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Biotechnology's Challenge to the Law of Torts

Julie A. Davies* and Lawrence C. Levine**

I. INTRODUCTION

The tort issues that may potentially arise in the biotechnology arena are as vast and varied as tort law itself. All three of the general bases for tort liability may be implicated. There can be intentional torts, such as conversion or trespass to land, negligence arising from unreasonable conduct, and even strict liability from either an abnormally dangerous activity or product defects.

Before considering potential tort liability, we need to address a fundamental preliminary issue. Although tort issues *can* arise readily in the biotechnology context, an essential question is whether traditional tort principles *should* apply to biotechnology-created harms. Some scholars have argued forcefully that the biotechnology arena is so unique that it should be exempted from traditional tort liability.¹ Other commentators have suggested a less dramatic route, advocating a restricted role for the tort system in the biotech context.² A third option, of course, is to treat injuries caused by biotechnology the same as other harms.

The advocates for removing biotech from the tort system stress the uniqueness of the industry. They contend that even negligence liability is too burdensome on the developing and vital biotech industry. Dan Burk and Barbara Boczar, for example, view biotechnology as a "strategic industry," an enterprise fundamental to entire industrial sectors of American society and, perhaps, critical to the economic success of the country itself.³ They contend that applying the current tort system to products and processes created by biotechnology will severely impede the

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1. See, e.g., Dan L. Burk & Barbara Boczar, *Biotechnology and Tort Liability: A Strategic Industry at Risk*, 55 U. PITT. L. REV. 791 (1994)[hereinafter Burk & Boczar].

2. See, e.g., Joseph L. Amos Jr., *Advanced Technology and Tort Law: Reasonable, Responsible Standards*, 58 DEF. COUNS. J. 198 (1991) (hereinafter Amos) (arguing against strict liability for injuries caused by biotechnology, but supporting liability for negligence); Eleanor M. Fox and Michael Traynor, *Biotechnology for Human Life and Health—The Special Case for Negligence—Only Rule to Promote Critical Innovation*, 6 HIGH TECH. L. J. 1 (1991) (arguing against strict liability for harms caused by biotechnological products, but supporting liability for negligence).

3. Burk & Boczar, *supra* note 1, at 791-806. The authors see biotechnology as affecting a wide range of products and manufacturing processes in countless industries. They compare the impact of biotechnological developments to that of the railroad in the nineteenth century, which opened new markets for agricultural and manufactured goods.

development of a vital industry. Ultimately, Burk and Boczar propose a no-fault legislative solution which removes biotechnological harms from the tort system.⁴

The authors who recommend a more modest approach than the wholesale removal of biotechnology from the tort system generally favor eliminating strict liability as a viable legal theory. These commentators suggest that fault-based liability (such as negligence) is the only appropriate basis on which tort liability may rest. They argue, for example, that negligence provides a more workable framework because there would be an appropriate consideration of the industry practices in a determination of reasonableness.⁵

We join those commentators who have determined that there is nothing so special about biotechnology and the products it creates that special treatment is merited. Despite Burk and Boczar's valiant effort, we are not persuaded that biotechnology is so distinct from other harm-generating enterprises that it warrants an exemption from tort liability.⁶ Further, we think that strict liability should apply in appropriate cases.⁷ Thus, for purposes of this Article, we assume that traditional tort principles should and do apply to harms brought about in the biotechnology context.

4. Burk and Boczar concede that many of their arguments could be made by other scientifically complex and important enterprises as well (e.g., the entire pharmaceutical industry) in an effort to exempt themselves from tort liability. Burk and Boczar, however, view the biotechnology industry as particularly vulnerable because of the structure of the industry, the difficulty in assessing risk given the novelty of the products and technology, and because of a generalized, though unfounded, public distrust of the industry. *Id.* at 834-39.

5. Amos, *supra* note 2, at 200. Mr. Amos also argues that negligence liability would "provide strong incentives for potentially co-liable defendants to act under a joint and several liability framework." *Id.* We do not see why joint and several liability would not apply as well if strict liability were the basis for liability. *See infra* notes 29-35 and accompanying text.

6. It is hard to believe that Burk and Boczar would favor exempting a company from tort liability if its contribution to humanity was the development of a genetically engineered tobacco designed to have twice the nicotine of naturally produced tobacco. *See* Barry Meier, *Tobacco Company Subject of Investigation, Officials Say*, N.Y. TIMES, May 11, 1998, at A3 (discussing a criminal plea from a small biotech company that worked under contract with Brown & Williamson to develop genetically engineered tobacco with double the nicotine of leaf tobacco). At any rate, we would not.

Additionally, we note that, while the challenges to biotech companies can be substantial, large corporations (often pharmaceutical concerns) frequently fund these enterprises which are proving quite profitable. Cynthia Robbins-Roth, *Magic Bullets, the Breakthroughs, the Business and the People of Biotechnology*, FORBES ASAP, May 31, 1999, at 42.

7. *See* Debra Dahl, Note, *Strict Product Liability for Injuries Caused By Recombinant DNA Bacteria*, 22 SANTA CLARA L. REV. 117 (1982) (arguing for use of strict products liability for harms caused by products using recombinant DNA bacteria).

Rather than discuss every possible tort that could arise,⁸ we highlight in this brief piece the several areas where tort liability is most likely to arise: trespass to land, conversion, negligence,⁹ strict liability for abnormally dangerous activities and, most critically, strict products liability.

II. INTENTIONAL TORTS

There may be liability for intentional torts in the biotechnology context. The two intentional torts most likely to arise are trespass to land and conversion.

