No. 03-1237

IN THE

Supreme Court of the United States

MERCK KGAA,

Petitioner,

v.

INTEGRA LIFESCIENCES I, LTD. AND THE BURNHAM INSTITUTE,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR *AMICUS CURIAE* BAR ASSOCIATION OF THE DISTRICT OF COLUMBIA — PATENT, TRADEMARK & COPYRIGHT SECTION IN SUPPORT OF NEITHER PARTY

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THE INTEREST OF *AMICUS CURIAE*

The Patent, Trademark & Copyright Section of the Bar Association of the District of Columbia ("BADC") respectfully submits this brief as *amicus curiae* in support of neither party.[1]

The BADC is one of the senior intellectual property bar associations in the United States uniquely situated in the nation's capital having a broad cross-section of members from government, industry and private practice, with members often representing both the patent owner and the accused infringer. The BADC is entirely *pro bono* to help advance and create a uniform body of predictable case law to guide the patent community. The BADC has no stake in the parties to this litigation or interest in the result in the case, other than an interest in seeking correct and consistent interpretation of intellectual property law.

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[1] This *amicus curiae* brief is presented by the Patent, Trademark & Copyright Section of the Bar Association of the District of Columbia under Supreme Court Rule 37.3(a). The parties have consented to the filing of this *amicus curiae* brief. The letters of consent from the parties are filed herewith. In accordance with Supreme Court Rule 37.6, *amicus curiae* states that no counsel for a party authored any part of this brief. Only this *amicus curiae* made a monetary contribution to the preparation and submission of this brief. Counsel for *amicus curiae* prepared this brief on a *pro bono* basis.

STATEMENT OF THE CASE

Respondents are the owners of five patents claiming compositions and methods relating to a tri-peptide, RGD. *Integra Lifesciences I, Ltd. v. Merck KGaA,* 331 F.3d 860, 862 (Fed. Cir. 2003). RGD is a tri-peptide of the protein fibronectin, and interacts with or blocks $\alpha_v\beta_3$ receptors on cell surface proteins called integrins. *Id.* at 862-63. Respondents believed that because of the ability of RGD to block $\alpha_v\beta_3$ receptors, peptides containing the RGD were potentially useful in promoting wound healing and prosthesis adhesion. *Id.* at 863. Respondents were, however, unsuccessful in commercializing a product. *Id.* at 873 (Newman, J., dissenting)

Petitioners theorized that blocking $\alpha_v\beta_3$ receptors could, *inter alia*, inhibit tumor proliferation. *Id.* at 863. They, therefore, conducted research using various peptides having the RGD peptide. *Id.* "[T]he purpose of the research was to (1) assess the potential efficacy of the peptides as therapeutic agents; (2) discover the mechanism of action of the peptides; and (3) shed light on the histopathology, toxicology, circulation, diffusion and half-life of the peptides in the bloodstream." *Id.* at 874 (Newman, J., dissenting); *see also Integra*, 331 F.3d at 863. The ultimate goal of these activities was to develop and commercialize a product that was effective in treating angiogenic diseases such as, for instance, cancer. *Integra*, 331 F.3d at 874 (Newman, J., dissenting).

The district court found that Petitioners' activities constituted unexcused infringement. *Id.* at 862. In essentially a 2-1 split panel decision, the United States Court

of Appeals for the Federal Circuit affirmed. *Id.* at 872. The majority based its holding on the statutory safe harbor provision of 35 U.S.C. § 271(e)(1) and refused to consider whether the common law exemption applied. *Id.* The dissenting opinion would have held that both the safe harbor provision of 35 U.S.C. § 271(e)(1) and the common law exemption applied to the Respondents' activities. *Id.* at 873 (Newman, J., dissenting).

SUMMARY OF THE ARGUMENT

The BADC takes no position on whether the Petitioner's activities were statutorily exempt from infringement liability under 35 U.S.C. § 271(e)(1). However, the Petitioner's development activities are of the type that have traditionally been excluded from infringement liability under the common law experimental use exemption.

