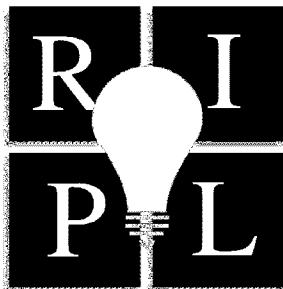


THE JOHN MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW



A NEW DAY YESTERDAY: BENEFIT AS THE FOUNDATION AND LIMIT OF EXCLUSIVE RIGHTS IN PATENT LAW

N. SCOTT PIERCE

ABSTRACT

The exclusive right afforded by patent protection to an inventor is in exchange for contribution to the public domain of an enabling disclosure of the subject matter claimed. The requirement of novelty and the prohibition against infringement are both based on statute, and linked in well-established judicial precedent as “that which infringes, if later, anticipates, if earlier.” See, e.g., *Pairpearl Products, Inc. v. Joseph H. Meyer Bros.*, 58 F.2d 802 (D.C.D.M.S.D. 1932). Grant of a limited period of exclusivity to an inventor and interpretation of the scope of the right given in exchange for complete disclosure have engendered the judicial doctrines commonly known as inherent anticipation and experimental use. Analysis of three recent cases illustrate how historical conceptions of inherency and experimental use doctrines can greatly simplify determinations of the scope of exclusive rights under widely varying circumstances so long as those rights are not confused with the inexorable capacity of thought and a corollary right of exploration reserved to the public.

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N. SCOTT PIERCE*

If we were all destined for the same battles, life would have to be a war without rest or truce; but since it happens, on the contrary, that some objects become the property of each man, or in other words, since there is property ownership, it follows from this that life is possible; that the human species can exist in peace; that the natural instinct of sociability that characterizes our species is not a deception of our nature; that the work of yesterday serves the progress of tomorrow.¹

Antoine-Augustin Renouard

INTRODUCTION

Exclusive rights that are granted to inventors in exchange for disclosure to the public of useful inventions are calculated to provide an incentive to the population as a whole and to reward inventors for their discoveries. The period and scope of exclusivity are limited in order to permit society to fully exploit an inventor's contribution once the inventor has been given a reasonable opportunity to profit from the invention without competition. As stated by Antoine-Augustin Renouard, the French philosopher, patent rights are based on two propositions that must be reconciled:

Therefore, here are two propositions, both of which are incontestable: one, is that the legitimate rights of the inventor oppose the exploration of the discovery made by his genius with complete freedom of competition by whoever can understand it; the other, is that each member of the human species has the right to freely use his thought, regardless of where it comes from, and to impress on any part of matter that he masters the form of the invention which he has understood with his intellect and identified with his thought.

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¹ ANTOINE-AUGUSTIN RENOUEARD, TRAITÉ DES BREVETS D'INVENTION (Rue de Tournon, No. 6 1825), p. 19.

These two propositions, since they are both true, cannot be irreconcilable, regardless of their apparent contradiction, since truth has nothing to fear of being destroyed, fought, or even hindered, by [another] truth: it is only incompatible with error.²

For Renouard, these propositions were reconciled by a system of payment, whereby a temporary, exclusive privilege is granted to the inventor.³ The consequence of a temporary monopoly, according to Renouard, is freedom from competition, which will “have the effect of raising the average price at which the products will be delivered to consumers”⁴ whereby “one is reduced to so feeble an objection as the delay that the temporary monopoly could bring to reducing the price of the products of the invention.”⁵ Renouard is silent with respect to any delay in advancements of technology consequent to grant of an exclusive right to the inventor. However, as expressed above, reconciliation of the two propositions is contingent upon limiting the “legitimate rights of the inventor” to freedom from competition in the marketplace by substitute sources of his invention without limiting the right of “each member of the human species . . . to freely use his thought . . .”⁶ The temporary exclusive right of an inventor, therefore, should protect his freedom to profit or otherwise exclude others from benefiting by his invention. However, the benefit of his invention should not include the right to exclude discovery of the manner in which it operates or to improve upon it. Such a right would limit the public’s source of thought and the consequent ability of the public to master “the form of the invention which he has understood with his intellect and identified with his thought.”⁷

Inherency and experimental use doctrines, as applied under U.S. patent law through the nineteenth and twentieth centuries, have recognized benefit as a common limitation to the exclusive rights of patent protection. The inherency doctrine,⁸ which will bar patent protection for discovery or recognition of what is in the public domain, typically does not include instances where the claimed combination has not benefited the public, such as by trace, incidental, or even, under some circumstances, unrecognized presence in the prior art. Conversely, the experimental use doctrine⁹ limits the exclusive right of a patentee to the benefit afforded by his discovery, which, consistent with reconciliation of the propositions underlying patent protection articulated by Renouard, does not include the right to bar others from “exploration of the discovery made by his genius.”¹⁰ Viewed from a linking vantage point of benefit, these doctrines can be employed to reward those who advance “the work of yesterday to serve the progress of tomorrow”¹¹ without diminishing the rights of the public in what has gone before.

² *Id.* at 40.

³ *Id.*

⁴ *Id.* at 52.

⁵ *Id.* at 54.

⁶ *Id.* at 40.

⁷ *Id.*

⁸ *In re Seaborg*, 328 F.2d 996, 997–98 (C.C.P.A. 1964).

⁹ *See, e.g., Roche v. Bolar*, 733 F.2d 858, 862 (Fed. Cir. 1984).

¹⁰ RENOARD, *supra* note 1, at 40.

¹¹ *Id.* at 19.

I. DISCOVERY AND EXCLUSIVE RIGHTS IN PATENT LAW

Willard Phillips, in his 1837 treatise, *The Law of Patents for Inventions*, states that patent protection is founded on principals of equity: “[t]he granting of patents is not, accordingly, a mere matter of favor, as it has sometimes been represented by judges, but an equitable and just claim upon the government, as much so as the claim to protection of individual industry and private property.”¹² The equity is an establishment of positive law, which recognizes that “an inventor has not, independently of positive laws, an exclusive property in his invention, any longer than he keeps it secret.”¹³ Otherwise, inventors are precluded from exploiting their inventions, since “[t]hey can, in general, at most only lock up their secrets in their own breasts, not being able to turn it to any advantage to themselves, except by means of a law enacted in their behalf.”¹⁴

Following the logic of Renouard, that there is no natural exclusive right to invention,¹⁵ Phillips more broadly asserts that “the fact of one person being the first inventor or discoverer, affords no pretense for disenfranchising others of the right, in their turn, of making and using the same discovery.”¹⁶ Positive law must recognize, or limit, the natural right of others who may independently make the same discovery if it is to protect an inventor beyond his personal knowledge and ability to exploit his invention without disclosing it. Specifically, Phillips states that protections under positive law should be of limited term, but as a matter of practicality, must operate as an exclusive right as against all others who have made the same invention without any assistance from his ingenuity:

If it be then admitted that he is equitably entitled to the exclusive use and sale for a time, against all others who do not make use of the same invention independently of him, and without deriving any hint or facility from his prior ingenuity or experiments, we have sufficient ground for a law giving him the exclusive right against *all* others for a time, since it is a matter of law of too much difficulty and intricacy of proof, to distinguish the cases of others who have made the same invention without any assistance from his ingenuity, from those of mere imitations. The law, in order to be practicable and convenient to be administered, must give the exclusive right. To this point the law is only an equitable regulation, which does not *propose* to deprive others of any right on behalf of inventors, but *incidentally* deprives

¹² WILLARD PHILLIPS, *THE LAW OF PATENTS FOR INVENTIONS: INCLUDING THE REMEDIES IN LEGAL PROCEEDINGS IN RELATION TO PATENT RIGHTS* 6 (American Stationers' Co. 1837).

¹³ *Id.* at 7 (quoting RENOARD, *supra* note 1, at 32).

¹⁴ *Id.* at 8.

¹⁵ *Id.* at 4. Phillips stated:

M. Renouard, the author of an elaborate French work on Patents, goes into particular discussion of the question whether an inventor has, by the principles of universal equity, and independently of the positive law, an exclusive right to his invention; and he very satisfactorily establishes the conclusion to which every mind is constrained to yield assent, that no such natural right exists.

Id.

¹⁶ *Id.*

them of a right, which they would otherwise have, because it is necessary for the purpose of doing justice to inventors.¹⁷

The rights that members of the community are deprived of by positive law are stated by Phillips to be “first, that of discovering or inventing that same thing, independently of the prior invention, and that of using or vending it for a limited time; and second, the right of profiting by the prior invention or discovery of another, for a limited time.”¹⁸ The “grounds and motives” of such laws are stated by Phillips to be “in the first place, to indemnify inventors, in the second to secure to the public the benefit of inventions, and stimulate ingenious minds to make improvements, and in the third place to reward the inventors as public benefactors, according to the importance of their invention . . .”¹⁹ As explained by Phillips: “[i]t is as M. Renouard says, an *exchange* between the two parties, the inventor on one side, who grants the community a new art or machine, and the community on the other, which grants in return to the inventor, indemnity and compensation.”²⁰

Phillips also stated that, “the great mass of useful inventions is made up, and must be, not of what is altogether new, but improvements in what is already practised [sic],”²¹ and the reward to the inventor for his discovery under law should be commensurate with the benefit conferred on the public by the improvement:

Though the *property* in a discovery, therefore, like that in land, originates in and is created by legislation, the *right* to such property exists to an imperfect degree, independently of the positive laws. In this view, Mr. Rawle remarks, that upon the provisions of the [C]onstitution of the United States on this subject, that it was not intended thereby to create rights, but merely to regulate those already existing. The inventor has a *right* to keep his secret, and if he discloses it he has a just claim to remuneration and reward, according to the amount of his expenditure, and the importance of his improvement.²²

As a practical matter, however, as with the inability under positive law to “distinguish the cases of others who have made the same invention without any assistance from his ingenuity, from those of mere imitations,”²³ there is, likewise, an inability to distinguish between those who base an improvement upon the subject matter of another inventor’s exclusive right and those who invent the same improvement by virtue of their own inventive faculty only in view of other prior art. In other words, it is too difficult to discern discovery made possible by disclosure of a patented invention from that made possible by the remainder of the art of which that

¹⁷ *Id.* at 6.

¹⁸ *Id.* at 5.

¹⁹ *Id.* at 17.

²⁰ *Id.*

²¹ *Id.* at 9.

²² *Id.* at 8–9 (citing William Rawle on the U.S. Constitution, c. 9, p.102 (1825)).

²³ *Id.* at 6.

disclosure is now a part. Therefore, the opportunity for subsequent discovery should be reserved to the public as a matter of equity.

Phillips summarizes “the principles and motives of patent laws” as “1, the securing to the inventor the remuneration of his outlay; 2, a reward for his ingenuity, and the benefit he confers on the community; and 3, to encourage and stimulate invention and improvements.”²⁴ To grant an inventor an exclusive right over discovery would be a reward for his ingenuity at the expense of the object of encouraging and stimulating subsequent invention and improvement. Although contributions to the art are benefits to the community that may be granted exclusivity on the basis of equity, discovery of those contributions are not part of that benefit, since discoveries, in themselves, are not, and have never been, the basis for grant of exclusive rights in patent law. Rather, only improvements based on discoveries have been granted an exclusive privilege. Therefore, the natural right of discovery is reserved to the community from the grant of exclusivity consequent to a contribution of an improvement in the art. Any benefit to the community of an improvement derived from subsequent discovery should be granted exclusivity that is limited to the improvement based on the subsequent discovery, subject to an existing exclusive right of the first inventor. The right to discovery is not part of the grant of a patent because, in contrast to other benefits conferred upon the community by use of an invention, society’s ability to progress would be impeded, contrary to the “principles and motives of patent laws.”²⁵

II. GENESIS AND DEVELOPMENT OF EXPERIMENTAL USE AND INHERENCY DOCTRINES

A. *Experimental Use*

1. *Distinction Between Experimental Use and Statutory Exclusivity in Early Case Law*

A distinction between the benefit of an invention to the public for which an inventor is to be rewarded, and discovery associated with it as a natural right unimpeded by positive law, can be found in very early court decisions. The most famous of these cases is *Whittemore v. Cutter*,²⁶ in which Justice Story introduced what was later to become known as the “experimental use”²⁷ exception to patent infringement:

Another objection is to the direction, that the making of a machine fit for use, and with a design to use it for profit, was an infringement of the patent right, for which an action was given by the statute. This limitation of the making was certainly favorable to the

²⁴ *Id.* at 16.

