The Application of Trade Secret Protection To Safety And Effectiveness Data of Patented Drugs

The application of trade secret protection to safety and effectiveness data of patented drugs promotes drug manufacturers' incentive to invent, but denies the public access to important data. This Comment proposes a model federal statute which mandates compensated disclosure of safety and effectiveness data as an alternative to the dual protection of patent and trade secret law.

INTRODUCTION

Both trade secret law and patent law promote the development of inventions for the public good.[1] Despite this similarity, debate persists over whether the two may coexist.[2] The most recent conflict concerns a manufacturer claiming both trade secret and patent protection on the

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[1] *See, e.g.*, U.S. CONST. art. I, § 8, cl. 8 (Congress has the power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries"); Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974) ("The maintenance of standards of commercial ethics and the encouragement of invention are the broadly stated policies behind trade secret law."). In *Kewanee*, the defendants violated a trade secret agreement by producing a crystal in competition with the plaintiff. The district court granted an injunction against defendants because they had violated Ohio trade secret law. The Sixth Circuit Court of Appeals reversed on the ground that trade secret law conflicted with federal patent law and was therefore preempted by federal law. The United States Supreme Court, holding that trade secret law and federal patent law were complementary, reversed the court of appeals. For further discussion, see notes 45-53 and accompanying text *infra*. *See also* Graham v. John Deere Co., 383 U.S. 1 (1966) ("Innovation, advancement and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must 'promote the Progress . . . of useful Arts.' This is the *standard* expressed in the Constitution and it may not be ignored.").

[2] *See, e.g.*, Burke, *The 'Non-Informing Public Use' Concept and Its Application to Patent-Trade Secret Conflicts*, 45 ALB. L. REV. 1060 (1981) (trade secret and patent law come into direct conflict when a patent is issued on an item previously used by another as a trade secret).

same drug.[3]

Policy conflicts arise when trade secret protection is sought for safety and effectiveness data[4] of patented drugs. Trade secret protection denies the public access to important information concerning a drug's safety. Denying trade secret protection, however, enables competitors to use the original manufacturer's research to expedite entry into the pharmaceutical market without incurring initial research costs. The shortened lead time and sole burden of research costs result in competitive injury which could reduce the manufacturer's incentive to develop new drugs.

This Comment focuses on the policies at issue and presents an alternative to the dual protection of patent and trade secret law. First, the Comment reviews the statutory and common law background of patent and trade secret law. Next, it presents and critiques the cases which have developed the relationship between the two protections. Because the cases suggest no effective means of balancing these competing interests of preventing competitive injury and protecting the public's right to safety and effectiveness data, the Comment proposes a model statute mandating compensated disclosure. The proposed statute provides an alternative to the current practice of applying trade secret protection and patent law to the same drug. Under the model statute, manufacturers would be required to disclose test data necessary for new drug applications. Moreover, competitors relying on the safety and effectiveness test data of the original manufacturer would be required to reimburse the manufacturer for his costs. Hence, the statute would encourage the development of new drugs while providing public access to safety and effectiveness information.

I. STATUTORY AND COMMON LAW BACKGROUND

A. Protection Through Patent Law

Congress derives its power to create a patent system from the federal constitution.[5] The Constitution provides that the purpose of patent law

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[3] *See, e.g.*, Johnson v. HEW, 462 F. Supp. 336, 338 (D.D.C. 1978) (discussed in notes 60-66 and accompanying text *infra*).

[4] 21 C.F.R. § 314.14(i) (1982) defines safety and effectiveness data: "For purposes of this regulation, safety and effectiveness data include all studies and tests of a drug on animals and humans and all studies and tests on the drug for identity, stability, purity, potency and bioavailability."

[5] 35 U.S.C. §§ 1-376 (1976 & Supp. V 1981) contains all statutory provisions pertaining to patents; *see* U.S. CONST. art. I, § 8, cl. 8, note 1 *supra*.

is to "promote the Progress of Science and useful Arts."[6] Patent law encourages an inventor to disclose his invention to the public by giving him a seventeen-year monopoly on his inventions.[7]

To obtain patent protection, the inventor must publicly disclose the information in his patent application.[8] All applications must include a "specification," which is a written description of the invention that would allow a person "skilled in the art" to duplicate the design.[9] In addition, the applicant must submit a drawing[10] and an oath stating that he is the original inventor.[11] Once a patent is granted, the application information may be disseminated to the public or to any person wishing to obtain it.[12] Ideally, disclosure will "stimulate ideas and the eventual development of further significant advances in the art."[13] When the patent expires after seventeen years, the invention becomes public property, free of any restrictions imposed by the inventor.[14]

The patent statutes set forth five conditions that must be strictly met before a patent is issued. The patent application must show: patentable

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[6] U.S. CONST. art. I, § 8, cl. 8.

[7] 35 U.S.C. § 154 (1976 & Supp. V 1981) ("a grant to the patentee, his heirs or assigns, for the term of seventeen years . . . of the right to exclude others from making, using, or selling the invention throughout the United States"). *See also* 35 U.S.C. § 261 (1976) ("Subject to the provisions of this title, patents shall have the attributes of personal property.").

[8] 35 U.S.C. § 11 (1976): "The Commissioner may print, . . . the following:
1. Patents, including specifications and drawings, . . .
4. Annual indexes of patents and patentees, ..."

[9] 35 U.S.C. § 112 (1976):
> 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.

[10] 35 U.S.C. § 113 (1976) ("The applicant shall furnish a drawing where necessary for the understanding of the subject matter sought to be patented.").

[11] 35 U.S.C. § 115 (1976) ("The applicant shall make oath that he believes himself to be the original and first inventor . . . for which he solicits a patent.").

[12] 35 U.S.C. § 10 (1976) (Commissioner of Patents and Trademarks may disclose any information within the patent application once a patent is issued).

[13] Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974).

[14] *See, e.g.*, United States v. Dubilier Condensor Corp., 289 U.S. 178, 186-87 (1933). In *Dubilier*, government employees permitted patent discovery made during employment because invention was independent of employment goals. The Supreme Court stated that a patent is granted in exchange for public disclosure. A seventeen-year monopoly is guaranteed; when this period expires, the knowledge of the invention becomes the property of the public to use without restriction.

subject matter,[15] novelty,[16] utility,[17] non-obviousness,[18] and originality.[19] If an invention fails to meet these requirements, or if the patentability of a product is uncertain, an inventor may choose to rely on the protec-

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[15] 35 U.S.C. § 101 (1976) (patentable subject matter includes "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof "). *See* O.M.I. Corp. of Am. v. Kelsh Instr. Co., 279 F.2d 579, 584 (4th Cir. 1960) (stereoscopic projection map-making instrument patentable though all elements of the device were found in prior art; matters are patentable if persons knowledgeable in the field did not anticipate the possible improvements until disclosed in the patent application).

