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Patently Unreasonable: Reconsidering the Responsibility of Patentees in Today's Inventive Climate

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I. INTRODUCTION

Patents attract the benefits of property rights, but not the responsibilities commonly associated with other forms of property rights. Property holders are subject to tort actions if their property directly or indirectly injures another person or her property. Actions are commonly commenced in nuisance, trespass, strict liability, or negligence. No legal bar currently exists that prevents liability from extending to patentees. Patentees' avoidance of liability is a consequence of the traditional policy that inventors should be rewarded for their inventions. This Article asserts that this policy is no longer justifiable in the face of the changing nature of invention and the widened scope of patentable subject matter. For example, the increasing use of biotechnology in agriculture raises questions about who will be liable for any resulting harm.

We have already seen that the introduction of patented, genetically modified seeds is not risk-free. The recent problems with Starlink corn highlighted some of the injuries that may result. Starlink was approved by the Environmental Protection Agency (EPA) for sale and use as animal feed.¹ It was not approved for human consumption when it was made commercially available to farmers for planting because of similarities between Starlink and known human allergens.² Notwithstanding this use restriction, Starlink corn was repeatedly found in products designed for human consumption and led to a manufacturer's recall of many corn-based products.³

Parties to the Starlink suit were farmers whose products were unsuitable for sale as food products.⁴ This group potentially included farmers who did not plant Starlink, but whose crop was contaminated either in the field or after harvest. Also, buyers in the export market lost confidence in the safety of the American food system and began to purchase corn elsewhere, further devaluing the price of corn.⁵ The reduced prices affected farmers without Starlink contamination.⁶ The legal system is now being asked to determine who is liable for these injuries.⁷

It is feared that the short-term benefits of this technology will lead to the creation of super-bugs and super-weeds. For instance, through

1. *In re Starlink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d 828 (N.D. Ill. 2002).

2. *See id.* at 834.

3. *See id.* at 835.

4. *See id.* at 833.

5. *See id.* at 835.

6. *See id.*

7. *See id.*

genetic modification, a variety of crops now have the capacity to produce the natural pesticide *Bacillus thuringiensis* (Bt). Widespread planting of these crops raises concerns that the overall efficacy of Bt will be undermined as resistant pests multiply. Organic farmers, who have long relied on Bt as a natural pesticide, stand to lose an important pest management tool. In addition, there are now reports that sows that have consumed Bt corn have experienced decreased farrowing rates.⁸

Likewise, seeds that have been genetically modified to be resistant to the herbicide Round-up are proving very difficult to eliminate. Reports of weed resistance to Round-Up have been alleged with respect to its use in Roundup Ready canola⁹ and soybean crops.¹⁰

Injury caused by genetic drift from genetically modified seeds was recently highlighted in the Canadian case *Monsanto v. Schmeiser*.¹¹ In that case, the defendant alleged that his crop was tainted by Monsanto's patented Roundup Ready canola after it entered his field from either growers producing Roundup Ready canola nearby or when the patented seed was improperly transported.¹²

As the examples above indicate, injuries associated with biotechnology in agriculture are not speculative. The consequences can be widespread and long-term. The usefulness of some patented biotechnology will not necessarily last the duration of the patent. This Article argues that there is no justification for allowing a patentee to profit, without consequence, from the state-granted monopoly over her technology and then leave society with the long-term consequences of the technology's introduction. Injured parties can rely on tort actions of negligence and strict liability to hold patentees legally responsible for injuries caused by their inventions.

This Article begins with a brief summary of patent rights and then provides an overview of the application of negligence and strict liability to patentees. It concludes by addressing anticipated implications and objections to extending liability to patentees.

8. See CALIFORNIA FARM BUREAU FEDERATION: FOOD & FARM NEWS (Apr. 29, 2002), at http://www.cfbf.com/ffn/2002/ffn_042902.htm.

9. See Gillian Steward, *A New Breed of Superweed*, GLOBE & MAIL (Toronto), June 15, 2000, at <http://www.organicconsumers.org/ge/superweed.cfm>.

10. See Philip Brasher, *Roundup-Resistant Weeds Are Cropping up*, DES MOINES REG., Jan. 10, 2003, at 1A.

11. [2001] F.C. 256. Though the defendants lost the initial trial, an appeal is pending. [2003] S.C.R. *Carswell Nat*, 1158.

12. See *id.*

II. AN OVERVIEW OF PATENT RIGHTS

A patent is a property right.¹³ Most people associate property rights with ownership. Ownership is a complete bundle of rights over property, but one can have some rights in property (e.g., a lessor) and not be an owner. One of the best explanations of the nature of ownership is that “to which the following label can be attached:

To the world:

Keep off (X) unless you have my permission, which I may grant or withhold.

Signed: Private citizen.

Endorsed: The state.”¹⁴

That is, ownership is associated with exclusive possession, control and enjoyment of a specific res, by a particular person.¹⁵ Also, the rights of ownership exist to the extent they are recognized by the state.¹⁶

The current Patent Act does not specifically define a patent.¹⁷ As a result, one must read a number of sections to determine what a patentee obtains when she receives a patent. Section 261 makes it clear that patents are a form of property ownership, stating, “[s]ubject to the provisions of this title, patents shall have the attributes of personal property.”¹⁸ These rights include the exclusive right to grant or convey the patent.¹⁹ Moreover, the Patent Act gives a patentee the right to exclude others from making, using, offering for sale, and selling the patented invention within the United States.²⁰ If infringement occurs, “[a] patentee shall have remedy by civil action for infringement of his patent.”²¹

The common law has placed limitations upon the exercise of property rights.²² *Sic utere tuo et alienum non laedas* is the guiding maxim meaning that “one should use his own property in such a manner as not to injure that of another.”²³ Because patents are a form of property,

13. H.A. TOULMIN, PATENTS AND THE PUBLIC INTEREST 12 (1939).

14. Felix S. Cohen, *Dialogue on Private Property*, 9 RUTGERS L. REV. 357, 374 (1954).

15. See MARJORIE BENSON & MARIE ANN BORDEN, UNDERSTANDING PROPERTY: A GUIDE TO CANADA’S PROPERTY LAW 15 (1997).

16. See *id.*

17. See 35 U.S.C. §§ 1-376 (2000).

18. *Id.* § 261.

19. See *id.*

20. See *id.* § 271.

21. *Id.* § 281.

22. See *Chapman v. Barnett*, 169 N.E.2d 212, 214 (Ind. Ct. App. 1960) (holding defendant liable when a fire spread from her property to her neighbor’s causing damage).

23. BLACK’S LAW DICTIONARY 1380 (6th ed. 1990).

this maxim is applicable to the exercise of patent rights as there is neither a bar to its applicability in the Patent Act, nor has one been found at common law. It is therefore appropriate to extend the laws of negligence and strict liability for product defects to cover losses or injury occasioned by the action of a patentee.

This failure to attach liability to patent rights is not the result of a statutory or common law bar, but is a direct result of the historical rationale for creating a patent system for inventions. The provision of exclusive rights to inventors has long been considered an important mechanism to encourage inventiveness.²⁴ The drafters of the United States Constitution thought it so important that they gave Congress the explicit power to issue patents.²⁵ Article I, Section 8 provides that Congress has the authority “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”²⁶ Notwithstanding the constitutional authority to do so, the first American Patent Act was not enacted until 1790.²⁷ Two patent acts were repealed and replaced between 1790 and 1836.²⁸ The Patent Act of 1836²⁹ is identified as the origin of the current American patent system.³⁰

Inventiveness was thought to be the means through which American manufacturing would develop.³¹ Society would benefit from the expansion of knowledge, the growth of industry, and the disclosure of the invention.³² Patents were viewed principally as a means of rewarding the patentee for the cost and effort of invention.³³ In *Grant v. Raymond*, the United States Supreme Court stated:

The great object and intention of the act [of 1793] is to secure to the public the advantages to be derived from the discoveries of individuals, and the means it employs are the compensation made to those individuals for the

24. See EDWARD C. WALTERSCHEID, TO PROMOTE THE PROGRESS OF THE USEFUL ARTS: AMERICAN PATENT LAW AND ADMINISTRATION, 1798-1836, at 141-42 (1998). Italy provided exclusive rights to inventors for their inventions through the Venetian Law of 1474; England followed in 1623 with the Statute of Monopolies.

