# Analysis of the Experimental Use Exception

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## Introduction:

Undoubtedly, if you are reading this article, your life has been affected dramatically by inventions. You may be reading this on the printed page, thereby owing much of your enjoyment to the printing press. You could also be reading this from the screen of a computer, an invention that has more recently had a tremendous impact on the world. If you are sitting under an artificial light, in a chair, or just about anywhere, the inventive spirit of others has had an impact on your life. In fact, almost every aspect of our lives has been altered by inventions. For that reason, the importance of inventions and the inventive spirit is hard to deny, and the value to people is easy to understand.

The significance and importance of inventions are so great that the Constitution of the United States offers protections for the interests of inventors. Essentially, it gives Congress the power to grant inventors exclusive rights to their inventions.[2] During this time of exclusivity, the inventor can reap the appropriate commercial, reputational, or personal benefits that come from his invention. This protection is also significant, not because the inventor has rights to his invention, but because his rights are exclusive and allow him to forbid others to use, make, offer to sell, or sell the invention. This protection is the basis for today's patent laws in the United States.

Patent laws offer inventors the right to "exclude others from making, using, offering for sale, or selling the invention" or process; this protection extends for a period of 20 years.[3] In

[2] U.S. CONST., art. I, § 8 (giving Congress the power "[t]o 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").
[3] 35 U.S.C. § 154(a) (2001).

exchange for this veritable monopoly, the patentee must file an application for the patent with the U.S. Patent Office. This application must include a description of the invention or process with such detail that one skilled in the particular art would be able to duplicate the invention or process. As of November 29, 2000, this information will be published eighteen months from the effective filing date of the application, even if it has not yet been approved.[4]

Patent laws exist to protect inventors from such would-be "idea thieves." However, the right to exclude others from making or using a patented item certainly must have its limitations. After all, certainly some unlicensed use by others is expected if the patentee is required to describe his invention in such great detail. Otherwise, one could argue that a description should just accompany the license to use the invention. It is likely that other parties may wish to simply use the invention for various reasons of their own that may not include harming the patentee's rights. For example, other parties may want to assess the usefulness of the patented product to see if it would fit their needs or even use it for academic research.

Other parties may also want to use the invention to improve commercial processes in which they are engaged. Arguably, processes that would improve technology or lead to more productive use of the invention, and not do so at the expense of the patentee's rights, should not be considered infringing. In fact, many would suggest that most inventions are the result of previous inventions. In the words of Ralph Waldo Emerson, "[o]nly an

[4] 35 U.S.C. § 122(b)(1)(A) (2001). *See generally* 35 U.S.C. § 122 (b)(2)(A)(i) (2001).

inventor knows how to borrow, and every man is or should be an inventor."[5]

Courts have in fact found that some unlicensed uses of patented devices are not infringing. One doctrine that allows such a use to be reached is the experimental use exception. The "experimental use exception" actually describes two entirely separate legal doctrines: (1) an exception to the public use bar; and (2) a defense to unlicensed use of a patented item. The former will be discussed only briefly. The main focus of this paper is an analysis of the experimental use exception as a defense to unlicensed use of a patented item.

**Experimental Use Exception as a Defense to the Public Use Bar**

Under 35 U.S.C. § 102(b), an invention may not be patented if it was in public or sale use in the United States more than one year prior to the date of application for the patent. This bar prevents the inventor from enjoying exclusive control over his invention for more than the statutorily permissible time[6] and is commonly known as "the public use bar." Other public policy justifications for the public use bar are that: (1) it protects the public if the public had begun using the device prior to application for the patent; and (2) it encourages disclosure of new and useful information.[7]

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[5] Ralph Waldo Emerson (1803-1882), U.S. philosopher, poet, essayist, in JASON SHULMAN & ISAAC ASIMOV, ISAAC ASIMOV'S BOOK OF SCIENCE AND NATURE QUOTATIONS (1988).

[6] *See* Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 550 (Fed. Cir. 1990).