[16] 35 U.S.C. § 102 (1976): A person shall be entitled to a patent unless —

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or (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 a patent in the United States, or (c) he has abandoned the invention, or (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, in this country on an application . . . filed more than twelve months before the filing of the application in the United States, or (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, . . . or (f) he did not himself invent the subject matter sought to be patented, or (g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining the priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

[17] *Id.*; *see also* Imperial Stone Cutters, Inc. v. Schwartz, 370 F.2d 425, 429 (8th Cir. 1966) (patent held invalid because an obvious and nonutilitarian change in a stone cutting machine is not patentable; even a non-obvious change without utility cannot obtain patent protection).

[18] 35 U.S.C. § 103 (1976):

> A patent may not be obtained . . . 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.

See In re Keller, 642 F.2d 413, 425 (C.C.P.A. 1981) (applicant's patent for use of a digital timing circuit in a cardiac pacer was an obvious invention and therefore unpatentable; the test of obviousness is whether those with ordinary skill would have discovered it based on the current state of the art).

[19] 35 U.S.C. § 102(f) (1976) ("[A] person shall be entitled to a patent unless — . . . he did not himself invent the subject matter sought to be patented.").

tion of trade secret law.[20]

A patent, however, does not protect information not included in the application. Safety and effectiveness data received from tests upon a patented product normally is not included in the application. Hence, such information is not protected by the patent and may be publicly disclosed. Failure to protect this information or to compensate for its disclosure discourages invention. Currently trade secret law serves the purpose of protecting this data.[21]

B. Protection Through Trade Secret Law

The *Restatement of Torts* contains the most widely used description of trade secret:[22] "A trade secret may consist of any . . . compilation of information which is used in one's business, and gives him an advantage over competitors who do not know or use it."[23]

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[20] *See* Kewanee Oil v. Bicron Corp., 416 U.S. 470, 482 (1974) (trade secret law protects items not protected by patent law); Application of Sarkar, 575 F.2d 870 (C.C.P.A. 1978) (material disclosed in patent application heard *in camera* and record sealed so that in event of adverse decision trade secret protection would be retained).

[21] *See* notes 24-27 and accompanying text *infra*.

[22] RESTATEMENT OF TORTS § 757 comment b (1939); *see* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 474 (Restatement of Torts § 757 is widely relied upon as a definition of trade secret). For an alternative definition, see R. ELLIS, TRADE SECRETS 19-20 (1953), *citing* 79 C.J.S. *Secret* § 117 (1952) (business information confidential to the owner and specified employees); UNIF. TRADE SECRETS ACT § 1(4), 14 U.L.A. 541 (1979) (adopted in Louisiana, *see* LA. REV. STAT. ANN. §§ 51:1431-1439 (West 1965) and Minnesota, *see* MINN. STAT. ANN. §§ 325C.01 to 325C.08 (West 1981)):

> "Trade Secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process that:
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> (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and
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> (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

Id.; *cf.* Consumers Union v. Veterans Admin., 301 F. Supp. 796, 801 (S.D.N.Y. 1969), *appeal dismissed as moot*, 436 F.2d 1363 (2d Cir. 1971). The *Consumers Union* court held that records of the Veterans Administration regarding data from a hearing aid testing program were not trade secrets. The court defined trade secret as "an unpatented secret, commercially valuable plan, appliance, formula or process, which is used for the making, preparing, compounding, treating, or processing of articles or materials which are trade commodities." 301 F. Supp. at 801.

[23] RESTATEMENT OF TORTS § 757 comment b (1939). B. WITKIN, SUMMARY OF CALIFORNIA LAW *Equity* § 83 (8th ed. Supp. 1982) explains that although Restatement of Torts § 757, comment b concerned trade practices, this section was omitted from Restatement Second because it was felt that unfair competition had developed into

This definition of a trade secret is nebulous. It is clear, however, that safety and effectiveness data used to gain a competitive business advantage is included within the *Restatement* definition[24] and the equivalent, but less frequently used, Uniform Trade Secret Act definition.[25] Because safety and effectiveness data is considered a trade secret, manufacturers may claim exemption four of the Freedom of Information Act (FOIA),[26] which precludes full public disclosure of trade secret data.[27] Thus, potential competitors in a product market must conduct duplica-

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an independent field and was no longer controlled by tort principles. An attempt to fill this gap was made by the Commission on Uniform State Laws, which approved the UNIF. TRADE SECRETS ACT, 14 U.L.A. 537 (1979). *See* note 22 *supra.*

[24] RESTATEMENT OF TORTS § 757 comment b (1939). The Restatement lists six factors to consider in deciding whether something is a trade secret:

> (1) [T]he extent to which the information is known outside of his business; (2) the extent to which it is known by employees and others involved in his business; (3) the extent of measures taken by him to guard the secrecy of the information; (4) the value of the information to him and his competitors; (5) the amount of effort or money expended by him in developing the information; (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

Id. See also notes 25-26 *infra.*

[25] *See* UNIF. TRADE SECRETS ACT definition, note 22 *supra.* 21 C.F.R. § 314.14(g) (1982) sets forth the standard for disclosing information to the public. The information within a New Drug Application, which includes safety and effectiveness data, 21 U.S.C. § 355 (1976) (*see* note 65 *infra*) is not available for public disclosure unless it loses its trade secret status.

[26] 5 U.S.C. § 552(a)(2)(c) (1976) states:

> Each agency shall also maintain and make available for public inspection and copying current indexes providing identifying information for the public as to any matter issued, adopted, or promulgated after July 4, 1967, ...

Exemption four of FOIA is set forth in 5 U.S.C. § 552(b) (1976):

> This section does not apply to matters that are — . . . (4) trade secrets and commercial or financial information obtained from a person and privileged or confidential.

See also 39 Fed. Reg. 44,612-13 (1974):

> The Commissioner concludes, upon review of the comments and the relevant case law, that the Restatement definition of a trade secret should remain the basic guideline for application of this exemption from the Freedom of Information Act. . . . The definition of trade secret as set forth in the proposed Uniform Trade Secret Protection Act was suggested as a possible alternative definition . . . . The Commissioner concludes that there is no significant difference between this definition and the Restatement definition. Both place primary emphasis upon competitive advantage.

[27] 21 C.F.R. § 314.14(e)(2) (1982) permits release of summaries of selected portions of the data. *See also* note 98 and accompanying text *infra.*

tive tests, which add to their costs and delay entry into the market.[28]

Unlike federal patent law, trade secret law is a product of the common law.[29] Whereas public disclosure is required to receive the protection of a patent, confidentiality is a necessary element of trade secret protection.[30] As a result, trade secret protection conceivably can exist forever.[31]

Trade secret protection is weaker than patent protection because it relies solely on the maintenance of secrecy. For example, an inventor may keep his information secret and still lose his trade secret because he has no legal protection against anyone who discovers the trade secret through fair and honest means such as independent invention, accidental disclosure, or reverse-engineering.[32]

II. DEVELOPMENT OF THE RELATIONSHIP BETWEEN TRADE SECRET AND PATENT LAW

Patent law grants a limited monopoly on inventions.[33] Although this

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[28] *See* Comment, *FDA Disclosure of Safety and Effectiveness Data: A Legal and Policy Analysis*, 1979 DUKE L.J. 286, 319 (discussing benefit of reducing occurrence of duplicative testing).