A. *Trespass to Land*

Use of genetically engineered crops creates a significant risk of trespass to land. Trespass to land arises where a defendant intentionally enters the land of another or intentionally causes something to enter the land of another. Although intent is required, it is the intent to enter the land, not the intent to trespass, that is key.¹⁰ Thus, if a defendant enters the plaintiff's land reasonably believing that she has permission to do so, or even under a reasonable belief that the property is hers, she will be liable for trespass to land.

In the biotechnology context, if the defendant knows that it is substantially certain that seeds from her pesticide-resistant plants will find their way on to the

8. A vast array of torts issues could arise in the biotechnology context. For example, criticism of products created through biotechnology could lead to a product defamation action. See RESTATEMENT (SECOND) OF TORTS § 626 (1977) (allowing a defamation action, known as trade libel, for the disparagement of the quality of the plaintiff's goods that caused him pecuniary loss or difficulty in selling the goods); see also Margaret A. Jacobs, *Public-Interest Groups Want Law On Product Defamation Killed*, WALL ST. J., Feb. 25, 1998, at B5 (detailing the recent enactment of "veggie libel" laws in several states allowing agricultural producers to bring more easily defamation actions to defend their products); *Jury Decides in Favor of TV Star Winfrey In Suit by Cattlemen*, WALL ST. J., Feb. 27, 1998, at B19 (providing a recent example of trade libel brought against television talk show host Oprah Winfrey by cattle producers). Other possible bases of liability include liability for breach of confidentiality and public disclosure of private facts. These causes of action are an ever-growing possibility as more and more people have access to information such as a person's predisposition to certain diseases and genetic disorders. See Roberta Berry, *The Genetic Revolution and the Physician's Duty of Confidentiality: The Role of the Old Hippocratic Virtues in the Regulation of the New Genetic Intimacy*, 18 J. OF LEGAL MED. 401 (1997) (discussing a doctor's obligation to keep her or his patients' genetic information confidential); Cara Dunne & Catherine Warren, *Lethal Autonomy: The Malfunction of the Informal Consent Mechanism Within the Context of Prenatal Diagnosis of Genetic Variants*, 14 ISSUES IN L. & MED. 165 (1998) (discussing a genetic counselor's duty of disclosure); L.J. Deftos, *Genomic Torts: The Law of the Future—The Duty of Physicians to Disclose the Presence of a Genetic Disease to the Relatives of their Patients with the Disease*, 32 U.S.F. L. REV. 105 (1997) (detailing the duty of physicians to disclose genetic information to patients' relatives); Lori Andres, *Body Science*, ABA J., Apr. 1997, at 44 (discussing the growing debate over the use of information obtained from genetic testing of individuals).

9. No doubt negligence will be a common cause of action in the biotech context as it is in most others. Negligence liability arises where the defendant has failed to act with due care. We do not see any special negligence issues in the biotech context that would not apply equally in other contexts involving highly technical matters. Accordingly, we limit our discussion in the piece to intentional torts and strict liability.

10. JOHN L. DIAMOND, LAWRENCE C. LEVINE & STUART MADDEN, UNDERSTANDING TORTS § 18.02 [B], at 388-89 (1996).

plaintiff's property, she can be liable for trespass to land.¹¹ Further, she is liable for all harm that ensues as a result of the trespass.¹² Genetically engineered crops pose a real risk of trespass to land liability if they cross-pollinate with neighboring plants or otherwise contaminate the land of adjoining land owners.

B. Conversion

The intentional tort that thus far has received the most attention in the biotechnology context is the tort of conversion. Conversion arises when a defendant intentionally exercises "dominion and control over a chattel which so seriously interferes with the right of another to control it that the actor may justly be required to pay the other the full value of the chattel."¹³ Although an intentional tort, as with trespass to land, it is simply the intent to do the act—here the exercise of dominion and control—that gives rise to liability.

The propriety of a conversion action in the biotechnology context was first considered in the now-famous case of *Moore v. Regents of the University of California*.¹⁴ Moore had been undergoing medical care for hairy-cell leukemia, a rare and potentially fatal form of cancer. As part of the medical treatment for the disease, Moore's spleen was removed, a standard treatment for the disease. The defendants used Moore's spleen to develop a cell-line that was patented and highly valuable.¹⁵ Moore had no knowledge of the defendants' commercial use of his cells. In fact, Moore was induced to make about a dozen trips to the defendants under the guise of continuing medical treatment when, in fact, the trips were solely to assist the defendants with their ongoing commercial use of Moore's cells. Moore sued, alleging several torts including conversion. A divided California Supreme Court reversed an appellate court that had permitted Moore to pursue a conversion claim.¹⁶

11. See Allen R. Myerson, *Cotton Growers Say Strain Cuts Yields*, N. Y. TIMES, Nov. 19, 1997, at D2 (discussing genetically engineered gene designed to make cotton plants resistant to Roundup weed killer); see also Stephen Kelly Lewis, Comment, "Attack of the Killer Tomatoes?" *Corporate Liability for the International Propagation of Genetically Altered Agricultural Products*, 10 TRANSNAT'L LAW 153 (1997) (discussing how genetically altered plants can cross-pollinate across international borders); Gary Stix, *The Butterfly Effect*, SCI. AM., Aug. 1999, at 28 ("One company, Terra Prima, had to recall 80,000 bags of organic corn chips because the corn was found to be contaminated with residues of genetically modified corn that had blown into organic farmers' fields.").

12. According to the Restatement, a trespassing defendant is liable for all harm caused by the trespass even if faultlessly caused and even if unforeseeable. RESTATEMENT (SECOND) OF TORTS § 163 (1965).

13. *Id.* at § 222A.

14. 51 Cal.3d 120, 128-29, 793 P.2d.479, 483, 271 Cal. Rptr. 146-150 (1990).

