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Misappropriation of Trade Secrets in Biotechnology Licensing

by

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MISAPPROPRIATION OF TRADE SECRETS IN BIOTECHNOLOGY LICENSING*

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I. INTRODUCTION

After a long period of research and development, biotechnology is now poised to fulfill its promise. Intense investment in biological research has yielded an abundance of intriguing discoveries in pharmaceutical, agricultural, chemical, and other commodities.[1] Few of these products are as yet available to consumers.[2] However, some products are beginning to reach the marketplace, and more are on the way, suggesting that the biotechnology industry is finally coming of age.[3]

As this industry matures, its priorities will naturally begin to shift toward production and marketing rather than invention and discovery.[4] Marketing plans, customer lists, manufacturing processes, and the other business necessities of mature firms will lend themselves to protection as trade secrets.[5] For the most part, maintaining such information as trade secrets in a biotechnology firm will raise only the familiar issues raised by trade secrets in any firm. In other instances, however, biotechnology trade secrets will generate issues unique to their industry.[6]

One area has already been identified in which trade secret disputes involving biotechnology will likely present an unusual profile because of the technology involved. Employee movement between competing firms presents classic trade secret concerns.[7] It is a problem of particular concern in biotechnology, where the proprietary materials are often alive, microscopic, and able to reproduce themselves if removed from a former employer's facilities.[8] A vari-

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[1] OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONG., BIOTECHNOLOGY IN A GLOBAL ECONOMY 3 (1991) [hereinafter BIOTECHNOLOGY IN A GLOBAL ECONOMY].

[2] *See id.* at 6.

[3] *See* Ann M. Thayer, *Higher Third-Quarter Revenues Help Boost Biotechnology Stocks*, CHEMICAL & ENGINEERING NEWS, Nov. 23, 1993, at 11; Ann M. Thayer, *Biotech Companies in Good Shape Despite Large Losses in 1991*, CHEMICAL & ENGINEERING NEWS, Mar. 30, 1992, at 9, 11.

[4] Robert W. Payne, *The Emergence of Trade Secret Protection in Biotechnology*, 6 BIO/TECHNOLOGY 130, 130 (1988).

[5] *See id.*

[6] *See* Michael A. Epstein & Beth K. Neelman, *Trade Secrets: Novel Applications to Biotechnology*, 1 J. PROPRIETARY RTS. 16, 18 (1988).

[7] *See* [12 Business Organizations] ROGER M. MILGRIM, MILGRIM ON TRADE SECRETS § 5.02 (1993) [hereinafter MILGRIM ON TRADE SECRETS] (employee-employer relationship is a common forum for trade secret disputation).

[8] See STEPHEN A. BENT ET AL., INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY WORLDWIDE 346-47 (1987); Epstein & Neelman, *supra* note 6, at 20; *see also* Charles E. Lipsey et al., *Protecting Trade Secrets in Biotechnology* (Pt. 1), 2 TRADE SECRET L. REP. 21, 22 (1986) (discussing employee misappropriation from

ety of biotechnology trade secret misappropriation suits have already been brought involving employee removal of proprietary biological materials.[9]

A second emerging problem area involving biotechnology trade secrets is that of trade secret licensing, whereby firms agree to the exchange of proprietary information.[10] Here, too, trade secrecy issues unique to biotechnology are beginning to surface, but in this area the issues appear to take their distinctive character from the structure of the industry rather than from the attributes of the technology.[11] The litigation in this area has been meager in frequency, but significant in impact when it does occur.[12]

This Article focuses on this latter problem area, that of trade secret licensing, where the issues unique to biotechnology are only now beginning to crystallize. Part II of the Article reviews the general law of trade secrecy with particular emphasis on the economic incentives and consequences that will affect biotechnology trade secret licensing. Part III discusses the unusual character of the developing American biotechnology industry, examines the manner in which the industry uses and licenses trade secrets, and describes current litigation that profiles trade secret issues important to the industry. Finally, Part IV analyzes those issues against current trade secret law, suggesting the potential influence of the law on the development of biotechnology licensing.

II. Trade Secrecy

The law of trade secrets is state law but is surprisingly uniform across U.S. jurisdictions.[13] This is in part because the law surrounding trade secrecy has been largely shaped by the definitions

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American Cyanamid Co.).

[9] *See, e.g.*, Eli Lilly & Co. v. Genentech, Inc., 17 U.S.P.Q.2d (BNA) 1531 (S.D. Ind. 1990); American Cyanamid Co. v. Fox, 140 U.S.P.Q. (BNA) 199 (N.Y. Sup. Ct. 1964); *see also* David J. Brezner et al., *Protecting Trade Secrets in Biotechnology, in* Protecting Trade Secrets 1989, at 495, 507-13 (David A. Anderson & Melvin F. Jager eds., 1989) (describing other biotechnology trade secret cases involving employee movement); Robert W. Payne, *Trade Secret Litigation in the Biotechnology Industry: The Coming Storm, in* Biotech USA 1988, at 127, 128-29 (1988) (same).

[10] *See* Geoffrey M. Karny, *Biotechnology Licensing*, 8 Licensing L. & Bus. Rep. 1, 2 (1985).

[11] *See id.* at 2, 3.

[12] *See* Lipsey et al., *supra* note 8, at 22.

[13] *See* Gregory M. Wasson, Annotation, *Misappropriation of Trade Secrets Under the Restatement of Torts*, 14 Am. Jur. Proof of Facts 3d 619, 629-30 (1991).

of trade secrecy incorporated into the Restatement of Torts,[14] which has been recognized in almost every U.S. jurisdiction.[15] More recently, the Uniform Trade Secrets Act (UTSA) has been adopted in some form by a majority of jurisdictions.[16] The UTSA, however, relies on the Restatement definition and on the case law interpreting it; thus, the Restatement continues to be important in both UTSA and non-UTSA jurisdictions.[17]

A. Legal Doctrines

The law of trade secrets, whether applied to biotechnology or other businesses, arises out of an assemblage of principles drawn from tort, contract, agency, and unfair competition law.[18] Trade secrets may be any type of information that is not generally known to the public but gives the holder of the information some business advantage over competitors.[19] The trade secret itself is a legal interest in business information or technical know-how, which may include anything besides tangible capital and labor necessary to start up a business.[20] A trade secret interest entitles the holder to possession and use of the proprietary information and to protection against appropriation of the information by nefarious or unfair means.[21] Typical trade secret information includes proprietary processes, customer lists, or chemical formulas.[22] The trade secret holder must take reasonable precautions to keep the secret from becoming generally known but may reveal the secret as necessary to employees, licensees, or others under an agreement of confidentiality.[23]

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[14] RESTATEMENT OF TORTS § 757 (1939). The Restatement sections on trade secrecy were omitted from the second Restatement of Torts because the drafters felt that trade secrecy had evolved into a separate body of law independent from tort law. Wasson, *supra* note 13, at 630.

[15] Wasson, *supra* note 13, at 630.

[16] *Id.* at 629.

[17] *Id.*

[18] Richard H. Stern, *A Reexamination of Preemption of State Trade Secret Law After* Kewanee, 42 GEO. WASH. L. REV. 927, 937-38 (1974) (reviewing common law bases of trades secret law).

[19] UNIFORM TRADE SECRETS ACT § 1 commentary, 14 U.L.A. 433 (1985); RESTATEMENT OF TORTS § 757 cmt. b.

[20] David R. Macdonald, *Know-How Licensing and the Antitrust Laws*, 62 MICH. L. REV. 351, 355 (1964).

[21] *Id.* at 353-54.

[22] RESTATEMENT OF TORTS § 757 cmt. b.

[23] *Id.*

1. Confidentiality

It is the breach of duty created by a confidential disclosure that is the hallmark of trade secrecy.[24] This formulation of trade secrecy suggests that protection is extended under a liability rule rather than under a property rule.[25] Indeed, the Restatement and case law from the early part of the twentieth century explicitly reject consideration of trade secrets as property.[26] The features of trade secrecy lend some support to this view: a trade secret holder has no universal right to exclude others from using the trade secret.[27] The law does not penalize or bar discovery of the trade secret through reverse engineering, independent laboratory research, canvassing published literature, or inadvertent disclosure by the holder.[28]

Rather, trade secrecy prohibits misappropriation: unauthorized disclosure or use of another's trade secret when the information is obtained by improper means or through a breach of confidence.[29] Improper means include a variety of illegal or tortious actions, as, for example, through industrial espionage or through unauthorized use by a licensee.[30] Breach of confidence involves use or disclosure of the secret after it has been disclosed by another party pursuant to a confidential agreement.[31]

2. Patents and Trade Secrets

As might be expected, the interaction of trade secret laws with other forms of intellectual property protection is an important criterion in determining the function of trade secrecy. In particular,

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[24] *See* Burten v. Milton Bradley Co., 763 F.2d 461, 462-63, 226 U.S.P.Q. (BNA) 605, 606 (1st Cir. 1985); Electro-Craft Corp. v. Controlled Motion, Inc., 332 N.W.2d 890, 903, 220 U.S.P.Q. (BNA) 811, 821 (Minn. 1983).