²⁵ *Id.*

²⁶ 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

²⁷ *See, e.g., Roche v. Bolar*, 733 F.2d 858, 862 (Fed. Cir. 1984).

defendant, and it was adopted by the court from the consideration, that it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.²⁸

This statement by Justice Story must, however, be taken in context with other statements made in response to further arguments by the defendant to limit the nature of infringing activity. For example, Justice Story answered an argument “that the making of a machine is, under no circumstances, an infringement of the patent” by quoting the literal language of the Patent Act of 1793 and its subsequent revision in 1800, and by positing that the exclusive rights to “make, devise, use or sell” the invention were each to be considered under the Acts to be a “substantive ground of action.”²⁹ With respect to the further argument by the defendant that the making of a machine cannot be infringed because there can be no actual damages, Justice Story made clear that “[e]very violation of a right imports some damage, and if none other be proved, the law allows a nominal damage.”³⁰ Giving literal effect to the phrase “make, devise, use or sell” of the Patent Act, and denying an attempt to escape infringement for lack of measurable damages, can only be reconciled with the premise, “that it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described

²⁸ *Whittemore*, 29 F. Cas. at 1121.

²⁹ *Id.* Justice Story stated:

It is now contended by the defendant’s counsel, that the making of the machine is, under no circumstances, an infringement of the patent. The first section of the act of 1793 expressly gives to the patentee “the full and exclusive right and liberty of making, constructing, using and vending to others to be used” the invention or discovery. The fifth section of the same act gives an action against any person, who “shall make, devise, and use or sell” the same. From some doubt, whether the language of the section did not couple the making and using together to constitute an offence so that making without using, or using without making, was not an infringement, the legislature saw fit to repeal that section; and by the third section of the act of April 17, 1800, gave the action against any person, who should “make, devise, use or sell” the invention. We are not called upon to examine the correctness of the original doubt, but the very change in the structure of the sentence affords a strong presumption, that the legislature intended to make every one of the enumerated acts a substantive ground of action.

Id.

³⁰ *Id.* As stated by Justice Story:

It is further argued, that the making of a machine cannot be an offence, because no action lies, except for actual damage, and there can be no actual damages, or even a rule for damages, for an infringement by making a machine. We are however of opinion, that where the law gives an action for a particular act, that doing of that act imports of itself a damage to the party. Every violation of a right imports some damage, and if none other be proved, the law allows a nominal damage. On the whole, we see no reason for departing from the plain import of the language of the statute, and this objection also must be overruled.

Id.

effects,”³¹ by an understanding that such activity does not fall within the scope of the phrase, “make, devise, use or sell,” of the Act.

*Sawin v. Guild*³² was decided in October of 1813, five months after *Whittemore*.³³ In *Sawin*, the plaintiffs asserted that seizure and subsequent sale of a patented machine for cutting brad nails in settlement of a debt was an infringement of their patent.³⁴ Justice Story distinguished between sale of a machine, as a compilation of materials, from “the right, expressed or implied, of using the same in the manner secured by the patent”;³⁵ that, to be a tortious sale under the statute, the purpose must be that of depriving the owner of the “use and benefit of his patent,” and not “merely of depriving the owner of the materials.”³⁶ The court in *Sawin* reiterated that to find infringement of a patent right required an intent to deprive the owner of “the lawful rewards of his discovery” and not for “the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification.”³⁷ The sale of the machine, without the purpose of depriving the owner of the “use and benefit of his patent,” would, accordingly, put the purchaser at risk for infringement because there would have been no transfer from the owner of the patent to the purchaser of the right to use the machine “in the manner pointed out in the patent-right.”³⁸ Profit, therefore, as a monetary gain, was partitioned from infringement of a patent

³¹ *Id.*

³² 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391).

³³ *Id.* at 554.

³⁴ *Id.* Justice Story summarized the plaintiffs’ position as follows:

[T]he defendant is a deputy sheriff of the county of Norfolk, and having an execution in his hands against the plaintiffs for the sum of \$567.27 debt and costs, by virtue of his office, seized and sold, on said execution, the materials of three of said patented machines, which was at the time complete and fit for operation, and belonged to the plaintiffs The plaintiffs contend that it cannot be so seized and sold, and they rely on the language of the third section of the act of the 17th of April, 1800, which declares that if ‘any person, without the consent of the patentee, his or her executors, first obtained in writing, shall make, devise, use, or sell within, whereof the exclusive right is secured to said patentee, such person, so offending, shall forfeit,’

Id. (citations omitted).

³⁵ *Id.* at 555.

³⁶ *Id.*

³⁷ *Id.* Justice Story stated:

This court has already had occasion to consider the clause in question, and upon mature of deliberation, it has held that the 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. 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.

Id. (citation omitted).

³⁸ *Id.* The court stated:

There is no pretence, in the case before us, that the officer had either sold or guaranteed a right to use the machine in the manner pointed out in the patent-right. He sold the materials as such, to be applied by the purchaser as he should by law have a right to apply them. The purchaser must therefore act upon his peril, but in no respect can the officer be responsible for his conduct.

Id.

right: for a sale to be an infringement under the Patent Act, it must be in conjunction with a deprivation of the right to exclusive use and benefit of the invention.

If, according to the decisions in *Whittemore* and *Sawin*, the Act of 1793 (as amended by the Act of April 17, 1800) gave a cause of action “against any person, who should make, devise, use or sell the invention,”³⁹ and if there is no exception to infringement for such activity because “every violation of a right imports some damage,”⁴⁰ then Justice Story’s clarification of *Whittemore* in *Sawin* must mean that the making of a machine “merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects,”⁴¹ as stated by the court in *Whittemore*, or, as stated by the court in *Sawin*, “for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification,”⁴² cannot be a “making, constructing, using, and vending to others to be used” within Section 1 of the statute.⁴³ Further, because profit alone (in the absence of depriving an inventor of an exclusive right to benefit from his invention) also is inadequate to find infringement, it follows that making or using an invention “for the mere purpose for philosophical experiment, or to ascertain the verity and exactness of the specification”⁴⁴ or “for the purpose of ascertaining the sufficiency of the machine to produce its described effects,”⁴⁵ even with the prospect of monetary gain as a consequence, is not activity within the Patent Act, and no cause of action for infringement should lie. In other words, the “lawful rewards of his discovery,” and “the use and benefit of his patent” recited by Justice Story in *Sawin*, is exclusive of “philosophical experiments, or ascertaining the sufficiency of the machine to produce its described effects or the verity and exactness of the specification,”⁴⁶ regardless of whether there was, as stated in *Whittemore*, a “design to use it for profit.”⁴⁷

Subsequent experimental use by the public of a patented invention has a parallel in experimental use by another person prior to independent invention by a patentee. For example, in *Watson v. Bladen*,⁴⁸ Justice Washington held that prior experimental use by Christian of a cracker making machine defeated the right of patentee Treadwell:

But the point mainly relied upon by the plaintiff’s counsel is, that no evidence is given that Christian’s machine was ever used within the true meaning of that expression in the patent act. It is admitted that an experiment was made with it, but this, it is argued, was not such a using as the act intends. It surely cannot be denied that the act of making crackers with it amounted to a using of it according to the common and accepted meaning of that phrase; and I am quite at a loss to imagine how this meaning can be varied by the particular

³⁹ *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600).

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Sawin*, 21 F. Cas. at 555.

⁴³ Patent Act of 1793, ch. 11, § 1, 1 Stat. 318–23 (repealed 1836).

⁴⁴ *Sawin*, 21 F. Cas. at 555.

⁴⁵ *Whittemore*, 29 F. Cas. at 1121.

⁴⁶ *Sawin*, 21 F. Cas. at 555.

⁴⁷ *Whittemore*, 29 F. Cas. at 1121.

⁴⁸ 29 F. Cas. 424 (C.C.E.D. Pa. 1826) (No. 17,277).

motive which induced the inventor so to employ the machine. I can discover nothing in the patent act which will authorize the court to depart from the ordinary meaning of this expression, and to declare that a machine which is put into operation for the sole purpose (if such be the case) of trying its practical utility, is not used within the meaning and intent of the sixth section of that act.⁴⁹

This case was considered by the court to be distinct from earlier cases, including *Boulton v. Bull*⁵⁰ and *Bedford v. Hunt*,⁵¹ where “mere speculation of a philosopher or a mechanic, which had never been tried by the test of experience, and never put into actual operation by him, . . . 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.”⁵² Justice Washington, nevertheless, found that these earlier cases were consistent with his holding in *Watson* in that they “manifestly contrast the confining of the invention to the closet of the inventor and a mere speculative invention, with putting it into use, practice, or operation; and not the putting of it into practice for the purpose of an experiment, with any other purpose whatever.”⁵³ In essence therefore, Justice Washington agreed with the earlier cases, that “mere speculation of a philosopher or mechanic, which had never been tried by the test of experience,”⁵⁴ is inadequate to defeat the right of a later inventor, but held that prior *use* of an invention, regardless of the experimental nature of that use, *is* adequate to defeat a later inventor’s right to patent protection:

Upon the whole, I am of opinion, that the experiment of this machine made by Christian, in the year 1807, amounted to a using of it within the true meaning of the sixth section of the patent act If Christian’s machine was invented and used prior to the discovery of Treadwell, then this patent is void, because it covers all the essential parts of Christian’s machine, without which it could not operate at all to produce the intended result.⁵⁵

Similarly, a British case, *Jones v. Pearce*,⁵⁶ distinguished between earlier use by another that was “openly in public, so that everybody might see it, and had continued

⁴⁹ *Id.* at 425–26. Section 6 of the Patent Act of 1793 provides a defense to infringement of public use prior to discovery by the patentee:

Provided always, and be it further enacted, [t]hat the defendant in such action shall be permitted to plead the general issue, . . . that the thing, thus secured by patent, was not originally discovered by the patentee, but had been in use, or had been described in some public work anterior to the supposed discovery of the patentee, . . . in either of which cases, judgment shall be rendered for the defendant, with costs, and the patent shall be declared void.

Patent Act of 1793, ch. 11, § 6, 1 Stat. 318–23 (repealed 1836).

⁵⁰ 126 Eng. Rep. 651 (1795) (C.P.).

⁵¹ 3 F. Cas. 37 (C.C.D. Mass. 1817) (No. 1,217).

⁵² *Id.* at 38.

⁵³ *Watson*, 29 F. Cas. at 426.

⁵⁴ *Bedford*, 3 F. Cas. at 38.

⁵⁵ *Watson*, 29 F. Cas. at 426.

⁵⁶ 1 Webst. Pat. Cas. 122 (K.B. 1831).

to use the same thing up to the time of taking out the patent,” which “would be a ground to say that the plaintiff’s patent is not new,” from an unsuccessful experiment, whereby the prior user “found it did not answer, and ceased to use it altogether, and abandoned it as useless, and nobody else followed it up,” which would not suffice to defeat the patent.⁵⁷ Stated another way, activity was anticipatory only if the benefit of the invention was derived by the public, regardless of the experimental nature of the use.

Later cases expanded on a policy of defeating an inventor’s exclusive rights for lack of novelty only where the benefit of prior use was deemed to have been placed in the public domain. For example, the Supreme Court in *Gayler v. Wilder*⁵⁸ held that prior construction and use of a fireproof safe by a business owner for the purpose of protecting his papers for several years did not constitute a statutory bar to later patenting by an independent inventor of the same device.⁵⁹ The Court affirmed an instruction by the circuit court to the jury that upheld the right of the patentee against the prior use.⁶⁰ Specifically, the jury was instructed:

[T]hat if Conner had not made his discovery public, but had used it simply for his own private purpose, and it had finally been forgotten or abandoned, such a discovery and use would be no obstacle to the taking out of a patent by Fitzgerald or those claiming under him, if he be an original, though not the first, inventor or discoverer.⁶¹

⁵⁷ *Id.* at 124–25. The court instructed the jury as follows:

If on the whole of this evidence, either on the one side or the other, it appeared that this wheel constructed by Mr. Strutt’s order in 1814, was a wheel on the same principles and in substance the same wheel as the other for which the plaintiff [Jones] has taken out his patent, and that was used openly in public, so that everybody might see it, and had continued to use the same thing up to the time of taking out the patent, undoubtedly then that would be a ground to say that the plaintiff’s invention is not new, and if it is not new, of course this patent is bad, and he cannot recover in this action; but if, on the other hand, you are of opinion that Mr. Strutt’s was an experiment, and that he found that it did not answer, and ceased to use it altogether, and abandoned it as useless, and nobody else followed it up, and that the plaintiff’s invention, which came afterwards, was his own invention, and remedied the defects, if I may so say, although he knew nothing of Mr. Strutt’s wheel he remedied the defects of Mr. Strutt’s wheel, then there is no reason for saying that the plaintiff’s patent is not good . . .