[29] *See* R. ELLIS, TRADE SECRETS 4 (1953) (trade secret protection derives its origin from common law and equity, not statutes).

[30] *Id.* at 5-6. The requirement of disclosure for a patent is statutory and absolute. This differs from trade secrets because public disclosure of a trade secret would destroy the competitive advantage. Hence, owners of trade secrets attempt to prevent disclosure. *Id.*

[31] Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 494 (1974) (Marshall, J., concurring) (the inventor who intends to use or sell the product himself may wish to use state trade secret law because of the unlimited duration in contrast with the patent monopoly of seventeen years). *See also* RESTATEMENT OF TORTS § 757, comment a (1939):

> The protection afforded by the rule stated in this section is in some respects greater and in some respects less than that afforded by the patent law. It is greater in that it is not limited to a fixed number of years and does not require novelty and invention as in the case of patents.

[32] Reverse-engineering is "starting with the known product and working backward to divine the process which aided its development and manufacture." Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 476 (1974).

[33] 35 U.S.C. § 154 (1976 & Supp. V 1981). *See* Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 229 n.6 (1964):

> The Statute of Monopolies, 21 Jac. I, c. 3 (1623), declared all monopolies "contrary to the Laws of this Realm" and "utterly void and of none Effect." Section VI, however, excepted patents of 14 years to "the true and first Inventor and Inventors of new Manufactures" so long as they were "not contrary to the Law, nor mischievous to the State, by raising Prices of Commodities at home, or Hurt of Trade, or generally inconvenient

conflicts with the free enterprise system, it is assumed that granting a monopoly encourages new development,[34] and that society ultimately benefits from the development of new inventions.[35]

The scope of federal patent law was tested when states attempted to grant similar protection under the guise of unfair competition or trade secret law. The courts have had to determine under which circumstances states may provide such protection.[36] The question most recently raised is whether trade secret protection may be applied to safety and effectiveness data of a patented product.[37]

A. *United States Supreme Court Decisions:* Sears, Compco *and* Kewanee

The United States Supreme Court addressed the question of whether federal patent laws preempt state unfair trade provisions in two similar cases: *Sears, Roebuck and Co. v. Stiffel Co.*[38] and *Compco Corp. v. Day-Brite Lighting.*[39] In both cases, the plaintiff sued under state un-

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. . . ." Much American patent law derives from English patent law.

See also United States v. Dubilier Condensor Corp., 289 U.S. 178, 186 (1933):

> Though often so characterized a patent is not . . . a monopoly, for it is not created by the executive authority at the expense and to the prejudice of all the community except the grantee of the patent. . . . An inventor deprives the public of nothing which it enjoyed before his discovery, but gives something of value to the community by adding to the sum of human knowledge.

See also note 7 and accompanying text *supra.*

[34] *See, e.g.*, Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974) (discussing the government's assumption that the grant of a monopoly for seventeen years in exchange for disclosure will induce further advances in the art); Stern, *A Reexamination of Preemption of State Trade Secret Law After* Kewanee, 42 GEO. WASH. L. REV. 927, 930 (1974) (the federal patent system and free competition work together to promote progress of science and useful arts, make best allocation of economic resources, and support economic, social, political, and intellectual institutions).

[35] *See* note 13 and accompanying text *supra.*

[36] Federal patent legislation may preempt state protection of discoveries. Relying on Cooley v. Board of Wardens, 53 U.S. (12 How.) 298 (1851), the Court in Goldstein v. California, 412 U.S. 546 (1971), stated the test of preemption was whether the subject matter requires a national, uniform system. The *Goldstein* interpretation was further expanded in Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1974), see notes 45-53 and accompanying text *infra. Kewanee* held that rare conflicts between state and federal laws are permissible, hence, there is no preemption between trade secret and patent law. *See* Abrams & Abrams, Goldstein v. California: *Sound, Fury and Significance*, 1975 SUP. CT. REV. 147, 180.

[37] Johnson v. HEW, 462 F. Supp. 336 (D.D.C. 1978).

[38] 376 U.S. 225 (1964).

[39] 376 U.S. 234 (1964). *Sears* and *Compco* are discussed in Doerfer, *The Limits on*

fair competition law for the defendant's reproduction of an article not protected by a valid patent. In both cases the Seventh Circuit Court of Appeals affirmed the district court's finding that defendants engaged in unfair competition by selling products so similar as to create a likelihood of confusion about the source of the products.[40] In overruling the Seventh Circuit, the Supreme Court relied on the supremacy clause,[41] holding that the states could not provide monopoly protection when federal patent law had denied such protection.[42]

The *Sears/Compco* doctrine bars a state from granting a monopoly under unfair trade laws.[43] However, the Supreme Court did not address the relationship between state trade secret law and federal patent law. As a result, the confusion between the two areas continued.[44]

The Court later attempted to clarify this relationship in *Kewanee Oil Co. v. Bicron Corp.*[45] Plaintiff Kewanee Oil Company had devel-

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Trade Secret Law Imposed by Federal Patent Law and Antitrust Supremacy, 80 HARV. L. REV. 1432 (1967); French, *The Scott Amendment to the Patent Revision Act: Should Trade Secrets Receive Federal Protection?*, 1971 WIS. L. REV. 900.

[40] Stiffel Co. v. Sears, Roebuck & Co., 313 F.2d 115, 118 (7th Cir. 1963); Compco Corp. v. Day-Brite Lighting, 311 F.2d 26 (7th Cir. 1962).

[41] U.S. CONST. art. VI., cl. 2. ("This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; . . . shall be the Supreme Law of the Land; . . . .").

[42] Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 228 (1964), *citing* THE FEDERALIST NO. 43, at 288 (J. Madison) (J. Cooke ed. 1961).

[43] *See* notes 36-42 and accompanying text *supra*. *See also* Painton & Co. v. Bourns, Inc., 442 F.2d 216, 223 (2d Cir. 1971) (discussed in note 44 *infra*).

[44] *See* Painton & Co. v. Bourns, Inc., 442 F.2d 216 (2d Cir. 1971). In *Painton* the defendant contracted to supply plaintiff with information on manufacturing patented ion meters in exchange for royalties. Defendant terminated the contract and requested that all materials be returned. Plaintiff refused and sued to retain all materials. The district court held for plaintiff, applying the *Sears/Compco* doctrine. Painton & Co. v. Bourns, Inc., 309 F. Supp. 271 (S.D.N.Y. 1970). The Second Circuit reversed and held that trade secret agreements were enforceable on unpatented items. 442 F.2d at 223. However, this agreement applied only to contracting parties. It did not preclude "copying" the article through fair and honest means. For an explanation of fair and honest means, *see* Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 476 (1974) (accidental disclosure or reverse-engineering are permissible means of independent discovery). *See* note 32 *supra*.