25. 24a See U.S. CONST. art. I, § 8, cl. 8.

26. *Id.*

27. See FLOYD L. VAUGHAN, THE UNITED STATES PATENT SYSTEM: LEGAL AND ECONOMIC CONFLICTS IN AMERICAN PATENT HISTORY 18 (1956).

28. See *id.* at 19.

29. Act of July 4, 1836, 5 Stat. 117 (current version at 35 U.S.C. §§ 1-376 (2000)).

30. See VAUGHAN, *supra* note 27, at 19.

31. See WALTERSCHEID, *supra* note 24, at 431-32.

32. See *id.*

33. See *id.*

time and labour devoted to these discoveries, by the exclusive right to make, use and sell, the things discovered for a limited time.³⁴

Providing remuneration to inventors remains an important goal in the modern patent system. Section 18 of the 1836 Patent Act required the Patent Commissioner to extend the term of a patent if

it [was] just and proper that the term of the patent should be extended, by reason of the patentee, without neglect or fault on his part, having failed to obtain, from the use and sale of his invention, a reasonable remuneration for the time, ingenuity, and expense bestowed upon the same, and the introduction thereof into use³⁵

It is generally believed that society prospers from invention. It is thought that attaching liability to an inventor for injury caused by one's invention would seem to contradict this public policy. The remainder of this Article will challenge this belief. A patentee should be held to the same standard applicable to other property holders.

III. APPLICATION OF NEGLIGENCE TO PATENTEES

An action in negligence has as a primary goal the compensation of losses suffered by a plaintiff because of a defendant's conduct.³⁶ The Restatement (Second) of the Law of Torts defines negligence as "conduct which falls below the standard established by law for the protection of others against unreasonable risk of harm. It does not include conduct recklessly disregardful of an interest of others."³⁷ The failure to act when there is a duty to do so may constitute negligence.³⁸ Section 284 of the Restatement (Second) provides:

Negligent conduct may be either:

- (a) an act which the actor as a reasonable man should recognize as involving an unreasonable risk of causing an invasion of an interest of another, or
- (b) a failure to do an act which is necessary for the protection or assistance of another and which the actor is under a duty to do.³⁹

Not all losses are recoverable. Each element of a cause of action for negligence must be analyzed to determine when a loss is recoverable. The Restatement (Second) specifically defines these elements:

34. 31 U.S. 218, 243 (1832).

35. Act of July 4, 1836, 5 Stat. 123, 124 (current version at 35 U.S.C. §§ 1-376 (2000)).

36. See DAN B. DOBBS, THE LAW OF TORTS 1 (2000).

37. RESTATEMENT (SECOND) OF TORTS § 282 (1965).

38. See *id.* § 282 cmt. a.

39. *Id.* § 284.

The actor is liable for an invasion of an interest of another, if:

- (a) the interest invaded is protected against unintentional invasion, and
- (b) the conduct of the actor is negligent with respect to the other, or a class of persons within which he is included, and
- (c) the actor's conduct is a legal cause of the invasion, and
- (d) the other has not so conducted himself as to disable himself from bringing an action for such an invasion.⁴⁰

These elements are best understood as a series of questions addressing a specific aspect of a cause of action in negligence:

- (1) Damage or Loss—Has the plaintiff suffered any actual losses or damages?
- (2) Duty—Is there a duty, recognized in law, that required the defendant to take care to avoid subjecting others to unreasonable risks?
- (3) Standard of Care—Has the defendant breached her duty owed to the plaintiff by acting unreasonably in the circumstances?
- (4) Causation—Is the defendant's conduct the cause of the plaintiff's loss or damage?
- (5) Proximate Cause—Was it foreseeable that the defendant's breach of the standard of care would result in the plaintiff's loss or damage?
- (6) Defenses—Are there any reasons in law or has the plaintiff contributed in any way to the loss thereby barring recovery or reducing the damages awarded?⁴¹

If the first five questions are answered in the affirmative, a cause of action in negligence will be established.⁴² Whether the plaintiff will be compensated for the defendant's negligent conduct depends on whether the defendant can establish a defense to the action.⁴³ This Article will explore each of the concepts identified by the above questions and analyze how each concept may be applied in a cause of action against a patentee for negligence.

A. *Damage or Loss*

A defendant will not be liable for her negligence unless the plaintiff has suffered some loss or damage.⁴⁴ “Nominal damages, to vindicate a technical right, cannot be recovered in a negligence action, where no actual loss has occurred.”⁴⁵ The loss suffered will usually be in the form

40. *Id.* § 281.

41. WILLIAM L. PROSSER, HANDBOOK OF THE LAW OF TORTS 143 (4th ed. 1971) (modified from Prosser's four elements).

42. *See id.*

43. *See id.* at 416-17.

44. *See id.* at 143-44.

45. *Id.* at 143.

of personal injury or damage to property. In general, purely economic losses are not recoverable.⁴⁶

It is not necessary that the damage coincide in time with the wrongful act or default.⁴⁷ Many courts now hold that the relevant statute of limitations does not run until the plaintiff discovers her injury.⁴⁸ This is an important consideration when dealing with a patentee whose negligence will likely have occurred before the injured party encountered the invention.

While many inventions serve to improve the quality of life for others, the risk of injury they pose to human health or the environment remains unknown. This uncertainty continues because of the ongoing expansion of patentability. Unless one is arguing pure economic loss, quantifying the damage or loss will likely be more contentious than actually proving the occurrence of damage or loss.

B. Duty

A tortfeasor is only responsible for injuries to those people to whom a duty is owed.⁴⁹ Precisely defining to whom a duty is owed has proven problematic because it is highly dependent on the circumstances of the case. While commenting on its vagueness, Prosser, in *Law of Torts*, borrows a formula from the English courts after, presumably, not finding a suitable definition in American jurisprudence:

The rule that you are to love your neighbour becomes in law, you must not injure your neighbour; and the lawyer's question, Who is my neighbour? receives a restricted reply. You must take reasonable care to avoid acts or omissions which you can reasonably foresee would be likely to injure your neighbour. Who, then, in law is my neighbour? The answer seems to be—persons who are so closely and directly affected by my act that I ought reasonably to have them in contemplation as being so affected when I am directing my mind to the acts or omissions which are called in question.⁵⁰

This definition of duty introduces the concept of foreseeability. A duty is owed to those who one can reasonably foresee as likely to be affected by one's action.⁵¹

46. See *Sandarac Ass'n v. W.R. Frizzell Architects*, 609 So. 2d 1349, 1352 (Fla. Dist. Ct. App.), *review denied*, 625 So. 2d 207 (Fla. 1992).

47. See PROSSER, *supra* note 41, at 144.

48. See *id.* (citation omitted).

49. See *id.*

50. *Donoghue v. Stevenson*, 1932 App. Cas. 562, 580 (appeal taken from Scot.).

51. See *id.*

Interestingly, a definition of duty is conspicuously absent from the Restatement (Second). A proposed definition in the tentative draft of the proposed Restatement (Third) of the Law of Torts: Liability for Physical Harm (Basic Principles) does not offer much guidance. It provides:

Even if the defendant's conduct can be found negligent . . . and is the legal cause of the plaintiff's physical harm, the defendant is not liable for that harm if the court determines the defendant owes no duty to the plaintiff, either in general or relative to the particular negligence claim. Determinations of no duty are unusual and are based on judicial recognition of special problems of principles or policy that justify the withholding of liability.⁵²

What this definition indicates is that a finding of no duty is rare. Thus, in this definition, there is really no barrier in principle from extending the concept of duty to patentees.