[25] *See* David D. Friedman et al., *Some Economics of Trade Secret Law*, 5 J. ECON. PERSPECTIVES 61, 62 (1991).

[26] E.I. Du Pont de Nemours Powder Co. v. Masland, 244 U.S. 100, 102 (1917); RESTATEMENT OF TORTS § 757 cmt. b.

[27] RESTATEMENT OF TORTS § 757 cmt. a.

[28] UNIFORM TRADE SECRETS ACT § 1 commentary; RESTATEMENT OF TORTS § 757 cmt. a.

[29] RESTATEMENT OF TORTS § 757.

[30] *See* UNIFORM TRADE SECRETS ACT § 1. Comments to the Uniform Trade Secrets Act point out that otherwise lawful conduct, such as flying an airplane over a competitor's manufacturing facility, may be improper when used to discover a trade secret. *Id.* commentary (citing E.I. Du Pont de Nemours & Co. v. Christopher, 431 F.2d 1012, 166 U.S.P.Q. (BNA) 421, 167 U.S.P.Q. (BNA) 1 (5th Cir. 1970), *cert. denied*, 400 U.S. 1024 (1971).

[31] *See id.*; RESTATEMENT OF TORTS § 757.

the interaction of trade secret law and federal patent law must be carefully defined because these forms of intellectual property protection are not only incompatible forms of protection but could be viewed as conflicting in policy. Whereas patent law encourages disclosure of new discoveries in return for a limited grant of exclusivity,[32] trade secret laws appear to encourage concealment of new discoveries, and discoveries so concealed can be exploited for an indefinite period of time.[33]

This apparent conflict of intellectual property policies was addressed by the United States Supreme Court in *Kewanee Oil Co. v. Bicron Corp.*[34] The Court found no conflict between the two types of law, holding instead that each has an important, different, and complementary role to play in fostering new discoveries and innovation.[35] The Court in *Kewanee* suggested that trade secrecy is addressed to a different class of invention than is the patent system.[36] Trade secret protection is available for items that do not meet the criteria of novelty, utility, and nonobviousness required to be eligible for patent protection.[37] Thus, trade secret law encourages innovation in areas where patent law does not reach: the area comprising inventions and information that, however valuable to the owner, are not the type of discovery for which society would offer the seventeen-year exclusive right of a patent.[38]

Inventions that would be eligible for a patent, the Court suggested, will generally not be withheld from the public as trade secrets.[39] Under the patent system, broad protection is traded for full disclosure;[40] trade secrecy offers narrower protection without disclosure.[41] Trade secret protection can be easily lost through independent discovery, reverse engineering, or inadvertent disclosure.[42] Thus, inventors with discoveries that are eligible for patent protection are likely to seek such protection rather than relying on

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[32] *See* Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 331 (1945); Universal Oil Prods. Co. v. Globe Oil & Refining Co., 322 U.S. 471, 484 (1944).

[33] *See* 12 MILGRIM ON TRADE SECRETS, *supra* note 7, § 2.02[2]; 12A *id.* § 8.02[2].

[34] 416 U.S. 470 (1974).

[35] *Id.* at 484.

[36] *Id.* at 481-82.

[37] *Id.* at 482-83.

[38] *Id.* at 485.

[39] *Id.* at 483.

[40] *Id.* at 480-81.

[41] *Id.* at 490.

[42] *Id.*

the more mercurial protection of trade secrecy.[43]

In addition, for inventions whose patentability is dubious, the option of trade secrecy may prevent a flood of marginal applications from overwhelming the United States Patent Office, which is required to review and assess such applications.[44] The inventor can simply rely on trade secret protection, which arises spontaneously, rather than spending the money for a patent examination that may be fruitless.[45] The *Kewanee* Court suggested that the option of relying on trade secrecy may also help prevent the issuance of invalid patents, because marginal inventions, some of which might slip through the patent examination process, will not be submitted for examination.[46]

B. Economic Considerations

As discussed above, the Restatement formulation of trade secrecy eschews any concept of property, and trade secrecy certainly began as an equitable legal mechanism rather than as an economic incentive to invention.[47] Nonetheless, trade secrecy has clear economic characteristics flowing from the rights that are recognized, and the Supreme Court has recently recognized that these characteristics resemble property rights.[48] Such rights in intellectual property help to encourage proper allocation and development of information, which, lacking the tangible characteristics of physical property, could be freely appropriated without payment to the information developer.[49]

1. Purposes of Trade Secrecy

Perhaps the most obvious purpose of trade secrecy is to maintain order in a competitive market. Trade secrecy laws promote "ethical" behavior among competing businesses by penalizing misappropriation of a competitor's proprietary information.[50] Without the trade secret penalties for stealing a competitor's invention,

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[43] *Id.*

[44] *Id.* at 485.

[45] *Id.*

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

[47] *See supra* note 25 and accompanying text.

[48] *See* Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1003-04 (1984).

[49] *See* ROBERT P. BENKO, PROTECTING INTELLECTUAL PROPERTY RIGHTS 16-17 (1987).

[50] *See, e.g.*, ILG Indus., Inc. v. Scott, 273 N.E.2d 393, 398, 171 U.S.P.Q. (BNA) 371, 375 (Ill. 1971) (finding trade secrecy preserves "commercial morality").

companies hoping to enter a given market could simply spy out a previous entrant's methods and appropriate those for their own. The trade secret penalties associated with such industrial espionage encourage competitors to channel their resources into efforts at research rather than into efforts at piracy.[51]

This incentive is further supported by the allowance of trade secrecy for imitation through reverse engineering or independent discovery.[52] Rather than channeling resources into industrial espionage, for which they will be penalized, competitors are encouraged to channel resources into either scrutinizing and learning the characteristics of an existing product or into independent research along the same lines as that of an existing product.[53] In either case, the would-be competitor develops valuable industrial experience and know-how, rather than "free riding" off the developments of the first inventor.[54]

Trade secrecy has the added benefit of relieving a manufacturer from the burden of actual secrecy.[55] Trade secrecy requires that a trade secret owner take reasonable precautions to screen proprietary information from the public, but the owner need not make the larger investment of resources necessary to keep the information actually, absolutely secret.[56] Competitors who misappropriate a reasonably protected trade secret will be penalized; in the absence of such penalties, the only protection against misappropriation would be true secrecy. This would require owners of proprietary information to make an enormous investment in security to keep the information away from spying competitors.[57] Trade secrecy laws allow those resources to be devoted to more productive uses.

Trade secrecy laws also promote the sharing of knowledge by facilitating licenses under agreements of confidentiality.[58] If the owner of industrially useful but proprietary information could only rely on actual secrecy, he might be less inclined to license out the information because licensing could create an opportunity for his information to become generally known or misappropriated. Trade

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[51] *See* Friedman et al., *supra* note 25, at 70.

[52] *Id.*

[53] *Id.*

[54] *Id.*

[55] *See* Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 193 (1987).

[56] *See id.*

[57] *See* Friedman et al., *supra* note 25, at 67.

[58] *See* Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 277-78 (1977).

secrecy laws penalize misuse of licensed proprietary knowledge, thus providing extra surety to a potential licensor.[59]

2. Protected Subject Matter

Trade secrecy's criterion of reasonable secrecy defines a particular boundary on the pool of inventions that may be protected: as a practical matter, this pool is likely to be distinct from inventions freely available to the public and from the pool of inventions for which patents are sought. As suggested by the Supreme Court's *Kewanee* opinion, a portion of the trade secret invention pool will be made up of inventions that are not patentable subject matter; these may only be protected by trade secrecy.[60] Another portion of the trade secret invention pool will be made up of patentable inventions that are never patented. For those inventions that are patentable subject matter, concurrent patent protection and trade secret protection are incompatible because the disclosure required by the patent destroys trade secrecy.[61] However, patents will only be sought for items whose disclosure was inevitable; the incentive of seventeen year's patent protection will not prompt the disclosure of intellectual goods that can be kept secret indefinitely.[62]

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[59] *Id.* at 278.

[60] *See supra* notes 34-39 and accompanying text. Limited exceptions to this rule exist under specific provisions of other federal intellectual property laws. For example, some unpatentable software inventions may be protected under federal copyright provisions. *See* 17 U.S.C. §§ 101-102, 117 (1988). Certain unpatentable pharmaceutical inventions may be protected under the Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as amended in scattered sections of 15, 21, 43, and 45 U.S.C.). In addition, protection for mask works falls under the Semiconductor Chip Protection Act. *See* 17 U.S.C. §§ 901-914 (1988).

[61] *See* 12 MILGRIM ON TRADE SECRETS, *supra* note 7, § 2.06[2]; 12A *id.* § 8.02[2].