15. The cell line had a potential value exceeding \$3,000,000,000. Moore was not told of the value of the cell line until the patent had already been approved. *Id.* at 482.

16. The court did permit Moore to proceed on his claims for breach of fiduciary duty and lack of informed consent. *Id.* at 483-88.

The *Moore* decision was a tremendous victory for the biotechnology industry.¹⁷ The decision foreclosed a conversion action against those who exercised dominion and control over the patient's tissue samples without the patient's consent.¹⁸ The majority determined that Moore's cells were not property and, thus, could not be converted.¹⁹ The court admitted that its conclusion was reached in an effort to protect medical research, which, the majority believed, could have been harmed by permitting conversion liability.²⁰

The impact of *Moore* remains substantial and its application to biotechnological harms is yet to be seen. For example, one author argues that the tort of conversion should apply in the context of the misappropriation of human eggs and embryos, notwithstanding the restrictive holding of *Moore*.²¹ Such an action, however, may well be foreclosed if a court elects to adopt the California Supreme Court's reasoning in *Moore*.

III. STRICT LIABILITY

Strict liability, though quite rare and controversial in modern American tort law, may apply to biotechnologically created harms. In general, strict liability applies in very limited contexts, such as injuries caused by wild animals, abnormally dangerous activities and defective products. The latter two may be relevant in the biotechnology context and are examined in turn.²²

17. James P. Leeds, Note, *Moore v. Regents of the University of California: More for Biotechnology, Less for Patients*, 25 IND. L. REV. 559, 586 (1991) (criticizing the decision for failing to sufficiently protect patient rights); Michael Traynor et al., *Moore v. Regents of the University of California*, LOS ANGELES LAW., Oct. 1990, at 38 (calling the *Moore* decision "a victory for the biotechnology industry," while supporting its outcome).

18. Traynor, *supra* note 17, at 39 ("If [a conversion claim] applied to the human tissue samples that form the basis for a high percentage of biotechnology research, it would have exposed medical researchers and biotechnology companies to potentially devastating liability" in light of conversion's broad reach and generous remedy).

19. 793 P.2d at 488-89.

20. *Id.* at 493-97.

21. Judith D. Fischer, *Misappropriation of Human Eggs and Embryos and the Tort of Conversion: A Relational View*, 32 LOY. L.A. L. REV. 381 (1999). Professor Fischer makes several persuasive arguments in her effort to distinguish the reproductive context from the misappropriation of other human body products, such as Moore's tissue. She points to the highly personal nature of human reproduction, to the other causes of action available to a person in Moore's situation, and to the fact that Moore's spleen cells were abandoned, unlike eggs and embryos. *Id.* at 406. Despite Professor Fischer's efforts to distinguish *Moore*, it appears that she truly believes that the *Moore* decision is wrong in its refusal to permit the plaintiff to pursue a conversion remedy. For example, she points out that an "overarching criticism of the *Moore* decision rests on its failure to sufficiently weigh personal considerations" and she cites the dissenters' arguments favorably. *Id.* at 405.

22. For strict liability due to an abnormally dangerous activity, the focus is on the activity in which the defendant is engaged. Strict liability applies in the product liability context where the product itself proves defective.

A. *Abnormally Dangerous Activities*

Where a defendant is engaged in a so-called abnormally dangerous activity, she is strictly liable for harm she causes even absent proof of fault on her part. While there are many proffered explanations for this rule, an underlying justification is that there are certain undertakings that are so inherently dangerous that fairness dictates that those engaging in them should bear the costs of harms that ensue.²³ Biotechnology-related harms arising from a defendant's activity may prove to be exactly the sort of undertaking that will be deemed abnormally dangerous, thereby leading to strict liability.

For strict liability to apply in the abnormally dangerous context, two factors are key: first, the activity must present a high level of unavoidable danger, and, second, the activity must not be a common one.²⁴ Ironically, those who advocate most strongly for the exemption of biotechnologically created injuries from the tort system may ultimately be making the strongest case for strict liability in the abnormally dangerous activity context. For example, in their thoughtful article, Burk and Boczar repeatedly point out that no matter how well tested and despite the degree of care used, biotechnology may create harm. They note, for example, that "biotechnology products arise in the highly complex milieu of living organisms, where the interaction of hundreds of biochemical pathways lends an atmosphere of *inherent unpredictability to the technology*."²⁵ Further, while the use of biotechnologically created products is increasing, it still is unlikely to be viewed as commonplace.²⁶

In fact, the modern development of strict liability arose in the context of competing land uses, situations where a plaintiff's land was injured due to activity

23. Professor King asserts that the multiple goals supporting strict liability for abnormally dangerous activities are fairness, administrative efficiency, protection of individual autonomy, loss allocation, loss avoidance, and loss spreading. Joseph H. King, Jr., *A Goals-Oriented Approach to Strict Liability for Abnormally Dangerous Activities*, 48 BAYLOR L. REV. 341 (1996) (criticizing the current treatment of strict liability for abnormally dangerous activities and advocating a more restrictive approach).

24. The Second Restatement of Torts in a rather controversial approach provides for a balancing of factors to determine whether a given activity should properly be viewed as abnormally dangerous. See RESTATEMENT (SECOND) OF TORTS § 520 (1977) (providing six factors for a judge to weigh).

25. Burk & Boczar, *supra* note 1, at 832 (emphasis added); see also Amos, *supra* note 2, at 199-200, warning that: "[S]ignificant risks attend the new technology. Genetically altered bacteria are dangerous because they are designed to outcompete organisms already existing in the environment, and they could radically alter the ecological balance of an entire region. The commercial marketing of [recombinant] DNA organisms may cause new untreatable diseases or develop virulent unknown strains of crop-ravaging parasites. Additional problems might arise if, along with a beneficial gene, a gene with a repressed function is introduced, making the bacteria fatally toxic to plant, animal, or man."