It is unlikely that the mere act of invention and the subsequent patenting of that invention will give rise to a duty. Conceivably, one could argue that the holder of a patent on an inherently dangerous invention, like a death ray, is negligent when she discloses the ability to create the product in the patent application. It would be very difficult, however, to argue successfully that the mere act of disclosing the specifications of the invention in the patent application creates a duty. Such a result is inconsistent with protection given to free speech.

On the other hand, injury may occur if the inventor of a patented lifesaving invention refuses to exercise the right to license the product for manufacture and sale pursuant to § 261 of the Patent Act, thus making it unavailable to the public. In those circumstances, one could argue that merely creating such an invention gives rise to a duty owed to humanity. Unfortunately, it is doubtful the courts will recognize such a duty. Generic drug manufacturers who, it is argued, make lifesaving drugs available to the public at reduced costs have been found to violate patents.⁵³ Restricting access to lifesaving drugs on the basis of the inability to pay for use is a protected right of a patentee. It is yet to be determined if courts will make a distinction between refusing all access and restricting access to purchasers.

A duty can arise, however, once a patentee chooses to exercise her exclusive rights to license and sell her invention pursuant to section 261 of the Patent Act. A number of factors can illustrate why this is so. First, for a patent to be issued, the Patent Act provides:

52. RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM (BASIC PRINCIPLES) § 7 (Tentative Draft No. 1, 2001).

53. See *Bristol-Myers Squibb Co. v. Royce Lab.*, 69 F.3d 1130 (Fed. Cir. 1995).

The specification shall contain a written description of the invention, and of the manner and process of making and *using it*, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and *use* the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.⁵⁴

Therefore, utility will be explicitly defined in the patent application. In fact, it is to the applicant's advantage to define utility in the broadest possible terms to enlarge the scope of the monopoly when the patent is granted. Thus, it will be difficult for many patentees to argue subsequently that the injury was not foreseeable. In the case of breast implants, its inventor will have a difficult time arguing that he never contemplated that his product would be put into women's bodies. In this way, the description of utility in the patent application may be *prima facie* evidence of a duty owed to anyone identified in the application.

Similarly, the act of licensing the right to use, sell, or manufacture the subject of the patent may also provide evidence that the patentee contemplated the injured party. Licensing agreements can be very specific as to the scope of the license granted.⁵⁵ If a license to sell the product is granted, then clearly a consumer is contemplated. Likewise, if the right to manufacture the product is licensed, a person employed in the manufacturing process must also be contemplated. Thus, a duty should be found if either the consumer or the manufacturer's employee is injured by the invention.

For example, a seed dealer may obtain a license to sell a patentee's genetically modified corn to a farmer in a particular region. One can expect that the license will contain requirements that the dealer ensures that unlicensed buyers do not use the planted technology. Such an agreement specifically contemplates the licensed farmer and unlicensed growers. If the seed causes injury, as it did in the Starlink example, it will be very difficult for the patentee to argue that the injured farmers, licensed or not, were unforeseen.

As previously indicated, whether a patentee owes a duty to a consumer who is injured by the patentee's invention has not been litigated. Negligence actions, however, against authors, book publishers, and publishers of navigational charts may be instructive in this situation.

Generally, a plaintiff injured by relying on or following written words contained in a published work will not have a cause of action

54. 35 U.S.C. § 112 (2000) (emphasis added).

55. See IVER P. COOPER, BIOTECHNOLOGY AND THE LAW §§ 10:17-18 (2002).

against either the author or the publisher.⁵⁶ This conclusion is often motivated by First Amendment concerns.⁵⁷ In *Cardoza v. True*, the court refused to hold a book dealer liable for inaccuracies in a cookbook and stated:

ideas hold a privileged position in our society. They are not equivalent to commercial products. Those who are in the business of distributing the ideas of other people perform a unique and essential function. To hold those who perform this essential function liable, regardless of fault, when an injury results would severely restrict the flow of the ideas they distribute.⁵⁸

Notwithstanding these concerns for free speech, courts have found publishers of navigational charts negligent for injuries caused by defects found in the charts.⁵⁹ The courts have justified this by viewing navigational charts as products, not ideas or expressions worthy of First Amendment protection.⁶⁰ Patentees are in the same position as publishers of navigational charts because patents are granted for tangible products, not ideas.⁶¹ It is only after an idea is put into a tangible, reproducible form that it becomes patentable.⁶² Finding patentees liable in negligence does not infringe the constitutionally protected right of free speech.

C. Standard of Care

Next, a plaintiff in an action alleging negligence must identify the standard of care owed by the defendant. The defendant is only liable for conduct that does not meet the requisite standard of care. This general standard was articulated in *Brown v. Kendall* as requiring the use of ordinary care.⁶³ The court held, “what constitutes ordinary care will vary with the circumstances of cases. In general, it means that kind and degree of care, which prudent and cautious men would use, such as is

56. See, e.g., *Demuth Dev. Corp. v. Merck & Co.*, 432 F. Supp. 990, 994 (E.D.N.Y. 1977); *Herceg v. Hustler Mag., Inc.*, 565 F. Supp. 802, 803 (S.D. Tex. 1983); *Winter v. G.P. Putnam’s Sons*, 938 F.2d 1033, 1037 (9th Cir. 1991); *Alm v. Van Nostrand Reinhold Co.*, 480 N.E.2d. 1263, 1267 (Ill. App. Ct. 1985).

57. See *Alm*, 480 N.E.2d at 1267.

58. 342 So. 2d 1053, 1056-57 (Fla. Dist. Ct. App.), cert. denied, 353 So. 2d 674 (Fla. 1977).

59. See, e.g., *Saloomey v. Jeppesen & Co.*, 707 F.2d 671, 679 (2d Cir. 1983); *Brocklesby v. United States of America*, 767 F.2d 1288, 1299 (9th Cir. 1985), cert. denied, *Jeppesen & Co. v. Brocklesby*, 474 U.S. 1101 (1986).

60. See *Saloomey*, 707 F.2d at 676-77; see also *Brocklesby*, 767 F.2d at 1294-95.

61. PETER D. ROSENBERG, PATENT LAW FUNDAMENTALS § 2:01 (1981).

62. See *id.*

63. See 60 Mass. 292 (1850).

required by the exigency of the case, and such as is necessary to guard against probable danger.”⁶⁴ Likewise, the Restatement (Second) provides, “[u]nless the actor is a child, the standard of conduct to which he must conform to avoid being negligent is that of a reasonable man under like circumstances.”⁶⁵

Reference to the reasonable, prudent, and cautious person indicates that a breach of a standard of care is largely determined by an objective test.⁶⁶ The reasonable person is deemed to have the following attributes:

- (1) Normal intelligence;
- (2) normal perception, memory, and at least a minimum of standard knowledge;
- (3) all the additional intelligence, skill, or knowledge actually possessed by the individual actor; and
- (4) the physical attributes of the actor himself.⁶⁷

The consideration of specific attributes of the actor can be viewed as a subjective analysis.⁶⁸ It is likely, then, that the circumstances of invention will influence the standard of care owed by the patentee. If the inventor is considered an expert, her superior knowledge will likely raise the requisite standard of care because she can be expected to employ techniques customarily used in her industry.⁶⁹ One can expect that a person who is employed at a university or a corporation for the very purpose of developing and inventing new patents will be considered an expert, and consequently held to a high standard of care for the same reason. On the other hand, the inexperienced or accidental inventor who puts his idea into some material form and obtains a patent without the aid of sophisticated laboratories and the resources to conduct extensive trials would not be held to the same standard as an expert.