[7] T.P. Labs. v. Prof'l Positioners, 724 F.2d 965 (1984).

A defense to the public use bar exists if the defendant can show that his "public use" of the invention was for the purpose of research and development of the item, not for "commercial exploitation" of the product.[8] Notice that this defense is actually raised when claims are rejected during application prosecution or by the patentor when the infringing user claims that the patent is invalid because of a violation of the public use bar.

This application of the experimental use exception has often been described in case law. For example, in one case, a dentist had designed an orthodontic device to use on patients, and the dentist gave the device to three patients free of charge. His later-acquired patent was challenged on grounds that this use violated the public use bar. The Court of Appeals for the Federal Circuit found that the use of the device did not violate the public use bar because there was not even the slightest degree of commercial exploitation prior to filing the patent application. The court noted that since there was no commercial exploitation, the patent term was not extended beyond the statutorily permissible time by the patentee's actions.[9]

## Experimental Use Exception as a Defense to Patent Infringement

### *Birth of the Experimental Use Exception*

Even before the turn of the Twentieth Century, courts recognized that some unlicensed uses of patented items should be permissible. In 1883, Justice Joseph Story first described and

[8] *Id.* at 973.
[9] *Id.*

applied what has become the modern common law experimental use exception. In *Whittemore v. Cutter*, the plaintiff accused the defendant of infringing the patent assigned on a machine used to produce playing cards.[10] Justice Story's comments in that case are considered to be the birth of the experimental use exception. He said that the legislature could not have intended to punish those who undertook "philosophical experiments" with protected items.[11]

In the case of *Sawin v. Guild*,[12] Justice Story further described that exceptions to infringement could exist and he began to set out the boundaries of these exceptions. In this case, plaintiff brought an action against a deputy sheriff who had seized a machine to settle a debt. The machine was patented, and the plaintiff charged that he, as the patent holder, had the exclusive right to sell the machine. In the Court's decision, Justice Story looked back to *Whittemore* and noted that for the making of a patented machine to be infringing, it must "be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification." He continued to say, "[t]he making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery." He applied this same reasoning to whether the *selling* of a patented article is infringing: "It must be a tortious sale, not for the purpose merely of depriving the owner of the materials, but of the use and benefit of his

[10] Whittemore v. Cutter, 29 F. Cas. 1120 (C.C.D. Mass. 1883).
[11] *Id.* at 1121.
[12] Sawin v. Guild, 21 F. Cas. 554 (C.C.D. Mass. 1813).

patent."[13] The sheriff's sale of the machine did not meet this standard for infringement.[14]

Justice Story's comments show that an exception to infringement should exist only when the rights of the patent holder are not being harmed. One of the major factors in determining whether the patentee is harmed is whether the alleged-infringer derives a profit from the patented article.

That said, however, Congress has taken this legal theory further and codified a narrow portion of the experimental use exception that does allow the use of a patented article, even if its use is with an eye to future profit.[15]

*Maturation of the Experimental Use Exception*

*Common Law:*

This article has described the origin of the common law experimental use exception and noted that it addresses the degree to which a non-licensed user of a patented item can use the item without being liable for patent infringement. Though the common law experimental use exception is not the most common item for judicial review, case law does exist to describe some of its boundaries.

*1. Cases In which the Exception Failed*

An example in which the exception failed involved a defendant who used plaintiff's patented culture media to further his

[13] *Id.*
[14] *Id.*
[15] 35 U.S.C. § 271(e)(1) (2001).

own experiments, which were designed to develop transgenic cattle. Defendant, however, intended to use this resulting transgenic animal directly for commercial purposes. In recognizing that these experiments were done with an eye toward commercial exploitation, the United States District Court of Wisconsin said that no common law research experimentation exception was available and that the use of the media was infringing.[16] The court noted that the experiments were not "philosophical" nor were they "carried out merely to satisfy the curiosity of researchers...." Rather, the court said that the use was part of "ongoing business activities of the defendant."[17]

Another case involved using a machine similar to a patented one for processing furs. The defendant claimed that he was using the machine to see if he could make some improvement on it. However, the defendant conducted his experiments by using the furs that his customers brought him for processing. The court found that he was infringing the patent on the machine because he was using it in the ordinary course of business.[18]

These cases suggest that the focus of the use cannot be for commercial advancement if the use is to be seen as experimental.[19]

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[16] *See* Infigen, Inc. v. Advanced Cell Technologies, Inc., 65 F. Supp. 2d 967 (W.D. Wis. 1999).