[62] *See* FRITZ MACHLUP, THE POLITICAL ECONOMY OF MONOPOLY 281 (1952). Note that this assertion differs from that of the Supreme Court in Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 181 U.S.P.Q. (BNA) 673 (1974), in which Chief Justice Burger claimed that an inventor whose discovery was eligible for patent protection was unlikely to rely on trade secret protection. *Id.* at 490, 181 U.S.P.Q. at 681. This assertion was based on the assumption that a patent would be more attractive because its protection is absolute, whereas trade secrecy may be annulled by reverse engineering or independent invention. *Id.*, 181 U.S.P.Q. at 681. However, the relevant criterion is not the breadth of protection, but the maximization of profits. The rational inventor will choose whichever form of protection will give him the greatest return on his investment. If an inventor believes that his discovery may be screened from the public indefinitely, he may well opt for perpetual income under trade secrecy rather than seventeen years' income under a patent. *See* K. David Crockett, *The Salvaged Dissents of* Bonito Boats v. Thunder Craft, 13 GEO. MASON U. L. REV. 27, 63 (1990); Stern, *supra* note 18, at 946-47. The Coca-Cola soft drink formula provides the classic example of such a

The trade secret invention pool will not, however, include patentable subject matter whose disclosure is inevitable. Trade secret protection is almost impossible to maintain for product inventions that, once on the market, may be acquired, examined, and duplicated or reverse engineered;[63] for example, biotechnology process discoveries that are not themselves placed into the stream of commerce may lend themselves to trade secret protection.[64] Trade secrets may be maintained as trade secrets only because they can be feasibly screened from public view.[65] Consequently, trade secrets are by definition private goods rather than public goods: were they public goods, they must either be patented or passed into the public domain.[66]

3. Licensing and Profits

The economics of trade secrecy is also characterized by the return that a trade secret holder may receive for licensing her invention. An exclusive property right, such as a patent, entails both the right to practice the invention and the right to exclude others from practicing the invention.[67] A trade secret, by contrast, is *not* an exclusive right and entails only the right to practice the invention.[68] A trade secret holder has no right to exclude: she has only limited protection against competitors who appropriate her intellectual property through a circumscribed class of illegitimate actions.[69] Stated another way, trade secret rights cannot be used as an offensive weapon against those who independently develop the intellectual good.[70] When licensing a trade secret, the trade secret

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situation: as a trade secret, it has remained proprietary for decades rather than for the seventeen years of exclusivity it would have received had it been disclosed in a patent. *See* Tom G. Palmer, *Intellectual Property: A Non-Posnerian Law and Economics Approach*, 12 HAMLINE L. REV. 261, 293 (1989).

[63] *See* Martin J. Adelman, *Property Rights Theory and Patent-Antitrust: The Role of Compulsory Licensing*, 52 N.Y.U. L. REV. 977, 982 (1977).

[64] *See* ROMAN SALIWANCHIK, LEGAL PROTECTION FOR MICROBIOLOGICAL AND GENETIC ENGINEERING INVENTIONS 10 (1982).

[65] *See* Michael I. Krauss, *Property, Monopoly, and Intellectual Rights*, 12 HAMLINE L. REV. 305, 312 (1989); *see also* Palmer, *supra* note 62, at 293.

[66] *See* Krauss, *supra* note 65, at 312.

[67] 2 MELVIN F. JAGER, TRADE SECRETS LAW § 11.01 (rev. ed. 1992).

[68] *Id.*; 12 MILGRIM ON TRADE SECRETS, *supra* note 7, § 6.05[2].

[69] 12 MILGRIM ON TRADE SECRETS, *supra* note 7, § 6.05[2].

[70] *See* Elizabeth Miller, Note, *Antitrust Restrictions on Trade Secret Licensing: A Legal Review and Economic Analysis*, 52 LAW & CONTEMP. PROBS., Winter 1989, at 183, 185.

holder can bargain only for disclosure of the secret.[71] The trade secret holder cannot offer a licensee any protection against third parties who may independently develop or reverse engineer the proffered non-tangible goods.[72]

In addition, because the trade secret holder has only disclosure to offer, the position he must take in exploiting his ideal good poses something of a paradox. The trade secret licensor bargains for disclosure, yet the potential licensee cannot assess the value of the secret until it is disclosed.[73] The secret may perhaps be disclosed under some obligation of confidence, but this imposes an additional cost on the potential licensee who accepts the constraint before he is able to evaluate the secret.[74] The cumbersome security measures that therefore surround any trade secret sales or licensing transaction entail costs that may significantly affect the price that the trade secret holder can demand for his invention.[75]

Transactional costs aside, the trade secret holder is severely constrained in the price that he may demand for disclosure. This constraint is inherent in the nature of the trade secret right, which does not preclude re-invention or reverse engineering.[76] Should the trade secret licensor set his price too high, the potential licensee may choose to independently develop the proffered item or expertise.[77] To avoid this outcome, the trade secret inventor may reduce his licensing fees to a level at which the cost of independent reinvention is greater than the cost of purchasing a license.[78] This reduces the inventor's profit, in effect redistributing it to share the wealth of the new technology.[79] Thus, trade secret protection entails a form of self-regulation that prevents a substantial disparity from developing between the cost of creating new technology and the value that can be privately appropriated from that technology.[80] Such self-regulation seems appropriate for a class of inven-

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[71] 2 JAGER, *supra* note 67, § 11.01; 12 MILGRIM ON TRADE SECRETS, *supra* note 7, § 6.05[2]; Miller, *supra* note 70, at 187.

[72] 12 MILGRIM ON TRADE SECRETS, *supra* note 7, § 6.05[2]; *see* Miller, *supra* note 70, at 186.

[73] Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1029-30 (1989); *see* Kitch, *supra* note 58, at 278.

[74] *See* Kitch, *supra* note 58, at 278.

[75] Adelman, *supra* note 63, at 982; Kitch, *supra* note 58, at 279.

[76] Adelman, *supra* note 63, at 981.

[77] 12 MILGRIM ON TRADE SECRETS, *supra* note 7, § 6.05[2].

[78] *See* Adelman, *supra* note 63, at 981.

[79] *Id.*

[80] *Id.* at 981-82.

tions that need not be novel, useful, and nonobvious, already entail natural barriers to exclude free-riders, and are eligible for perpetual protection.

III. The Biotechnology Industry

The common law rules of trade secrecy, now codified in most jurisdictions through the UTSA, have been successfully applied to every conceivable type of business over a long period of time. For the most part, the application of these rules in biotechnology will be straightforward, differing little from that in any other business—commercial biotechnology is, for the most part, concerned with the same goals as any other business. And, like any business, biotechnology will have some unique attributes of its own that will require application of the rules in ways different from any other business.[81] However, in biotechnology, these unique quirks will be harder to anticipate and accommodate: the industry is not only relatively new, but rapidly changing due to its underlying technology.

A. Nature of the Technology

Biotechnology is the scientific manipulation of living processes to benefit humankind.[82] Biotechnology has been with us since the dawn of civilization when humans first began to systematically use microorganisms to ferment beer, leaven bread, or curdle milk into yogurt and cheese.[83] Modern biotechnology, however, focuses upon manipulations at the cellular or molecular level.[84] Techniques of biochemistry and molecular biology, including cell culture, hybridoma fusion, and genetic engineering allow the molecules of life to be manipulated to advantage.[85] Desirable genetic traits can be quickly introduced into important crops or laboratory animals.[86] Microorganisms can be engineered to produce otherwise rare but pharmacologically important proteins.[87]

Biotechnology mimics natural processes.[88] Biotechnology cannot

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[81] *See* Karny, *supra* note 10, at 2.

[82] *See* Biotechnology in a Global Economy, *supra* note 1, at 29.

[83] *Id.*

[84] *See* Howard E. Simmons, *Biotechnology: A New Marriage of Chemistry and Biology*, *in* Biotechnology and Materials Science 7, 9 (Mary L. Good ed., 1988).

[85] *See* Karny, *supra* note 10, at 1-2.

[86] *See* Simmons, *supra* note 84, at 8.

[87] *Id.*

[88] *See* Jacqueline Barton, *What Is Biotechnology?*, *in* Biotechnology and

evade nature; it can only discover mechanisms already at work in living organisms and employ them to best advantage.[89] For this reason, biotechnology is highly materials-intensive: scientific and industrial biotechnology rely heavily upon possession of biological materials that will enable the desired result.[90] This technology rarely, if ever, fabricates critical macromolecules *de novo*; they are adapted or engineered from those already found in living organisms.[91]

As a consequence, enormous resources are devoted to discovering and characterizing the biological materials necessary to any biotechnological enterprise.[92] Researchers have at their command an arsenal of sophisticated biochemical search techniques, but the task is nonetheless formidable. The materials sought lie primarily at the molecular level and are, for all practical purposes, invisible.[93] They are contained in fantastically tiny volumes of matter.[94] Yet, within those tiny volumes are innumerable bits of unwanted material as well as the desired molecules. The process of extracting the desired molecules might be likened to blindly casting a magnet tied to string into an enormous haystack, hoping eventually to retrieve a needle that may not be there at all.