Id.

⁵⁸ 51 U.S. 477 (1851).

⁵⁹ *Id.* at 495. The Court summarized the prior activity as follows:

It appears that James Conner, who carried on the business of a stereotype founder in the city of New York, made a safe for his own use between the years 1829 and 1832, for the protection of his papers against fire; and continued to use it until 1838, which [sic] it passed into other hands. It was kept in his counting-room and known to the persons engaged in the foundry; and after it passed out of his hands, he used others of a different construction.

Id.

⁶⁰ *Id.* at 498.

⁶¹ *Id.* at 496 (quoting the circuit court).

In finding no error in the jury instruction,⁶² the Court explained what it believed to be the intention of the legislature in the Patent Act of 1836, specifically sections 6 and 15.⁶³ In particular, the Court admitted that Fitzgerald could not be the “original and first inventor or discoverer” given what was known about the Conner safe “upon a literal construction” of the Act.⁶⁴ However, to “carry into effect the intention of the legislature,” the Court stated that, to be consistent with the 15th section of the Patent Act of 1836, the words “knowledge” and “use” under that section would have to mean knowledge and use that is accessible to the public:

In the case thus provided for, the party who invents is not strictly speaking the first and original inventor. The law assumes that the improvement may have been known and used before his discovery. Yet his patent is valid if he discovered it by the efforts of his own genius, and believed himself to be the original inventor. The clause in question [section 15 of the Patent Act of 1836] qualifies the words before used, and shows that by knowledge and use the legislature meant knowledge and use existing in a manner accessible to the public.⁶⁵

The later, independent inventor should, therefore, not be deprived of the right to a patent in view of knowledge or use that is not accessible to the public, because “[t]he means of obtaining knowledge would not be within their reach; and, as far as their interest is concerned, it would be the same thing as if the improvement had never been discovered,”⁶⁶ whereas:

It is the inventor here that brings it to them, and places it in their possession. And as he does this by the effort of his own genius, the law regards him as the first and original inventor, and protects his patent,

⁶² *Id.* at 498. (“Upon the whole, therefore, we think there is no error in the opinion of the Circuit Court, and the judgment is affirmed.”).

⁶³ *Id.* at 496. The Court paraphrased sections 6 and 15 of the Patent Act of 1836 as follows:

The act of 1836, ch 357, § 6, authorizes a patent where the party has discovered or invented a new and useful improvement, “not known or used by others before his discovery or invention.” And the 15th section provides that, if it appears on the trial of an action brought for the infringement of a patent that the patentee “was not the original and first inventor or discover of the thing patented,” the verdict shall be for the defendant.

....
... And in the 15th section, after making the provision just mentioned, there is a further provision, that if it shall appear that the patentee at the time of making his application for patent believed himself to be the first inventor, the patent shall not be void on account of the invention or discovery having been before known or used in any foreign country, it not appearing that it had been before patented or described in any printed publication.

Id.

⁶⁴ *Id.* (“Upon a literal construction of these particular words, the patentee in this case certainly was not the original or first inventor or discoverer, if the Conner safe was the same with his, and preceded his discovery.”).

⁶⁵ *Id.* at 496–97.

⁶⁶ *Id.* at 497.

although the improvement had in fact been invented before, and used by others.⁶⁷

As summarized by the Court: “But he would be the first to confer on the public the benefit of the invention. He would discover what is unknown, and communicate knowledge which the public had not the means of obtaining without his invention.”⁶⁸ With respect to prior activities by Conner, the Court concluded that “[t]he public could derive no benefit from it until it was discovered by another inventor,” which, in this case, was Fitzgerald, whose patent the Supreme Court held to be valid and infringed.⁶⁹

Justices McLean and Daniel dissented in separate opinions. Justice McLean asserted that if Conner abandoned his invention, it would be “given up to the public” and, therefore, “fatal to the right of Fitzgerald,” and that, regardless, the public had access to the safe less than five years before Fitzgerald obtained his patent and, therefore, as a matter of law, it could not have been lost to the public.⁷⁰ Justice Daniel found that, contrary to the conclusion by the majority, Conner’s activities were public,⁷¹ and challenged the presumption that the public is better benefited by granting patent protection to a later, independent inventor rather than acknowledging that placement in the public confers a benefit, regardless of the circumstances:

It is said that patent privileges are allowed as incitements to inventions and improvements by which the public may be benefited. This position, that mby[sic] be conceded in general, should not be made a means of preventing the great and public purposes its legitimate enforcement is calculated to secure. The admission of this principle leaves entirely upon the inquiries, whether he is more the benefactor of the public who makes a useful improvement which he generously shares with his fellow-citizens, or he who studies some device which he denies to all, and limits by every means in his power to a lucrative monopoly; and still more, whether the latter shall be permitted to seize upon that which had already (as is here admitted) been

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.* at 498.

⁷⁰ *Id.* at 501 (McLean, J., dissenting). Justice McLean stated, in dissent:

When an invention is abandoned, it is said to be given up to the public, and this is the sense in which the term abandonment is used in the patent law. Such an abandonment would be fatal to the right of Fitzgerald.

Conner’s safe, as it appears from the bill of exceptions, was used in his counting-house, being accessible to every one, some six or eight years. In 1838 it passed into other hands; but into whose hands it does not appear. In 1843, Fitzgerald obtained his patent. How long before that he made experiments to test the invention is not proved. At most, the time must have been less than five years. This is a short period on which to found a presumption of forgetfulness. The law authorizes no such presumption. It can never become the law. It is not founded on probability or reason.

Id.

⁷¹ *Id.* at 507. (Daniel, J., dissenting). (“It is shown that Conner used his safe publicly; that is, he concealed it from no one . . .”).

given to the public, thereby to levy contributions, not only on the community at large, but upon him even who has been its generous benefactor. It was doubtless to prevent consequences like those here presented, that the priority and originality of inventions are so uniformly and explicitly insisted upon in all the legislation of Congress, as will presently be shown.⁷²

Regardless of their differences of opinion about the facts in *Gayler*, the majority opinion and those of the dissenting justices are all consistent in that they recognize an overriding policy of awarding patent protection commensurate with the benefit conferred on the public. As succinctly stated by Justice McLean in his dissent: “[t]he law is adopted on a settled public policy, which, while it is just to inventors, protects the rights of the public.”⁷³

An example of the comparison between what is “just to inventors,” and the “rights of the public,” can be found in *Byam v. Bullard*,⁷⁴ where the Circuit Court for the District of Massachusetts found that sale of a patented device by the defendant to the plaintiff patentee was not an infringement “per se.”⁷⁵ The court relied on what it phrased as “the general rule of common law,” whereby *volenti non fit injuria* (“to a willing person no wrong is done”).⁷⁶ Earlier cases, including *Whittemore*, *Sawin*, and *Jones*, were distinguished by the court as holding that there was no damage and, consequently, no cause of action:

Nor can I find any solid foundation on which to rest the right of a patentee to support an action on the case for the violation of his exclusive right, except that settled and reasonable common-law basis of all such actions, injury and damage; injury by a violation of the incorporeal right, and damage, at least nominal, presumed by the law to arise from such violation. Such I understand to have been the principle proceeded upon by Mr. Justice Story, in *Whittemore v. Cutter*, where he held that making a machine for a philosophical experiment, or to test the sufficiency of the specification, would not be an infringement; and in *Sawin v. Guild*, where he says the act must be with intent to deprive the patentees of some lawful profit; and also by Mr. Justice Patteson, in *Jones v. Pearce*, where he accepts the making of a patented article for mere amusement, and not for profit. In these cases, in as much as there was supposed to be no damage, there was thought to be no action.⁷⁷

Rather, by having sold the device to an agent of the plaintiff, the defendant in *Byam* deprived the plaintiff patentee of the profit that would otherwise be gained, and yet

⁷² *Id.* at 506 (Daniel, J., dissenting).

⁷³ *Id.* at 501–02 (McLean, J., dissenting).

⁷⁴ 4 F. Cas. 934 (C.C.D. Mass. 1852) (No. 2,262).

⁷⁵ *Id.* at 935 (“In this case, I am of opinion that the sale to the plaintiffs’ agent was a sale to them, and that such a sale is not, per se, an infringement.”).

⁷⁶ *Id.* at 934 (“As to the injury, the general rule of the common law is, ‘*volenti non fit injuria*,’ and, in accordance with this maxim, no one can maintain an action for a wrong, where he has consented, or contributed to the act of which he complains.”).

⁷⁷ *Id.* at 935 (citations omitted).

no infringement was found because, by having cooperated in the sale, the plaintiff's activities "must be supposed to have been done for his own benefit, or at least not to have been to his loss."⁷⁸ Therefore, the court effectively severed profit, either its gain by an accused infringer or its loss by the patentee (both of which in this case were a matter of fact), from infringement. Instead, the measure of infringement was deprivation by the patentee of the benefit of his invention, which, as in *Sawin*, could not be inferred by loss of profit. In *Byam*, by acquiring the device from the defendant, the plaintiff patentee could not be said to have been deprived of such benefit, as a matter of law.

The court in *Byam* also paraphrased *Watson* with approval, questioning "the assumption" made in *Whittemore*, *Sawin*, and *Jones*, that there is no damage in "making a machine for a philosophical experiment or to test the sufficiency of the specification"⁷⁹ or in "the making of a patented article for mere amusement and not for profit,"⁸⁰ and stated that, if the assumption were correct, there would be no cause of action for infringement.⁸¹ However, the court in *Watson* does not question any such assumption. Rather, as discussed above, the court in *Watson* only stated that the making of a machine by another prior to the discovery by a patentee is anticipatory, regardless of any intent to use the machine only experimentally.⁸² Therefore, despite the statement by the court in *Byam*, no question of infringement was decided in *Watson* because the patent relied upon by the plaintiff was held to be invalid as having been anticipated by prior activity in the public domain.⁸³

Byam stands for the proposition that the benefit of an invention is not necessarily in its possession or in profit to be derived from it.⁸⁴ Therefore, as in *Sawin*, possession, without more, cannot be considered a deprivation of the benefit conferred by a patent right, despite loss or gain of profit by the patent holder or the public. Subsequent cases based infringement on whether the patentee was deprived of the benefit of the invention. However, neither the experimental nature of the use, nor profit derived by the sale of the invention, was determinative for the courts.

For example, the court in *Poppenhusen v. New York Gutta Percha Comb Co.*⁸⁵ held that despite the fact that a use was experimental, and without profit, "the product of that experiment," could nevertheless be an infringement if it was

⁷⁸ *Id.* at 934. Judge Curtis, for the court stated:

Here, the plaintiffs not only consented, but cooperated; for, through their agents, they were themselves the purchasers. As to the damage, it is true that, in general, the law imports damage from the violation of a right, but I am not aware that damage has ever been presumed by law from an act in which the plaintiff cooperated, and which, therefore, must be supposed to have been done for his own benefit, or at least not to have been to his loss.

Id.

⁷⁹ *Byam*, 4 F. Cas. at 935 (paraphrasing *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600)).

⁸⁰ *Byam*, 4 F. Cas. at 935 (paraphrasing *Jones v. Pearce*, 2 Webst. Pat. Cas. 125 (K.B. 1831)).

⁸¹ *Byam*, 4 F. Cas. at 935 ("And though I am rather disposed, with Mr. Justice Washington, in *Watson v. Bladen*, to doubt whether the assumption is correct, that in such cases there is no damage; yet if the assumption be correct, I think the inference is sound that no action lies.") (citation omitted).

⁸² *Watson v. Bladen*, 29 F. Cas. 424, 426 (C.C.E.D. Pa. 1826) (No. 17,277).

⁸³ *Id.*

⁸⁴ *See Byam*, 4 F. Cas. at 935.

⁸⁵ 19 F. Cas. 1059 (C.C.S.D.N.Y. 1858) (No. 11,283).

employed by the agents of defendants “for their benefit; and if they adopted and approved of it by selling it in the market [through their agent] . . . , they will be deemed to have authorized the act, and will be bound by it.”⁸⁶ Therefore, despite the fact that use of patented subject matter by the defendants was only experimental, infringement of the patent could be found if the defendants benefited by activities adopted and approved by their agent. Infringement was based on competition in the market, which deprived the inventor of the benefit of his patent, regardless of profit.