In addition, the aforementioned definitions indicate that a breach of the standard of care occurs when one undertakes an unreasonable risk. What constitutes an unreasonable risk is a question of mixed law and fact.⁷⁰ The Restatement (Second) defines unreasonableness:

Where an act is one which a reasonable man would recognize as involving a risk of harm to another, the risk is unreasonable and the act is negligent if

64. *Id.* at 296.

65. RESTATEMENT (SECOND) OF TORTS § 283 (1965).

66. *See* DOBBS, *supra* note 36, at 280.

67. *Id.* (footnotes omitted).

68. *See id.*

69. *See* J.D. LEE & BARRY A. LINDHAL, MODERN TORT LAW: LIABILITY AND LITIGATION § 3:35 (2d ed. 2002).

70. DOBBS, *supra* note 36, at 335-36.

the risk is of such magnitude as to outweigh what the law regards as the utility of the act or of the particular manner in which it is done.⁷¹

Thus, the test for unreasonableness requires balancing the magnitude of the risk against the utility of the action.⁷² To assist in this balancing test, the Restatement (Second) lists factors to be considered in determining the utility of one's conduct:

In determining what the law regards as the utility of the actor's conduct for the purpose of determining whether the actor is negligent, the following factors are important:

- (a) the social value which the law attaches to the interest which is to be advanced or protected by the conduct;
- (b) the extent of the chance that this interest will be advanced or protected by the particular course of conduct;
- (c) the extent of the chance that such interest can be adequately advanced or protected by another and less dangerous course of conduct.⁷³

To determine if the risk is unreasonable, these factors are balanced against the following factors considered in evaluation of the magnitude of risk:

In determining the magnitude of the risk for the purpose of determining whether the actor is negligent, the following factors are important:

- (a) the social value which the law attaches to the interests which are imperiled;
- (b) the extent of the chance that the actor's conduct will cause an invasion of any interest of the other or of one of a class of which the other is a member;
- (c) the extent of the harm likely to be caused to the interests imperiled;
- (d) the number of persons whose interests are likely to be invaded if the risk takes effect in harm.⁷⁴

The Restatement (Second) falls short of requiring the trier of fact to undertake a cost-benefit analysis to determine if there is a breach of the standard of care. Such analysis was proposed by Judge Hand in *United States v. Carroll Towing Co.*⁷⁵ The Hand Formula provides a mathematical expression of factors to be considered: $B < PL$ (whereas B is the burden of adequate precaution, P is the probability of loss, and L is the magnitude of the loss suffered).⁷⁶

71. RESTATEMENT (SECOND) OF TORTS § 291 (1965).

72. *See id.*

73. *Id.* § 292.

74. *Id.* § 293.

75. 159 F.2d 169, 173 (2d Cir. 1947).

76. *See id.*

The Hand Formula may best be understood if it is applied to an example, for instance the problem with genetic drift. An organic farmer who finds her corn crop contaminated with genetically modified corn may argue that the bioengineered seed was not adequately tested for its susceptibility to cross-pollination with organic crops. In determining the standard of care expected from the patentee, the court would consider the probability that the corn pollen would spread and contaminate other crops, the gravity of the harm that would pose to nongenetically modified growers, and how difficult it would have been to prevent the genetic drift from occurring.

Although the Restatement (Second) does not explicitly require the consideration of the burden of adequate precaution, the Hand Formula continues to be employed as a mechanism to determine breach of the requisite standard of care.⁷⁷ This kind of analysis may discourage the use of food crops for the production of bioengineered industrial products, like plastics, if other crops are available in order to avoid contamination of the food supply.

The element of foreseeability is essential to the consideration of reasonable versus unreasonable risk.⁷⁸ Under the Restatement (Second), foreseeability is included in the second factor to be considered in determining the magnitude of risk—the risk of invading another’s interest.⁷⁹ The Hand Formula presumes foresight of the risk by a reasonable person in the circumstances when it calls for a consideration of the burden of adequate precaution.⁸⁰ No one can be expected to take precautions against unforeseen risks. Thus, a foreseeable risk “must be recognized or reasonably recognizable, and it must also be an unreasonable risk because it could be reasonably avoided or reduced.”⁸¹

It is difficult to foresee what standard of care will be required of patentees because the question has never been put to the courts to determine. A review of the standard to which manufacturers are held can provide some guidance. Similar to a patentee, a manufacturer is unlikely to have a direct contractual relationship with the product’s end-user, thereby foreclosing any contractual remedy.

The jurisprudence on product liability has identified a certain standard of care expected of manufacturers based on the utility of the

77. See, e.g., *Estate of Clarence Michael Thurman v. City of Milwaukee*, 197 F. Supp. 2d 1141, 1148 (E.D. Wis. 2002) (applying Hand Formula to determine whether search and seizure was reasonable).

78. See RESTATEMENT (SECOND) OF TORTS § 293.

79. See *id.*

80. See *Carroll Towing*, 159 F.2d at 173.

81. DOBBS, *supra* note 36, at 334.

product and the magnitude of the risk it poses to consumers.⁸² For example, a manufacturer of a product will be held liable in an action for negligence for failing to adequately warn consumers of the risks associated with use of their product as a matter of public policy.⁸³ A patentee should be held to a similar standard of care where the subject of her patent is a consumer product.

In many states, the duty to warn arises the moment the manufacturer becomes, or should have become, seized with the knowledge of the risks.⁸⁴ As such, some courts have found that this duty is ongoing long after the product's sale, and continues after the product line is discontinued.⁸⁵ Willful ignorance of risk will not assist in avoiding liability because manufacturers are also liable for risks they should have discovered.⁸⁶ Section 289 of the Restatement (Second) states:

The actor is required to recognize that his conduct involves a risk of causing an invasion of another's interest if a reasonable man would do so while exercising

- (a) such attention, perception of the circumstances, memory, knowledge of other pertinent matters, intelligence, and judgment as a reasonable man would have; and
- (b) such superior attention, perception, memory, knowledge, intelligence, and judgment as the actor himself has.⁸⁷

The adequacy of the warning determines whether there has been a breach of the standard of care.⁸⁸ The adequacy of the warning is determined objectively but courts often hold that, as a matter of law, a warning was adequate in a particular case.⁸⁹ Specifically, the warning must be "reasonably calculated to bring home to the reasonably prudent person the nature and extent of the danger."⁹⁰ This analysis considers the warnings content, form, and frequency.⁹¹

The high standard contained in section 289 of the Restatement (Second) flows from the doctrine of informed consent and is best understood when one considers the relationship between the typical

82. See generally *id.* at 997-1002.

83. See RESTATEMENT (THIRD) AMERICAN LAW OF PRODUCTS LIABILITY § 2 (2002).

84. See DOBBS, *supra* note 36, at 1019.

85. See *Owens-Ill., Inc. v. Zenobia*, 601 A.2d 633, 646-47 (Md. 1991).

86. RESTATEMENT (SECOND) OF TORTS § 289 (1965).

87. *Id.*

88. See DOBBS, *supra* note 36, at 1008.

89. See *Town of Bridport v. Sterling Clark Lurton Corp.*, 693 A.2d 701, 705 (Vt. 1997) (holding that "bold and prominent" warnings to the product were adequate where plaintiff offered no evidence to the contrary).

90. *D'Arienzo v. Clairol, Inc.*, 310 A.2d 106, 110 (N.J. Super. Ct. Law Div. 1973).

