102(b). The Court would rather ask the question: "Was there public use under section 102(b)?"⁷⁷ The existence of "experimental use" is inextricably tied to this inquiry. The Court showed this by listing factors that would be important in determining whether "experimental use" occurred, e.g.,

the length of the test period, whether any payment [was] made for the device, whether there [was] a secrecy obligation on the part of the user, whether progress records were kept, whether persons other than the inventor conducted the asserted experiments, [the number of] tests [that] were conducted, and how long the testing period was in relationship to tests of similar devices.⁷⁸

The purpose of the testing must be for experimental reasons. The last "experimental use" case decided by the Federal Circuit in 1984, *Pennwalt Corp. v. Akzona, Inc.*,⁷⁹ addresses this issue in a decision which held that patent validity must be decided using objective evidence and that the mere showing that sales or uses occurred under a federal regulatory testing procedure "does not make such uses or sales per se experimental for purposes of 35 U.S.C. §102(b)."⁸⁰

⁷⁴ 731 F.2d at 837, 221 U.S.P.Q. at 565. The Court, on this issue, was referring to the test enunciated in *Timely Products Corp. v. Aaron*, 523 F.2d 288, 187 U.S.P.Q. 257 (2d Cir. 1975) which requires that a physical embodiment of what is offered by in existence before the running of the statutory time period.

⁷⁵ 740 F.2d 1529, 222 U.S.P.Q. 553 (Fed. Cir. 1984).

⁷⁶ *Id.* at 1535, 222 U.S.P.Q. at 557.

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ 740 F.2d 1573, 222 U.S.P.Q. 833 (Fed. Cir. 1984).

⁸⁰ *Id.* at 1580, 222 U.S.P.Q. 838.

CONCLUSION

The United States Court of Appeals for the Federal Circuit, in deciding cases involving the "experimental use" exception, has followed the leading cases discussed in this paper and seems to be heading toward a more unified understanding of the doctrine. This can only benefit all who are involved in patent law. The issues of commercial exploitation, control, sale, and public use, have been addressed by the Federal Circuit in a manner which acknowledges the precedents already established in these areas. The Court, however, does not seem to like the term "experimental use exception" but would rather focus on whether a "public use or sale" has occurred. If the inventor has experimented with his invention, a "public use or sale" will not be found. In order to find an "experimental use," it is necessary to objectively observe the intentions of the inventor before the critical date. If his use is motivated by commercial considerations or if he has lost control of the invention, the doctrine is not available. But if he has not exploited the invention commercially and has exhibited sufficient control over it, he can experiment and refine it for as long as it takes him to be satisfied that it "answers the purpose intended."

CURRENT LITERATURE IN LAW/SCIENCE: POLICY AND INTELLECTUAL AND INDUSTRIAL PROPERTY

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