In an opinion by the Supreme Court in *Seymour v. Osborne*,⁸⁷ Justice Clifford cautioned against regarding letters patent as monopolies, which, he stated, are “created by the executive authority at the expense and to the prejudice of all the community except the persons therein named as patentees.”⁸⁸ Rather he asserted that letters patent should be considered “public franchises . . . as matter of compensation to the inventors for their labor, toil, and expense in making the inventions, and reducing the same to practice for the public benefit, as contemplated by the Constitution and sanctioned by the laws of Congress.”⁸⁹ Therefore, as with *Renouard and Phillips*, the Supreme Court expressly recognized patent protection as a benefit conferred upon the inventor and the public rather than a privilege conferred at the public’s expense.

⁸⁶ *Id.* at 1063. The question posed to the jury by the court was as follows:

The next question, gentlemen, is: Has there been a violation or infringement? It is said, gentlemen, that there has not been, for the reason that whatever use was made of it was an experimental use—a use merely for experiment, and not with a view to profit; and when there has been no profit and no sale, it will not make a party liable, because the patentee would not be injured by it. But where, gentlemen, it is done as a matter of business, where the product of that experiment has been thrown into the market, to compete with the products of the plaintiff, although he may call it an experiment, yet, if it is a matter of business, and thrown into the market for the purpose of being sold, and is sold with his other products, why, that will be such a use as will make the party liable. . . . You are here to determine, gentlemen, whether these articles, manufactured by their agent, he being in the employment of the corporation, whether he did it in the business or employment of the corporation, whether it was for their benefit; and if they adopted and approved of it, by selling it in the market, and thereby took advantage of it, they will be deemed to have authorized the act, and will be bound by it.

Id.

⁸⁷ 78 U.S. 516 (1871).

⁸⁸ *Id.* at 533.

⁸⁹ *Id.* at 533–34. The Court stated:

Letters patent are not to be regarded as monopolies, created by the executive authority at the expense and to the prejudice of all the community except the persons therein named as patentees, but as public franchises granted to the inventors of new and useful improvements for the purpose of securing to them, as such inventors, for the limited term therein mentioned, the exclusive right and liberty to make and use and vend to others to be used their own inventions, as tending to promote the progress of science and the useful arts, and as matter of compensation to the inventors for their labor, toil, and expense in making the inventions, and reducing the same to practice for the public benefit, as contemplated by the Constitution and sanctioned by the laws of Congress.

Id.

In another British case, cited by William Robinson,⁹⁰ *Frearson v. Loe*,⁹¹ the Chancery division held that “*bona fide*” experimentation, without the intention of selling and making a patented invention, was not an infringement if the experimental use was made “with the view of improving upon the invention the subject of the patent, or with the view of seeing whether an improvement can be made or not.”⁹² However, use of the patented machine for its intended purpose, in this case, that of making screws, “with the view of trying the screws themselves,” did not rise to the level of “*bona fide*” experimental use.⁹³ The court held that testing of the product of a patented machine was not an experimental use of the machine itself and, therefore, was not exempt from infringement of the patent to that machine.⁹⁴ Therefore, infringement of the patent to the machine for making screws was not found on the basis of profit derived from the machine. Rather, use of the patented machine could not be considered experimental because the benefit of the machine, that of making screws, had been obtained. Testing of the finished screws was not considered to be experimental use of the machine that made them.

Unsuccessful experimental use was admitted to by the defendants in *Albright v. Celluloid Harness-Trimming Co.*,⁹⁵ “at their factory . . . in the course of perfecting their manufacture of harness-trimmings coated with celluloid.”⁹⁶ The court found “technical infringement,” but only on the basis of testimony by both a superintendent

⁹⁰ 3 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 898 n.1 (1890).

⁹¹ (1878) 9 Ch.D 48.

⁹² *Id.* at 66–67. The court stated that:

[N]o doubt if a man makes things merely by way of *bona fide* experiment, and not with the intention of selling and making use of the thing so made for the purpose of which a patent has been granted, but with a view of improving upon the invention the subject of the patent, or with the view of seeing whether an improvement can be made or not, that is not an invasion of the exclusive rights granted by the patent.

Id.

⁹³ *Id.* at 67. The court explained:

He has made a machine, and, knowing it to be an infringement of patent, he claims the right to make and use it, and his experiment is made to see how his machine works. That is the experiment, as he calls it, putting his machine to work from time to time, and then making screws according to the other patent, and making the screws with the view of trying the screws themselves. It does not appear to me, when I consider the circumstances under which the Defendant made these alleged experiments, that I ought to treat this as coming within the rule which prevents mere experiments being subject to the liability of action being brought against those who make them

Id.

⁹⁴ *Id.*

⁹⁵ 1 F. Cas. 320 (C.C.D.N.J. 1877) (No. 147).

⁹⁶ *Id.* at 323. The court characterized the admission by the defendants as follows:

They admit in their answer that subsequent to the date of said letters patent 137,873, among other experiments made or caused to be made at their factory in Newark, in the course of perfecting their manufacture of harness-trimmings coated with celluloid, they tried dies of substantially the form and construction, and having the same operation described in said letters patent; but such use was only experimental, and the said experiment demonstrated the fact that harness-trimmings coated with celluloid cannot be manufactured in dies thus constructed, and that they accordingly abandoned the experiment.

Id.

employed by the defendant, and by the plaintiff, of having seen infringing articles in the defendant's factory.⁹⁷ By limiting the evidence of infringement to the testimony of the superintendent and the plaintiff, the court, by inference, did not consider the admission of experimental use in its determination. In excluding the admission, the court seemed to draw a parallel with early experimental use by a third party prior to patenting of the invention by the plaintiff, when a Mr. Sturgis made a pair of dies on an experimental basis, which also was abandoned as unsuccessful:

Nothing was brought forward in the case which casts serious doubts on the originality of the complainant's patent, except the Sturgis die, Exhibit No. 18, produced by the complainant. Mr. Sturgis says that, in the spring or summer of 1865, he made a pair of dies to press up a composition with which he wished to coat an iron buckle to imitate the stitched leather buckle. He pressed up different compositions, experimenting with leather and paper and cloth. He never made any quantity, or ever put any on the market, "being a mere matter of experimenting." It does not appear that these experiments were successful, as he testifies he abandoned them Under these circumstances, what he did must be put in the category of abandoned experiments. "He is the first inventor," says the [S]upreme [C]ourt "and entitled to the patent, who, being an original discoverer, has first perfected and adapted the invention to actual use."⁹⁸

Therefore, like the "experimental use" by the defendant, activity, including making and using subject matter considered to be within the scope of patent protection, was held by the court to be neither anticipatory nor an infringement, on the basis that no benefit was derived.⁹⁹ In other words, experimental use, or, at least failed experimental use, in and of itself, was considered to be neither anticipatory activity that would bar a subsequent inventor from patent protection, nor infringement of an issued patent that would provide a cause of action to a patentee. In neither case was the benefit of the invention obtained, and, with respect to the defendant's admitted experimental use, profit clearly was a motive.

As another example of the overriding nature of benefit over profit as a motive, manufacture and experimental use of patented equipment by the Army was held in

⁹⁷ *Id.* The court summarized the basis for infringement as follows:

Their [the defendants'] superintendent, Lockwood, says that prior to July 1874, he saw in their factory a die similar to Exhibit No. 8, which it is admitted was constructed according to the patent under consideration, and the complainant, Albright, testified that he visited the defendant's rooms in Newark, in October or November, 1873, and saw there one large oval brace-buckle die and one or two ring-dies constructed on the plan of Exhibit No. 8, and also buckles and rings, which, from their general appearance, he believed had been pressed in these dies. That seems to be the extent of the testimony as to the making and using the dies. It is a technical infringement, and is sufficient to authorize an injunction restraining their future use; but no reference will be ordered, as no damage or profits have been shown or suggested.

Id.

⁹⁸ *Id.* at 322 (citation omitted) (quoting *Whitely v. Swayne*, 74 U.S. (7 Wall.) 685, 686 (1869)).

⁹⁹ *Id.* at 323.

*Palmer v. United States*¹⁰⁰ to be the basis for recovery of a reasonable royalty only to the extent that the equipment had been issued for use.¹⁰¹ The Court of Claims held that 10,500 sets of equipments manufactured by the Ordnance Department of the Army, although they “may have been ‘a huge experiment,’” in the absence of an express license, the fact that their manufacture was an experiment provided to the Ordnance Office “no more right to take for these experimental knapsacks the claimant’s invention than to take another man’s leather.”¹⁰² Despite finding an exception for experimental use, however, the court held that “inventions which are still in the stage of trial and experiment, and which are as likely to involve the purchaser in loss as to bring him gain,” had fallen into a class of value where “the right to manufacture and use the first 10,000 would have been granted for a very moderate royalty.”¹⁰³ Accordingly, the decision of the trial court was affirmed, whereby the plaintiff “could not recover . . . for equipments manufactured, but that his recovery must be for equipments manufactured and used,” which was only 9,027 of the 10,500 equipments manufactured.¹⁰⁴ Therefore, infringement was found despite characterization of the manufacture and use of the patented device as experimental, but compensation was awarded only to the extent to which benefit of the invention could be presumed, for example, by use of the claimed device, rather than simply by its manufacture. Again, the finding of infringement was independent of an intent to use for profit, and rested solely on advantage gained by the utility of the patented subject matter:

But where the validity of a patent is conceded, he who uses the invention must judge for himself of its utility, and the government stands upon no more irresponsible ground than the farmer who buys a right to make and use a “patent hive” or pays for a license to sink a “drive-well.”¹⁰⁵

On appeal to the Supreme Court, the decision by the United States Court of Claims was affirmed.¹⁰⁶ With respect to “questions related to the character and amount of use which the government had of the claimant’s invention, and of the proper compensation due therefor,” the Court spoke with approval of the lower court decision:

As to the questions relating to the character, and amount of use which the government had of the claimants’ invention, and of the proper compensation due therefor, we do not see anything in the findings of the court below, or in its conclusions deduced therefrom, to call for serious observation. What evidence the court may have had on these points is not disclosed by the

¹⁰⁰ 20 Ct. Cl. 432 (1885).

¹⁰¹ *Id.* at 432.

¹⁰² *Id.* at 437–38.

¹⁰³ *Id.* at 438.

¹⁰⁴ *Id.*

¹⁰⁵ *Id.* at 437.

¹⁰⁶ *United States v. Palmer*, 128 U.S. 262 (1888).

record, and should not be, and the facts found are sufficient to sustain the judgment.¹⁰⁷

In the cases summarized above, experimental use was not considered to be a function of public benefit. Anticipation of a patented article or process generally was not found unless the product of prior experimental work by another became part of the public weal. Similarly, activities conducted by another within the scope of the exclusive right of an issued patent generally were not considered to be infringing if the activities were only “philosophical experiments, or for the purpose of ascertaining the sufficiency” of the patented subject matter “to produce its described effects,” as stated in *Whittemore*,¹⁰⁸ or “to ascertain the verity and exactness of the specification” as stated in *Sawin*,¹⁰⁹ despite an intent to profit by the result of such experiments, because the patentee was not deprived of his exclusive rights unless he had been deprived of a “use and benefit of his patent.”¹¹⁰ In other words, experimental use, for the purpose of scientific inquiry, or for ascertaining sufficiency of patented subject matter for an intended use or the verity and exactness of a specification, as such, were not proscribed under the Patent Act, regardless of an intent to profit by the result obtained. Rather, for an accused infringer to make, use, or sell patented subject matter within the scope of the Act, the patentee must be deprived of his exclusive right to the use and benefit of the patent beyond its availability for philosophical experiment, or ascertainment of the suitability of patented subject matter or of the verity and exactness of the patent specification. Intent to profit was not a threshold consideration.

In *Standard Measuring Machine Co. v. Teague*,¹¹¹ the Circuit Court for the District of Massachusetts held that, despite an admission by the defendant (who owned a patent to an improvement of a machine patented by the plaintiff) that they made “one machine like [the defendant’s] patented improvement . . . and exhibited it,” there was insufficient evidence to pursue the question of infringement further.¹¹² Specifically, the court found that, because the defendants did not admit use or sale of that machine, there was no basis for infringement:

The only evidence of infringement is an admission by the defendants that they made one machine like their patented improvement . . . and exhibited it at the mechanics fair, in Boston, in 1878. They do not admit that they ever used or sold such a machine, but contend that it was made, or may have been made, as a model or illustration of their own patent. We consider the evidence of infringement of this patent insufficient to require us to compare the inventions with each other.¹¹³

Therefore, manufacture or, at least, admitted possible manufacture as a model or illustration, of a patented machine, without more, i.e., use or sale, was an insufficient

¹⁰⁷ *Id.* at 272.

¹⁰⁸ *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600).

¹⁰⁹ *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391).