91. See DOBBS, *supra* note 36, at 1008-09.

manufacturer and consumer.⁹² A consumer is often forced to rely on a manufacturer for information concerning the manufacturer's product.⁹³ This reliance is reasonable because the manufacturer is in the best position to research and test the product. This informational advantage justifies the continuing duty.⁹⁴ Consumers are vulnerable to misrepresentations if they are unable to make informed choices. Inadequate information about risks can have direct consequences for consumers. When a manufacturer fails to give adequate warning, a consumer's ability to consent to assume the risks associated with the manufacturer's product is undermined.⁹⁵ A warning may also permit the consumer to use the product with greater safety, thereby reducing the risk of harm.⁹⁶

There is nothing in principle to prevent the duty to warn from extending to patentees when the test is merely: Did the defendant know or ought she have known about the dangers associated with the product? Because the first owner of a patent is the inventor she should have intimate knowledge of the product and, thus, an informational advantage over the consumer. Anyone who subsequently acquires the patent acquires the rights associated with it. Justice requires that they also assume the responsibilities and liabilities.

It may be appropriate to distinguish between patentees who profit from their patent rights and those who provide free access to their invention. A higher standard of care is appropriate on public policy grounds for all manufacturers because they are presumed to seek economic reward when they offer their products to the public for sale.⁹⁷ The manufacturer's ability to spread the risk of loss through numerous transactions also justifies the high standard of care.⁹⁸ A patentee who invents in a public institution, and does not exchange access to the invention for profit, should be held to a different standard of care than either the patentee who invents in a private, for-profit institution or one who licenses access to the invention for a fee, regardless of the location

92. See *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1089-90 (5th Cir. 1973), *cert. denied*, 419 U.S. 869 (1974).

93. See *id.*

94. See *id.*

95. See *id.* at 1089.

96. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998).

97. This benefit may come directly through immediate sales or indirectly in the form of free samples offered to introduce the consumer to the product in hope of future sales.

98. Noriko Kawawa, *Comparative Studies on the Law of Tort Relating to Liability for Injury Caused by Information in Traditional and Electronic Form: England and the United States*, 12 ALB. L.J. SCI. & TECH. 493, 583 (2002) (citing *La Rossa v. Scientific Design Co.*, 402 F.2d 937, 942 (3d Cir. 1968)).

of invention. This is because the nonprofit patentee is not in a position to spread the risk of loss.

In sum, once the patentee chooses to exercise a right granted to her in section 271 of the Patent Act, she must do so with the care exercised by a reasonable patentee in the circumstances. Courts will likely consider the circumstances of invention, including the expertise of the inventor and the location of invention, when assessing the appropriate standard of care.

D. Causation

The issue of causation is often confused with that of proximate cause despite the fact that the two concepts are distinct.⁹⁹ Causation is primarily a question of fact while proximate cause is principally a question of law.¹⁰⁰ As a question of fact, the trier of fact must determine if the defendant's action or omission caused the plaintiff's harm.¹⁰¹ Prosser defines causation as follows:

Causation is a fact. It is a matter of what has in fact occurred. A cause is a necessary antecedent: in a very real and practical sense, the term embraces all things which have so far contributed to the result that without them it would not have occurred. It covers not only positive acts and active physical forces, but also pre-existing passive conditions which have played a material part in bringing about the event. In particular, it covers the defendant's omissions as well as his acts.¹⁰²

To determine causation, many courts have used the "but for" or *sine qua non* test.¹⁰³ This test recognizes that one will not be responsible for injuries that would have occurred notwithstanding the defendant's conduct.¹⁰⁴ This is because the defendant's conduct did not cause the loss. As such, the defendant is not held accountable. Prosser cautions that this test is best perceived as a "rule of exclusion" because "if the event would not have occurred 'but for' the defendant's negligence, it still does not follow that there is liability."¹⁰⁵ A defendant may still escape liability if the defendant's conduct is not found to be the proximate cause of the plaintiff's injuries.¹⁰⁶

99. Fedorczyk v. Caribbean Cruise Lines, Ltd., 82 F.3d 69, 73 (3d Cir. 1996).

100. See PROSSER, *supra* note 41, at 237, 244.

101. See *id.* at 237.

102. *Id.* (footnotes omitted).

103. See *id.* at 238-39.

104. See *id.* (footnotes omitted).

105. *Id.* at 239.

106. The principle of proximate cause will be discussed in the next Part.

The burden of proof to establish causation generally rests with the plaintiff.¹⁰⁷ The plaintiff must establish a reasonable basis for the conclusion that the defendant's conduct caused the plaintiff's injury.¹⁰⁸ The plaintiff, however, is not required to establish causation beyond a reasonable doubt.¹⁰⁹ Sufficient proof establishes a relation of cause and effect and occurs, "[i]f as a matter of ordinary experience a particular act or omission might be expected, under the circumstances, to produce a particular result, and that result in fact has followed."¹¹⁰ A mere possibility of causation or proof on a balance of probabilities is not sufficient.¹¹¹

As explained, a patentee will only be liable if the plaintiff can establish a reasonable basis for the conclusion that the patentee's conduct caused the plaintiff's injury. This requires the plaintiff to persuade the trier of a fact that had the patentee undertaken different, nonnegligent conduct, no harm would have been done.¹¹² It is reasonable to anticipate that in some situations injury may be the result of a patentee's failure to adequately test a product or to ensure in the licensing agreement that adequate warnings concerning the product's proper use would be given to the consumer.

E. Proximate Cause/Foreseeability/Remoteness

Proximate cause is "the limitation which the courts have placed upon the actor's responsibility for the consequences of his conduct."¹¹³ Without such limitation, a negligent act could result in infinite liability for the defendant. The goal of proximate cause is only to hold the defendant liable for the risk of harm she assumed by her negligent conduct.¹¹⁴ As such, it is more a question of policy than of fact. "[L]egal responsibility must be limited to those causes which are so closely connected with the result and of such significance that the law is justified in imposing liability."¹¹⁵

Proximate cause only becomes an issue when both a breach of the requisite standard of care and causation have been established.¹¹⁶ Courts

107. See PROSSER, *supra* note 41, at 241.

108. See *id.*

109. See *id.* at 242.

110. *Id.*

111. See *id.* at 241.

112. See DOBBS, *supra* note 36, at 409.

113. PROSSER, *supra* note 41, at 236.

114. See DOBBS, *supra* note 36, at 443.

115. PROSSER, *supra* note 41, at 237.

116. See DOBBS, *supra* note 36, at 443.

have devised a number of terms to describe this limitation of liability including proximate cause, remoteness, legal cause, scope of risk or duty, and foreseeability.¹¹⁷ The concept of foreseeability was first introduced in the Part of this Article dealing with duty.¹¹⁸ In that Part, it was shown that a duty is owed to those a person can reasonably foresee as likely to be affected by that person's action.

The test for proximate cause outlined in *Overseas Tankship (UK) Ltd. v. Morts Dock & Engineering Co.*,¹¹⁹ a British case, is accepted as an appropriate articulation of the American approach.¹²⁰ The decision in *Overseas Tankship* rejected an earlier decision *In re Polemis & Furness, Withy & Co.* where it was held that one is liable for all damage "directly traceable to the negligent act, and not due to the operation of independent causes having no connection with the negligent act."¹²¹ Under the *In re Polemis* approach, "[o]nce the act is negligent, the fact that its exact operation was not foreseen is immaterial."¹²² The court in *Wagon Mound (No. 1)* held that the directness test led to an unjust result because one could be liable for injuries she could not have foreseen and therefore avoided.¹²³

American courts have accepted this approach and stated that the analysis involves a question of whether the defendant "should have foreseen the kind of harm that in fact resulted."¹²⁴ Proximate cause is established when "the harm giving rise to the action could have reasonably been foreseen or anticipated by a person of ordinary intelligence and prudence."¹²⁵ Although this analysis does not concern itself with evaluating what is reasonable conduct in the circumstances, it is based on the premise that a nonnegligent person will take precautions to avoid foreseeable risks. To hold otherwise, would lead to the nonsensical result that a defendant will be liable for failing to take precautions against unforeseen risks.¹²⁶

Admittedly, on its face, proof of proximate cause may present a formidable challenge for a plaintiff attempting to recover damages from a defendant patentee. This task is less daunting when one considers that

117. *See id.* at 443-45.