[45] 416 U.S. 470 (1974). *See* Stern, note 34 *supra*; Goldstein, Kewanee Oil Co. v. Bicron Corp: *Notes on a Closing Circle*, 1974 SUP. CT. REV. 81 (criticizes *Kewanee* because the Court failed to completely overrule *Sears* and *Compco*). *See also* Aronson v. Quick Point Pencil Co., 440 U.S. 257 (1979). In *Aronson*, federal patent law was held not to preempt a state statute regarding enforcement of a contract to pay royalties for unpatented design. The Court discussed and relied on aims of federal patent policy as set forth in *Kewanee*. These aims are first, to reward and encourage inventions,

oped a seventeen-inch crystal that detected ionizing radiation. The plaintiff's employees had signed an agreement with the company promising not to disclose this trade secret. Subsequently, these employees left Kewanee and joined the defendant company. The employees then helped defendant to produce an identical seventeen-inch crystal. The district court issued an injunction preventing the use of plaintiff's trade secret. The Sixth Circuit Court of Appeals reversed, concluding that a patentable product must be patented.[46] The circuit court cited the *Sears/Compco* doctrine, and held that patent law preempts state trade secret law, and that plaintiff was not protected absent a valid patent.[47] The Supreme Court reversed, holding that because states may regulate discoveries, the constitutional domain of patent law is not exclusive.[48] The Court stated that state laws not conflicting with federal patent law are proper.[49]

The Supreme Court in *Kewanee* cited several additional reasons for holding that states may regulate discoveries. First, both trade secret and patent protections are aimed at the same policy: encouraging inventions.[50] For instance, trade secret law furthers this policy in the area of unpatentable articles by allowing contracts for the sale and dissemination of knowledge to those who can efficiently use the information.[51] Second, if the article is clearly patentable, the Court reasoned that the rewards and protection of a patent far outweigh those provided by trade secret law. Thus, the Court observed, no real conflict exists because inventors would naturally choose to obtain a patent.[52] In addition, for articles of dubious patentability, an inventor may prefer to utilize

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second, to assure public disclosure of inventions and third, to allow the public free use of the ideas once the patent expires. *Id.* at 262.

[46] 478 F.2d 1074 (6th Cir. 1973).

[47] *Id.* at 1085.

[48] Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 478-79 (1974) (the power of Congress to grant patents is not exclusive; the states may regulate discoveries).

[49] *Id.* at 479; *cf.* Goldstein v. California, 412 U.S. 546 (1973). In *Goldstein*, California granted state copyright protection, which plaintiffs sought to invalidate on the ground that it was a copyright of unlimited duration which conflicted with the constitutional grant of a limited copyright. The Court, in upholding the state copyright law, looked to whether the state law obstructed the purpose and objectives of Congress. *Id.* at 561. *See also* note 36 *supra.*

[50] Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480-81 (1974) (patent laws promote the objectives of the Constitution by allowing a monopoly in order to create incentives to risk marketing costs; in contrast, the trade secret laws are available to maintain commercial ethics and encourage development of inventions).

[51] *Id.* at 485.

[52] *Id.* at 489.

the trade secret protection to avoid the risk of disclosure from obtaining a patent which may be invalidated by a court.[53]

In each of the above situations, the Court hypothesized a choice between the two protections. Under the Court's analysis, trade secret and patent law are compatible because they are alternative protections. The Court, however, did not consider a situation in which both protections are applied to the same article. Thus, the Court failed to reconcile fully the relationship between patent and trade secret law. The coexistence issue arose again in subsequent cases.

B. Lower Court Decisions: Sarkar *and* Johnson

In *Application of Sarkar*,[54] the Court of Customs and Patent Appeals addressed the application of both protections to the same article. During the proceeding, the court granted a motion to seal the record so that the applicant could retain the patent application material as a trade secret if the appeal failed.[55] The court reasoned that loss of trade secret protection during an uncertain application for a patent would discourage an applicant from pursuing his right to appeal, and that this conflict between the two protections could deprive the public of many inventions.[56] Thus, in a patent appeal, the two protections are not only compatible, but trade secret protection is also necessary to promote the use of patents.

Despite the apparent compatibility of trade secret law and patent law in *Kewanee*[57] and *Sarkar*,[58] all coexistence issues have not been resolved.[59] A second problem is whether both protections can be applied simultaneously to different aspects of the same article. In *Johnson v.*

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[53] *Id.* at 487-89.

[54] 575 F.2d 870 (C.C.P.A.) (per curiam) (patent application rejected; appellant's motion granted to seal the record on appeal so that material disclosed in patent application might be retained, if appeal failed, as a trade secret), *aff'd*, 588 F.2d 1330 (C.C.P.A. 1978).

[55] 575 F.2d 870, 872 (C.C.P.A. 1978). *Sarkar* is discussed in Comment, *Patent Law Preservation of Trade Secret Protection During a Patent Application Appeal* — Application of Sarkar, 15 WAKE FOREST L. REV. 559 (1979).

[56] 575 F.2d 870, 872 (C.C.P.A. 1978).

[57] 416 U.S. 470 (1974).

[58] 575 F.2d 870 (C.C.P.A. 1978).

[59] One problem arises when a person is issued a patent on an article which another person protects under trade secret law. The question is which person has the right to exploit the invention. One proposal suggests granting full protection to the patentee, while granting limited protection to the trade secret user. *See* Burke, note 2 *supra*.

HEW,[60] the plaintiff wished to compel disclosure of safety and effectiveness data relating to the patented drug cimetidine. The defendant drug company claimed the trade secret exemption of FOIA.[61] The district court ruled that the requested test data was not part of the patent application for cimetidine and therefore refused to mandate disclosure of the data.[62] Furthermore, the court held that "possession of a patent does not as a matter of law" preclude trade secret protection.[63] The court in *Johnson* found that patent protection of the drug did not necessarily prevent competitive injury, and allowed trade secret protection to be invoked to mitigate this injury.[64] The court declined to extend the requirements of obtaining a patent to include submission of safety and effectiveness data because the required patent disclosure includes only the information which would enable one skilled in the art to make the invention.[65] In addition, the court recognized that the data may have independent commercial value and should not be disclosed.[66]

The *Johnson* court, however, failed to address the broader issue concerning public access to safety and effectiveness data. The section that follows addresses the conflicting interests of public access to test data and the proprietary interest in this data[67] and examines solutions to this

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[60] 462 F. Supp. 336 (D.D.C. 1978).

[61] *See* note 26 *supra*.

[62] Johnson v. HEW, 462 F. Supp. 336, 338 (D.D.C. 1978).

[63] *Id.*

[64] *Id.*

[65] *Id.* Although safety and effectiveness data is not required to obtain a patent, see notes 8-21 and accompanying text *supra*, this data is required to obtain FDA approval to market a drug. 21 U.S.C. § 355 (1976). The process entails submitting a New Drug Application (NDA) to the FDA. The NDA includes information and test data that proves by "substantial evidence" that the drug is safe and effective. This means using investigations, tests, and qualified experts to evaluate each drug. Once the NDA is approved, the drug may be introduced into the marketplace. SUBCOMM. ON SCIENCE, RESEARCH AND TECHNOLOGY OF THE HOUSE COMM. ON SCIENCE AND TECHNOLOGY, 96 CONG., 2D SESS.,THE FOOD AND DRUG ADMINISTRATION'S PROCESS FOR APPROVING NEW DRUGS 1 (Comm. Print 1980) [hereafter PROCESS FOR APPROVING NEW DRUGS].