[17] *Id.*

[18] Cimotti Unharing Co. v. Derboklow, 87 F. 997 (C.C.E.D.N.Y. 1898). *See also* Northill Co. v. Danforth, 51 F. Supp. 928 (N.D. Cal. 1942) (noting that use of a patented article was not experimental because it was "in connection with [the user's] business").

[19] *See* Douglas v. United States, 181 U.S.P.Q. 170 (1974), *aff'd,* 510 F.2d 364 (1975) (noting that the experimental use exception has never been allowed where "there was a pattern of systematic exploitation, extending over a prolonged period"). *See also* Baxter Diagnostics, Inc. v. AVL Scientific Corp., 798 F. Supp. 612 (C.D. Cal. 1992) (holding that the experimental use exception

Even a use for the purpose of testing will be infringing if it also will have a proximate commercial purpose.

### 2. *Cases In Which the Exception Was Successfully Applied*

The common law experimental use exception has been used successfully subsequent to *Whittemore* and *Sawin*. Those cases in which the exception has been successful suggest that using a product strictly for assessing its applicability to a commercial process is not an infringing activity. In *Akro Agate Co. v. Master Marble Co.*,[20] the defendants used the plaintiff's patented marble-making machine to assess its applicability to their business. They later abandoned the machine and adopted a machine that did not follow the same process as the plaintiff's machine. The court noted that the defendant's use of a patented machine was not infringement because it was merely to assess its usefulness and that it was later abandoned voluntarily.[21]

In another case, *Chesterfield v. United States*,[22] the plaintiff, Chesterfield, filed an action against the United States for infringing a patent describing an invention used to produce improved cutting-tools. Although the Court found the patents themselves were invalid, it pointed out that the defendant's use would not have been infringing even if that were not the case.

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does not protect experiments or tests which have a commercial purpose); *Derboklow*, 87 F. at 997 (1898) (finding that defendant's use of a patented article was in the "ordinary course of business" and, therefore, its use was not experimental).

[20] Akro Agate Co. v Master Marble Co., 18 F. Supp. 305 (N.D.W.V. 1937).

[21] *Id.*

[22] Chesterfield v. United States, 159 F. Supp. 371 (Ct. Cl. 1958).

They said that the defendant did not manufacture or sell any of the patented articles; therefore, the use by the defendant was experimental.

The case law distinguishes the use of a patented product for commercialization and the use of a patented product to assess its applicability to a commercial process. Although it may lead to certain commercially viable results, the latter seems not to be regarded as infringing.

### *Codification of the Experimental Use Exception: 35 U.S.C. § 271(e)(1)*[23]

In addition to the common law, there is a statutory exception to experimental use which entitles those who use a patented product for certain specific purposes to have their use regarded as non-infringing. This exception was born to protect drug manufacturers whose use of products was necessary to satisfy

[23] 35 U.S.C. § 271(e)(1) (2001):

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are described in the Federal Food, Drug, and Cosmetic Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

extensive pre-market testing requirements by the Food and Drug Administration (FDA).[24]

This statute came into being as a response to the Supreme Court's ruling in *Roche v. Bolar*.[25] In *Roche*, the drug company Bolar, which manufactured generic drugs, needed to meet FDA testing requirements of a new generic drug it was producing. However, the testing of the generic drug, which was necessary to comply with FDA regulations, required Bolar to use certain items protected by patents held by Roche. Bolar began this testing with the intention of shortening the time needed before the drug could be introduced to the market. The Federal Circuit found that since the infringing activities were performed for business reasons and not for curiosity, Bolar's use infringed Roche's patent.[26]