The common law experimental use exemption applies not only to pharmaceutical and biotechnology research and development, but to research and development activities spanning all industries. The underlying principle of this common law exemption permits non-patentees to experiment on a patented product or process in order to test its parameters, to conduct tests to ascertain the veracity of the patent, to test a patented claim against a new invention to establish nonobviousness under the *Graham v. John Deere Co.*[2] factors, and to utilize the claimed invention as a benchmark to invent around and develop a new invention, including finding new uses for a patented composition.

Although recent Federal Circuit case law has clouded this established principle, and even questioned whether or not an exemption exists, the common law experimental use exemption has been part of patent jurisprudence for over a hundred and fifty years. An experimental use exemption is recognized either by statute or by common law in developed countries and is fundamentally necessary to foster innovation. Failure to recognize this important exemption to infringement will deter research in the United States and encourage companies to conduct their research and development off-shore.

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[2] 383 U.S. 1, 17-18 (1966).

ARGUMENT

I. STATUTORY SUBSET OF EXPERIMENTAL USE

To understand the setting of the *statutory* right to experiment with a pharmaceutical invention as in this case – and under the question raised by the Petitioner – it is essential to understand the context of the overall experimental use doctrine that historically has excluded certain activities from infringement liability, including activities conducted in the present case. This exclusion has been a central core of the American patent case law since first enunciated by Justice Joseph Story in *Whittemore v. Cutter,* 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600) (*Whittemore I).*

A. An Axiomatic Truth First Identified by Justice Story

It is a fundamental aspect of the American patent system that while the inventor receives the exclusive right to *commercialize* his or her invention, everyone has a right to *study* the patented invention. That is, the public has traditionally had the right to see whether a patented invention achieves the results stated in the patent (particularly to challenge the validity of the patent), to use the patented invention as a control for comparative tests (to demonstrate to a patent examiner that a yet newer invention is unobvious under the secondary considerations of *Graham v. John Deere Co.,* 383 U.S. 1, 17-18 (1966)), or to make experiments *on* the patented invention to make yet further inventions. Thus,

> [e]xperimental use as a defense to infringement is likely to be particularly important where it is

> difficult or impossible to evaluate a product or design around a patent without reproducing the product itself. . . . The experimental use doctrines accommodate the general rules of patent law to the needs of iterative industries in which copying or open use of prototypes is a practical necessity.

Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law,* 89 VA. L. REV. 1575, 1648 (2003). This is the heart and soul of the experimental use exemption. Without this important exemption to infringement, innovation in certain scientific areas would be impossible or, at the very least, impracticable.

Accordingly, reason dictates "that it could never have been the intention of the legislature to punish a man, who constructed [a patented] machine merely for *philosophical experiments*, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects." *Whittemore I*, 29 F. Cas. at 1121 (emphasis added); *see also* John F. Duffy, *Harmony and Diversity in Global Patent Law,* 17 BERKELEY TECH. L.J. 685, 717-18 (2002) (quoting *Whittemore I,* 29 F. Cas. at 1121). Later cases show that the term "philosophical," as used in *Whittemore I*, is synonymous with the term "scientific."

In the very same year and court in which *Whittemore I* was decided, Justice Story clarified the meaning of the term "philosophical experiment." *See Sawin v. Gould*, 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391). In the *Sawin* case, the court explained:

> [T]he making of a patented machine to be an offence within the purview of 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. [*Whittemore I*]. In other words, that the making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.

Sawin, 21 F. Cas. at 555.

A further understanding that Justice Story used the term "philosophical" as synonymous with "scientific" can be gained from the usage of the same terminology by Justice Story, just five months after *Whittemore I,* in a second Whittemore case. In *Whittemore v. Cutter,* 29 F. Cas. 1123, 1124 (C.C.D. Mass. 1813) (No. 17,601) (*Whittemore II)* the court observed:

> By the principles of a machine, (as these words are used in the statute) is not meant the original elementary principles of motion, which *philosophy and science* have discovered, but the modus operandi, the peculiar device or manner of producing any given effect. The expansive powers of steam, and the mechanical powers of wheels, have been understood for many ages; yet a machine may well employ either the one or the other, and yet be so entirely new, in its mode of applying these elements, as to entitle the party to a patent for his whole combination.