[66] Johnson v. HEW, 462 F. Supp. 336, 338 (D.D.C. 1978).

[67] *See* 18 U.S.C. § 1905 (1976 & Supp. V 1981) (provides protection against disclosure by federal employees). *See also* McGarity & Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 HARV. L. REV. 837, 857 (1980) ("proprietary information" as a general term for "trade secrets"). *But see* E.I. du Pont de Nemours Powder Co. v. Masland, 244 U.S. 100, 103 (1917) (plaintiff sought to enjoin defendant from disclosing trade secrets obtained through confidential relationship with plaintiff-employer; the Court held that although confidentiality will be protected, trade secrets are not a property right). *See*

conflict which have been applied in the pesticide and chemical industries. In addition, a federal statute is proposed to balance these interests.

III. A STATUTORY SOLUTION TO THE DUAL PROTECTION PROBLEM

A. Status Quo and Proposed Legislative Change

Currently, safety and effectiveness data falls within the ambit of trade secret protection.[68] Furthermore, the existence of a patent does not necessarily bar the application of trade secret protection to test data concerning the patented article.[69]

Since 1938, the Food and Drug Administration (FDA) has permitted simultaneous application of trade secret and patent protection to test data, construing such data as valuable property which qualifies as a trade secret.[70] Although the FDA has recognized that disclosure of this information would benefit the public,[71] it has concluded that Congress mandated nondisclosure of safety and effectiveness data through exemption four of FOIA.[72] This exemption, however, does not discuss the use of trade secret law when patent protection is already present.[73] Thus, the FDA's interpretation of this "mandate" is questionable.

The United States Department of Health, Education, and Welfare

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also Carter Prods. v. Colgate-Palmolive Co., 130 F. Supp. 557, 580 (D. Md. 1955) (citing *E.I. du Pont* in granting relief for co-inventors' disclosure to employer), *aff'd*, 230 F.2d 855 (4th Cir.), *cert. denied*, 352 U.S. 843 (1956).

[68] *See* notes 24-26 and accompanying text *supra*.

[69] Johnson v. HEW, 462 F. Supp. 336, 338 (D.D.C. 1978) (patent protection did not "as a matter of law" preclude trade secret protection). *See also* notes 60-66 and accompanying text *supra*.

[70] 39 Fed. Reg. 44,632 (1974).

[71] 39 Fed. Reg. 44,633 (1974).

[72] 5 U.S.C. § 552(b)(4) (1976 & Supp. V 1981). 39 Fed. Reg. 44,614 (1974) explains that the FDA relies on the premise that Congress has adopted the Restatement definition of trade secret in exemption four of FOIA. However, because the FDA and not Congress chose the definition of trade secret, it had the discretion to adopt a narrower definition which precluded safety and effectiveness data from trade secret protection. *See* note 26 *supra*. *See also* REVIEW PANEL ON NEW DRUG REGULATION, U.S. DEP'T OF HEALTH, EDUCATION AND WELFARE, INTERIM REPORT: AN EVALUATION OF FDA'S TRADE SECRETS AND FREEDOM OF INFORMATION POLICIES (Nov. 15, 1976), *published in* 1 INTERIM REPORTS, REVIEW PANEL ON NEW DRUG REGULATION, U.S. DEP'T OF HEALTH, EDUCATION AND WELFARE 21-22 (1977) [hereafter INTERIM REPORT].

[73] 5 U.S.C. § 552(b)(4) (1976 & Supp. V 1981); *see* note 26 *supra*.

(HEW)[74] has criticized the FDA for its nondisclosure policy.[75] HEW has stated that safety and effectiveness data should not be given trade secret protection because of the enormous social and economic costs of "protecting" such information. Economic costs result from unnecessary duplicative testing. Social and health costs result from the additional and unwarranted risks imposed on human subjects involved in repeated tests. Furthermore, HEW has stated that patent law is the proper vehicle for protecting the competitive and economic interests at stake.[76]

The FDA has conceded that since the advent of FOIA, a policy of partial disclosure has fostered greater public accountability of agency procedure and decisions.[77] However, the FDA has also stated that any change in disclosure of safety and effectiveness data is a public policy matter that should be decided by congressional legislation and not by the FDA.[78]

A statutory solution to the problem is necessary for several reasons. First, it would clarify the common law regarding application of trade secret protection to test data of patented products. Second, a statute would prevent conflict between the application of trade secret law and the federal domain of patent law.[79] Third, and most important, a statute would resolve policy conflicts by permitting public access to information without creating disincentives to invent.

B. Problems That Arise Because Of Failure To Disclose Safety And Effectiveness Data

Nondisclosure of safety and effectiveness data has numerous ramifications. First, the protected information is unavailable for public and

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[74] HEW is now known as the Department of Health and Human Services (HHS). 21 U.S.C.A. § 335 (West Supp. 1982).

[75] *Congressional Oversight of Administrative Agencies: Hearings Before the Subcomm. on Separation of Powers of the Senate Comm. on the Judiciary*, 94th Cong., 1st Sess. 14-15 (1975) [hereafter *Congressional Oversight of Administrative Agencies*].

[76] *Drug Safety Amendments of 1976: Hearings on H.R. 12391 Before the Subcomm. on Public Health and Environment of the House Comm. on Interstate and Foreign Commerce*, 94th Cong., 2nd Sess. 38-39 (1976) (Statement of Dr. Theodore Cooper, Assistant Secretary of HEW) [hereafter *Drug Safety Amendments of 1976*].

[77] 39 Fed. Reg. 44,602 (1974).

[78] 39 Fed. Reg. 44,634 (1974); *see also Drug Safety Amendments of 1976*, note 76 *supra*, at 60; *Congressional Oversight of Administrative Agencies*, note 75 *supra*, at 19. A bill was introduced that would allow safety and effectiveness data to be fully disclosed. Competing companies would be prevented from using the data in support of their own application for a five-year period. This bill never passed. S. 2755, 95th Cong., 2d Sess., 124 CONG. REC. 53,873 (1978).

[79] *See* notes 36-44 and accompanying text *supra*; *see also* note 108 *infra*.

professional scrutiny.[80] Disclosure of the data would serve as a check on the FDA's approval process because the scientific community would be able to independently review the decision.[81] Nondisclosure may also subject the FDA to criticism without being given an opportunity to respond and explain the basis for its decision. These attacks undermine morale in the FDA and generate further public criticism of the agency.[82] Furthermore, the absence of review by the scientific community can result in a pro-industry bias.[83] The FDA's purpose is to protect the consumer by ensuring that drugs are safe, effective, and properly manufactured and labeled;[84] but without independent scientific review, the FDA is less effective in achieving this objective.[85]

Second, trade secret protection precludes the dissemination of scientific knowledge.[86] The purpose of patent law is to encourage invention by allowing a limited protection under which inventions eventually become part of the public domain.[87] By allowing nondisclosure under trade secret protection, the scientific community and the public are pre-

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[80] INTERIM REPORT, note 72 *supra*, at 38-39; *see also* McGarity & Shapiro, note 67 *supra*, at 841-44.