An additional result of biotechnology's reliance on materials drawn from living systems is an element of variability and unpredictability inherent in the field.[95] The macromolecules on which biotechnology relies are enormous and intricate chemical structures with complex physical characteristics.[96] Many of these properties are still poorly understood. Alterations made to such structures—such as changing an amino acid subunit in a protein—with the intent of improving their usefulness to humans may have unforseen and even undesirable side effects.[97]

Similarly, the milieu of biotechnology processes is often that of a living organism, a collection of complex and interrelated chemical

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MATERIALS SCIENCE, *supra* note 84, at 6.

[89] See *id.*

[90] *See* Dan L. Burk, *Copyrightability of Recombinant DNA Sequences*, 29 JURIMETRICS J. 469, 483 (1989).

[91] *Id.* at 484.

[92] *Id.* at 483.

[93] *See* Barton, *supra* note 88, at 3.

[94] *See id.*

[95] *See* Karny, *supra* note 10, at 2.

[96] *See* Barton, *supra* note 88, at 4.

[97] *See* George D. Rose, *Structural Themes in Native Proteins, in* PROTEIN FOLDING 1, 1 (Lila M. Gierasch & Jonathan King eds., 1990) ("[W]e cannot yet reliably predict structural motifs from sequence alone . . . .").

pathways.[98] Many if not most of these chemical pathways are poorly characterized, poorly understood, or completely unknown at present.[99] Linkages between cellular chemical reactions are only partially known. Feedback mechanisms within an organism invariably cause changes in one chemical process to affect other processes. Consequently, biotechnological disturbance or alteration of one of an organism's chemical processes may affect the functioning of other pathways in an unexpected manner.[100]

This problem is heightened by the frequent use of biotechnology to express biological materials in foreign hosts. For example, such difficulties may arise in industrial scale-up of biotechnology products. Genes for a rare human protein, having valuable pharmaceutical uses, may be spliced into a fast-growing microorganism in order to produce the protein in large quantities.[101] However, the host organism does not normally produce the protein. Host organism enzymes, designed to degrade foreign or defective native proteins, may degrade the unfamiliar biotechnology product, stymieing production.[102]

Optimally, for industrial production, the organism should also secrete the product into the surrounding medium, from which it can be easily extracted.[103] However, the host may not recognize the unfamiliar protein as one to be excreted; it will buildup inside the host, which must then be broken open to recover the product.[104] This buildup may not only make industrial extraction difficult, but may also prove toxic to the host, further stalling production.[105] Problems such as these, often unanticipated, have plagued industrial applications of biotechnology since the industry's inception and continue to do so today.

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[98] *See* James E. Bailey, *Toward a Science of Metabolic Engineering*, 252 SCIENCE 1668, 1668 (1991).

[99] *See id.* at 1674.

[100] *See* J.E. Bailey et al., *Strategies and Challenges in Metabolic Engineering, in* BIOCHEMICAL ENGINEERING IV, ANNALS OF THE NEW YORK ACADEMY OF SCIENCES, vol. 589, 1, 1, 11 (Walter E. Goldstein et al. eds., 1990); Baily, *supra* note 98, at 1674.

[101] *See* JAMES D. WATSON ET AL., RECOMBINANT DNA 454 (2d ed. 1992).

[102] *Id.*

[103] *See* JAMES D. WATSON ET AL., RECOMBINANT DNA: A SHORT COURSE 235 (1983).

[104] *See id.*

[105] *See* WATSON ET AL., *supra* note 101, at 454.

B. Nature of the Industry

The constellation of firms making up the biotechnology industrial sector presents an unusual collective profile.[106] Although many established chemical and pharmaceutical manufacturers have now entered the realm of biotechnology, the majority of biotech companies are classified as "dedicated biotechnology firms" or DBCs.[107] The presence of these small but numerous firms, dedicated to commercializing one or, at most, a few products, lends to certain distinctive characteristics.

1. Academic Ties

The U.S. biotechnology industry is characterized by exceptionally close ties to the academic community.[108] The knowledge and techniques on which commercial biotechnology are based were initially developed in research universities.[109] The possibility of profit from materials isolated through basic research prompted many researchers to form commercial companies dedicated to producing and marketing discoveries transferred from their own academic laboratories.[110] Much of the basic research for such firms continues to originate in university laboratories. Most of the personnel in these companies, including officers and directors, were initially drawn from an academic setting, and key personnel in such companies will often continue to hold university appointments.[111] Continuing research agreements with universities are also quite common, where university research is sponsored by a biotechnology company, and the results are then licensed out to the sponsoring company for commercialization.[112] Such arrangements are often permitted or encouraged by the sponsoring university, which is often entitled to share in potential profits.[113] As a result, biotechnology start-ups have both geographically and philosophically gravitated toward major research institutions.

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[106] *See* 4 OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONG., NEW DEVELOPMENTS IN BIOTECHNOLOGY, U.S. INVESTMENT IN BIOTECHNOLOGY 79-80 (1988) [hereinafter U.S. INVESTMENT IN BIOTECHNOLOGY].

[107] BIOTECHNOLOGY IN A GLOBAL ECONOMY, *supra* note 1, at 39.

[108] *See id.* at 165.

[109] *Id.*

[110] *See id.*

[111] *See id.* at 165-66.

[112] *See* U.S. INVESTMENT IN BIOTECHNOLOGY, *supra* note 106, at 113.

[113] *Id.*

2. Atomistic Firms

Out of the United States' myriad science facilities have come myriad biotechnology companies, each bent on capitalizing on the discoveries of its progenitor laboratory. These small, entrepreneurial firms are, for the most part, devoted to developing one or two biotechnology products.[114] Consequently, their fortunes are tied to those products, and when the products' prospects fail, so do their sponsoring firms. Numerous small biotechnology firms disappear before their singular products ever see the market, but new ventures touting new products always seem to appear to take their places. Thus, the roster of firms in the industry is in constant flux, but the general contours and numbers of the roster seem to be more or less stable.

There are also a few giants among the lilliputians. The traditional pharmaceutical and chemical firms have not been blind to the benefits of this technology, and these well-established firms have turned some of their resources to developing biotechnology products.[115] Often, the larger firms have entered the biotechnology field by simply acquiring a small biotechnology company and turning it into a division of the larger company.[116] In general, however, each type of firm seems to have found a complementary role within the industry.[117] The interactions between these types of firms help define yet another of the industry's important characteristics.

3. Strategic Alliances

The close relationship between the biotechnology industry and university research reflects yet another aspect of commercial biotechnology: development of commercial products in this industry has been highly research-intensive, and as a consequence, highly capital-intensive.[118] These costs stem from both the basic research necessary to develop marketable biotechnology products and the formidable problems of industrial scale-up that have attended the

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[114] BIOTECHNOLOGY IN A GLOBAL ECONOMY, *supra* note 1, at 3, 5.

[115] *See id.* at 54-57.

[116] *Id.*; Ashish Arora & Alfonso Gambardella, *Complementarity and External Linkages: The Strategies of the Large Firms in Biotechnology*, 38 J. INDUS. ECON. 361, 365 (1990) (discussing acquisition of dedicated biotechnology firms by larger firms).

[117] *See* Ann M. Thayer, *Biotechnology Industry Looks to More Creative Financing Options*, CHEMICAL & ENGINEERING NEWS, Aug. 23, 1993, at 11, 12.

[118] *See* BIOTECHNOLOGY IN A GLOBAL ECONOMY, *supra* note 1, at 47-48.

manufacturing of such products.[119] Such technological problems have manifested themselves in the business world as long delays between the start-up of a biotechnology firm and the marketing of its first commercial product.[120]

During this lag period, the small firms must continue to attract funding to remain in business.[121] Some small firms have weathered this difficult period by pooling their resources with other small firms, forming alliances, or even merging to streamline their operations.[122] More often, cash poor firms have sought alliances with larger traditional manufacturers.[123] In such alliances, the smaller firm supplies particular research expertise and the necessary biological materials; the larger firm supplies production scale-up, manufacturing, and marketing capabilities.[124] In effect, the smaller firm becomes a temporary research division of the larger firm without outright acquisition by the larger firm.[125] The large firm is spared the expense of acquiring and maintaining a new division, and the smaller firm is spared the expense of developing manufacturing and marketing infrastructure.[126]

C. Trade Secrets in Biotechnology

Trade secrecy is becoming an important form of protection for information and biomaterial in the biotechnology industry, especially for process-related materials that will not be available for public scrutiny or reverse engineering.[127] Such materials may include the organisms that produce biotechnology products, the recombinant materials that genetically "program" the organisms to produce the product, and the DNA molecules or vectors that are used to shuttle genes between organisms.[128] The culturing techniques to grow the organisms may also be protected as trade

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[119] *See id.* at 47.

[120] *Id.*

[121] *Id.* at 47-48.

[122] Thayer, *supra* note 117, at 10, 11.

[123] Brezner et al., *supra* note 9, at 517; Karny, *supra* note 10, at 2; Thayer, *supra* note 117, at 10, 11.

[124] Arora & Gambardella, *supra* note 116, at 364-65; Thayer, *supra* note 117, at 11-12.

[125] Thayer, *supra* note 117, at 11-12.