Congress noted that when an item is used to satisfy extensive pre-market testing requirements, such as Bolar's, there are no adverse economic effects on the patent holders by allowing such use to occur. In fact, it noted that forbidding others to conduct experiments until after the patent expires effectively extends the patent holder's period of "commercial exclusivity."[27] This simply serves to extend the patent privileges beyond those given by the patent.[28] Congress questioned whether such extension was appropriate for a product that offered benefits to mankind such as those offered by medicine. Recognizing the need to make an

[24] *See* Eli Lilly v. Medtronic, 496 U.S. 661, 670 (1990).
[25] Roche Products v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984).
[26] *Id.* at 863.
[27] Drug Price Competition and Patent Term Restoration Act, H.R. 98-857, 98th Cong. § 857(I)(1984).
[28] 35 U.S.C. § 154(a)(2) (2001) (gives patent protection for 20 years from the date of application).

allowance for such use, Congress enacted the Drug Price Competition and Patent Term Restoration Act[29] in 1984.

The provisions under § 202 of the Drug Price Competition and Patent Term Restoration Act, later codified as 35 U.S.C. § 271(e)(1),[30] provide an exception to patent infringement for uses of drugs that are reasonably related to providing information needed, "under a Federal law which regulates the manufacture, use, or sale of drugs."[31]

After the decision of the Court in *Roche*, drug companies began to lobby Congress for a change in laws governing the use of a patented article for pre-market testing required by the FDA. Congress responded by codifying § 202 of the Drug Price Competition and Patent Term Restoration Act into 35 U.S.C. § 271(e)(1).[32]

The wording of § 271(e)(1) says that the patented product should be "used solely for purposes reasonably related to testing requirements under federal law."[33] Case law provides a better understanding of the limits of this statute. *Intermedics* describes the parameters of § 271(e)(1). The court establishes a boundary for what acts Congress intended to be covered by the statute. It first points out that it is unlikely that Congress intended the wording, "uses reasonably related" to include all uses of the

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[29] Drug Price Competition and Patent Term Restoration Act, H.R. 98-857, 98th Cong. (1984).
[30] Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 665 (1990). *See also* 35 U.S.C. § 271(e)(1) (2001).
[31] 35 U.S.C. § 271(e)(1) (2001).
[32] *See* Intermedics, Inc. v. Ventritex, Inc., 775 F. Supp. 1269, 1272 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993).
[33] 35 U.S.C. § 271(e)(1) (2001).

patented article.[34] In other words, when looking to whether the use of a patented article is covered by § 271(e)(1), one must simply decide whether these actual uses are "'reasonably related to the development and submission of information' to the FDA." The court continued and said that § 271(e)(1) will not apply for any use that is more than de minimis and that is not reasonably related to producing data for the FDA.[35] Further, the court pointed out that it would not make sense to forbid § 271(e)(1) coverage for a firm which performed any actions associated with testing that could also be in their business interest and, therefore, arguably not *solely* for the purposes of FDA testing. After all, the firm is performing the tests to ensure that the product can be safely sold to the public. The court stressed, however, that actions that may have a secondary purpose will not be covered by § 271(e)(1). It does not, however, preclude other actions, done solely for FDA testing, from being exempted under the statute. In short, when deciding which acts should be analyzed under the "solely related" language, courts will not look to all uses of the patented article, which would describe a subjective test. Instead, courts will use an objective test and look only to the acts that would be deemed infringing, but-for § 271(e)(1).[36]

In *Roche*, the court held that Bolar's use was infringing despite the fact that it was "limited" to "testing and investigation strictly related to FDA drug approval."[37] Since § 271(e)(1)

[34] *Intermedics*, 775 F. Supp. at 1285.
[35] *Id.* at 1278.
[36] *See id.* at 1280.
[37] Roche Products v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984). The acts described here are now permitted under 35 U.S.C. § 271(e)(1). Nevertheless, this description still serves to describe what use would be deemed "experimental."

addresses this particular type of use, and it is designed to permit the use that was found infringing in *Roche*, these words give a good indication as to the "use" the statute views as non-infringing.