[81] *Drug Regulation Reform Act of 1978: Hearings Before the Subcomm. on Health and Scientific Research of the Senate Comm. on Human Resources*, 95th Cong., 2d Sess. 668 (1978) [hereafter *Drug Regulation Reform Act of 1978*]; *see also* McGarity & Shapiro, note 67 *supra*, at 841-44. (Although consumers and the scientific community may lack the time and resources to review fully safety and effectiveness data, the possibility of independent scrutiny will motivate the agency to be more efficient and careful.)

[82] *See* note 81 *supra*; *see also* INTERIM REPORT, note 72 *supra*, at 39.

[83] *See* McGarity & Shapiro, note 67 *supra*, at 843 (the agency's personnel are overworked, resulting in a reliance on the judgments of the pharmaceutical industry). However, the FDA does have advisory committees which attempt to provide differing viewpoints. Unfortunately, this has failed to replace the benefits of open peer review. Instead, an "old boy" network has arisen and the scope of review is severely limited. *Id.* at 871.

[84] PROCESS FOR APPROVING NEW DRUGS, note 65 *supra*, at 1; *see also* McGarity & Shapiro, note 67 *supra*, at 841.

[85] PROCESS FOR APPROVING NEW DRUGS, note 65 *supra*, at 1; *see also* McGarity & Shapiro, note 67 *supra*, at 841.

[86] INTERIM REPORT, note 72 *supra*, at 37.

[87] *See, e.g.*, General Elec. Co. v. Jewel Incandescent Lamp Co., 326 U.S. 242, 249 (1945) (a patent for a frosted glass electric lamp bulb that contained rounded crevices rather than the known angular crevices held invalid because it only improved a prior art; a patent will not be granted unless it advances the "frontiers of science"); Griffith Rubber Mills v. Hoffar, 313 F.2d 1, 3 (9th Cir. 1963) (patents for an elastomer muffler held invalid because they were obvious to anyone skilled in the art; the purpose of patent law is for public good, the 17-year monopoly is an incentive to disclose inventions that will ultimately add to available public knowledge).

vented from obtaining information contained in these tests. Disclosure would allow scientists to use this information as a basis for further research,[88] which in turn might lead to scientific advances which benefit society.[89]

Additionally, nondisclosure of health and safety data hampers the national policy of free competition.[90] Protecting this data reduces competition due to the high cost of data production.[91] This barrier burdens the small manufacturer who cannot afford to fund the initial research needed to enter the market,[92] and results in higher prices for the consumer due to a market-imposed "domestic cartel."[93]

Finally, failure to disclose this data results in needless duplicative testing,[94] which wastes the nation's resources and poses an unreasonable and unjustifiable risk to human test subjects.[95] The high cost of replicating data results in higher priced drugs. Although it may be argued that further testing substantiates the drug's safety and effectiveness,[96] a similar check is available if the information is released for review by the scientific community.[97]

The FDA has responded to the public's demand for disclosure by releasing summaries of test results.[98] However, these summaries are of

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[88] DRUG EQUIVALENCE PANEL, OFFICE OF TECHNOLOGY ASSESSMENT, DRUG BIOEQUIVALENCE 48 (1974).

[89] *Id.*

[90] *See* INTERIM REPORT, note 72 *supra*, at 42-43; Stern, note 34 *supra*, at 930.

[91] 39 Fed. Reg. 44,634 (1974).

[92] S. REP. NO. 92-970, 92d Cong., 2d Sess., *reprinted in* 1972 U.S. CODE CONG. & AD. NEWS 4097 (statement by Acting Attorney General Kleindienst).

[93] INTERIM REPORT, note 72 *supra*, at 42 (a policy of nondisclosure erects a semi-permanent barrier, allowing a limited number of manufacturers to control the entire market). *See also* 39 Fed. Reg. 44,634 (1974).

[94] INTERIM REPORT, note 72 *supra*, at 36; *Drug Safety Amendments of 1976*, discussed in note 76 and accompanying text *supra*.

[95] *See* note 94 *supra*. *See also* S. REP. NO. 92-970, 92d Cong., 2d Sess., *reprinted in* 1972 U.S. CODE CONG. & AD. NEWS 4097 (statement by Acting Attorney General Kleindienst) ("Duplication of such tests is a waste to the economy and a needless and undesirable burden on any subsequent applicant.").

[96] *See, e.g., Federal Insecticide, Fungicide, and Rodenticide Act: Hearings Before the House Comm. on Agriculture*, 95th Cong., 1st Sess. 321-22 (1977) (statement of John E. Donalds, Dow Chemical U.S.A.) (duplicative testing is not wasteful because the original methods are imprecise; further testing is beneficial to assure safety and effectiveness).

[97] *See* McGarity & Shapiro, note 67 *supra*, at 847.

[98] 21 C.F.R. § 314.14(e)(2) (1982). These summaries are the basis for NDA approval and a summary of the data is prepared by either the applicant or the Bureau of Drugs. In 1976 Congressman Rogers introduced a bill in the House of Representatives,

limited significance because they fail to provide sufficient information for effective peer review.[99] Furthermore, the problems arising from duplicative testing remain.[100]

C. Problems Arising From Disclosure, and a Proposed Solution

Patent protection is specific and the requirements of patent issuance are strict.[101] One patent requirement is complete disclosure of information to allow anyone skilled in the art to enter the market.[102] Test data should also be disclosed because product testing is necessary before a manufacturer may enter the pharmaceutical market.[103] However, trade secret protection prevents disclosure of safety and effectiveness data.

Denying trade secret protection to a patented product creates several problems. First, absolute disclosure would cause a "likelihood of substantial competitive injury."[104] This injury would occur to the original manufacturer when competitors immediately enter the domestic market upon expiration of the patent.[105] But, this "interest" should not be protected; the purpose of patent law is to facilitate entry into the market once the patent expires.[106] When the seventeen-year monopoly ends, competitors may enter the field and prices may decrease.[107] However,

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H.R. 14289, 94th Cong., 2d Sess., § 9 (1976), which would have mandated a *detailed* summary of information, including the basis for approval or denial of an NDA, all information concerning adverse effects on health, and an explanation of why the benefits outweigh the risks of using a particular drug. The bill was heard in June 1976 but was never passed. *Drug Safety Amendments of 1976*, note 76 *supra*, at 263-64.

[99] *See* McGarity & Shapiro, note 67 *supra*, at 869-70.

[100] *See* INTERIM REPORT, note 72 *supra*, at 35-36.

[101] *See* notes 9-20 and accompanying text *supra*.