26. See, e.g., *Langan v. Valicopters, Inc.*, 567 P.2d 218, 223 (Wash. 1977) (holding that cropdusting is not so common as to be exempted from strict liability). But see Amos, *supra* note 2, at 201. Mr. Amos weakly tries to contend to the contrary noting that "[g]enetic research is increasing, and its techniques are becoming common; it should not be considered 'abnormally dangerous.'" *Id.*

by the defendant on the defendant's neighboring property.²⁷ This is exactly the context in which biotechnological-based strict liability will most likely arise. For example, if a farmer planted a crop genetically designed to resist application of certain pesticides, and the crop spread to neighboring property, it could pass the pesticide resistance on to other plants, such as weeds, which could harm the neighbor's crops.²⁸ The use of genetically engineered plants is one that involves an unavoidable risk of serious harm and it is not a commonplace activity. Strict liability appears to be an appropriate theory in such a situation.

B. *Strict Products Liability*

As products created by biotechnological methods make their way into the marketplace, it seems likely that if and when personal injury or property damage result, the victims will invoke the theory of strict liability for defective products.²⁹ Despite the fact that the biotech industry has been developing products for the last twenty-five years,³⁰ biotechnology products have not been the subject of strict products liability actions until very recently.³¹ Despite the virtual absence of litigation, enough genetically engineered products now exist on the market that the potential for liability is real.

As noted at the beginning of this Article, the overriding policy issue in this area is whether biotechnology products, or the biotechnology industry, are so different from other products and manufacturers that departure from traditional tort law is

27. *Rylands v. Fletcher*, 3 L.R.- E. & I. App. 330 (H.L. 1868) (finding that a defendant, who is using property for milling, must pay neighbor, using his property for mining, even though defendant is not at fault because milling is a non-natural use of the land).

28. See Warren E. Leary, "Gene Inserted in Crop Plant is Shown to Spread to Wild," N.Y. TIMES, Mar. 7, 1996, at B5. ("A field study has shown that a gene inserted into a crop plant can easily be transferred to a close relative, highlighting potentially unseen consequences of the genetic engineering of plants . . . The unwanted gene exchange has been a particular concern with herbicide tolerance."); Carol Kaesuk Yoon, "When Biotechnology Crops and Their Wild Cousins Mingle," N.Y. TIMES, Nov. 3, 1999, at A18 (reporting that recent studies of radishes, grain sorghum, canola and sunflowers found that genes moved quickly and easily from crops to wild relatives). Harm other than resistance to pesticides, can lead to strict liability as well. For example, a company was forced to recall 80,000 bags of organic corn chips when it discovered that the corn it used had been contaminated with residues of genetically modified corn that had blown onto the organic farmers' fields. Gary Stix, *The Butterfly Effect*, SCI. AM., Aug. 1999, at 28. The farmer growing the genetically modified corn could be held strictly liable. Cf. *Langan v. Valicopters, Inc.* 567 P.2d 218 (Wash. 1977) (imposing strict liability against cropduster who rendered the plaintiffs' organic produce unfit to sell as "organic" due to pesticide residue.).

29. Strict products liability is recognized in the RESTATEMENT (SECOND) OF TORTS § 402A (1965), in the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 1 (1998), and in the case law of numerous jurisdictions.

30. Over the past twenty five years, over two thousand biotechnology firms have been founded. U.S. Dept. of Commerce, Office of Technology Policy, *Meeting the Challenge: US Industry Faces the 21st Century—The U.S. Biotechnology Industry* 9 (1997).

31. An extensive search of both reported case law and the popular press revealed only one case that could be identified as products liability litigation. On December 14, 1999, suit was filed against Monsanto alleging that the company rushed genetically engineered seeds to the market without properly testing them, and that the company formed an international cartel that conspired to control the market in soybean and corn seeds. David Barboza, *Monsanto Sued Over Use of Biotechnology in Developing Seeds*, N.Y. TIMES, December 15, 1999, at C1.

warranted. A number of commentators strongly believe that the biotechnology industry is so important to human health and to national self-interest, that strict products liability should not apply.³² These arguments merit serious consideration. Commentators believe that product liability law will erode innovation and commercial growth within the biotechnology industry.³³ Some believe that medical products produced through biotechnological techniques offer unique benefits, above and beyond those that can be provided by traditional drugs, and that current case law is a disincentive to the development of those products.³⁴ In addition, because American law has not yet addressed issues involving biotechnology and the application of strict products liability, potential defendants such as biotechnology firms lack the ability to predict how courts will address liability when the issues arise. Other countries, such as Germany, have enacted legislation that will govern liability for some injuries that arise from use of biotechnology.³⁵

As we noted above, neither courts nor legislatures have yet accepted arguments for completely exempting biotech products from strict products liability. It may well be that the protection existing law gives to producers of other products of high social utility, such as prescription drugs, will be deemed sufficient.³⁶

Assuming then that injuries occurring as result of products created through biotechnology receive the same treatment by the legal system as other products, we can begin to think through the major issues that will arise. It appears likely that firms that design and implement bio-engineered products can properly be included within the reach of strict products liability law. Under the Restatement and the law of most jurisdictions, strict products liability applies to manufacturers and others in the chain of supply.³⁷ Further, the law in many jurisdictions is quite broad as to the range of potential plaintiffs who may bring suit, encompassing persons injured by products who are not the purchaser or even the user.³⁸ Thus, it seems fair to say there may be

32. Fox & Traynor, *supra* note 2; James T. O'Reilly, *Biotechnology Meets Products Liability: Problems Beyond the State of the Art*, 24 HOUS. L. REV. 451 (1987).