[126] *See id.*

[127] *See* SALIWANCHIK, *supra* note 64, at 10; Charles E. Lipsey et al., *Protecting Trade Secrets in Biotechnology* (Pt. 2), 2 TRADE SECRET L. REP. 42, 44 (1986).

[128] *See* Payne, *supra* note 9, at 129-31; Payne, *supra* note 4, at 130.

secrets.[129] Methods for separating and extracting the final product will also be good candidates for trade secret protection.[130] However, the choice whether to actually employ trade secrecy for such materials and methods will rest upon particular legal and scientific considerations.

1. Employing Trade Secrecy

Trade secrecy may be the only form of protection available for many biotechnology products.[131] To date, patents have been the premier method of protection for biotechnology due to the broad scope of patent rights; unlike trade secrecy, patents block reverse engineering and independent discovery of their subject matter.[132] However, patents are available only to technology that meets strict criteria of novelty and nonobviousness.[133] Recombinant versions of products that have already been isolated from nature may not be considered novel, and, as application of biotechnology becomes more established, the use of recombinant DNA or similar techniques to produce biological substances may be considered routine and obvious.[134] Current patent doctrine also holds that even when a firm has isolated novel starting materials, processes employing those materials and products produced with those materials are not necessarily patentable.[135]

The subject matter of patents is limited to processes, manufactured items, and compositions of matter.[136] Any other resource—such as the accumulation of industrial ideas and experience that is termed "know-how"—is ineligible for patent protection, even if critical to a firm's successful competition.[137] For example, negative information is ineligible for patenting but may

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[129] *See* Payne, *supra* note 9, at 130.

[130] *Id.* at 131.

[131] *See* U.S. INVESTMENT IN BIOTECHNOLOGY, *supra* note 106, at 103.

[132] *See* Lipsey et al., *supra* note 127, at 44; Payne, *supra* note 4, at 130.

[133] *See* 35 U.S.C. §§ 101-103 (1988).

[134] *See* Donna Smith, Comment, *Copyright Protection for the Intellectual Property Rights to Recombinant Deoxyribonucleic Acid: A Proposal*, 19 ST. MARY'S L.J. 1083, 1093-95 (1988).

[135] *See* David Beier & Robert H. Benson, *Biotechnology Patent Protection Act*, 68 DENV. U. L. REV. 173, 175 (1991); Dan L. Burk, *Biotechnology and Patent Law: Fitting Innovation to the Procrustean Bed*, 17 RUTGERS COMPUTER & TECH. L.J. 1, 42-43 (1990); Kerin Kelly, Comment, *The Elimination of Process: Will the Biotechnology Patent Protection Act Revive Process Patents?*, 24 J. MARSHALL L. REV. 263, 266-67 (1990).

[136] 35 U.S.C. § 101 (1988).

[137] *See* Payne, *supra* note 4, at 130.

be the subject of trade secrecy.[138] Given the "needle in a haystack" nature of biotechnology research, proprietary negative information may become as important as proprietary positive results: knowing where not to look and what techniques are ineffectual may give biotechnology firms a market advantage.[139] Certainly, firms that have already explored numerous blind alleys in discovering and developing their products will want to shield such information from other firms who could use the information to shorten development of competing products, essentially "free riding" off the pioneering firm's mistakes.[140]

In other situations, trade secrecy may not be a matter of necessity, but the intellectual property protection of choice. Industrial process and process enabling materials not only can be maintained as trade secrets, but are often best maintained as trade secrets.[141] Process inventions are hard to "police." If a proprietary process is disclosed in a patent, and a competitor begins using that process, the infringement may be hard to detect—the only evidence may be a marketed product that could have been produced by the patented process, or perhaps by another process.[142] It may be preferable not to disclose the process and maintain it instead as a trade secret.[143]

In addition, the patent requirement of full disclosure of the invention will often mean that the patentee must make a publicly available deposit of essential biological materials to enable the patent.[144] The patent then expires after seventeen years, whereas trade secret protection may last indefinitely.[145] Biotechnology firms may prefer to hold secret their biological materials rather than place them in the hands of their competitors through the deposit required for patenting.[146] Because development of commercially important biological materials tends to be both expensive and lengthy, a firm holding such materials can often license them to a

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[138] *See* SALIWANCHIK, *supra* note 64, at 11. This is more likely to be true under the Uniform Trade Secrets Act definition than under that of the Restatement; the latter requires that a secret be actively employed in the trade secret holder's business. UNIFORM TRADE SECRETS ACT § 1 commentary, 14 U.L.A. 433. The UTSA specifically provides for protection of negative findings. *Id.*

[139] SALIWANCHIK, *supra* note 64, at 11; Payne, *supra* note 9, at 133.

[140] *See* SALIWANCHIK, *supra* note 64, at 11; Payne, *supra* note 9, at 133.

[141] SALIWANCHIK, *supra* note 64, at 10.

[142] *Id.*

[143] *Id.*

[144] *See* Lipsey et al., *supra* note 127, at 41-42.

[145] SALIWANCHIK, *supra* note 64, at 12.

[146] *See* Lipsey et al., *supra* note 127, at 41-42.

competitor at a cost below that at which the competitor could develop the materials independently.[147] This may in fact be the optimal strategy for smaller, research-oriented biotechnology firms: rather than incur the cost to produce and market biotechnology products, develop proprietary materials to be licensed to larger established pharmaceutical firms.[148]

2. Potential Problems

Although trade secrecy may be the required or desired form of intellectual property protection, the characteristics of the biotechnology industry reviewed above pose certain problems for this type of protection.[149] First, the prevalence of strategic alliances in this industry means that a great many trade secrets will be licensed to partner firms, and a high frequency of agreements alone will increase the likelihood of trade secrets disputes.[150] More importantly, however, these secrets will change hands in a young industry that has little experience or case law to guide it in fashioning or interpreting such agreements.[151]

The parties to such ventures will undoubtedly attempt to allocate their risks in the agreement by defining the license terms as carefully as possible; however, not all contingencies will be foreseen by the parties. Particularly when a new technology is involved, the definitions and parameters of many contractual provisions may remain uncertain for a long period of time until litigation or industry custom has defined the meaning of important terms—simply determining what constitutes a legitimate biotechnology trade secret may be difficult.[152] When such ambiguities exist in contracts and licenses, litigation is bound to follow.

The academic roots of the biotechnology industry may also pose special problems.[153] The professional norms of the scientific com-

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[147] This will depend in part on the useful life of the technology, cash flow considerations, and the extent to which the cost of development serves as a barrier to entry into that technological field. For example, the overall cost of the license may be more than the total for independent development of the materials, but the cost of independent development must be borne up front, while the cost of the license may be spread over time.

[148] *See* Karny, *supra* note 10, at 2.

[149] *See* Epstein & Neelman, *supra* note 6, at 18.

[150] *See* Payne, *supra* note 4, at 130.

[151] *See* Karny, *supra* note 10, at 8.

[152] *See id.* at 3 (discussing the lack of consensus on terms in biotechnology licenses).

[153] *See* Epstein & Neelman, *supra* note 6, at 18-19.

munity have long required that scientists share data and materials with one another, both to allow repetition and validation of reported results and to facilitate new discoveries.[154] Indeed, many peer review journals require the authors of papers published in those journals to make their biological materials freely available.[155] University researchers have routinely supplied other researchers with requested materials and have expected to have their own materials requests freely fulfilled in return.[156] Such free exchange of materials and data is generally incompatible with the requirements of trade secrecy.[157] This may make trade secrecy difficult in research ventures involving universities.[158] And as former academic researchers enter commercial firms, their continued desire to publish and exchange research results with colleagues may compromise the trade secret position of their new employer.[159]

These exchange practices have to some extent been constrained by an unwritten and often unspoken agreement among researchers that the materials shared will not be used for commercial gain and will not be passed on without permission from the original owner.[160] As biotechnology has made biological materials increasingly valuable, this unwritten understanding has more often been committed to some form of writing, but the form taken thus far is problematic.[161] Particularly in a university setting, materials sent to another researcher at her request will be accompanied by a form letter reciting the conditions of the materials transfer.[162] The legal and practical efficacy of such letters in restricting use of the materials is open to question.[163]

A related practice, drawn apparently from the "shrink wrap licenses" accompanying commercially distributed computer

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[154] Eisenberg, *supra* note 55, at 197-206; Epstein & Neelman, *supra* note 6, at 18-19; Lipsey et al., *supra* note 8, at 23.

[155] *See* Eisenberg, *supra* note 55, at 197-205.

[156] *See* Karny, *supra* note 10, at 8.

[157] Eisenberg, *supra* note 55, at 191-93; Epstein & Neelman, *supra* note 6, at 19.

[158] *See* Bertram I. Rowland, *Legal Implications of Letter Licenses for Biotechnology*, 1 HIGH TECH. L.J. 99, 120-21 (1986).

[159] *See* SALIWANCHIK, *supra* note 64, at 14-15; Epstein & Neelman, *supra* note 6, at 18-19.

[160] *See* Brezner et al., *supra* note 9, at 516; Lipsey et al., *supra* note 8, at 23.

[161] *See* Karny, *supra* note 10, at 8.