[102] *See Drug Safety Amendments of 1976*, note 76, and accompanying text *supra*.

[103] *Drug Regulation Reform Act of 1978*, note 81 *supra*, at 667.

[104] Johnson v. HEW, 462 F. Supp. 336, 337 (D.D.C. 1978). *See also* National Parks & Conservation Ass'n v. Morton, 498 F.2d 765 (D.C. Cir. 1979). In *National Parks*, plaintiff wanted to inspect pursuant to FOIA, the agency records of the concession operations of the National Park Service. The trial court granted defendants' motion for summary judgment. The circuit court reversed, stating that in order to claim exemption four of FOIA disclosure must pose a likelihood of substantial competitive injury. *Id.* at 770. The court recognized two justifications for exempting trade secrets from disclosure: 1) to encourage agencies to provide mandatory information to the government and 2) to protect the rights of those who must disclose. *Id.* at 769.

[105] *See* INTERIM REPORT, note 72 *supra*, at 29-30.

[106] *See* note 87 and accompanying text *supra*.

[107] *See* Comment, note 28 *supra*, at 319 (discussing promotion of marketing generic drugs through use of shared information). Presently, rivalry in the field promotes early application of a patent. As a result, actual market time is reduced to about 10 years. *See* INTERIM REPORT, note 72 *supra*, at 30-31; L.A. Times, Aug. 12, 1982, § 1, at 3,

trade secret protection of test data effectively serves to prolong the patent period. After the patent expires, the unavailability of test data slows market entry. Such an "extension" of the patent encroaches on federal patent law and frustrates the objective patent law seeks to achieve.[108]

Second, competitors may use disclosed test data information to obtain foreign licenses to manufacture the patented product before the patent expires.[109] The impact of the foreign market on the United States pharmaceutical industry is not entirely clear. Because United States patents are not recognized in many countries, secrecy may be the only way to maintain a competitive advantage. Without this trade secret protection, domestic innovation may be discouraged and impeded. The market for American-made products in foreign countries might be lost and drug research may be harmed worldwide.[110]

However, an FDA study refutes this conclusion.[111] The study concludes that the release of safety and effectiveness data has a minimal effect on the ability of drug manufacturers to maintain an advantage in markets abroad.[112] Because of the conflict of authority and the benefits of disclosure, the foreign market argument should not be a deciding factor in precluding disclosure. International regulations are available and should be used as a solution to the foreign market problem.[113]

Drug manufacturers argue that potential competitive injury in the

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col. 3. The 17-year patent period was not calculated on a marketing basis but was a compromise between the British 14-year patent protection and the Continental 21-year patent protection. *Drug Safety Amendments of 1976*, note 76 *supra*, at 61. The House of Representatives recently passed the Patent Restoration Act, which would extend the patent period on drugs because of regulatory delays. 128 CONG. REC. H6919-25, H6932-82 (daily ed. Sept. 13 & 15, 1982).

[108] Johnson v. HEW, 462 F. Supp. 336, 337 (D.D.C. 1978) (trade secret protection on information required in the marketing process unfairly extends both the period and the scope of the patent). *See also* Stern, note 34 *supra*, at 940 (if state laws block public from processes that would otherwise be in the public domain, state law should be preempted).

[109] Johnson v. HEW, 462 F. Supp. 336, 337 (D.D.C. 1978).

[110] *Drug Regulation Reform Act of 1978*, note 81 *supra*, at 300-01 (statement by C. Joseph Stetler, President of the Pharmaceutical Manufacturers Association).

[111] *See* McGarity & Shapiro, note 67 *supra*, at 853 (citing U.S. FOOD & DRUG ADMIN., SUPPLEMENTARY ANALYSES OF THE IMPACT OF PROVISION IN S. 2755 REGARDING DISCLOSURE OF SAFETY AND EFFECTIVENESS DATA ON FOREIGN MARKETS OF U.S. MULTI-NATIONAL FIRMS I).

[112] *Id.*

[113] *See* Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, T.I.A.S. No. 8733; Paris Convention for the Protection of Industrial Property, *as revised*, July 14, 1967, 21 U.S.T. 1583, 24 U.S.T. 2140, T.I.A.S. Nos. 6293, 7727 (implemented at 35 U.S.C. § 119 (1976)).

domestic market and losses in foreign markets would create disincentives to produce and market drugs. They claim that these disincentives would harm rather than benefit the public in the long run because of a resulting reduction in development of new drugs.[114] However, there is no evidence that the absence of trade secret protection would actually create disincentives.[115]

The model statute proposed in this comment would create incentives for developing new drugs by compensating manufacturers who disclose trade secret information. The statute would require subsequent manufacturers to pay for the entire cost of the research necessary to develop a new drug. "Cost-free" research to the original applicant of a new drug application would serve as a great economic incentive to invent. Through the sharing of research costs by all subsequent applicants, every manufacturer would incur reduced costs for necessary product testing. The public would also benefit because the reduction in research costs and the added competition would decrease consumer drug prices. Furthermore, cooperative use of the same data would reduce duplicative testing, resulting in a more efficient use of the nation's resources.[116] Efficient test results could be assured primarily by the FDA's supervision and by the scientific community's review of test data.

D. Parallel Solutions in Other Industries

Federal statutes currently govern the pesticide and chemical industries. Under both the Toxic Substance Control Act (TSCA)[117] and the 1972 and 1978 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[118] Congress exempted health and safety studies from trade secret protection.[119] Both statutes mandate disclosure

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[114] INTERIM REPORT, note 72 *supra*, at 28.

[115] INTERIM REPORT, note 72 *supra*, at 29, 72 (suggests a study to discover the costs of research and development, and possible disincentives due to disclosure of safety and effectiveness data).

[116] *See* notes 93-96 and accompanying text *supra*.

[117] 15 U.S.C. §§ 2601-2629 (1976 & Supp. V 1981).

[118] 7 U.S.C. § 136-136y (1976 & Supp. V 1981).

[119] 15 U.S.C. § 2613(b)(1) (1976 & Supp. V 1981); 7 U.S.C. § 136h (1976 & Supp. V 1981). *See also* Union Carbide Agric. Prods. Co. v. Costle, 632 F.2d 1014 (2d Cir. 1980). *Union Carbide* provides a history of FIFRA. FIFRA was first introduced in 1947 as a statute requiring registration of pesticides with the federal government. The statute contained no prohibition against using effectiveness data produced by one applicant to support another. There was also no prohibition against public disclosure; but no disclosure was made. The 1972 amendment prohibited disclosure of trade secrets and the use of data from one applicant to support later applicants. The definition of trade

of test data while requiring reimbursement for its producer's cost.[120]

The pesticide industry challenged the constitutionality of FIFRA,[121] claiming that it constituted a taking without just compensation[122] and that it denied due process of law.[123] The Environmental Protection Agency was temporarily enjoined from disclosing the data. This injunction lasted until 1981. Although the acts have been held constitutional,[124] the pesticide industry is lobbying for an amendment to restrict the use of data by other manufacturers.[125] As a result, the scheme set forth in FIFRA has yet to be fully implemented.