Although *Roche* was overruled by § 271(e)(1), it provides insight into what is considered "experimental" for the purposes of the statute. In *Roche*, the court noted that infringement of a patent cannot be allowed under the "guise of 'scientific inquiry' when that inquiry has definite, cognizable, and not insubstantial commercial purposes."[38] This seems to suggest that a use is deemed infringing unless it can be shown that the use fits into a carve-out that does not have "definite, cognizable, and not insubstantial commercial purposes." This understanding of commercial purposes seems to be similar to that which is described by the common law.[39]

In 1990, the Supreme Court referenced the statutory provision in *Eli Lilly v. Medtronic*.[40] In *Eli Lilly*, the Court not only acknowledged the statute's application to pharmaceuticals, but also extended it to protect medical devices in an effort to compliment the patent term extensions under 35 U.S.C. § 156.[41] These extensions serve to protect not only drugs but also medical devices and food additives that are subject to the FDCA regulations.[42]

Since § 271(e)(1) was written to address items covered by the patent term extensions, the Court in *Eli Lilly* said that "Federal law" in the statute referred to an entire act that regulates drugs. If

[38] *Id.* at 863.
[39] *See* Sawin v. Guild, 21 F. Cas. 554 (C.C.D. Mass. 1813).
[40] Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990).
[41] *Id.* at 667. *See also* 35 U.S.C. § 156(a)(4).
[42] *Eli Lilly*, 496 U.S. at 667.

that act also includes medical devices, then the use of those is also protected under the provision.[43]

The language in § 271(e)(1) also includes "new animal drug[s] or veterinary biological products" in the experimental use exception.[44] The statute looks to the Federal Food, Drug, and Cosmetic Act (FDCA) for a definition of these terms.[45] The FDCA defines "new animal drug" as "any drug intended for use for animals other than man, including any drug intended for use in animal feed."[46] This legislation does not define "veterinary biological products" separately, however. This leaves unanswered the question of whether this was intended to apply to modified animal feed or to animal feed modified exclusively by the addition of new animal drugs. In addition to the codified experimental use exception courts have also begun to focus on what the experimental use exception *excludes*. The case of *Embrex Inc. v. Service Engineering Corp.*[47] is a good illustration of this point. Embrex had received a patent under the Bayh-Dole Act[48] for a

[43] *Id.* at 666.
[44] 35 U.S.C. § 271(e)(1) (2001).
[45] *Id.*
[46] 21 U.S.C. § 321 (2001).
[47] *See* Embrex Inc. v. Service Engineering Corp., 216 F.3d 1343 (Fed. Cir. 2000).
[48] 35 U.S.C. § 200 (2001):

> It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise

method of inoculating bird ova in the egg prior to hatching. Service Engineering Corp. (SEC) then tried to secure Embrex's permission to manufacture machines to do the inoculating. Embrex, however, refused.[49]

After settling an initial dispute over SEC's attempt to design around the Embrex patent, SEC continued in its efforts to build a machine to inoculate ova. The SEC machine, however, was designed to inoculate in a different area of the egg than that described by the Embrex method. To determine the efficacy of its revised method, SEC conducted tests to compare its inoculation to that of Embrex. Embrex, once again, sued SEC for infringing its patented inoculation method.[50] In their defense, SEC claimed that its performance of the Embrex method was done to test the effectiveness of their new method and, therefore, was not infringing under the experimental use exception.[51]

The Federal Circuit commented that the experimental use exception is construed "very narrowly." The Court pointed out that the experimental use exception was construed very narrowly in *Roche* and like the experiments in *Roche*, the experiments performed by SEC had, "definite, cognizable, and not insubstantial

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> without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

[49] *Embrex*, 216 F.3d at 1346.