Whittemore II, 29 F. Cas. at 1124 (emphasis added). Other contemporaneous cases use the term "philosophical" as synonymous with "scientific." *See Barrett v. Hall,* 2 F. Cas.

914, 919 (C.C.D. Mass. 1818) (No. 1,047) ("Suppose the defendants insist, that the patent is claimed for a bare *philosophical principle*. This in like manner must be referred to the jury, unless *mechanical philosophy* be law, and as such be presumed to exist in the breast of the court.") (emphasis added); *Bedford v. Hunt,* 3 F. Cas. 37 (C.C.D. Mass. 1817) (No. 1,217) ("If [a prior invention] were the *mere speculation of a philosopher or a mechanician*, which had never been tried by the test of experience, and never put into actual operation by him, the law would not deprive a subsequent inventor, who had employed his labor and his talents in putting it into practice, of the reward due to his ingenuity and enterprise.") (emphasis added); *Lowell v. Lewis,* 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8,568) ("It has been often decided, that a patent cannot be legally obtained for a mere *philosophical* or abstract theory; it can only be for such a theory reduced to practice in a particular structure or combination of parts.") (emphasis added).

Further, as the *Integra* dissent aptly notes, contemporaneous standards of the United States Patent Office confirm that, at the time, the term "philosophical" that Justice Story referred to was synonymous with "'natural philosophy,' the term then used for what we today call 'science.' For example, in [1868] the volume on *Classification of Subjects of Inventions Adopted by the United States Patent Office* . . . , the section headed 'Philosophical Instruments – Class XXV' lists 'Philosophical Apparatus, Scales, Measures, and Instruments of Precision.'" *Integra*, 331 F.3d at 874 n.8.

B. An Experimental Use Defense Has Been Recognized by This Court for Over 150 Years

Neither in the definition of a "public use" under 35 U.S.C. § 102(b) nor "infringement" under 35 U.S.C. § 271(a) is there a single statutory hint or suggestion of an "experimental use" exception. Yet, it has been well-settled by the Court since the nineteenth century that what is a public use or what is an infringement gives way to an "experimental use" defense.

In the context of "public use" under what is today 35 U.S.C. § 102(b), the early *Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126 (1877) case is still valid today. In the *Elizabeth* case, the Court stated:

> It is sometimes said that an inventor acquires an undue advantage over the public by delaying to take out a patent, inasmuch as he thereby preserves the monopoly to himself for a longer period than is allowed by the policy of the law; but this cannot be said with justice when the delay is occasioned by a *bona fide* effort to bring his invention to perfection, or to ascertain whether it will answer the purpose intended. His monopoly only continues for the allotted period, in any event; and it is the interest of the public, as well as himself, that the invention should be perfect and properly tested, before a patent is granted for it. Any attempt to use it for a profit, and not by way of experiment, for a longer period than two years before the application, would deprive the inventor of his right to a patent.

Elizabeth v. Am. Nicholson Pavement Co., 97 U.S. 126, 137 (1877), *quoted in Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 64-65 (1998). Further, more recently, the Court has expressly acknowledged that there is such an exemption from the statutory wording by stating that "[t]he law has long recognized the distinction between inventions put to experimental use and products sold commercially." *Pfaff*, 525 U.S. at 64.

C. Absence of a Codification Fifty Years Ago

The simple answer for the absence of a codification of the experimental use doctrine when the patent law was codified as the 1952 Patent Act is that it was so axiomatic that the doctrine was present, particularly since there had been no serious challenge to the fundamental truths set forth by Joseph Story so many years earlier in *Whittemore I* and *II*.