¹¹⁰ *Id.*

¹¹¹ 15 F. 390 (C.C.D. Mass. 1883).

¹¹² *Id.* at 392–93.

¹¹³ *Id.*

basis even to further investigate whether the machine was, in fact, within the scope of the plaintiff's patent.

The Chancery Division, in *United Telephone Co. v. Sharples*,¹¹⁴ which also is cited by Robinson in his treatise,¹¹⁵ held that importation of patented telephones and transmitters to England, and their subsequent sale, "although to a foreign customer, [of] an instrument which he knows would if made, sold, or used in this country be an infringement of an English patent, . . . would be an infringement of such patent."¹¹⁶ Those, indeed, were found to be the facts and, accordingly, the court held the patents to be infringed.¹¹⁷ In explaining the facts of the case, the court denied the argument by the defense that the patented telephones and transmitters were imported and used only on an experimental basis for the instruction of pupils.¹¹⁸ The court found that the purchase and use of the patented device for the purpose of instruction was, in fact, a use.¹¹⁹ However, the basis for this holding was not financial gain, but whether the user, namely the instructor, was using the invention to his advantage:

I asked Mr. *Goodeve* whether he carried his proposition thus far, that there could be no user of a patent unless it produced a direct pecuniary advantage to the person who used it? At first, he seemed inclined to go so far, but I think at last he receded from that position; because I put to him this very obvious case: Suppose for example, if the *Singer* sewing machine were protected by a patent, a man should buy a cheaper instrument which he knows is an infringement of the patent, for some member of his household, who uses it, let us say, for amusement simply, would that be a user in this country or not? Without any doubt it would, although it did not produce to or save him one farthing. Therefore Mr. *Goodeve* modified his proposition to this, that "it must be a user for the purpose of advantage." Well, then, is not the user which I had been describing a user for the purpose of advantage?¹²⁰

The court did not hold that the students conducting the experiments were infringers, and did not hold that experimental use *per se* was an infringement; the court only

¹¹⁴ (1885) 29 Ch.D. 164.

¹¹⁵ ROBINSON, *supra* note 90, at § 898. Section 898 is entitled "No Act an Infringement unless it Affects the Pecuniary Interests of the Owner of the Patented Invention." *Id.*

¹¹⁶ *United Telephone*, 29 Ch.D. at 167.

¹¹⁷ *Id.* at 166.

¹¹⁸ *Id.* at 167 ("The witness *Sharples* says, 'We use these instruments for the purpose of experiment; the cost of them was so small that we could afford to allow our pupils to pull them to pieces or experiment with them.'").

¹¹⁹ *Id.* at 168. The court stated:

And to say that to buy a telephone which is an infringement of an English patent for the purpose of instructing your pupils who are learning the business, to let them use and experiment with it, to let them, if they please, pull it in pieces, for the purpose of saving the expense of using the patent telephone and experimenting with or pulling that to pieces, to say that that is not a user in this country, is a thing to which I cannot accede. It seems to me plainly to be a user.

Id.

¹²⁰ *Id.* at 168–69.

found that the use of a patented device to instruct others constituted a use that was infringement.¹²¹

Negation of public use by an inventor as being experimental and, therefore, not depriving the inventor of a right to patent protection was found in *Beedle v. Bennett*.¹²² In that case, the Supreme Court held that an inventor of a driven well was entitled to patent protection despite having put down a well at his house and publicly having driven such a well at a fairground for the use of soldiers in his regiment more than two years before filing for patent protection, because such uses were “merely experimental.”¹²³ Section 7 the Act of March 3, 1839 was recited by the Court:

And no patent shall be held to be invalid by reason of such purchase, sale, or use prior to the application for a patent as aforesaid, except on proof of abandonment of such invention to the public, or that such purchase, sale, or use has been for more than two years prior to such application for a patent.¹²⁴

The Court upheld the validity of the patent and affirmed the lower court decision of infringement by defendants who had used wells driven by “an ordinary well-driver” on their farm for several years.¹²⁵ Therefore, as with anticipatory use by another, prior use by an inventor would only bar patent protection if it had become part of the public domain, and experimental use was not considered to be that type of activity.

In *Bonsack Machine Co. v. Underwood*,¹²⁶ the court held that, despite the defendant’s (Underwood’s) argument that the “plaintiff permitted him to make the one machine that he made, and that he has never used that machine for commercial purposes,” the machine was, in fact, used “for the purpose of selling the [defendant’s] patent.”¹²⁷ The court relied on *Sawin* for the proposition that, “[t]o constitute an infringement, the making must be with an intent to use for profit, and not for the mere purpose of philosophical experiment.”¹²⁸ In *Bonsack*, the “defendant, besides making a contract by which he gave a 60-days option to . . . an original co-defendant,

¹²¹ *Id.* at 168.

¹²² 122 U.S. 71 (1887).

¹²³ *Id.* at 77. The Court found the following:

There is no evidence in the record of any use or sale of the invention by Green before his application for a patent, and no evidence from which to conclude that any use of any driven well by others before his application was consented to or allowed by him, except in the instances mentioned at Cortland, which were merely experimental tests, made by himself.

Id.

¹²⁴ *Id.* (citing Patent Act of 1839, ch. 87, 88, 5 Stat. 353, 354 (effective Mar. 3, 1839)).

¹²⁵ *Beedle*, 122 U.S. at 78.

¹²⁶ 73 F. 206 (C.C.E.D.N.C. 1896).

¹²⁷ *Id.* at 211. The court disagreed with the defendants’ contention that even the one machine was authorized in that the company which built the machine “was under contract not to construct any other cigarette machine any part of which was substantially covered by the Bonsack patents.” *Id.* The plaintiff owned three patents, referred to as the “Hook,” “Emery” and “Bonsack” patents. *Id.* at 207. The defendants owned one patent, covering the “Underwood” machine, which was found to fall within the scope of claim 2 of the “Hook” patent and of claim 13 of the “Emery” patent. *Id.* at 209–10.

¹²⁸ *Id.* at 211.

to purchase, has taken his machine to St. Louis, and assisted in organizing a company in that city for manufacturing cigarettes under his patent.”¹²⁹ The court found a basis “for an injunction upon well-grounded proof of the intention of [sic] violate the patent right.”¹³⁰ Therefore, despite the fact that the one machine made with consent had never been used in commercial manufacture of cigarettes, it had been used to develop the facility to deprive the patent owner of the exclusive ability to exploit his invention, thereby exceeding the authorization granted under the license from the plaintiff to make the one machine.¹³¹

In *Clerk v. Tannage Patent Co.*,¹³² the Third Circuit held that:

[M]ere expression of willingness to grant or sell licenses [by the patentee] will not, of itself, confer upon any, the privilege to use the specialty of the patent, and claim exemption from a charge of infringement on the ground of being simply engaged in experimentally testing its desirability or utility.¹³³

This decision by the court does not expressly state that there is no experimental use exception or that any such exception to infringement is contingent upon lack of commercial intent.

The Circuit Court for the Eastern District of New York in *Cimiotti Unhairing Co. v. Derboklow*,¹³⁴ held that where, for a period of “nearly three years,” a defendant employed a patented machine to dehair pelts provided by customers in the ordinary course of business, it was no defense for the defendant to “excuse this use of infringing devices on the theory that defendant was ‘experimenting’ with the machines in order to see if he could not discover some improvement.”¹³⁵ The court concluded that “[t]his is not fairly within any legitimate use for experimental purposes only.”¹³⁶ Again, experimental use was denied as a defense to the inventor because regular use over an extended period of time, without more, could not be considered to be “for experimental purposes only.”¹³⁷

Similarly, the Circuit Court for the Western District of Pennsylvania in *United States Mitis Co. v. Carnegie Steel Co.*,¹³⁸ held that commercial use over a period of several months in the course of business and for profit could not be excused on the suggestion that it was “merely experimental.”¹³⁹ As with *Clerk* and *Cimiotti*, mere

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ *Id.* (“As for the alleged license, it is not contended that any consent was given to any commercial use of the machine.”).

¹³² 84 F. 643 (3d Cir. 1898).

¹³³ *Id.* at 644.

¹³⁴ 87 F. 997 (C.C.E.D.N.Y. 1898).

¹³⁵ *Id.* at 999.

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ 89 F. 343 (C.C.W.D. Pa. 1898).

¹³⁹ *Id.* at 351. The court stated:

The suggestion that the use of aluminum while the defendant was engaged in the practice of the so-called “armor-plate process” was merely experimental cannot be accepted. That was a commercial use, extending over a period of several months, and involved a very large product. It was use in the course of business and for profit.

assertion that use was experimental while the benefit of the invention was being derived was inadequate to escape a holding of infringement. However, as in those earlier cases, the court did not hold that experimental use could not be a defense to infringement if the experimentation was conducted with commercial intent.

The District Court for the Southern District of New York in *Hoegger v. F.H. Lawson & Co.*¹⁴⁰ held that unauthorized sale by an agent of the defendant of a sample wall cabinet manufactured by the defendant corporation, and arguably within the scope of the plaintiff's patent claims, did not constitute infringement.¹⁴¹ As stated by the court, "the mere sale to Mr. Carroll of the shopworn sample, under the circumstances already described, is insufficient to establish an act of infringement."¹⁴² The court reasoned that the sale was an isolated incident that was outside the scope of the agent's employment.¹⁴³ Mere sale, then, of the sample manufactured by the defendant was not a deprivation of rights by the defendant sufficient to constitute an infringement of the plaintiff's patent. However, like *Sawin*, the court did not hold the purchaser of the patented device would be free to use the patented article as a consequence of the sale. As will be recalled, the court in *Sawin*, in fact, suggested that sale of the patented device that did not deprive the patent owner "of the use and benefit of his patent," carries with it "no pretense . . . [that] guaranteed a right to use the machine in the manner pointed out in the patent-right."¹⁴⁴ It must be inferred that, as in *Sawin*, "the purchaser must therefore act on his own peril."¹⁴⁵

In *Scott & Williams, Inc. v. Hemphill Co.*,¹⁴⁶ the court held that use of a machine "to convince buyers of its merit and as a way of making sample stock to send out to the trade" was a "use" of the machine that constituted "much more than the mere exhibition of an alleged infringing article, which was held in *Hoegger v. F.H. Lawson & Co.*, (D.C.) 35 F.2d 219, not to amount to an act of infringement."¹⁴⁷ The contrast,

Id.

¹⁴⁰ 35 F.2d 219 (D.C.S.D.N.Y. 1929).

¹⁴¹ *Id.* at 220–22 ("The defendant is an Ohio corporation. Its chief office and place of business is at Cincinnati. It there manufactures wall cabinets (including a cabinet, model No. 925, of the type claimed to infringe plaintiff's patent), laundry appliances, and various other articles.")

¹⁴² *Id.* at 222.

¹⁴³ *Id.* at 221–22. The court stated:

The supplemental fact that a single shopworn sample—plainly sent to New York by defendant and kept there by Mr. Newman solely for purposes of exhibition and not for sale—was sold and delivered by Miss Reilly to Mr. Carroll at the Lexington avenue office is not enough to convert that office into the kind of place, prescribed by the statute—"regular and established"—for carrying on defendant's business in New York. That seems obvious from mere statement. This is particularly true since the incident was isolated and it cannot be fairly inferred from the evidence that it occurred from the knowledge, much less the sanction, of the defendant.

... It follows that Mr. Newman was not "engaged in conducting" for defendant the type of business required to render him subject to service as the agent of defendant pursuant to Section 48 of the Judicial Code.

Id.

¹⁴⁴ *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391).

¹⁴⁵ *Id.*

¹⁴⁶ 14 F. Supp. 621 (D.C.S.D.N.Y. 1931).

¹⁴⁷ *Id.* at 622 (referencing *Hoegger v. Lawson & Co.*, 35 F.2d 219 (D.C.S.D.N.Y. 1929)).

once again, is between use of a machine whereby the benefit of the machine, however slight, is obtained, such as by demonstration of its operation, and that of “mere exhibition,” whereby no such benefit is obtained.

A patent to a method for separating crystals of guanine, also known as pearl essence, from raw material, such as fish scales, was held by the District Court for the District of Maine in *Pairpearl Products v. Joseph H. Meyer Bros.*,¹⁴⁸ to be infringed by defendants who claimed that use of soap was “experimental only, incidental to their search for a new agent which they claimed to have discovered, and was not a commercial operation.”¹⁴⁹ The court found that “during these operations some two hundred pounds of [soap] was used and that the resulting pearl essence, or the principal part, was afterwards sold by the defendant and found its way into commerce through the usual channels.”¹⁵⁰ Experimental use was denied as a defense because the “amount of product, while not large, would be large enough to be included in any accounting that would be taken.”¹⁵¹ The court concluded that there “is no doubt that the operations that the defendants referred to, using soap . . . , were an infringement of the first patent in suit, assuming it’s validity.”¹⁵² Infringement, therefore, was based on the benefit gained by practice of the claimed method; no mention was made by the court of the purpose of the experimental use, which was clearly commercial in nature.