33. Michael D. Stovsky, Comment, *Product Liability Barriers to the Commercialization of Biotechnology: Improving the Competitiveness of the U.S. Biotechnology Market*, 6 HIGH TECH L. J. 363, 372-379 (1991); Fox & Traynor, *supra* note 2, at 7, 20 (1991).

34. O'Reilly, *supra* note 32, at 452-53.

35. Lewis, *supra* note 11, at 1993 (describing Germany's Genetic Technology Act, which imposes strict liability, criminal penalties under some circumstances, a requirement that insurance be obtained and a cap on the recovery amount). It is worth noting that though the German system seems to resemble the no-fault system Burk and Boczar urge, Germany is widely viewed as highly antagonistic to the biotechnology industry. Nathaniel C. Nash, *Germany Shuns Biotechnology*, N. Y. TIMES, Dec. 21, 1994, at D3.

36. See *infra* notes 44-49 and accompanying text (discussing the exemption of certain products because of their social utility).

37. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. f (1965) ("The rule stated in this Section applies to any person engaged in the business of selling products for use or consumption. It therefore applies to any manufacturer of such a product."); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 1 cmt. c (1998) (upholding the same principle with no significant alteration in language).

38. While the Second Restatement expressed no opinion on whether bystanders may recover for defective products, RESTATEMENT (SECOND) OF TORTS § 402A cmt. o (1965), many courts have allowed this type of plaintiff to recover, see, e.g., *Elmore v. American Motors Corporation*, 70 Cal. 2d 578, 75 Cal. Rptr. 652, 451 P.2d 84

a large group of potential plaintiffs.³⁹ For example, if Farmer A purchases genetically engineered cotton seed that produces blue cotton, and that blue cotton cross-pollinates with white cotton grown by Farmer B a mile away, damaging B's crop, under current law B should be permitted to bring suit against the blue cotton manufacturer even though B did not purchase or use the genetically engineered cotton.⁴⁰

The largest hurdle in strict liability cases is proving that the product is defective in design or manufacture.⁴¹ Manufacturing defects are typically the easiest types of defect to prove; under the Restatement (Second) of Torts, the question is whether the product performed as safely as the ordinary consumer would expect.⁴² While this test is easy to apply in cases of exploding coke bottles or faulty hasps on a truck, it may be harder to apply when products are created through bio-engineering. The average consumer may have no expectation regarding the product he or she buys, or, may have a general expectation of safety without any true understanding of certain risks or side effects, even if these are explained. The ambiguity of the consumer expectation test, however, is common also to non-biotechnology cases.⁴³

It is difficult to predict whether the ambiguity of the test for a production defect will in fact be problematic in cases involving bio-engineered products. Courts have simply not yet confronted the dilemma of whether and how alleged defects in bio-

(1969); *Mitchell v. Miller*, 26 Conn. Supp. 142 (1965). The Third Restatement is in accord, allowing recovery to all persons injured, not merely consumers. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 1 (1998).

39. The potential breadth of plaintiffs is not so much a function of unique risks posed by bio-engineered products as an application of well-established tort law.

40. It should be noted that on these facts both strict products liability and abnormally dangerous activity strict liability theories might apply. See *supra* notes 23-28 and accompanying text discussing strict liability for abnormally dangerous activities. There may be significant doubt as to whether the development or growth of a blue cotton variety should be characterized as an abnormally dangerous activity or a defective product. In a sense, the bio-engineered seed is only doing what happens naturally through cross-pollination of plants. However, bio-engineering isolates traits that might not occur as readily in nature and speeds up the process of genetic change that occurs naturally.

41. Manufacturing defects are those that affect only one or a few products out of a given product line; they represent flaws in the manufacturing process. Design defects affect an entire product line; they represent aspects of the manufacturers intended design that are later judged defective. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. d (1998) ("Whereas a manufacturing defect consists of a product unit's failure to meet the manufacturer's design specifications, a product asserted to have a defective design meets the manufacturer's design specifications but raises the question whether the specifications themselves create unreasonable risks.").

42. RESTATEMENT (SECOND) OF TORTS § 402A (1965) cmt. g. The Restatement Third defines a manufacturing defect as one that arises when a product "departs from its intended design." RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. d (1998). The consumer expectation test is retained for cases involving foods. *Id.* cmt. g.

43. Some commentators have criticized the consumer expectations test as inadequate for determining the defective nature of a product: "[T]here is a fallacious assumption underlying the . . . test that the ordinary purchaser knows what he is buying. In most cases, the purchaser does not have any idea about the safety or danger of what he is buying. He is generally buying on price, on beauty, and on function . . . [S]ometimes consumers have no definite expectations about what they are purchasing, and in these instances the jury can only speculate as to a product's defectiveness." W. Page Keeton, *The Meaning of Defect in Products Liability Law—A Review of Basic Principles*, 45 MO. L. REV 579, 591 (1980). The Third Restatement's redefinition of the test for manufacturing defects should alleviate this ambiguity if courts begin to follow it.

engineered products fit within the traditional analytical niches. To anticipate how these questions will be answered, one must predict whether defects that occur will pervade every bio-engineered product of a certain type that is produced and therefore be deemed design flaws, or whether the defects will be sporadic and easily identifiable as a departure from the intended output and therefore deemed manufacturing flaws. Also, defects could arise that hybridize the two existing concepts. For example, a defect in an inspection or quality control process could result in failure to detect an impurity in a bio-engineered product. A defect of this character would share attributes of both manufacturing and design defects. For purposes of this Article, however, one can reasonably assume that some types of design defect will be alleged. The question then, will become how the vast case law regarding design defect liability will apply.