Ironically, while in more recent years the United States has been contracting the experimental use doctrine and calling its very existence in doubt, numerous foreign governments have created their own patent laws emulating the traditional American principles. John F. Duffy, *Rethinking The Prospect Theory Of Patents,* 71 U. CHI. L. REV. 439, 457 n.68 (2004) ("[A]n experimental use exception to infringement is expressly recognized in the statutory law of many other jurisdictions, including Japan, Korea, Germany, the United Kingdom, and most other European nations. . . . Canada also has a well-established experimental use exception, but it was judicially created and not legislatively enacted.").

Because foreign jurisdictions generally recognize the experimental use doctrine, the recent United States restriction on the doctrine may have only a modest effect on

companies. Firms seeking to research improvements in a patented technology can always locate their research overseas and still maintain the right to obtain United States patents on the results of that research. The effect on skilled professional scientists in the United States, however, will be more serious as a growing number of companies take their research off-shore. *See* John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 BERKELEY TECH. L. J. 685, 717-19 (2002) (discussing the effect of the divergence between the United States law on experimental use and the laws of other nations); Janice Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development,* 56 BAYLOR L. REV. 917, 920 (2004). ("Without such an [experimental use] exemption, scientific research functions that require the use of patented inventions are more likely to be shifted offshore to legally hospitable forums.")

D. Fundamental Necessity for *Some* Experimental Use Doctrine; Contours of the Exemption

There is an absolute necessity to maintain some experimental use exemption for the operation of the patent system. For example, it is necessary that those seeking to invalidate a patent have the ability to experiment with an invention to determine its operability in accordance with the teachings of the patent specification. *See Crown Operations Int'l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1380 (Fed. Cir. 2002) ("[A] claim may be invalid if it reads on significant numbers of inoperative embodiments."); *see also Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 929 n.9 (Fed. Cir. 2004) ("[Morse] claims an exclusive right to use a manner and process which he has not described and indeed

had not invented, and therefore could not describe when he obtained his patent." (quoting *O'Reilly v. Morse*, 56 U.S. 62, 113 (1853)); *Whittemore I,* 29 F. Cas. at 1121 (authorizing experimentation "for the purpose of ascertaining the sufficiency of the machine to produce its described effects."); *Sawin,* 21 F. Cas. at 555 (authorizing use to "ascertain the verity and exactness of the specification.").

Experimentation may also be necessary to establish patentability of a new invention through comparative testing to establish presence of a secondary consideration under *Graham v. John Deere Co.,* 383 U.S. 1, 17-18 (1966). Detailed regulations have been established by the United States Patent and Trademark Office. *See, e.g.*, MANUAL OF PATENT EXAMINING PROCEDURE § 716.02(b) (8th ed., rev. 2 2004) ("Evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims."). If the "closest prior art" is patented prior art, then the applicant may be required to infringe another's patent in order to obtain a patent.

Another instance of the scope of the exclusion that permits experimentation is inventing around another's patented invention in order to bring another innovation to the public. As the late Judge Rich recognized in *State Industries, Inc. v. A.O. Smith Corp.,* 751 F.2d 1226 (Fed. Cir. 1985), designing around is one of the benefits of a patent system:

> [K]eeping track of a competitor's products and designing new and possibly better or cheaper functional equivalents is the stuff of which competition is made and is supposed to benefit the consumer. One of the benefits of a patent

> system is its so-called 'negative incentive' to 'design around' a competitor's products, even when they are patented, thus bringing a steady flow of innovations to the marketplace.

State Indus., 751 F.2d at 1235-36.

E. The Limits of the Exemption

The common law exemption to infringement is necessarily narrow and strictly limited. The exemption must be carefully balanced to protect a patent system that rewards innovation.