In *Ruth v. Sterns-Roger Manufacturing Co.*,¹⁵³ the District Court for the District of Colorado held that use by the Colorado School of Mines of patented machines and cut up versions of patented machines in a laboratory was experimental.¹⁵⁴ The doctrine of experimental use was summarized by the court:

The use of the patented machine for experiments for the sole purpose of gratifying a philosophical taste or curiosity or for instruction and amusement does not constitute an infringing use. The making or using of a patented invention merely for experimental purposes, without any intent to derive profits or practical advantage therefrom, is not infringement.¹⁵⁵

¹⁴⁸ 58 F.2d 802 (D. Me. 1932).

¹⁴⁹ *Id.* at 804.

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.* at 803–04.

¹⁵³ 13 F. Supp. 697 (D. Colo. 1935).

¹⁵⁴ *Id.* at 703. The court described the use as follows:

The Colorado School of Mines, which is shown on table F as a purchaser of parts, had various kinds of flotation machines, some of which were Minerals Separation subaeration flotation machines, one Fahrenwald, and two Hunt pneumatics. These machines were all used in a laboratory and were cut up and changed from day to day. Their use was experimental. . . .

The evidence is insufficient to show that the metal tank and flanges contributed to the use of an infringing machine. With respect to the other sales of parts, they were for use in laboratory machines used for experimental purposes, and consequently did not contribute to an infringing use.

Id.

¹⁵⁵ *Id.* at 713 (citations omitted).

In holding that there was no “intent to derive profits or practical advantage” from the patented invention, the court did not specify whether the experimental use by the Colorado School of Mines had a business purpose.¹⁵⁶

Testing of patented radio receiver sets to determine operability and efficiency as a step toward manufacture and sale of a defendant’s product was held by the District Court for the Eastern District of New York in *Radio Corp. of America v. Andrea*¹⁵⁷ not to be “experimental in the generally accepted connotation of that term,” because it was “not a scientific research,” and “not pursued in the efforts to improve the set or any element therein, nor, of course was the test one of curiosity or amusement.”¹⁵⁸ The experimental use exception was described as “mere casual appropriation for amusement or even scientific purpose” and, therefore, a “trifle,” in contrast to “solely commercial” testing, which was a “a step which defendants apparently deemed necessary in the manufacture and sale of their product.”¹⁵⁹

By this holding, the court implied that testing that was properly considered “scientific research or an engineering inquiry,” or “pursued in the efforts to improve” a patented invention, would qualify as “experimental in the generally accepted connotation of that term” and thus escape a holding of infringement, despite commercial intent.¹⁶⁰ Even so, the court narrowed the strict construction of Justice Story’s holding in *Whittemore*, which specifically excluded from infringement construction of “a machine . . . for the purpose of ascertaining the sufficiency of the machine to produce its described effects.”¹⁶¹ As previously discussed, infringement must “deprive the owner of the lawful rewards of his discovery,” which includes deprivation of the patent owner “of the use and benefit of his patent.”¹⁶² Justice Story never considered “philosophical experiments” or “ascertain[ing] the sufficiency of the machine to produce its described effects,” or even “ascertaining the verity and exactness of the specification” of a patent to be “trifles” that should be ignored by the law as “mere casual appropriation for amusement.”¹⁶³ Rather, such uses simply were outside the scope of the statutory exclusive right.

¹⁵⁶ *Id.*

¹⁵⁷ 15 F. Supp. 685 (E.D.N.Y. 1936).

¹⁵⁸ *Id.* at 687.

¹⁵⁹ *Id.* The court stated the following:

It was not a scientific research or an engineering inquiry. It was not pursued in the efforts to improve the set or any element therein; nor, of course, was the test one of curiosity or amusement. It was a step which the defendants apparently deemed necessary in the manufacture and sale of their product. . . .

The statute does not limit the monopoly right conferred. Logically, it would seem that any use of the invention is an invasion of the patentee’s rights. It has been repeatedly held that to sustain a patent it is not necessary that the patent disclose that the inventor knew of or specified all the possible uses to which his invention could be put. It should follow then that any use is within the exclusive right of the patentee, though, of course, one can well understand that the law, not concerning itself with trifles, would ignore a mere casual appropriation for amusement or even scientific purpose. But in the present case the defendant’s use was solely commercial.

Id. (citations omitted).

¹⁶⁰ *See id.*

¹⁶¹ *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600).

¹⁶² *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391).

¹⁶³ *Whittemore*, 29 F. Cas. at 1121.

The District Court for the Northern District of West Virginia, in *Akro Agate Co. v. Master Marble Co.*,¹⁶⁴ categorically held that experimental testing of patented machinery employed to produce articles was not “an act of infringement” because the articles, in this case, marbles, produced by the patented machine, were not commercially sold.¹⁶⁵ Specifically, citing *Sawin* and *Bonsack*, the court stated, as a finding of fact: “[t]hat the experimental testing by defendants of off-set rolls, for a brief period before going into commercial production, in the period prior to the adoption by defendants of their commercially used rolls without grooved offsets, was not in law an act of infringement as marbles were not commercially sold.”¹⁶⁶

Experimental use was not a defense when customers benefited by the invention in the ordinary course of business. For example, in *Sprout, Waldron & Co. v. Bauer Bros. Co.*,¹⁶⁷ the District Court for the Southern District of Ohio found that the accused infringer operated a “sales-demonstration laboratory” that “operated on a commercial scale,” and “that in this laboratory defendant itself has actually practiced the process of the Manson patent as a commercial operation as an adjunct to selling defendants’ machines, with the result that defendant is liable not only as a contributory infringer but as a direct infringer as well.”¹⁶⁸ Under the findings of fact, the court stated that “work was done for clients of defendant who paid for the work and operation of these machines by defendant was on a commercial basis for profit.”¹⁶⁹ The court held as a conclusion of law that experimental use was not a defense “where the machines were used to operate upon customers’ products in the ordinary course of business.”¹⁷⁰

In *Northhill Co., Inc. v. Danforth*,¹⁷¹ the court dismissed the defendant’s contention that he used anchors that “were made at his direction and for his benefit,” only for “experimental purposes” because they “were evidently not made for philosophical or amusement purposes but were made in connection with his business as a manufacturer and salesman of anchors.”¹⁷² Unlike *Akro Agate*, there were, in fact, commercial sales consequent to the accused infringing activity.¹⁷³ The court in *Northhill* did not specify exactly what constituted the purported experimental use, but clearly hinged its dismissal of experimental use defense on derivation of benefit of the claimed invention by the accused infringer.¹⁷⁴

The court in *Dugan v. Lear Avia, Inc.*,¹⁷⁵ in an action against a defendant who had developed a system for use of radio beacons to automatically guide aircraft and other vehicles, dismissed a portion of the suit because there was no manufacture for sale of that particular embodiment.¹⁷⁶ Despite commercial intent of the defendant’s activities, experimental use was successful as a defense with respect to those

¹⁶⁴ 18 F. Supp. 305 (N.D.W.Va. 1937).

¹⁶⁵ *Id.* at 333.

¹⁶⁶ *Id.* (citations omitted).

¹⁶⁷ 26 F. Supp. 162 (S.D. Ohio 1938).

¹⁶⁸ *Id.* at 165.

¹⁶⁹ *Id.* at 169.

¹⁷⁰ *Id.*

¹⁷¹ 51 F. Supp. 928 (N.D. Cal. 1942).

¹⁷² *Id.* at 929.

¹⁷³ *Id.*

¹⁷⁴ *Id.*

¹⁷⁵ 55 F. Supp. 223 (S.D.N.Y. 1944).

¹⁷⁶ *Id.* at 229.

embodiments because the defendant “neither manufactured it for sale nor sold any.”¹⁷⁷

In *Chesterfield v. United States*,¹⁷⁸ the Court of Claims held that use by the United States of a “422-19” alloy was “only for testing and for experimental purposes,” and not infringing because “the evidence shows that a portion of the 422-19 alloy procured by the defendant was used only for testing and for experimental purposes, and there is no evidence that the remainder was used other than experimentally. Experimental use does not infringe.”¹⁷⁹ The court asserted that the experimental nature of the United States’ use of another alloy also did not infringe the plaintiff’s patent claims:

Plaintiff’s metallurgical expert testified that 6059 alloy was used experimentally. As pointed out above, experimental use is not an infringing use. It is noted that plaintiff has stated that 6059 alloy does not make full use of the plaintiff’s patented invention.

The claims in suit, if valid, are not infringed by defendant’s use of the accused 6059 alloy.¹⁸⁰

The United States clearly was not conducting experiments for the purpose of mere amusement; the court recognized that the accused alloys were developed “for possible use in the manufacturer of blades or buckets for superchargers and gas turbines.”¹⁸¹ By explicitly noting that the experimental work did not “make full use of the plaintiff’s patented invention,”¹⁸² the court implied that the nature of use of the accused alloy did not confer on the United States the benefit of the patentee’s contribution to the art in exchange for which an exclusive patent right was granted.

Commercial application of a patented method was held by the court in *Spray Refrigeration Co. v. Sea Spray Fishing, Inc.*,¹⁸³ to be an infringement of plaintiff’s patent, despite assertions by the defendant that the method “was used on . . . two trips only for the purpose of experimentation as to the desirability of using this method.”¹⁸⁴ The court distinguished the facts from *Chesterfield* and *Dugan*,

¹⁷⁷ *Id.* (“The accused devices are represented by Exhibits 7, 8, 9 and 10. Exhibit 9 can be eliminated from consideration for it affirmatively appeared, without contradiction by plaintiff, that defendant built that device only experimentally and that it has neither manufactured it for sale or sold any.”).

¹⁷⁸ 159 F. Supp. 371 (Ct. Cl. 1958).

¹⁷⁹ *Id.* at 375.

¹⁸⁰ *Id.* at 376.

¹⁸¹ *Chesterfield v. United States*, 141 Ct. Cl. 838, 865 (1958). Specifically, the court stated, as a finding of fact:

The three accused alloys were developed for possible use in the manufacture of blades or buckets for superchargers and for gas turbines. The required physical properties of alloys for use in high-speed superchargers and gas turbines are different from the properties required of alloys for use in a cutting tool. Turbine blades are required to withstand rotational stresses, corrosive action, thermal shock, and impact stresses of a character not generally applied to cutting tools.

Id.

¹⁸² *Chesterfield*, 159 F. Supp. at 376.

¹⁸³ 322 F.2d 34 (9th Cir. 1963).

¹⁸⁴ *Id.* at 36.

discussed above, by the fact that “in neither of those cases was the experimental use coupled with a commercial use.”¹⁸⁵ Unlike the facts in *Chesterfield* and *Dugan*, the defendants in *Spray Refrigeration* obtained a benefit of the claimed method by their commercial application and, therefore, the experimental intent of the defendants’ use did not excuse them from a holding of infringement of the patentee’s exclusive right.¹⁸⁶ As stated by the court in *Spray Refrigeration*:

The method described in the claims of the patent here in question was used on one or two voyages of the *Vagabond* while that vessel was engaged in commercial fishing operations of the kind which the patent was designed to serve. Granting that the operators used the method experimentally it was nevertheless, under these circumstances, an infringement of the patent claims, and this without regard to whether the patented method proved to be practicable, and preferable over other methods.¹⁸⁷

In *Kaz Manufacturing, Inc. v. Chesebrough-Ponds, Inc.*,¹⁸⁸ the United States Court of Appeals for the Second Circuit held that use by the defendant of a “hybrid” embodiment of patentee’s claimed electric steam vaporizer, constructed from parts of plaintiff’s commercial models, in television advertisements to promote defendant’s product, was not an infringement of the plaintiff’s patent.¹⁸⁹ Relying on the cases discussed above, including *Ruth*, *Chesterfield*, *Dugan*, and *Bonsack*, the court summarized that “the purpose to which an unauthorized construction of a patented article is put may determine whether the construction constitutes an infringement of the patentee’s rights.”¹⁹⁰

The court recited, in a footnote, an analogy presented in the appellee’s (defendant’s) brief “suggesting that one who that constructs a patented wall safe[,] but uses it only as an anchor for his boat would not be a patent infringer since such use would not be for the purpose of utilizing the teachings of the patent.”¹⁹¹ This example, actually, is flawed, since, in *Whittemore*, Justice Story clearly stated, in response to the assertion that “the making of a machine, is under no circumstances, an infringement of the patent,” that the “act of April 17, 1800 gave the action against any person who should ‘make, devise, use or sell’ the invention.”¹⁹² The distinction, instead, should be upon whether the benefit of the invention is gained. Therefore, a more apt analogy would be to say that, although there would be no infringement if the patented wall safe were immersed for experimental purposes only, such as for the

¹⁸⁵ *Id.* (“In *Chesterfield*, the court quoted with approval that part of the *Dugan* opinion in which Judge Rifkind pointed out that while the device there in question was built experimentally the alleged infringer ‘has neither manufactured it for sale nor sold any.’”).