[162] *Id.*; Rowland, *supra* note 158, at 102-03.

[163] *See* Brezner et al., *supra* note 9, at 520-23 (such licenses may be disfavored on a variety of policy grounds). *But see* Rowland, *supra* note 158, at 103-04 (arguing that such licenses are valid and enforceable contracts).

software, has been "label licenses" for biological materials: opening and using the materials is considered acquiescence to the terms of an accompanying contract.[164] Again, even with the added indicia of acceptance, such licenses may be problematic both as a matter of substantive contract law and in attempting to maintain trade secrecy.[165] Certainly, as a practical matter, their boilerplate terms are unlikely to anticipate the circumstances of a given material's exchange: the outcome of research on biological materials is likely to be more variable than the rather predictable consumer use of a word processing program. Situations unanticipated by the license will be ripe for dispute.

IV. Trade Secret Disputes

If the maturing biotechnology industry generates trade secret licensing disputes, then the form of disputes to come may be seen in the ongoing litigation between Genentech, Inc. and Eli Lilly & Co.[166] This litigation concerns disagreements arising out of a licensing agreement between the two firms for the production and marketing of recombinant insulin.[167] Early in its development, Genentech, then a small but ambitious DBC, developed recombinant DNA technology to produce human insulin.[168] Strapped for cash and lacking the apparatus to manufacture and market recombinant insulin, Genentech licensed the technology to Eli Lilly, a large, established pharmaceutical firm.[169]

Under the agreement, Genentech provided recombinant microorganisms carrying plasmids with the insulin gene.[170] In particular, Genentech now alleges that the plasmids carrying the insulin coding regions included a DNA control sequence, or promoter, which

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[164] *See* Brezner et al., *supra* note 9, at 518-19.

[165] *See id.* at 520-21 (such licenses may be disfavored as adhesive contracts). *But see* Rowland, *supra* note 158, at 103-04 (arguing that such licenses are valid and enforceable contracts).

[166] *See* Plaintiff's Amended Complaint, Eli Lilly & Co. v. Genentech, Inc., 17 U.S.P.Q.2d (BNA) 1531 (S.D. Ind. 1990) (No. C-87 5642 TEH) (filed Dec. 18, 1987), *reprinted in* Protecting Trade Secrets 1989, *supra* note 9, at 629 [hereinafter Genentech's Amended Complaint]; *see also In re* Regents of Univ. of Cal., 964 F.2d 1128, 22 U.S.P.Q.2d (BNA) 1748 (Fed. Cir. 1992) (petition regarding consolidation of actions); *Eli Lilly*, 17 U.S.P.Q.2d 1531.

[167] *See* Brezner et al., *supra* note 9, at 513-16 (describing the dispute between Eli Lilly and Genentech).

[168] *Id.* at 514.

[169] *See* Biotechnology in a Global Economy, *supra* note 1, at 46-47.

[170] *See* Genentech's Amended Complaint, *supra* note 166, paras. 15, 16, at 5-7.

would allow greatly increased yields of insulin because it had been specially engineered to remove regulatory portions that would slow or stop insulin production in the organism.[171] In addition to these materials, Genentech also supplied related patent rights, trade secrets, and know-how.[172] Pursuant to the license agreement, Lilly used the Genentech materials and information in industrial production of insulin, paying Genentech research fees and 8% of the insulin sales as royalty.[173] Genentech alleges that under the agreement it retained the rights for application of this technology to any products other than insulin.[174]

Lilly has since produced a variety of recombinant products including human growth hormone (HGH) and bovine somatotropin (BST), some of which compete with products produced independently by Genentech.[175] Genentech alleges that production of these products was enabled by use of the licensed Genentech insulin technology, in breach of the licensing agreement and constituting, *inter alia*, a misappropriation of Genentech's trade secrets.[176] Lilly, in turn, claims that use of the licensed technology was not restricted to recombinant insulin development, and that Genentech's alleged trade secrets were not trade secrets at all, but were fraudulently or negligently misrepresented as such.[177]

A. Existence of a Trade Secret

The claims and defenses asserted by Eli Lilly and Genentech illustrate specific trouble spots for biotechnology trade secret licensing that will likely become frequent issues in biotechnology trade secret litigation.[178] In particular, the assertion by Eli Lilly that the material used by their scientists in non-insulin projects was not properly the matter of trade secrecy may become a familiar issue

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[171] *Id.* para. 18, at 8.
[172] *Id.* para. 16, at 6-7.
[173] *Id.*
[174] *Id.*
[175] *Id.* paras. 21-26, at 9-11.
[176] *Id.* para. 25, at 11. In addition to its trade secret misappropriation claims, Genentech also alleges multiple counts of patent infringement, theft, conversion, fraud, unfair competition, unjust enrichment, and interference with prospective business advantage arising from the same set of operative facts. *See generally id.*
[177] *See* Defendant's Answer and Cross Demands, paras. F, I, at 11, 13, Eli Lilly & Co. v. Genentech, Inc., 17 U.S.P.Q.2d (BNA) 1531 (S.D. Ind. 1990) (No. IP 88 1463 C), *reprinted in* PROTECTING TRADE SECRETS 1989, *supra* note 9, at 650 [hereinafter Eli Lilly's Answer].
[178] *See* Brezner et al., *supra* note 9, at 501.

in biotechnology. The substantive law of trade secrecy has been infrequently applied to biotechnology, and the peculiarities of the industry may lend ambiguity to this point for some time to come.

1. Novelty and General Knowledge

Generally, in order to qualify for trade secret protection, an intellectual good must be used in the owner's business and must confer some economic or competitive advantage upon the owner because it is not generally known.[179] The latter requirement implies that the property right in the secret exists only so long as it remains a secret. This does not mean that absolute secrecy must be maintained, but the owner must take reasonable steps to shield the intellectual good from common use and knowledge.[180] In addition, the criterion of "secrecy" implies some minimum degree of novelty or originality, because information that is generally known in the trade cannot qualify as a secret.[181]

It naturally follows from this definition that matters which are generally known in the particular trade or industry, or are readily available from published literature, are not "secret."[182] In some instances, a combination of known processes may become "secret" if the combination yields a unique result.[183] An obvious combination is unlikely to qualify as a secret; however, if a combination of known elements is so complex or intricate that independent discovery of the combination would be highly improbable or costly, the combination will be considered a trade secret.[184]

The question of cost for independent discovery is embodied in factors offered by the Restatement to assess the existence of a trade secret.[185] Under the Restatement analysis, the existence of a trade secret will be determined by assessing factors including the

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[179] *See* RESTATEMENT OF TORTS § 757 cmt. b (1939); 12 MILGRIM ON TRADE SECRETS, *supra* note 7, §§ 2.02, 2.03.

[180] *See* RESTATEMENT OF TORTS § 757 cmt. b; 12 MILGRIM ON TRADE SECRETS, *supra* note 7, § 2.02.

[181] *See* RESTATEMENT OF TORTS § 757 cmt. b; 12 MILGRIM ON TRADE SECRETS, *supra* note 7, § 2.02.

[182] UNIFORM TRADE SECRETS ACT, § 1 commentary, 14 U.L.A. 433; RESTATEMENT OF TORTS § 757 cmt. b.

[183] *See, e.g.*, H. L. Nickelson v. General Motors Corp., 361 F.2d 196, 199, 149 U.S.P.Q. (BNA) 885, 886 (7th Cir. 1966); Lee v. Cercoa, Inc., 433 So. 2d 1, 2 (Fla. App.), *review denied*, 444 So. 2d 417 (Fla. 1983); Jostens, Inc. v. National Computer Systems, Inc., 318 N.W.2d 691, 699, 214 U.S.P.Q. (BNA) 918, 923 (Minn. 1982).

[184] *H. L. Nickelson*, 361 F.2d at 199, 149 U.S.P.Q. (BNA) at 886.

[185] RESTATEMENT OF TORTS § 757 cmt. b.

extent to which the information is known outside of the business, the extent to which it is known by employees within the business, the security efforts undertaken to guard the secret, the money or effort initially invested in developing the secret, and the ease or difficulty of a competitor properly acquiring or developing the information.[186] These factors align with the economic goals of trade secrecy, limiting its subject matter to information with the characteristics discussed above.[187]

2. Preemption Limits

The subject matter limits of trade secrecy are also constrained by federal constitutional considerations. Federal patent law, catalyzed by the Constitution's Supremacy Clause, appears to require strict limitation of trade secret protection to knowledge that meets the secrecy criteria. Hence, no evolution or broadening of trade secrecy is likely—claims of trade secret protection cannot be permitted beyond the present subject matter confines without disturbing the balance established in the *Kewanee* decision.[188]

This conclusion flows directly from the language of *Kewanee* and related cases. In *Compco Corp. v. Day-Brite Lighting, Inc.*, the Supreme Court invalidated an Illinois unfair competition provision because for a state "[t]o forbid copying would interfere with the federal policy, found in Art. I, § 8, cl. 8., of the Constitution . . . allowing free access to copy whatever the federal patent and copyright laws leave in the public domain."[189] The Court's more recent preemption discussion in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.* confirms and in some measure extends this analysis.[190] According to *Bonito Boats*, "[t]he federal patent system . . . embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years."[191] Poised in opposition to this bargain is an equally carefully crafted determination that "free exploitation of ideas will be the rule, to which the protection of a federal patent

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[186] *Id.*

[187] *See supra* notes 52-57 and accompanying text.