TSCA and FIFRA are not perfect solutions. In particular, confusion

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secret was left to the Environmental Protection Agency (EPA), which adopted a narrow view and excluded health and safety data. The pesticide industry then initiated a series of lawsuits attempting to enforce the use of the Restatement definition of trade secret. *See, e.g.*, Chevron Chem. Co. v. Costle, 443 F. Supp. 1024 (N.D. Cal. 1978) and Mobay Chem. Corp. v. Costle, 447 F. Supp. 811, 826 (W.D. Mo. 1978) (the EPA may not issue a *blanket* exclusion of test data from trade secret protection). The FDA, however, chose a narrow trade secret definition, discussed in note 72 *supra*. The 1978 amendment codified the use of a blanket exclusion of health and safety data from trade secret protection and provided a compensation scheme for use by other manufacturers. 15 U.S.C. § 2613(b)(1) (1976 & Supp. V 1981).

[120] 15 U.S.C. § 2603(c)(1) (1976) exempts manufacturers from producing duplicative test data. If the exemption occurs during the five-year exclusive use period, the manufacturer must provide reimbursement to the original source of the data. 7 U.S.C. § 136a(c)(1)(D)(i) (Supp. V 1981) provides that if data is registered after 1978 it may not be used until it has existed for 10 years. After the 10-year period, the data can be acquired but the applicant must provide compensation for it; the compensation period lasts another five years.

[121] Petrolite Corp. v. EPA, 519 F. Supp. 966 (D.D.C. 1981). Petrolite, a producer of specialty chemicals, sought an injunction restraining the EPA from disclosing data which plaintiff had submitted. Petrolite claimed unsuccessfully that such disclosure was unconstitutional. *Id.* at 970-74. In Union Carbide Agric. Prods. Co. v. Costle, 632 F.2d 1014 (2d Cir. 1980) plaintiff sought declaratory and injunctive relief to prevent disclosure of test data, arguing that disclosure constituted a taking without just compensation. The district court granted the injunction, but the Second Circuit Court of Appeals reversed, holding that the producers had not shown "a likelihood of success on the merits." *Id.* at 1018-19.

[122] U.S. CONST. amend. V states, "nor shall private property be taken for public use, without just compensation."

[123] U.S. CONST. amend V states, "nor shall any person . . . be deprived of life, liberty, or property, without due process of law; . . . ."

[124] *See* note 121 *supra*.

[125] *Federal Insecticide, Fungicide, and Rodenticide Act: Hearings Before the Subcomm. on Department Operations, Research, and Foreign Agriculture, House of Representatives*, 97th Cong., 1st Sess. 285 (1981) (statement of Ralph Abascal, California Rural Legal Assistance).

arises over the measurement and apportionment of compensation.[126] Also, the statutes fail to state what portion of actual data production costs should be reimbursed and whether the producer of data should be compensated for lost monopoly profits.[127] A suggested "exclusive use period"[128] in addition to, or in lieu of compensated disclosure, would not fully address the problem because it would fail to prevent duplicative testing.[129]

E. The Model Statute: A Workable Compensatory Scheme

The purpose of the proposed statute set forth in the Appendix, is to provide full public disclosure of safety and effectiveness data. The statute protects the incentive to develop new drugs by compensating the original manufacturer for dissemination of test data necessary for market entry. The proposed statute addresses and resolves the problems present in TSCA and FIFRA by stating guidelines for measuring and apportioning compensation. Under the proposed statute, the amount of compensation would be held constant through a procedure of total reimbursement to the original data producer and equal sharing of cost among all subsequent manufacturer users, thus precluding any dispute or need for costly arbitration. Under the proposed statute, research subject to compensation and disclosure is clearly defined. Only research production costs would be reimbursed, and there would be no compensation for lost monopoly profits.[130] An arbitration clause is included, however, as a safety valve in the event of a conflict.

This statute would not provide for exclusive use periods, thereby avoiding the problem of duplicative testing present in TSCA and FIFRA. Instead, it would rely on the patent laws to protect those drugs that deserve a monopoly for seventeen years. This monopoly would not be extended by trade secret protection of test data. Market entry is facilitated when test data is made available to competitors after the patent expires.

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[126] McGarity & Shapiro, note 67 *supra*, at 876-82 (discussion of problems with compensated disclosure).

[127] *Id.*

[128] Exclusive use periods preclude a competitor from using the data, regardless of public disclosure, in obtaining a New Drug Application or license to market a pesticide. *See* McGarity & Shapiro, note 67 *supra*, at 882-86.

[129] *See* INTERIM REPORT, note 72 *supra*, at 57.

[130] The uncertainty and difficulty in determining lost monopoly profits would result in difficulty in the setting of prices for data compensation. For this reason, the proposed statute does not compensate for these lost profits. Reimbursed costs of research should provide sufficient incentives to develop and market new drugs. *See* INTERIM REPORT, note 72 *supra*, at 62-63.

CONCLUSION

The application of trade secret law to test data of patented products is an ambiguous area of the common law. The conflicting policies involved are the promotion of invention versus public access to information.

This Comment proposes a federal statute mandating disclosure of safety and effectiveness data. The model statute would require compensation for use of such disclosed data. By setting forth definitive guidelines for compensation, the model statute would avoid the weaknesses of similar legislation. In addition, it would prevent direct conflict between state trade secret law and federal patent law. Finally, the statute would benefit the public by simultaneously providing access to information and promoting equitable exploitation of inventions.

Roberta Schugmann
Leslie Shaw

APPENDIX

Model Compensation Statute

§1. *Purpose*:

The purpose of this statute is to:

(a) Make available safety and effectiveness data to the public;

(b) Provide a means of apportioning compensation so that original researchers of safety and effectiveness data will have an economic incentive to enter a new drug on the market.

§2. *Definition*:

For purposes of this section: *"Safety and effectiveness data"* means "all studies and tests of a drug on animals and humans and all studies and tests on the drug for identity, stability, purity, potency, and bioavailability."[131]

§3. *Requirement of Disclosure*:

All applicants for new drug applications must make available to the public all safety and effectiveness data necessary to market the drug.

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[131] This language is currently used in 21 C.F.R. § 314.14(3)(i) (1981), which describes confidentiality of data in a New Drug Application (NDA) file. *See* note 65 *supra*.

§4. *Compensation for Costs of Safety and Effectiveness Data*:

(a) Applicants subsequent to the original applicant for a new drug application must reimburse the original applicant for the cost of producing the study.

(b) This apportionment will be accomplished as follows:

(i) The first succeeding applicant will reimburse the original applicant for the full amount of the research cost.

(ii) The next applicant will reimburse his predecessor for one-half the sum in (i).

(iii) Each succeeding applicant will reimburse each predecessor a portion sufficient to create an equal distribution of the cost among all applicants following, but excluding, the original applicant.

§5. *Disputes*

An arbitrator will be appointed by the Federal Mediation and Conciliation Service to resolve any disputes which may arise.