[50] *Id.*

[51] *Id.* at 1349.

commercial purposes."[52] Even though SEC claimed that its test of the Embrex's method were merely scientific, the court found that, although the tests were done, "in the guise of scientific inquiry, that alone cannot immunize [its] acts."[53]

*Death of the Experimental Use Exception?*

As with any legal doctrine, the experimental use exception has been scrutinized and its usefulness has been questioned. This section reviews and responds to some of the more well-voiced criticisms the exception has received.

Some scholars believe that the experimental use exception is actually contrary to the intentions of those who wrote patent law. For example, Justice Randall R. Rader of the Federal Circuit said that the experimental use exception cannot last because it looks to the intent of the infringer for its application; intent, however, is irrelevant when analyzing infringement.[54] He points out that both the Federal Circuit and the Supreme Court have found that intent is of no consequence in determining infringement.[55] Infringement is analyzed without determining the purpose of the use. Therefore, one cannot justify what would otherwise be an infringing activity by calling it "experimental use." After all, the intent and purpose analyses should not even be made.

However, Justice Rader seems to rely on cases in which, though infringement was the question, the answer was found in

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[52] *Id. See also* Roche Products v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984).
[53] *Embrex*, 216 F.3d at 1349.
[54] *Id.* at 1352. *See also* Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1519 (Fed Cir. 1995).
[55] *Hilton Davis*, 62 F.3d at 1519.

determining whether the defendant practiced the patented article.[56] It is important to recognize that this does not necessarily dictate that the experimental use exception should not even exist. After all, in the cases Justice Rader cites to support his overwhelming generalization about the viability of the experimental use exception, the articles made by the alleged patent infringers were either to be used or were used for commercial exploitation.

Such commercial exploitation does not always exist, however. There are occasions when the use of a patented article is for strict scientific inquiry or is used to determine its usefulness to a particular process. These are the occasions in which the experimental use exception has been upheld as a viable defense. Justice Rader's lack of support of the exception (as described in *Embrex*) simply does not address these scenarios and, therefore, cannot be used to support abolishment of the exception in all cases.

## Conclusion

Patent laws are in place to protect inventors from unlicensed use of their inventions. Congress and the courts have noticed, however, that some acts which would normally be deemed infringing might deserve special treatment. It is for that reason that they have permitted some uses of patented items to be recognized as non-infringing through an experimental use exception. Usually, to fall within this exception, the use has to be one that is not for a commercial purpose and would not harm the patentee's interest in the item. A use made to determine commercial applicability may be acceptable if it would not lead to commercial gain for the user and a lost interest for the patentee. Although this exception has

[56] *Embrex*, 216 F.3d at 1349.

been deemed a narrow one, it nevertheless seems that it is accepted as a well-founded doctrine, even to the point of it being expanded in the interpretation of its statutory limits. Though the common law experimental use exception has been applied rather even-handedly, perhaps the limits of the statutory doctrine could be expanded further.

In § 271(e)(1), Congress seemed to expand the experimental use exception to cover the use of items that, though used commercially, were used to assess their medical benefits. At the time, the emphasis on products with medical benefits may have been appropriate. However, in today's agricultural market, in which science holds many keys to feeding people efficiently, the restrictions of § 271(e)(1) perhaps should be extended. Certainly this is not to suggest that the reading of § 271(e)(1) is to be broadened, but rather to suggest that some other legislation that serves to open the § 271(e)(1) protections to biotechnology products would be beneficial.

Perhaps Congress' drafting of § 271(e)(1) was influenced by a once-present perception that only medical products benefit mankind enough to be protected under the experimental use exception. This is simply erroneous.

Arguably, many of today's technological revolutions like biotechnology provide an equally, and perhaps greater, immediate benefit to mankind. Perhaps now is the time to recognize the importance of such vital industries and to encourage their growth through protections similar to those offered by § 271(e)(1).