[188] *See supra* notes 32-43 and accompanying text.

[189] 376 U.S. 234, 237, 140 U.S.P.Q. (BNA) 528, 530 (1964). The Court reached the same result in a companion case decided the same day. Sears, Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 140 U.S.P.Q. (BNA) 524 (1964).

[190] 489 U.S. 141, 9 U.S.P.Q.2d (BNA) 1847 (1989).

[191] *Id.* at 150-51, 9 U.S.P.Q.2d (BNA) at 1852.

is the exception."[192] This equilibrium may not be intruded upon by the states: "[S]tate regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws . . . . . Where it is clear how the patent laws strike that balance in a particular circumstance, that is not a judgment the States may second-guess."[193]

It has been argued that this federal preemption holding, originating with *Compco* and framed at the constitutional level, held the potential to sweep away all state regulation of ideal goods.[194] However, as discussed above, the Supreme Court has held in *Kewanee Oil Co. v. Bicron Corp.* that trade secrecy can coexist with the federal patent system.[195] This is primarily because, as analyzed by the Court in *Kewanee*, the two types of protection are oriented towards different subject matter. The Court reasoned that trade secret law does not conflict with patent law: because trade secret law provides a "weaker" form of protection than does patent law, no rational inventor would opt for trade secret protection if patent protection were available.[196] The Court therefore concluded that trade secret law is unlikely to divert patentable inventions from disclosure and eventual entry into the public domain after the seventeen-year patent expires.[197] In addition, the *Kewanee* opinion observes that once ideas are in the public domain, trade secret law cannot conflict with the congressional goal of keeping those ideas freely available.[198] This policy "is not incompatible with the existence of trade secret protection. By definition[,] a trade secret has not been placed in the public domain."[199]

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[192] *Id.* at 151, 9 U.S.P.Q.2d (BNA) at 1852.

[193] *Id.* at 152, 9 U.S.P.Q.2d (BNA) at 1852.

[194] *See* S. Stephen Hilmy, Note, Bonito Boats' *Resurrection of the Preemption Controversy: The Patent Leverage Charade and the Lanham Act "End Around,"* 69 TEX. L. REV. 729, 736-37 (1991) (suggesting that the purpose of *Sears* and *Compco* was to sweep away state law of unfair competition); *see also Bonito Boats*, 489 U.S. at 154, 9 U.S.P.Q.2d (BNA) at 1853 (discussing the perceived sweep of *Sears* and *Compco*).

[195] 416 U.S. 470, 491, 181 U.S.P.Q. (BNA) 673, 682 (1974).

[196] *Id.* at 483, 490, 181 U.S.P.Q. (BNA) at 679, 681.

[197] *Id.* at 490-91, 181 U.S.P.Q. (BNA) at 681-82. *But see* sources cited *supra* note 62 and accompanying text.

[198] *Kewanee*, 416 U.S. at 484, 181 U.S.P.Q. (BNA) at 679.

[199] *Id.*, 181 U.S.P.Q. (BNA) at 679. In this regard, the *Kewanee* opinion tends to plays fast and loose with the term "public domain." The meaning of "public domain" for purposes of patent law may be quite different from that of "public domain" for purposes of trade secrecy. *See* Hilmy, *supra* note 194, at 746-47. Nonpatentability is not the same as publicity, yet the Court confuses the two concepts. *Id.* An invention may lie in the "public domain" because it is unpatent-

The standards articulated in *Kewanee* were reaffirmed in the subsequent *Bonito Boats* decision, but so too was the holding of *Compco*.[200] Consequently, although the *Kewanee* rationale allows the continued operation of state trade secret protection, its operation appears to be sharply circumscribed: trade secrecy may not be oriented toward either public domain subject matter that Congress wishes to leave freely available, or patentable subject matter that Congress wishes to entice into the public domain. So long as the trade secret criterion of secrecy is upheld—the knowledge is not publicly available and is retained by its possessor as confidential—the holdings of both *Kewanee* and *Compco* will be satisfied. However, interpretation of trade secrecy as extending to include subject matter otherwise in the public domain may offend the federal patent system.[201]

3. Biotechnology Subject Matter

Several factors in the Restatement test for trade secrecy tend to favor such protection for biological materials. As discussed above, the trial and error nature of biotechnology may lend itself to satisfying important factors in the subject matter evaluation. Development of biological materials and processes employing those materials has in general proved to be costly and time consuming. The value of such materials and processes to both a biotechnology producer and its competitor is high; the materials and information are crucial to manufacture of the product. Additionally, the difficulty and expense of recreating the knowledge are often high.

At the same time, the rapid advance of biological research and the academic character of the biotechnology industry may work to frustrate the requirement of secrecy. For example, in the litigation between Eli Lilly and Genentech discussed above, Lilly alleges that Genentech's purported trade secrets were available publicly and

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able subject matter, yet be withheld from the "public domain" because it is not public knowledge. *See id.* Although these two types of "public domain" characteristics may overlap, the *Kewanee* Court's implication that they are synonymous is disingenuous. *See id.*

[200] 376 U.S. 234, 140 U.S.P.Q. (BNA) 528 (1964).

[201] *See, e.g.*, Crown Indus., Inc. v. Kawneer Co., 335 F. Supp. 749, 761, 171 U.S.P.Q. (BNA) 401, 411 (N.D. Ill. 1971) (unless information is shown to be secret, federal preemption cases dictate that it remains in the public domain); *see also* Dynamics Research Corp. v. Analytic Sciences Corp., 400 N.E.2d 1274, 1288, 209 U.S.P.Q. (BNA) 321, 332 (Mass. App. Ct. 1980) (even if confidential relationship is present, public policy prevents trade secret restraint of public domain knowledge).

from third parties, and so fall outside the purview of trade secrecy.[202] Overcoming such a defense—proving that claimed trade secrets were *not* publicly available—may be extremely difficult in biotechnology. This is, in part, due to the same forces that spawned the biotechnology boom in the first instance: government-sponsored university research. Academic research has generated a large and growing literature in basic and applied biological science. The most obvious danger in trade secrecy is simply that somewhere in that vast literature someone has independently developed the secret that a firm seeks to assert is protected.[203]

The academic roots of small biotechnology firms create additional hazards for trade secrecy. The employees of many biotechnology firms may be strongly inclined to disseminate reports of their research, destroying the possibility for trade secrecy.[204] As already noted, commercial biotechnology researchers, because of their academic background, still seek the recognition and approval of their scientific peers.[205] To retain top researchers, biotechnology firms must often promise a working environment that approximates that of university research, including allowing researchers to publish their discoveries.[206] Publication is generally subject to company review to redact important proprietary information, but important information may slip through. Even assuming that there is no inadvertent publication of trade secrets, the firm is likely to be caught between the pressures of losing its trade secrets and generating job dissatisfaction among its scientists.[207]

The academic ties of the biotechnology industry may also generate more subtle traps. Because of their academic background, biotechnology researchers will tend to draw on information that is available and freely exchanged in universities. The basic "bread-and-butter" techniques of biotechnology are available in the literature; often they are collected into commercially published laboratory "cookbooks" in common circulation.[208] Such procedures, which are readily available to those skilled in the biological sciences, cannot be claimed as trade secrets, and combinations of these procedures will often be ineligible for trade secrecy as well.

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[202] *See supra* note 177 and accompanying text.
[203] *See* Epstein & Neelman, *supra* note 6, at 19.
[204] *Id.*
[205] *See supra* notes 153-159 and accompanying text.
[206] *See* Epstein & Neelman, *supra* note 6, at 19.
[207] *See id.*
[208] *See* Rowland, *supra* note 158, at 121.

The combination of such procedures will generally be constrained by the physical requirements of biological systems and so may be unprotectable as obvious approaches that would be used by any researcher familiar with the literature.

For example, in the case of a recombinant plasmid such as that supplied by Genentech under its agreement with Eli Lilly, the DNA gene sequence that codes for the desired pharmaceutical product is likely to be proprietary.[209] However, the other individual genetic elements that will be incorporated into the plasmid may be well known in the literature. Their combination is also likely to be apparent from the literature, because the placement of the genetic elements is constrained by the way the plasmid operates; for example, the genetic control element called the promoter must be attached to one particular end of the coding sequence in a particular orientation.[210] Otherwise, the plasmid will not function.[211] Assembly of such genetic elements may be too obvious from the literature to constitute a "secret." Attempting to protect the molecule as such may offend the constitutional balance set out in *Kewanee*.[212]

Additionally, the practice of supplying materials to other researchers may place the information or materials in the public domain, letters licenses notwithstanding. Trade secrets need not be absolutely secret, but they cannot be widely known. If materials and information are disseminated, at some point, the number of people holding the "secret" will become too large for secrecy: one cannot consistent with trade secrecy claim that the whole world, or even the whole biotechnology industry, knew certain information and was still bound by form letters to confidentiality.[213]

B. Breach of Confidence

As this last example suggests, the question of confidentiality itself may be troublesome in this industry. The existence of a protectable trade secret is a necessary prerequisite to a finding of trade secret misappropriation, but equally necessary is the exis-

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[209] *See supra* notes 170-71 and accompanying text.