Under both the Second and Third Restatements of Torts, certain products are exempt from liability for design defects.⁴⁴ This protection is commonly afforded to prescription drugs, and is likely to be sought for many products that are developed through biotechnology methods. In many jurisdictions, courts decide which products are to be exempt from design defect analysis on a case by case basis.⁴⁵ Thus, they could evaluate a new vaccine and determine if its usefulness is high enough, and its risks unavoidable enough, to merit protection from design defect analysis. Some products viewed as central to health would qualify without question; others, such as hair-growth drugs, or weight loss panaceas, might well not qualify. In some jurisdictions, such as California, all prescription drugs are exempt from liability on the basis of design defects.⁴⁶ The California court was convinced that unless manufacturers knew from the outset that they would not be strictly liable for design defects, they would not invest the money necessary to develop drugs.⁴⁷ Given the enormous costs associated with production of new products using biotechnology,⁴⁸

44. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965); see also Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment K*, 42 WASH. & LEE L. REV. 1139 (1985). RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (1998); Teresa Moran Schwartz, *Prescription Products and the Proposed Restatement (Third)*, 61 TENN. L. REV. 1357 (1994).

45. Hill v. Searle Lab., 884 F.2d 1064, 1069 (8th Cir. 1989); Toner v. Lederle Lab., 732 P.2d 297, 309 (Idaho 1987); Glassman v. Wyeth Lab., 606 N.E. 2d 338, 342 (Ill. 1992); Savina v. Sterling Drug, 745 P.2d 915, 924 (Kan. 1990); White v. Wyeth Lab., 533 N.E. 2d 748, 752 (Ohio 1988); Tansy v. Dacomed, 840 P.2d 881, 886 (Okla. 1994).

46. Brown v. Superior Court, 751 P. 2d 470, 477 (1988).

47. The California Supreme Court based its protection of prescription drugs on the rationales present for comment k. Prescription drugs, because of their use and need, were felt to be similar to examples of treatments granted immunity under comment k because of their high utility. The court interpreted the test set down in comment k for these products as being based in negligence; liability will not be applied without fault. *Id.* at 475. To apply strict liability might dissuade companies from forwarding new drugs and treatments for fear of massive liability: "because of the public interest in the development, availability, and reasonable price of drugs, the appropriate test for determining responsibility is the test stated in comment k": negligence. *Id.* at 477.

48. Biotech is an industry known for slow growth at high expense. See Michael S. Malone, *The Lag*, FORBES ASAP, May 31, 1999, at 64 (providing the example of Scios, a company with eighteen years of effort but not one approved drug on the market); Lee C. Patterson, *Out of Control*, FORBES ASAP, May 31, 1999, at 73 (noting that, on average, it costs one biotech company \$350 million and seven to ten years in the effort to achieve approval of

the same arguments could no doubt be made forcefully. However, it remains to be seen whether courts are willing to grant the biotech industries such broad protection. The Restatement (Third) of Torts, if adopted by courts, will expand the protection that comment k affords in the Restatement (Second), because it specifically encompasses prescription drugs and medical devices.⁴⁹ However, even this expanded protection from design defect liability could leave unprotected significant areas such as agriculture.

Assuming then, that at least some injury-producing products created through biotechnological methods are subjected to strict liability for defective design, the question is whether the analysis will differ in any significant way from ordinary design defect cases. In jurisdictions that use a risk/utility balancing test, and in jurisdictions that require proof of a reasonable alternate design,⁵⁰ plaintiffs may have to be creative in applying the law. As an example, consider a genetically engineered fungus which is under development by Ag/Bio Con.⁵¹ The purpose of this fungus is to attack marijuana plants, and thereby serve as a tool in crime prevention.⁵² One fear, of course, is that the fungus might possibly mutate once released, injuring crops and the environment.⁵³ If that fear were realized, the plaintiff alleging a design defect would, of course, be required to present evidence, from which the jury would evaluate the risks of the design, the probability it would produce injury, and design alternatives. To meet this burden of proof, the plaintiff would most likely need an expert to testify as to scientifically feasible design alternatives. The need for such evidence is even clearer under the Restatement (Third), because proof of a reasonable alternative design is mandatory.⁵⁴ Regardless of the standard used, one wonders whether the plaintiff could actually present the required evidence. What is the alternative to a genetically-engineered fungus?⁵⁵ Would the plaintiff need to

one drug).

49. In addition to its broader scope, the Restatement (Third) also appears to lower the threshold for exemption from strict products liability. Whereas comment k of the Restatement (Second) described the eligible products narrowly, those that are "quite incapable of being made safe for their intended and ordinary use," the Restatement (Third) appears to exclude from strict products liability most prescription drugs and medical devices. It would impose liability on a design defect theory only when prescription drugs or medical devices have foreseeable risks of harm that are sufficiently great in relation to their foreseeable therapeutic benefits that reasonable health care providers, knowing of such risks and benefits, would not have prescribed the drug or medical device for any class of patient. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (1998).

50. This is the position taken by the Third Restatement. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. d (1998).

51. Rick Bragg, *A Fungus to Kill Marijuana Has Environmentalists Wary*, N.Y. TIMES, July 27, 1999, at A1.

52. *Id.*

53. This concern led the head of Florida's Department of Environmental Protection to write a letter to the Florida Office of Drug Control to urge caution in the use of this fungus, warning "[i]t is difficult, if not impossible, to control the spread of [the fungus]." *Id.*

54. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. d (1998).