118. *See supra* Part III.B.

119. [1961] App. Cas. 388 (P.C. 1961).

120. *See* DOBBS, *supra* note 36, at 454-55.

121. *In re Polemis & Furness, Withy & Co.*, [1921] 3 K.B. 560 (K.B. 1921).

122. *Id.*

123. *See Overseas Tankship*, [1961] App. Cas. at 426.

124. DOBBS, *supra* note 36, at 448.

125. *Haynes v. Hamilton County*, 883 S.W.2d 606, 612 (Tenn. 1994) (quoting *McClenahan v. Cooley*, 806 S.W.2d. 767, 775 (Tenn. 1991)).

126. *See Palsgraf v. Long Island R.R. Co.*, 162 N.E. 99 (N.Y. 1928).

the impetus for many patented inventions today is an identified consumer need.¹²⁷ In exchange for compensation, patentees are free to grant unrestricted licenses to make and market their products to the public without consequence.¹²⁸ Patentees, therefore, have the ability to limit the use to which their inventions are put through licensing agreements.

In fact, the failure to hold patentees accountable for injuries caused by their inventions may actually allow them to avoid considering foreseeable harm by not encouraging patentees to restrict permitted uses of their inventions. A patentee is in the best position to identify and avoid foreseeable risks because of her intimate knowledge of the invention. Currently, the consideration of foreseeable harms merely becomes a cost-benefit analysis in the hands of a licensed manufacturer or retailer.

In sum, a negligence action against a patentee will be subject to the principle of proximate cause. Even if damage resulted, a duty was owed, the causative link was drawn, and the patentee was found to have breached the requisite standard of care, recovery in negligence will be barred if the injury was unforeseen.

F. Defenses

Once the above five issues have been considered and determined to be in the plaintiff's favor, liability will result unless the defendant can establish an affirmative defense. A patentee will have available to her all of the defenses generally available to a defendant in any other negligence action. These defenses include, inter alia, contributory negligence, voluntary assumption of risk, and the bar of a statute of limitations.¹²⁹ Because the focus of this Article is the expansion of liability, not the avoidance, an analysis of such defenses is beyond this Article's scope.

IV. STRICT LIABILITY

Injuries caused by defects in goods were traditionally remedied through warranty actions.¹³⁰ In the 1960s, the courts began to hold manufacturers of commercial goods strictly liable for these injuries even

127. See *supra* Part III.B for a more thorough discussion of the current nature of patents.

128. 35 U.S.C. § 261 (2000).

129. See DOBBS, *supra* note 36, at 494.

130. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 1 cmt. a (Proposed Final Draft 1997).

when the plaintiff could not sustain an action in negligence or warranty.¹³¹ “Strict liability in tort for defectively manufactured products merges the concept of implied warranty, in which negligence is not required, with the tort concept of negligence, in which contractual privity is not required.”¹³² This provides a procedural advantage to plaintiffs over an action in negligence because they do not need to establish duty, breach of the standard of care, or proximate cause. It is unclear whether the courts will provide this procedural advantage to the plaintiff in action against a patentee. Therefore, any action against a patentee will need to include claims in negligence and strict liability.

The Restatement (Third) provides that “[o]ne engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.”¹³³ Section 20 outlines that section 1 has broad application:

For purposes of this Restatement:

- (a) One sells a product when, in a commercial context, one transfers ownership thereto either for use or consumption or for resale leading to ultimate use or consumption. Commercial product sellers include, but are not limited to, manufacturers, wholesalers, and retailers.
- (b) One otherwise distributes a product when, in a commercial transaction other than a sale, one provides the product to another either for use or consumption or as a preliminary step leading to ultimate use or consumption. Commercial nonsale product distributors include, but are not limited to, lessors, bailors, and those who provide products to others as a means of promoting either the use or consumption of such products or some other commercial activity.
- (c) One also sells or otherwise distributes a product when, in a commercial transaction, one provides a combination of products and services and either the transaction taken as a whole, or the product component thereof, satisfies the criteria in Subsection (a) or (b).¹³⁴

Unless a patentee is directly involved in the sale of her invention, it is unlikely that section 20(a) will apply. Arguably patentees who specifically license their product for manufacture or sale (as opposed to those who license for use in a research context, for example) fall within

131. See *Greenman v. Yuba Power Prods. Inc.*, 377 P.2d 897, 900-01 (Cal. 1963) (holding power tool manufacturer liable to injured party while using product even when no express agreement between the parties existed).

132. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 1 cmt. a.

133. *Id.* § 1.

134. *Id.* § 20.

the definition in section 20(b). Courts have interpreted the term “otherwise distributes” broadly and have justified the expansion of who has been held strictly liable on public policy grounds “to include distributors, retailers, processors of materials and makers of component parts, or *essentially to any one responsible for placing the defective product in the marketplace.*”¹³⁵ Patentees clearly fall within this broad description when they license their inventions for sale.

There are a number of public policy grounds for construing section 20(b) broadly. For instance:

[I]mposing liability would provide injured consumers with a greater opportunity to commence an action against the party responsible, fix liability on one who is in a position to exert pressure on the manufacturer to improve the safety of the product, or ensure that the burden of accidental injuries occasioned by products would be treated as a cost of production by placing liability upon those who market them.¹³⁶

Moreover, “[i]t is the defendant’s participatory connection, for his personal profit or other benefit, with the injury-producing product and with the enterprise that created consumer demand for and reliance upon the product . . . which calls for [the] imposition of strict liability.”¹³⁷ Each of these public policy rationales supports an expansion of strict liability to include patentees.

First, patentees control the invention and are therefore in a position to influence the actions of those releasing the product for sale. Patentees can license the sale of their product for a specific use. They can also ensure in the licensing agreements that the product be released for sale with adequate warnings about the product’s safety.

Second, patentees are in the best position to ensure the product is designed and tested to minimize potential design defects. It is therefore consistent with public policy that patentees be held accountable for the consequences of inadequate safety testing.

The last public policy reason supporting an expansion of the strict liability doctrine to include patentees is the fact that they are likely to be profiting from the sale. Once a patentee makes the decision to make her invention commercially available to the public with the goal of profiting from the invention’s sale, it is only appropriate she assume responsibility for any injury that results.

135. *Brumbaugh v. CEJJ, Inc.*, 547 N.Y.S.2d. 699, 701 (App. Div. 1989) (emphasis added) (citations omitted).

136. *Id.* (citations omitted).

137. *Kasel v. Remington Arms Co.*, 101 Cal. Rptr. 314, 323 (Cal. Ct. App. 1972) (citations omitted).

The Restatement (Third) outlines categories of product defects for which a patentee would be responsible:

A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product:

- (a) contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product;
- (b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe;
- (c) is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.¹³⁸

Each category of defect will be discussed in turn.

A. *Manufacturing Defects*

Manufacturing defects occur when products are physically flawed, damaged, or incorrectly assembled.¹³⁹ It is accurate to characterize these defects as a “random failing or imperfection” that occurs in their production.¹⁴⁰ The plaintiff must show that the “product deviated in a material way from the manufacturer’s specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer.”¹⁴¹ This standard reflects the view that because consumers rely on manufacturers to furnish them with safe products, liability is appropriate when their reasonable safety expectations are not met.¹⁴² In the traditional action against a manufacturer, the plaintiff is also required to establish that the manufacturing defect existed when it left the manufacturer’s control.¹⁴³

138. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2.

139. *See id.* § 2 cmt. c.

140. DOBBS, *supra* note 36, at 979.

141. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. c (citing LA. REV. STAT. ANN. § 9:2800.55 (West 1988)).

142. *See* DOBBS, *supra* note 36, at 979.

143. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. c.

This category of defect does not have much applicability to patentees because it is designed to capture production flaws that are incidental to the manufacturing process. Patentees can require safety testing and manufacturing standards in licensing agreements but will have little control over the activities of mass production once the product is licensed. Therefore, it will be difficult to hold patentees liable for these types of defects.