¹⁸⁶ *Id.* at 36–37.

¹⁸⁷ *Id.*

¹⁸⁸ 317 F.2d 679 (2d Cir. 1963).

¹⁸⁹ *Id.* at 681. The *Kaz* court stated that “[s]ince the construction and single use of the hybrid vaporizer in the commercial formed the only basis for plaintiff’s claim of infringement, Judge Tyler’s granting of defendant’s motion for summary judgment on count 1 was proper.” *Id.* (citation omitted).

¹⁹⁰ *Id.* at 680.

¹⁹¹ *Id.* at 681 n.3.

¹⁹² *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600) (citation omitted).

purpose of determining whether it would sink, there would be a cause of action for infringement in tying off one's boat from the sunken safe in the process of making that determination.

2. Subordination of Experimental Use to Commercial Intent

Although stated in dicta, since the patent at issue was held to be invalid, Trial Judge Cooper for the Court of Claims of the United States in *Douglas v. United States*¹⁹³ found that providing facilities at air bases for demonstrations of infringing aircraft did not establish liability under 28 U.S.C. § 1498 as a use "by or for the United States," nor was there liability consequent to the observation of demonstrations of the infringing aircraft by representatives of the United States.¹⁹⁴ The fact that purchase of the accused aircraft occurred after expiration of the patent was not sufficient to establish that actions conducted prior to its expiration were infringing.¹⁹⁵ The court concluded that, at most, the earlier activities could be evidence of intent and "intent is not a sufficient basis on which to establish liability."¹⁹⁶

The court then reviewed arguments made by the defendant that "it is not liable for the reason that its only use of those items was experimental."¹⁹⁷ The court disagreed, stating that "[t]he facts here plainly show that defendant's activities fall outside the scope of permissible use that would be afforded under any statement of the experimental use rule."¹⁹⁸ In coming to this conclusion, however, the court cited many of the cases discussed above and inaccurately characterized the vast majority of precedent as holding "that the experimental use defense is not available where the use, although of an experimental nature, was in connection with the user's business."¹⁹⁹ The court conceded that, "[s]ome few courts, where only a single

¹⁹³ 181 U.S.P.Q. 170 (Ct. Cl. 1974). The opinion in *Douglas* was later modified in a per curiam decision that did not incorporate the portions of Trial Judge Cooper's earlier opinion relating to infringement. See *Douglas v. United States*, 510 F.2d 364 (Ct. Cl. 1975).

¹⁹⁴ *Douglas*, 181 U.S.P.Q. at 176. The court stated:

To establish liability under 28 U.S.C. § 1498, there must be a manufacture or use by or for the United States. Clearly, the Harriers were not manufactured either by or for defendant. Nor was there a use of the Harriers by the United States, the only operational use being by the British. This leaves only the question of whether the demonstration was a use *for* the United States.

It is concluded that it was not. Defendant's role was solely that of providing the facilities and observing the demonstration. Although a sales demonstration may be an infringing use, plaintiff has cited no authority for the proposition that the observer of the demonstration can be held liable as an infringer.

Id. (citation omitted).

¹⁹⁵ *Id.* ("To be actionable, an act of infringement must be shown to have occurred prior to the expiration of the patent. The only proven action of defendant was procurement of the Harrier and that occurred after expiration of the patent.")

¹⁹⁶ *Id.* ("At most, this would suggest that, at the time of the demonstration, defendant intended to procure the accused aircraft. However, intent is not a sufficient basis on which to establish liability.")

¹⁹⁷ *Id.*

¹⁹⁸ *Id.* at 177.

¹⁹⁹ *Id.* at 176.

isolated use as been involved, have allowed the defense even though the alleged experiments were plainly related to a commercial operation.”²⁰⁰ However, it was the opinion of Trial Judge Cooper, in the “very restricted circumstances under which the defense has been permitted suggests, as at least one court has observed, that the defense is nothing more than an expression of the maxim *de minimis non curat lex*. *Radio Corp. of America v. Andrea, supra*.”²⁰¹

The decision by the District Court for the Eastern District of New York, in *Radio Corp. of America*, to which Judge Cooper refers in *Douglas*, denied the defense of experimental use because the tests conducted were “to determine the operability and efficiency” as “a step which the defendants apparently deemed necessary in the manufacture and sale of their product,” and, therefore, “not experimental in the generally accepted connotation of that term.”²⁰² The court in *Radio Corp. of America* did not use the phrase, “*de minimis non curat lex*,” but, rather, said that “one can well understand that the law, not concerning itself with trifles, would ignore a mere casual appropriation for amusement or even scientific purpose.”²⁰³ As discussed above, however, the many cases in the century and a half between *Whittemore* and *Douglas* do not bear out the conclusion of the court in *Douglas* that experimental use constituted a defense to infringement because of its trivial or petty (“*de minimis*”) nature. Rather, in the cases discussed above, experimental use was successfully invoked in defense of activities that, as aptly characterized by the court in *Radio Corp. of America*, were directed to “scientific research or an engineering inquiry” that were “pursued in the efforts to improve” a patented invention “or any element therein.”²⁰⁴ Moreover, in almost every case, and contrary to the statement by the court in *Douglas*, the experimental use was conducted “for the purpose of furthering the legitimate interests of the user.”²⁰⁵

Two cases, *Ordnance Engineering Corp. v. United States*²⁰⁶ and *Chesterfield*²⁰⁷ were identified by the court in *Douglas* as suggesting “that experimental use is applicable in other than *de minimis* situations.”²⁰⁸ The *Douglas* court explained that, in *Ordnance Engineering*, “the deduction for experimental use was uncontested, the court making no reference to the doctrine [of experimental use] in its opinion,” and, regarding *Chesterfield*, “there was no evidence as to the use of the bulk of the alloy so it was simply treated in the same manner as the small part that was found to have

²⁰⁰ *Id.*

²⁰¹ *Id.* at 177 (citing *Radio Corp. of Am. v. Andrea*, 15 F. Supp. 685, 687 (E.D.N.Y. 1936). The court considered case precedent where the “experimental use” defense has been successfully applied and concluded that “[m]ost certainly, in none of the cases from other federal courts has the defense been permitted where there was a pattern of systematic exploitation, extending over a prolonged period, of a plurality of the accused devices for the purpose of furthering the legitimate interests of the user.” *Id.*

²⁰² *Radio Corp.*, 15 F. Supp. at 687.

²⁰³ *Id.*

²⁰⁴ *Id.*

²⁰⁵ *Douglas*, 181 U.S.P.Q. at 177.

²⁰⁶ 32 U.S.P.Q. 614 (1936).

²⁰⁷ *Chesterfield v. United States*, 141 Ct. Cl. 838 (1958).

²⁰⁸ *Douglas*, 181 U.S.P.Q. at 177.

been used experimentally.”²⁰⁹ The court did not point out portions of the opinion in *Chesterfield*, discussed above, that stated, “[e]xperimental use does not infringe.”²¹⁰

Trial Judge Cooper, in *Douglas*, appeared to reflect the opinions of an article in the Journal of the Patent Office Society, which he referred to as “a more complete exposition of the development of the experimental use defense.”²¹¹ The author of the article, Mr. Richard E. Bee, argued that the “experimental use exception does not represent sound law,” and that, where it is applied, “the rule should be strictly construed and held inapplicable where a business purpose or profit motive exists.”²¹² In conducting his analysis, Bee began with a quotation from Robinson on patents, stating that, where “experiments are conducted with a view to the adaptation of the invention to the experimenter’s business, the acts of making or of use are violations of the rights of the inventor and infringements of his patent.”²¹³ Bee also quoted from Corpus Juris and Corpus Juris Secundum and commented that, “like Robinson, they both carefully qualify the exception by adding “This rule, however, cannot be invoked for the protection of one who uses a patented invention commercially, as in the course of business or for profit.”²¹⁴ Bee acknowledged that “there may be reasons of public policy for granting certain persons in certain circumstances immunity from the normal operation of the patentee’s rights” and included, as examples, “college and government research scientists,” but concluded that “it does not necessarily follow that experimental research conducted by a private industrial concern in order to develop products to compete with patentee’s products should be granted an exemption.”²¹⁵

Bee reviewed several of the cases discussed above, but dismissed, as inconsistent with case precedent, decisions, such as *Dugan* and *Akro Agate*, where experimental use was successfully employed as a defense, as appearing to be “clearly wrong” because they “appear to imply that any use which is in the nature of an experiment is not an act of patent infringement if the machine or the product made by the machine is not sold.”²¹⁶ Bee noted that the courts in both *Dugan* and *Akro Agate* relied on *Bonsack*.²¹⁷ Experimental use was raised as a defense in *Bonsack*, but dismissed by the court because the “machine has not been made simply as an experiment, but has been used for profit.”²¹⁸ As discussed above, the defendant in *Bonsack* obtained the intended benefit of the machine by its use and relied on that benefit to his advantage; any experimental aspect was overridden by the defendant’s promotional activities. The courts in both *Dugan* and *Akro Agate* based application of experimental use on

²⁰⁹ *Id.*

²¹⁰ *Chesterfield*, 141 Ct. Cl. at 846.

²¹¹ *Douglas*, 181 U.S.P.Q. at 176 n.3 (citing Richard E. Bee, *Experimental Use as an Act of Patent Infringement*, 39 J. PAT. OFF. SOC’Y 357 (1957)).

²¹² Bee, *supra* note 211, at 377.

²¹³ *Id.* at 358 (quoting Robinson, *supra* note 90).

²¹⁴ Bee, *supra* note 211, at 377 (quoting 48 C.J., Patents § 496 (1929); 69 C.J.S., Patents § 288 (1951)).

²¹⁵ *Id.* at 359.

²¹⁶ *Id.* at 375.

²¹⁷ *Id.* (“Both cases rely on the earlier case of *Bonsack Machine Co. v. Underwood* which, in turn, relies on Justice Story’s opinion in *Sawin v. Guild*”).

²¹⁸ *Bonsack Mach. Co. v. Underwood*, 73 F. 206, 211 (C.C.E.D.N.C. 1896).

the distinction from *Bonsack* that there was no commercial sale.²¹⁹ However, Bee further noted that the court in *Bonsack* relied, in turn, on *Sawin*, which, as paraphrased by Bee, “said there should be an intent to use for profit and did not say that there must be an actual use for profit,”²²⁰ and based his conclusion that *Dugan* and *Akro Agate* were wrongly decided on this distinction:

In both the *Dugan* and *Akro Agate* cases, the experiments were conducted in the ordinary course of business and with a view towards future profits, which would seem to be an intent to use for profit . . . Accordingly, the *Dugan* and *Akro Agate* cases would appear to be clearly wrong in so far as they require an actual sale to defeat the experimental use exception.²²¹

Bee was correct in reciting the portion of Justice Story’s opinion, which stated that there “must be the making with an intent to use for profit,”²²² but did not recite the context in which Justice Story’s statement was made. Recalling *Sawin*, although a machine within the scope of the patent and owned by the patentee was seized and sold in foreclosure of a debt by the plaintiff, neither the defendant, nor the purchaser put the machine sold into operation.²²³ The court in *Sawin* held that there was no infringement because there was “no pretence . . . that the officer had either sold or guaranteed a right to use the machine in the manner pointed out in the patent-right.”²²⁴ Focusing on what Justice Story refers to as “the use and benefit” of a patent, rather than “intent to use for profit,”²²⁵ renders *Dugan* and *Akro Agate* consistent with other cases summarized by Bee in which, unlike *Dugan* and *Akro Agate*, the court did not uphold an experimental use defense.²²⁶ In all of the cases summarized by Bee, except for *Beedle*, where the Supreme Court held that there was infringement by a defendant’s use of a patented well installed without the consent of the patentee in a house rented by the defendant,²²⁷ the infringing uses were “clearly in the course of business.”²²⁸ In *Dugan* and *Akro Agate*, for example, the use was held by the court in each case to be solely experimental, that is, a “philosophical

²¹⁹ See *Akro Agate Co. v. Master Marble Co.*, 18 F. Supp. 305, 333 (D.C.N.D.W.V. 1937) (“That the experimental testing by defendants of offset roles . . . was not in law an act of infringement as marbles were not commercially sold.”); *Dugan v. Lear Avia, Inc.*, 55 F. Supp. 223, 229 (D.C.S.D.N.Y. 1944) (“Exhibit 9 can be eliminated from consideration for it affirmatively appeared, without contradiction by the plaintiff, that defendant built that device only experimentally and that it has neither manufactured it for sale or sold any.”).