55. Biotech products present problems for a showing of design defect because of their unique genetic design. Unique genetic structure may also prevent comparison to other designs. See *Dreisonstok v. Volkswagenwerk, A.G.*, 489 F.2d 1066 (4th Cir. 1974) (finding it an error to compare the Volkswagen microbus, because of its unique

prove that another bio-engineered fungus would not be subject to the defect? Given the secrecy with which biotechnology companies surround their products and patents, obtaining evidence of the design of other bio-engineered fungi, if they even exist, could be difficult.⁵⁶ In short, application of the law relating to design defects appears possible, but would seem to require some unique adjustments and potentially difficult proof on the part of the plaintiff. It is not as easy to compare designs of genetically-engineered products as it is to compare, for example, different designs of a motor or lawn chair.

Failure to warn claims appear to be a much more fertile area for tort litigation regarding products that are made using biotechnology. Such claims are generally evaluated using a negligence standard.⁵⁷ These claims may occur more frequently with bio-engineered products because, due to the extremely high cost of developing the products, extensive testing is sometimes not financially feasible.⁵⁸ For example, Monsanto apparently rushed a Roundup Ready cotton to the market avoiding the customary three years of testing, with the result that Monsanto apparently did not know that the yield of cotton would be decreased.⁵⁹ Of course, regulatory processes, such as FDA approval, ensure that there is agency oversight of testing of many products,⁶⁰ but still, the Monsanto example shows that sometimes under-tested products can make their way to the marketplace. Liability for failure to warn of harm-causing properties may follow.

design, to a standard passenger vehicle). Altering genetic structure, as would be required for some alternate biotech product designs, may also alter the desired attributes of the product.

56. The patenting system of the biotech industry is another obstacle actively discouraging and preventing the development of alternative designs thereby making it more difficult for plaintiffs to show reasonable alternative designs. Companies holding patents often sue competitors for encroaching on their patents thereby preventing competing designs. The cutting edge nature of the industry may also not allow time for alternative design development. See generally Richard Korman, *Lo Here Comes the Technology Patents, Lo Here Comes the Lawsuits*, N.Y. TIMES, Dec. 27, 1998, at Sec. 3, 4.

57. DIAMOND, *supra* note 10, § 17.05[c], at 346 "The new conventional inquiry in duty to warn claims brought in strict liability is (1) whether the manufacturer knew or should have known the danger, and (2) whether the manufacturer was negligent in failing to communicate this superior knowledge to the user or consumer of its product." (internal quotation marks deleted).

58. Costs per test subject can run into the hundreds of millions of dollars. This may be bearable for a large and established pharmaceutical company, but it is a different story for new biotechnology companies struggling to bring their first product to market. "[F]or the host of small biotech companies burning through their venture capital investments, clinical testing becomes an all-or-nothing, one-time game: How can we choose the minimum number of the right patients so we can pass the FDA's muster without going broke?" Michael S. Malone, *The Lag*, FORBES, ASAP, May 31, 1999, at 64.

59. The custom in the area was to allow three years of testing of new cotton strains before introduction into the market. Myerson, *supra* note 11, at D2.

60. Oversight by government agencies is both the meal ticket and death sentence for some biotech companies. Because of the high cost and time investment attached to biotechnology products, see Malone *supra* note 58, a failure to gain government approval may devastate a biotech company. For the biotech company Scios, the FDA's deferral of approval for a proposed product caused the company's stock to drop by two-thirds its previous value. Companies may always attempt another phase of trials, but too many failures to obtain approval could bury a company.

There are many other issues that may arise with respect to products that are manufactured using biotechnology. For example, biotechnology companies may argue that FDA approval should constitute a complete defense to tort liability; if this proposition were accepted, it would be a radical departure from the way tort law treats other products.⁶¹ It might possibly be justified by the enormous amount of money that must be spent to gain FDA approval for bio-engineered products. However, if this defense were to be recognized, there would soon be a clamor from drug and chemical companies to afford them the same protection, and to do so would require major change in the law.⁶²

New issues will continue to emerge as the industry develops. For example, it is now possible to grow human body parts in petri dishes in a laboratory.⁶³ In a sense, a laboratory grown ear might be considered a product, but will it be subjected to the traditional rules regarding strict products liability, or will it be covered by the Restatement Third's exemption of human blood and tissue products?⁶⁴ It depends how broadly the Restatement's exemption is construed, and as yet we have no guidance. As more genetically engineered food, such as bio-engineered grain, makes its way into the marketplace, we may find litigants arguing over whether defective food should be analyzed under section 7 (which covers food products) or under Section 2 (design defects) of the Third Restatement. Section 7 is intended to cover easy cases like glass shards in tuna salad, using the reasonable consumer expectations test, while Section 2 addresses the complex issues design cases raise. The better choice appears to be Section 2, since any alleged defects probably pervade all products the defendant has brought to market. However, litigants and judges will find the issue to be a difficult one.

61. See generally Michael D. Green, *Safety As An Element of Pharmaceutical Quality: The Respective Roles of Regulation and Tort Law*, 42 ST. LOUIS U. L.J. 163 (1998) (discussing a proposed FDA regulation compliance defense to avoid tort liability for pharmaceutical products).

62. The FDA is not the only governmental agency that deals with biotechnology products. The United States Department of Agriculture must approve biotechnology products that will be used in agriculture. Identical issues regarding the weight, if any, given to agency approval, exist. Scientists who monitor USDA approvals of proposed crops have found that the Department has not rejected a single application for a genetically engineered crop. These scientists claim that the department has relied on unsupported claims and poorly assembled studies by seed companies. Yoon, *supra* note 28, at A1. In response to consumer outcry regarding the approval of bio-engineered seeds, the U.S. Department of Agriculture has announced that it will establish an independent scientific review of its biotechnology approval process. David Barboza, *Monsanto Faces Growing Skepticism on Two Fronts*, N.Y. TIMES, Aug. 5, 1999, at C1. Legal issues may arise as to the effect of decisions by an independent scientific review board as well.