B. Design Defects

Unlike a manufacturing defect, a design defect is not isolated or unique. Instead, a design defect “occurs when the intended design of the product line itself is inadequate and needlessly dangerous.”¹⁴⁴ Subsection 2(b) of the Restatement (Third) adopts a reasonableness test for evaluating a product defect when it calls for the consideration of a “reasonable alternative design.” The courts overwhelmingly require a consideration of the risk and utility of the product as compared to an alternative design without defect.¹⁴⁵ This analysis often includes a consideration of consumer expectations.¹⁴⁶ A minority of courts, however, only look at consumer expectations as they relate to the safety and utility of the product and do not consider an alternative design.¹⁴⁷

Although each jurisdiction adopts its own unique formula for the risk-utility test, the following factors have been identified as common considerations:

- (1) The usefulness and desirability of the product—its utility to the user and to the public as a whole.
- (2) The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury.
- (3) The availability of a substitute product which would meet the same need and not be as unsafe.
- (4) The manufacturer’s ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
- (5) The user’s ability to avoid danger by the exercise of care in the use of the product.
- (6) The user’s anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge

144. DOBBS, *supra* note 36, at 980.

145. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. e.

146. *See id.* § 2 cmt. f.

147. *See id.*

of the obvious condition of the product, or of the existence of suitable warnings or instructions.

- (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.¹⁴⁸

With the exception of the seventh factor, some argue that the risk-utility test is the equivalent of a test for negligence.¹⁴⁹ The risk-utility test essentially requires consideration of proximate cause, standard of care, and duty.

Similar to a negligence action, the plaintiff has the burden of establishing that the product design does not satisfy the risk-utility test.¹⁵⁰ The easiest way to do this is for the plaintiff to point to existing products with safer designs, although that is not always possible.¹⁵¹ The Restatement (Third) provides, however, that “the plaintiff is not required to establish with particularity the costs and benefits associated with adoption of the suggested alternative design.”¹⁵²

As previously indicated, whether patentees can be held strictly liable in tort for defects in the design of their products has not been litigated. A review of how the issue has been addressed with respect to book publishers and publishers of navigational charts provides support for the inclusion of patentees in those who can be held strictly liable in tort for product defects.

Traditionally, book publishers have not been found liable under a theory of strict liability for mistakes contained in the published work or for failing to warn of the risks associated with activities described in the book.¹⁵³ The court in *Lewin v. McCreight*, however, did not foreclose the idea where, “the publisher actually created, rather than merely printed,” a written material or “where the risk of harm is plain and severe such as the book entitled *How to Make Your Own Parachute*.”¹⁵⁴ Likewise, the court in *Winter v. G.P. Putnam’s Sons* indicated the publisher, “neither wrote nor edited the book” when it rejected the plaintiff’s argument for imposing strict liability on the publisher.¹⁵⁵ The court in *Jones v. Lippincott Co.* also stressed that the publisher had not taken any

148. John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss. L.J. 837-38 (1973) (footnotes omitted).

149. See DOBBS, *supra* note 36, at 986.

150. See *Cremeans v. Int’l Harvester Co.*, 452 N.E.2d 1281, 1284 (Ohio 1983).

151. See DOBBS, *supra* note 36, at 998.

152. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. f.

153. See, e.g., *Lewin v. McCreight*, 655 F. Supp. 282, 284 (E.D. Mich. 1987); *Jones v. J.B. Lippincott Co.*, 694 F. Supp. 1216, 1217-18 (D. Md. 1988); *Winter v. G.P. Putnam’s Sons*, 938 F.2d 1033, 1037 (9th Cir. 1991).

154. 655 F. Supp. at 283-84.

155. 938 F.2d at 1034.

responsibility for the book's content, and thus granted summary judgment in favor of the defendant publisher.¹⁵⁶

In contrast, the Court of Appeals of Michigan in *Central Soya Co. v. Rose*, affirmed a decision that held a feed supplier strictly liable for injuries resulting from defects in printed instructions describing its feeding program.¹⁵⁷ The plaintiff successfully established that the defendant's instructions were defective and were the proximate cause of his injury.¹⁵⁸ The court presumed that publishers could be liable for defects in the printed instruction as it made no findings of defect in the system itself.¹⁵⁹

Likewise, publishers of navigational charts have been found strictly liable for defects in their charts. In *Aetna Casualty & Surety Co. v. Jeppesen & Co.*, the defendant was found liable for a defect in one of its navigational charts because the "graphic depiction of the profile, which [covered] a distance of three miles from the airport, [appeared] to be drawn to the same scale as the graphic depiction of the plan, which [covered] a distance of 15 miles."¹⁶⁰ As a result of the defect, the pilot misjudged his approach and crashed on landing.¹⁶¹ As discussed, the same defendant was held liable for a defect in a navigational chart in *Saloomey v. Jeppesen & Co.*¹⁶² The chart erroneously indicated that the Martinsburg, West Virginia, airport contained a full instrument landing system.¹⁶³ As a result, the pilot crashed the plane into a ridge during descent.¹⁶⁴ Last, in *Brocklesby v. United States of America, Jeppesen & Co.*, the defendant was again found liable for another defect in its depiction of an approach outlined on a navigational chart.¹⁶⁵ The court specifically stated in *Saloomey v. Jeppesen & Co.* that strict liability is warranted in these cases because,

[b]y publishing and selling the charts, Jeppesen undertook a special responsibility, as seller, to insure that consumers will not be injured by the use of the charts; Jeppesen is entitled—and encouraged—to treat the

156. *Lippincott Co.*, 694 F. Supp. at 1216-17.

157. 352 N.W.2d 727, 729 (Mich. Ct. App. 1984).

158. *See id.* at 730.

159. *See id.*

160. 642 F.2d 339, 342 (9th Cir. 1980).

161. *See id.*

162. 707 F.2d 671 (2d Cir. 1983).

163. *See id.* at 673.

164. *See id.* at 672-73.

165. 767 F.2d 1288, 1298-99 (9th Cir. 1985).

burden of accidental injury as a cost of production to be covered by liability insurance.¹⁶⁶

Similar to the publishers of navigational charts and the feed program instructions, patentees take an active role in creating a product. These cases support the argument that patentees have a duty to make sure their products are free from defect. They are in the position to insure against injury. Thus patentees should not avoid liability for defects in production design, but protect themselves through other means including liability insurance.

C. Warnings

Subsection 2(c) of the Restatement (Third) requires warnings for foreseeable harms.¹⁶⁷ It is difficult to see how this differs in any way from a finding of negligence for failing to warn. In fact, some courts have clearly stated that warning claims in an action for strict liability in tort for product defects is in fact a claim of negligence:

[I]t was error to submit instructions regarding [the defendant's] failure to warn under both negligence and strict liability theories Both instructions essentially required the jury to determine whether [the defendant] negligently failed to warn users of the dangers We believe that the correct submission of instructions regarding a failure to warn claim for damages is under a theory of negligence and the claim should not be submitted as a theory of strict liability. In testing the defendant's liability for negligence in failing to warn, the defendant should be held to the standard of care of an expert in its field. The relevant inquiry therefore is whether the reasonable manufacturer knew or should have known of the danger, in light of the generally recognized and prevailing best scientific knowledge, yet failed to provide adequate warning to users or consumers.¹⁶⁸

As with negligence, there is nothing in principle to prevent the duty to warn from extending to patentees. As inventor, the first owner of the patent can be presumed to have intimate knowledge of the product and is in the best position to provide reasonable warning and instructions. Anyone who subsequently acquires the patent gains the rights associated with it. It is only fair that she also assumes the responsibilities and liabilities.¹⁶⁹

166. 707 F.2d at 676-77.

167. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(c) (Proposed Final Draft 1997).

168. Olson v. Prosoco, Inc., 522 N.W.2d 284, 289-90 (Iowa 1994) (citations omitted).

169. See *supra* Part III.C.

D. Defenses

Similar to an action in negligence, a patentee will have available to her all of the defenses generally available to a defendant in any other action in strict liability. These include, inter alia, contributory negligence, voluntary assumption of risk, and the bar of a statute of limitations.¹⁷⁰ Because the focus of this Article is the expansion of liability, not the avoidance, such defenses are not addressed.

V. OBJECTIONS—WOULD INVENTION OCCUR IN THE ABSENCE OF PATENTS?

It is anticipated that some will argue that the emphasis on remuneration as the means of encouraging inventiveness is inconsistent with the extension of liability to patentees. Fear of lawsuits may chill research. This argument presupposes that economic gain is the sole reason people invent and that all potential for profit will be lost if patentees assume legal responsibility for their inventions. This argument is both naïve and inaccurate.

The scope of patentable subject matter has expanded dramatically in recent years. Invention continued to occur without certainty that the inventor would be entitled to a patent. As a result, the scope of patentability has evolved in response to this ongoing invention. “Once confined to traditional fields of applied technology such as mechanics and chemicals, the patent system has moved into agriculture, medical procedures, computer software, and business methods.”¹⁷¹ Similarly, it was once thought that the extension of patents to inventions involving living things was barred. That understanding changed after the landmark United States Supreme Court decision in *Diamond v. Chakrabarty*.¹⁷² This case illustrates that invention was not hindered by the uncertain scope of patentability, but it continued to thrive.

Although patents were obviously desired in each of the cases that led to the expansion of patentable subject matter, the uncertainty that a patent would be granted indicates that economic reward is not the sole motivator for invention. People are drawn to invent for a number of reasons. Each of these reasons requires explanation to understand the

170. See DOBBS, *supra* note 36, at 493.

171. Rebecca S. Eisenberg, *Analyze This: A Law and Economics Agenda for the Patent System*, 53 VAND. L. REV. 2081, 2083-84 (2000) (footnotes omitted).

172. 447 U.S. 303, 318 (1980) (holding human-made, genetically engineered bacterium is patentable subject matter).

extent to which research and invention will be chilled by no longer shielding patentees from liability.

First, the instinct to invent is inherent in some people.¹⁷³ Those possessing a creative mind derive great pleasure in devising ways and means of making life easier. These people invent tools, machines, and systems that are efficient and master the task at hand. As F.W. Taussig wrote, “[t]he biographies of inventors give abundant illustrations of the state of inward happiness which comes from the exercise of the contriving bent.”¹⁷⁴ Similarly, an intellectual curiosity, possessed by some people, has resulted in significant inventions from mere accidents. Where others would have paid no attention to the outcomes of a chance interaction of previously unrelated items, others see a revelation. A story involving Charles Goodyear serves as an excellent example of how invention can result from intellectual curiosity:

Standing before a stove in a store at Woburn, Mass., he was explaining to some acquaintances the properties of a piece of sulphur-cured india-rubber which he held in his hand. They listened to him good-naturedly, but with evident incredulity, when suddenly he dropped the rubber on the stove, which was red hot. His old clothes would have melted instantly from contact with such heat; but, to his surprise, this piece underwent no such change. In amazement he examined it, and found that while it had charred or shriveled like leather, it had not softened at all. The bystanders attached no importance to this phenomenon, but to him it was a revelation.¹⁷⁵

Other inventors may be motivated by the desire for esteem among their peers and public at large.¹⁷⁶ To be the first to understand, to complete an impossible task, or to create an item that becomes indispensable garners great respect. It is for this reason that the receipt of a Nobel Prize is such an honor.

Alternatively, Adam Smith argued that the invention is a natural consequence of the division of labor:

Men are much more likely to discover easier and readier methods of attaining any object, when the whole attention of their minds is directed towards the single object, than when it is dissipated among a great variety of things. But in consequence of the division of labour, the whole of every man's attention comes naturally to be directed towards some one very simple object. It is naturally to be expected, therefore, that some one or other of those who are employed in each particular branch of labour should

173. See VAUGHAN, *supra* note 27, at 4.

174. *Id.* (citing F.W. TAUSSIG, *INVENTORS AND MONEY-MAKERS* 15 (1915)).

175. *Id.* at 6-7 (citing P.G. HUBERT, J.R., *MEN OF ACHIEVEMENT—INVENTORS* 167-68 (1893)).

176. See VAUGHAN, *supra* note 27, at 4.

soon find out easier and readier methods of performing their own particular work, wherever the nature of it admits of such improvement.¹⁷⁷

The desire to make the method of labor easier and readier, or perhaps more enjoyable, can also explain the motivation of the “Eureka” inventor, the noninventor who has an ingenious idea. One who happens upon an invention cannot be said to have invented for economic gain. All of the inventions and motivations referenced are such that years of time and money were not required.

For those motivated by economic gain, invention is best viewed as an investment. Time and money go into the inventive process with the hope of reaping a substantial financial return. As with any form of investment, there are risks. Patentees have been shielded unjustifiably from the risk of liability. For as long as there is a potential for economic gain, invention will occur notwithstanding economic risks.

VI. IMPLICATIONS

It is impossible to predict accurately the impact of no longer shielding patentees from liability for injury caused by their inventions. As explained, fear that invention will be chilled is not justifiable. One can predict, however, a number of positive public policy effects. The impact on the agricultural industry, particularly that involved with research and manufacturing of genetically modified organisms (GMOs), can be used to exemplify these effects.

Specifically, the threat of negligence liability for patentees will increase consumer access to information regarding these technologies. Mandatory labeling will no longer be a contentious issue as it will be in the best interest of patentees to provide this information to consumers so as not to be found liable in strict liability or negligence for failing to warn consumers of potential risks associated with their product. In that way, consumers will be in a better position to make the choice to use these products and to voluntarily undertake the potential risk associated with GMOs.

Also, inventors will need to consider seriously the impact of their research and include this analysis in their decision to invent. Ethics will no longer be removed from the scientific process. If an inventor can be held liable for the effects of her patented invention there will be less incentive to invent for the sole purpose of achievement. The imminent need for the technology will be a significant factor in the decision to

177. *Id.* at 5 (citing ADAM SMITH, AN INQUIRY INTO THE NATURE AND CAUSE OF THE WEALTH OF NATIONS Bk. I, Ch. I, Par. 8. (1937)).

release inventions to the public for profit where the risks are great or unknown.

Last, we may see a clear retreat by corporations from influencing research agendas at public institutions. As most corporations are profit-maximizing, agri-businesses will want to isolate themselves from the research process to share liability with a patentee if it arises. This will free up research agendas in public institutions, like universities, thus allowing them to pursue research in the public interest. This can help to restore consumer confidence in new GMO technologies, because fears of the “corporate agenda” influencing results will be lessened. Thus, it will be in agri-businesses’ interest to ensure that research continues without influence.

VII. CONCLUSIONS

As has been noted, causes of action in negligence and strict liability in tort for product defects are an unexplored source of liability for patentees. Common sense and principles of fairness dictate that some limitation must be placed on the exercise of patent rights because every other form of property right has restrictions. Currently, there is no common law or statutory bar preventing patentees from being held legally responsible for their inventions. The traditional policy perspective that inventors should be rewarded for their inventions, and thus shielded from liability, is no longer justifiable in the face of the changing nature of invention and the widened scope of patentable subject matter. A cause of action in negligence or strict tort liability for product defects against a patentee for harm caused by her invention would not require a substantial expansion of the law. As outlined, patentees currently fall within the traditional analysis of these causes of actions. The fact that no one has tried to sustain a cause of action against a defendant patentee either in negligence or strict liability for product defects is not sufficient justification for concluding it is not possible.