In the recent case of *Madey v. Duke University,* 307 F.3d 1351 (Fed. Cir. 2002), a panel of the Federal Circuit considered the scope of the very narrow and strictly limited experimental use defense. *Madey*, 307 F.3d at 1361-63. There, researchers at Duke University had used a patented laser without the permission of the patent owner to conduct research. *Id.* at 1352-53. But the Duke research did not involve investigating *into* the laser itself, rather the laser was being used as a research tool.[3] *See id.* As the *Integra* dissent correctly noted, the distinction is "between investigation *into* patented things, as has always been permitted, and investigation *using* patented things, as has never been permitted." *Integra* at 878 n.10 (Newman, J., dissenting) (emphasis added). Investigation "using patented things" is clearly beyond the scope of experimental exclusion envisioned by Justice Story in the *Whittemore I* and *II* line of cases. Accordingly, "the facts of *Madey* [would correctly]

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[3] "A research tool is a product or method whose purpose is *use* in the conduct of research . . . ." *Integra*, 331 F.3d at 878 (Newman, J., dissenting) (emphasis added).

not invoke the common law research exemption . . . ." *Integra*, 331 F.3d at 878 n.10 (Newman, J., dissenting).

The research exemption also does not permit a would-be copyist to experiment with a patented product during the term of the patent so that he or she can market the identical patented product after the expiration of the patent. *See Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (superseded by 35 U.S.C. § 271(e)(1)). However, the facts in *Roche* are distinguishable from the facts in this case where the Petitioners here innovated by experimentation and developed a new use for the RGD tri-peptides. That is, while the patent owners sought to develop a product using the RGD tri-peptide for adhesion, the accused infringers developed a peptide including the RGD tri-peptide for an entirely different application – treatment of angiogenic diseases such as cancer.

The fact, however, that there may be some ultimate commercial incentive in the experimental use does not preclude application of the exemption. Thus, the company that infringes a patented invention with the goal of designing around that invention is entitled to the exemption as much as the individual that infringes merely to satisfy some "idle curiosity."

F. Recent Challenges to the Exemption from the Federal Circuit

A common law experimental use exemption was well-established and without serious challenge of any kind until the past decade when the Federal Circuit transformed a gratuitous statement of dictum in one of its early opinions into an expression of black letter law. *See Roche Prods.*, 733 F.2d at 863; John F. Duffy, *Harmony and Diversity in*

Global Patent Law, 17 BERKELEY TECH. L.J. 685, 718 (2002) (citing Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1019-20 (1989)). The cardinal mistake of the dictum in *Roche* was to misunderstand the term "philosophical" by relying on a modern meaning of the term and not grasping the contemporary usage that Justice Story intended. At the time that Justice Story wrote his ground breaking opinions, "philosophical" was synonymous with "scientific." This fundamental misunderstanding of terminology, and thus mistake, has been carried forth in subsequent Federal Circuit cases, including *Madey v. Duke University,* 307 F.3d 1351 (Fed. Cir. 2002) and *Embrex Inc. v. Service Engineering Corp.,* 216 F.3d 1343 1353 (Fed. Cir. 2000) (Rader, J., concurring).

While there has not been a *precedential* Federal Circuit *holding* that experimentation on a patented invention to make an improvement is an act of infringement, loose *dicta* exists that lead to that conclusion. *Madey*, 307 F.3d at 1362 (observing that the experimental use defense is "limited to actions performed 'for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.'"; *see also Embrex, Inc. v. Service Eng'g Corp.,* 216 F.3d 1343, 1349 (Fed. Cir. 2000). Further, a panel of the Federal Circuit has issued a nonprecedential opinion that suggests this result. *See Soitec, S.A. v. Silicon Genesis Corp.*, 81 Fed. Appx. 734, 737 (Fed. Cir. 2003) (non-precedential) (per curiam) (citing the *dicta* in the Federal Circuit's *Madey* precedential decision, the court stated that "[t]here is no fair use or research and development exception for infringement of normal commercial processes.").