63. See Alex Frankel, *Tissue Engineering: Growing Spare Parts*, FORBES ASAP, May 31, 1999, at 46 (discussing the possibilities of producing human tissue and organs through biotechnology and providing examples of a human ear and thumb being grown by such means).

64. The Restatement (Third) exempts human blood and human tissue from traditional defective products liability rules. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 19 cmt. c (1998). The Restatement (Third) justifies this rule by citing to case law and statutes with this effect, "[L]egislation in almost all jurisdictions limits the liability of sellers to the failure to exercise reasonable care, often by providing that human blood and human tissue are not 'products' or that their provision is a 'service.' Where legislation has not addressed the problem, courts have concluded that strict liability is inappropriate." *Id.* at § 19, cmt. c.

While it is true that litigation about products manufactured using biotechnology has not yet flooded the courts, there is reason to believe that when it does, litigators will encounter juries with strong preconceptions and biases about biotechnology. Burk and Boczar fear that anti-biotechnology bias, coupled with the inability to understand the basic science, bodes poorly for the ability of the industry to defend itself.⁶⁵ Certainly, near hysterical public reaction to products such as bST, a hormone treatment for cows, bears out their apprehension.⁶⁶ No scientific evidence produced to date indicates the hormone is dangerous to humans,⁶⁷ yet there has been regulatory litigation to challenge its use,⁶⁸ as well as a threatened boycott of milk produced by cows treated with the hormone.⁶⁹ In addition, public opposition to genetically engineered food seems to be growing, in the United States⁷⁰ as well as in Europe⁷¹ and Asia.⁷²

65. Burk & Boczar, *supra* note 1, at 793.

66. The bST hormone is a synthetically reproduced version of a growth hormone occurring naturally in cows. Cows treated with this hormone will increase their milk production making the product valuable to dairy farmers. The hormone may produce certain side effects affecting reproduction and general health, among them was an increased chance of mastitis, a bacterial infection of the udder. Critics of bST were concerned that antibiotics used to treat cows with mastitis might be transferred to humans through milk from these cows. See Elie Gendoff, *Stauber v. Shalala: Are Environmental Challenges to Biotechnology Too Difficult?*, 4 WIS. ENVTL. L.J. 41, 44-45 (1997). In January 1999, the Canadian Government rejected the use of the hormone on animal-safety grounds. Kate Murphy, *More Buyers Asking: Got Milk Without Chemicals?*, N.Y. TIMES, Aug. 1, 1999, at Sec. 3, 6.

67. The bST hormone is inactive in humans and the FDA ruled that existing milk testing standards were sufficient to remove any milk contaminated from mastitis antibiotic treatment. Murphy, *supra* note 66, at sec. 3, 6.

68. Activists opposed to bST brought suit against the federal government challenging the adequacy of the FDA's approval of bST hormone and seeking that milk from bST treated cows be separately labeled, but this claim was defeated. *Stauber v. Shalala*, 895 F. Supp. 1178, 1183 (W.D. Wis. 1995).

69. Jane E. Brody, *Personal Health*, N.Y. TIMES, Nov. 17, 1993, at C1.

70. At the University of California at Davis, there have been several attacks on test plots growing genetically modified crops. While such attacks have occurred in Europe and Japan, they are new in the United States. Ted Bell, *More Crops Vandalized at UC Davis Official Denies Plants Were Genetic Experiments*, SACRAMENTO BEE, September 29, 1999, at B1.

71. The British public is vehemently opposed to genetically-altered crops. A recent poll says 79% of the British public think genetically modified crop testing should be stopped. Major food manufacturers have announced the removal of all genetically modified ingredients from their products sold in Britain. Protesters have ripped up and trampled test fields of some farmers who were willing to participate in government-run trials. Often protesters wear full body anti-contamination suits and goggles. Warren Hoge, *Britons Skirmish Over Genetically Modified Crops*, N.Y. TIMES, Aug. 23, 1999, at A3. The World Trade Organization summit in Seattle, Washington featured controversy regarding genetically-altered crops. Europeans have called such crops "Frankenfoods" and European importers have rejected \$400 million worth of U.S. feed corn on the ground that it could not be certified as being free of gene modifications. Tom Abate, *Trade Debate Echoes Business, Consumer Concerns*, S.F. CHRON., Nov. 25, 1999, at A1.

72. In August of 1999, the Kirin Brewery and its competitor, Sapporo, announced that they would use only corn that has not been genetically engineered. The Japanese government now wants mandatory labeling of gene-altered products. Melody Petersen, *New Trade Threat for U.S. Farmers*, N.Y. TIMES, Aug. 29, 1999, at Sec. 1, 1. In South Korea, another large importer of American grain, corn-processing companies have said they are considering buying corn from China instead of the United States because of concerns about genetically-altered crops. *Id.*

IV. CONCLUSION

Tort law will inevitably be forced to respond to the enormous technological breakthroughs in biotechnology that have already occurred and will occur in the future. The 21st century will no doubt bring hard choices as to how and whether tort principles should apply. Even if courts and legislatures see fit to leave traditional legal principles intact, the factual and scientific nuances unique to biotechnology will require increased knowledge and creativity on the part of attorneys. As the biotechnology industry's strongest supporters acknowledge, the industry has tremendous potential for good, as well as for harm. It will truly be a new frontier in tort law.