[210] *See* WATSON ET AL., *supra* note 103, at 86.

[211] *See id.*

[212] *See supra* notes 32-43 and accompanying text.

[213] *See* Rowland, *supra* note 158, at 120. One commentator suggests that this is not so much a function of the number of licensees possessing the secret, but lack of an accurate account of who the licensees are. *Id.* (citing Packard Instrument, Inc. v. Reich, 412 N.E.2d 617, 213 U.S.P.Q. (BNA) 617 (Ill. App. Ct. 1980)).

tence of a confidential relationship.[214] Breach of confidence has long been considered the essential characteristic of trade secret misappropriation.[215] For strategic alliances in biotechnology, it may seem obvious that this requirement would be met; it is well settled that during a joint business venture, one partner may not disclose or use a trade secret to the other's detriment.[216] What is not well settled, however, is how this rule may operate in the peculiar context of the biotechnology industry.

1. Notice

In determining breach of a confidential relationship, courts have tended to focus upon notice of confidentiality. Disclosure of a trade secret carries with it a general duty of good faith, including a duty not to abuse the confidence.[217] However, this duty attaches only if the receiving party has notice of the confidential character of the disclosure.[218] Confidence cannot be imposed on another party without that party's implied or express consent, and the circumstances surrounding the relationship must have been such that the alleged breacher knew or should have known of the information's confidentiality.[219]

As a consequence, the conduct of the parties during the agreement will have a substantial impact on determination of proper notice. The disclosing party must take reasonable precautions to maintain secrecy not only to protect his secret substantively, but also to alert the other party that the information is in fact confidential.[220] The notice requirement fits closely to the substantive question, discussed above, of whether a trade secret in fact existed: the party to whom the information is disclosed is unlikely to believe he has a duty to keep confidential information that is apparently in the public domain.

Use of letters licenses or label licenses in biotechnology materials exchange may be inadequate to satisfy the notice requirement. The supplier of the materials will of course argue that the letters li-

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[214] *See* 12 MILGRIM ON TRADE SECRETS, *supra* note 7, § 4.03.
[215] *See* RESTATEMENT OF TORTS § 757 cmt. b.
[216] *See* 12 MILGRIM ON TRADE SECRETS, *supra* note 7, § 5.03[7].
[217] RESTATEMENT OF TORTS § 757 cmt. a.
[218] *Id.* cmt. j.
[219] *Id.*
[220] *See, e.g.*, Food Processes, Inc. v. Swift & Co., 280 F. Supp. 353, 366, 155 U.S.P.Q. (BNA) 640, 651 (W.D. Mo. 1966) (finding no notice of confidential nature of information because information was not treated as a secret).

cense is itself notice of confidentiality and contains confidentiality language. However, actions speak louder than words, and the suppliers' actions may contradict or belie this position if the materials are supplied to any requesting researcher.[221] One might also legitimately question whether scientists read or even notice the letters license accompanying a materials exchange. Recipients of data or materials will not take form letters seriously if they are in fact simply a formality.

In other cases, the letters license, or even a negotiated license, may be ambiguous enough that it is arguably inadequate to place the trade secret recipient on notice as to which matters are confidential. This is clearly a problem in the dispute between Eli Lilly and Genentech, particularly if the Lilly scientists believed that the materials they used in non-insulin projects were in the public domain, and the license was too vague to suggest otherwise.[222]

The party disclosing the trade secret could perhaps argue scientists should be familiar with the academic custom of not using or distributing borrowed materials without the permission of the original supplier. However, as letters licenses and negotiated licenses become the norm, it may be argued that this custom has been superseded.[223] Eli Lilly might convincingly argue, for example, that it believed any obligations of confidentiality were spelled out in the license, and Lilly scientists could reasonably assume that no confidentiality attached to any matters outside the license. Notice analysis then folds into interpretation of the license, and the effect of academic custom may become part of the license by implication.

2. Implied Contract

As the discussion on notice suggests, breach of confidence analysis will be substantially affected by the license or contract—when trade secrets are disclosed pursuant to such an agreement, the license or contract will define the confidential relationship between the parties.[224] In situations in which misappropriation is alleged, the terms of the license will likely be in dispute, and as a corollary, so too will be the character of the relationship. This is particularly

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[221] *See* Rowland, *supra* note 158, at 120.

[222] *See supra* notes 174-177 and accompanying text.

[223] *See* Rowland, *supra* note 158, at 107-08.

[224] Indeed, trade secret liability based on the doctrine of breach of confidential relationship sounds in contract, whereas trade secret liability based on misappropriation sounds in tort. *See* Ramon A. Klitzke, *Trade Secrets: Important Quasi-Property Rights*, 41 BUS. LAW. 555, 557 (1986).

true when the circumstances of the dispute are not expressly addressed by the license.

In such situations, a court may have to assess the parties' relationship as a contract "implied in fact."[225] Looking to the circumstances surrounding the contract, including the parties' actions and writings, the court determines whether the parties intended to bind themselves to some terms that were not expressly stated.[226] Custom in an industry may indicate the unwritten meaning that the parties attach to the contact terms.[227] Or, one party's awareness that the terms of the contract are being given a particular meaning by the other party will create an obligation implied in fact.[228] In addition, some inferences are reasonable about any contract, for example, that in committing to a contractual obligation, a party will not hinder or frustrate performance of that obligation.[229]

Where trade secrets are concerned, disclosure of a trade secret within a confidential relationship carries with it an implied obligation not to disclose or misuse the trade secret to the detriment of the other party.[230] It is well settled that the privilege to use or disclose the secret may be implied from surrounding circumstances such as the trade secret owner's conduct.[231] Thus, all the indicia of implied-in-fact contract analysis—the language of the agreement, the conduct of the parties, and the custom of the industry—will be relevant to determining the parameters of this obligation.

For example, the practice of transferring biological materials via letters license may create a need to interpret the parties' relationship by implication; the language of such transfer agreement is sparse and, if disputed, may require judicial clarification.[232] The trade secret misappropriation claims advanced against Eli Lilly by

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[225] *See* 3 ARTHUR L. CORBIN, CORBIN ON CONTRACTS § 561 (1960).
[226] *Id.* § 562.
[227] *Id.* § 561.
[228] *Id.*
[229] *Id.*
[230] *See* 12 MILGRIM ON TRADE SECRETS, *supra* note 7, § 4.02.
[231] RESTATEMENT OF TORTS § 757 cmt. d.
[232] *See* Rowland, *supra* note 158, at 106. Some of these issues were fleetingly raised in the dispute between the French Institute Pasteur and the U.S. government. *See* Lipsey et al., *supra* note 8, at 22-23. Viral materials isolated by French AIDS researchers were transferred to U.S. laboratories accompanied only by a one-page letters license. *Id.* at 23. The U.S. laboratory subsequently filed a patent application for an AIDS diagnostic kit and licensed its manufacture to five U.S. companies. *Id.* The French filed suit for breach of express and implied contracts. *Id.* The suit was later settled by acknowledging the contributions of the French researchers and sharing royalties from the resulting products. *See* Brezner et al., *supra* note 9, at 506-07.

Genentech might also be characterized as implied-in-fact licensing claims: the parties dispute whether the license covered the use of Genentech's information outside of recombinant insulin manufacture.[233]

A court considering such claims under an implied-in-fact contract theory would consider essentially the same factors that were discussed above with regard to notice, including the customs attending materials transfers and the trade secret holder's security precautions.[234] The inquiry would be directed toward determining the parties' understanding of the licensing terms not as a matter of notice of confidentiality, but as a matter of intent to be bound by the terms. Although these inquiries closely parallel one another, they are not coextensive: claims for trade secret misappropriation may go beyond breach of contract.[235] However, the implied-in-fact contract inquiry promises to be an important subset of trade secret analysis in biotechnology licensing.[236]

V. Conclusion

Relatively little trade secret litigation has arisen from licensing in the biotechnology industry, in part because the industry is only now reaching an age at which the subject matter of trade secrets is important to commercial success. Some litigation is inevitable, and perhaps even desirable, to define for the whole industry the questions of trade secret subject matter, notice, and implied obligation discussed here. Until these areas are resolved, an awareness of the peculiar characteristics of this industry and its underlying technology will help in anticipating potential disputes and in drafting license agreements to avoid them where possible.

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[233] *See supra* notes 174-177 and accompanying text.
[234] *See supra* notes 215-218 and accompanying text.
[235] *See* Restatement of Torts § 757 cmt. j.
[236] *See* Brezner et al., *supra* note 9, at 516; Lipsey et al., *supra* note 8, at 23.