G. Federal Circuit Quest for Simple Black and White Patent Rules

The Federal Circuit has been dangerously close to repudiating the experimental use exemption. One member of the court has even stated, in a concurring opinion, that repudiation of the experimental use doctrine is dictated by *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 34 (1997). *Embrex, Inc. v. Service Eng'g Corp.*, 216 F.3d 1343, 1353 (Fed. Cir. 2000) (Rader, J., concurring). More particularly, the *Embrex* concurrence stated:

> The Supreme Court's recent reiteration that infringement does not depend on the intent underlying the allegedly infringing conduct, to my eyes, precludes any further experimental use defense, even in the extraordinarily narrow form recognized in *Roche*. Of course, even if the experimental use excuse retains some lingering vitality, the slightest commercial implication will render the 'philosophical inquiry/ experimental use' doctrine inapplicable, as occurs in the court's resolution today. Therefore, . . . I would lay to rest permanently [the accused infringer's] infringement excuses which find no support in the Patent Act.

Id. Drawing the contours of the experimental use doctrine requires a nuanced approach, which is antithetical to the current trend toward "formalism" at the Federal Circuit, as manifested by *Embrex*. Criticizing *Roche* and *Embrex*, two leading academics have noted that

> the court pointed not to changes in policy that rendered the rule obsolete, but to the absence of

> any specific authorization for the long-standing judicial rule in the Patent Act. The court has sought to confine other policy levers . . . by imposing narrow and specific rules on them, in effect cabining its own discretion. Still other policy levers, such as the pioneering patents doctrine, have not been eliminated so much as neglected. [Professor] Thomas reviewed these developments and concluded that the unifying theme in Federal Circuit jurisprudence over the last ten years is a shift toward simple rules and legal formalism."

Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law,* 89 VA. L. REV. 1575, 1673 (2003) (citing John R. Thomas, *Formalism at the Federal Circuit*, 52 AM. U. L. REV. 771, 773-74 (2003)).

II. A *DE MINIMUS* APPROACH IS UNWORKABLE

The *Integra* majority suggests that in lieu of an experimental use exemption, courts can, instead, look to a *de minimus* infringement and lessen damages. *Integra*, 331 F.3d at 864 n.2. This would be an unworkable approach for at least two reasons.

First, and most importantly, under the patent statutes, a patent owner is entitled to seek an injunction. 35 U.S.C. § 283. There are no mandatory license provisions in the patent statute, and courts have been reluctant to mandate licenses except in very extreme and unusual cases. Indeed, in this case, the Respondents had originally sought an injunction against Petitioners as well as damages for past activities. *Integra*, 331 F.3d at 863. If there is no common

law exemption to infringement, competitors could improperly freeze out competition merely by seeking injunctive relief.

Second, it is difficult to assess "*de minimus*" infringement. Often, it is not the amount of infringement, but the *consequences* of the infringement that has the greatest impact on the patent owner. Consider, for instance, the hypothetical example of the inventor of a patent application who infringes another party's patent only a single time in order to perform testing required by the United States Patent and Trademark Office to show superior results under the *Graham v. John Deere Co.* factors.[4] On the surface this seems to be a *de minimus* infringement. However, suppose the patent application of the one-time infringer issues as a patent that covers a blockbuster product that so successfully competes with the earlier-patented product and virtually replaces the first patent owner's product in the marketplace. While the one-time infringement appears to be *de minimus*, the damage to the first patent owner is enormous.

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[4] 383 U.S. 1, 17-18 (1966).

CONCLUSION

Pre-clinical testing of a pharmaceutical invention – as in the present case – may be held to be activities that fall within the statutory exception set forth in 35 U.S.C. § 271(e)(1). A holding for Petitioners may very well open the door to pharmaceutical experimental testing of inventions to satisfy the experimental use case law. Yet, while this may be a laudatory goal, it is respectfully requested that the Court, if not dealing directly with the *Embrex* aberrant line of case law, at least leave undisturbed a long line of well reasoned precedent that recognizes a common law exemption to infringement which is necessary for the operation of the patent system itself and critical for continued innovation in the United States.

Respectfully submitted,

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