²²⁰ Bee, *supra* note 211, at 375.

²²¹ *Id.*

²²² *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391).

²²³ *Id.* (“The purchaser, at the sheriff’s sale, has not, at any time since, put either of the said machines in operation; and the whole infringement of the patent consists in the seizure and sale by the defendant as aforesaid.”).

²²⁴ *Id.* at 555.

²²⁵ *Id.*

²²⁶ See Bee, *supra* note 211, at 375.

²²⁷ See *Beedle v. Bennett*, 122 U.S. 71, 77 (1887).

²²⁸ Bee, *supra* note 211, at 373. For example, with reference to the holding in *Akro Agate*, Bee stated that “[t]he court in this case appears to be clearly wrong. The use of the patented mechanism was clearly in the course of business.” *Id.*

experiment,” having as its purpose discovery, which, like sale, alone, is not a “use and benefit” that deprives the owner of the lawful rewards of his discovery.²²⁹

Cases decided after *Douglas*, for a time, preserved experimental use as a defense to infringement as it had been applied historically. For example, in *Pitcairn v. United States*,²³⁰ the court denied the Government’s contention that the plaintiff should not be compensated for “any aircraft used by the defendant for testing, evaluational, demonstrational or experimental purposes,” because “every new helicopter must be tested for lifting ability, for the effect of vibration on installed equipment, flight speed and range, engine efficiency, and numerous other factors.”²³¹ The court held that such tests are “intended uses . . . in keeping with the legitimate business of the using agency,” and that, therefore, “[e]xperimental use is not a defense in the present litigation.”²³² The court found that there was “no evidence in defendant’s offer of proof that any of the helicopters to which defendants’ ‘experimental use’ contentions pertain were built solely for experimental purposes.”²³³ The court, however, was careful to note that “static test mechanisms” and “experimental helicopters” designed, developed, and manufactured under “[n]umerous research and development contracts” were excluded by the plaintiff from litigation.²³⁴ Therefore, the court in *Pitcairn* was consistent with earlier decisions that excluded from infringement those activities that were conducted solely for experimental purposes, albeit in a commercial setting, and also was consistent with cases, such as, for example, *Radio Corp. of America*, discussed above, where factory testing preliminary to shipment was denied protection as “experimental use.”²³⁵ Interestingly, however, the court in *Pitcairn* specifically commended the view expressed by Trial Judge Cooper in his opinion in *Douglas* “as a well reasoned and historical analysis”:

Defendant has also referred to the experimental use portion of Trial Judge Cooper’s opinion and report to the court in *Douglas v. United States* While the trial judge’s discussion of the experimental use rule in various courts is not the law of the case in *Douglas*, it is a well reasoned and historical analysis.²³⁶

The Court of Appeals for the Federal Circuit in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,²³⁷ faced, for the first time, the question of infringement by use of

²²⁹ See *Akro Agate Co. v. Master Marble Co.*, 18 F. Supp. 305, 333 (N.D.W.Va. 1937); *Dugan v. Lear Avia, Inc.*, 55 F. Supp. 223, 229 (S.D.N.Y. 1944).

²³⁰ 547 F.2d 1106 (Ct. Cl. 1976), as amended on reh’g (1977).

²³¹ *Id.* at 1125.

²³² *Id.* at 1125–26 (“Tests, demonstrations, and experiments of such nature are intended uses of the infringing aircraft manufactured for the defendant and are in keeping with the legitimate business of the using agency. Experimental use is not a defense in the present litigation.”).

²³³ *Id.* at 1125.

²³⁴ *Id.* (“Plaintiff has excluded from its present claim static test mechanisms manufactured for defendant. Numerous research and development contracts were entered into by the defendant and various manufacturers for the design, development and manufacture of experimental helicopters and none of those specific helicopters are the subject of this litigation.”).

²³⁵ *Radio Corp. of Am. v. Andrea*, 15 F. Supp. 685, 687 (E.D.N.Y. 1936).

²³⁶ *Pitcairn*, 547 F.2d at 1126.

²³⁷ 733 F.2d 858 (Fed. Cir. 1984).

a patented article, a drug, to conduct federally mandated pre-marketing tests.²³⁸ The court reversed the decision of the United States District Court for the Eastern District of New York, which denied a permanent injunction requested by Roche on the basis that “Bolar’s use was de minimis and experimental.”²³⁹ The Federal Circuit, in summarizing the experimental use exception, as previously applied, noted that “Bolar concedes, as it must, that its intended use of flurazepam hcl does not fall within the ‘traditional limits’ of the experimental use exception as established in these cases or those of other circuits.”²⁴⁰ According to the court, the experimental use exception should be narrowly construed, and Bolar’s concession was determinative:

Its concession here is fatal. Despite Bolar’s argument that its tests are “true scientific inquiries” to which a literal interpretation of the experimental use exception logically should extend, we hold the experimental use exception to be truly narrow, and we will not expand it under the present circumstances. Bolar’s argument that the experimental use rule deserves a broad construction is not justified.²⁴¹

The “narrow” construction applied by the Federal Circuit was derived from case precedent, beginning with Justice Story’s opinion in *Whittemore* and Robinson’s treatise, *The Law of Patents for Useful Inventions*.²⁴² The court also referenced Bee’s article, discussed above, from the *Journal of the Patent Office Society*, and, like the court in *Pitcairn*, complimented Trial Judge Cooper’s nonprecedential opinion in *Douglas*:

Douglas has no precedential value here since the Court of Claims never affirmed the part of the trial judge’s opinion dealing with experimental use; moreover, Trial Judge Cooper’s well-reasoned analysis of the experimental use rule concluded that no case had permitted a pattern of systematic exploitation of a patented invention for the purpose of furthering the legitimate business interests of the infringer. The authority of Trial Judge Cooper’s views rests on his reputation as a fine patent lawyer, and on their own intrinsic persuasiveness.²⁴³

Pitcairn was cited as “the most persuasive of the Court of Claims cases concerning the experimental use defense,” and Judge Nichols, for the court in *Roche*, quoted a portion of *Pitcairn*, stating that “tests, demonstrations, and experiments . . . [which] are in keeping with the legitimate business’ of

²³⁸ *Id.* at 858.

²³⁹ *Id.* at 861.

²⁴⁰ *Id.* at 863.

²⁴¹ *Id.*

²⁴² *Id.* at 862 (“The so-called experimental use defense to liability for infringement generally is recognized as originating in a opinion written by Supreme Court Justice Story while on Circuit in Massachusetts.”). The court in *Roche* referred to Justice Story’s opinion in *Whittemore v. Cutter*. *Id.* The court further stated, “Professor Robinson firmly entrenched the experimental use exception into patent law when he wrote his famous treatise, W. Robinson, *The Law of Patents for Useful Inventions* § 898 (1890) . . .” *Id.*

²⁴³ *Roche*, 733 F.2d at 863.

the . . . [alleged infringer] are infringements for which ‘experimental use is not a defense.’”²⁴⁴ However, the *Roche* court did not mention that the plaintiff in *Pitcairn* excluded from litigation “static test mechanisms” as well as “experimental helicopters” designed, developed, and manufactured under “[n]umerous research and development contracts . . . entered into by the defendant and various manufacturers.”²⁴⁵ Other cases relied upon by the defendant in *Roche*, such as *Ordinance Engineering* and *Chesterfield*, were dismissed as providing “no guidance concerning the boundaries of an appropriately applied experimental use rule”²⁴⁶ or as “pure *obiter dictum*.”²⁴⁷

The court in *Roche* did not create new law. Rather, like the courts in several earlier cases, including *Douglas* and *Pitcairn*, testing, as a prerequisite to sale of a product, either as a demonstration or for assurance of suitability, was not considered to be “philosophical inquiry.”²⁴⁸ Rather, courts consistently held such use to be an infringement of a patentee’s exclusive right to benefit from his discovery. The difference in *Roche* was that the court was required to consider federally mandated testing that, if delayed until expiration of the patent, would, effectively, extend the patent term.²⁴⁹

According to the *Roche* court, Bolar argued “that even if no *established* doctrine exists with which it can escape liability for patent infringement, public policy requires that we create a new exception to the use prohibition.”²⁵⁰ The court explained the dilemma as follows:

Because most FDA-required testing is done after a patent issues, the remaining effective life of patent protection assertedly may be as low as 7 years. Litigation such as this is one example of how research-oriented pharmaceutical companies have sought to regain some of the earning time lost to regulatory entanglements.²⁵¹

²⁴⁴ *Id.*

²⁴⁵ See *Pitcairn v. United States*, 547 F.2d 1106, 1125 (Ct. Cl. 1976), as *amended on reh’g* (1977).

²⁴⁶ *Roche*, 733 F.2d at 863 (“The *Ordinance Engineering* case provides no guidance concerning the boundaries of an appropriately applied experimental use rule other than flatly stating that a device must have been ‘built for experimental purposes.’”).

²⁴⁷ *Id.* (“In *Chesterfield*, the court’s flat declaration that ‘experimental use does not infringe’ is pure *obiter dictum*.”).

²⁴⁸ *Douglas v. United States*, 181 U.S.P.Q. 170, 176 (Ct. Cl. 1974). Trial Judge Cooper distinguished between a “sales demonstration” as an infringing use from the mere act of observation of a sales demonstration:

Although a sales demonstration may be an infringing use, plaintiff has cited no authority for the proposition that the observer of the demonstration can be held liable as an infringer. The planes having been owned and operated by the British and the demonstration having been promoted and financed by them for the purpose of inducing a purchase of the aircraft, there was no taking by the United States and no use for the United States.

Id. (citation omitted).

²⁴⁹ *Roche*, 733 F.2d at 864.

²⁵⁰ *Id.* at 863.

²⁵¹ *Id.* at 864.

The court declined to adopt a new construction of the existing law of infringement in view of the Federal Food, Drug, and Cosmetic Act (“FDCA”), and presumed that Congress was aware of its effect:

Simply because a later enacted statute affects in some way an earlier enacted statute is poor reason to ask us to rewrite the earlier statute. . . . Rather, because “laws are presumed to be passed with deliberation, and with full knowledge of all existing ones on the same subject,” T. Sedgwick, *The Interpretation and Construction of Statutory Law* 106 (2d Ed. 1874), we must presume Congress was aware that the FDCA would affect the earning potentiality of a drug patent, and chose to permit it. Although arguably Title 21 and Title 35 are not laws on the “same subject,” we note that during Congress’ deliberations on the 1962 amendments to the FDCA, it considered the relationship and interaction of the patent laws with the drug laws.²⁵²

In *Deuterium Corp. v. United States*,²⁵³ the plaintiff, Deuterium Corporation, sued the United States for infringement of U.S. 4,123,506, which was directed to a process for removing hydrogen sulfide from geothermal steam.²⁵⁴ The purported infringing activity was conducted in a pilot plant owned by EIC Laboratories, Inc. (“EIC”).²⁵⁵ The court held that there was no literal infringement of the patent.²⁵⁶ Judge Rader, in dictum, disagreed with the defendant’s assertion that use of the heat exchanger in the pilot plant, even if within the scope of the ’506 patent, fits within

²⁵² *Id.* (citing S.Rep. No.1744, 87th Congress, 2d Sess., reprinted in 1962 U.S.C.C.A.N. 2884, 2911–15). The portion of the Senate report referenced by the court in *Roche* appears, in fact, to be openly hostile to patent protection for drug products:

In the major European countries the method historically followed is that exemplified by West Germany, which does not grant patents on drugs [sic] products, per se, but does grant them on drug processes, with the protection extending to the product as long as it is manufactured by that process; i.e., the patent protection of the product disappears upon the discovery of an alternative process, which frequently takes place in the drug industry; in testimony before the Antitrust Subcommittee Mr. P.H. Federico, examiner in chief of the Patent Office, acknowledged that the manufacture of drugs is particularly susceptible to the development of alternative processes. Incidentally it should be noted that the special treatment long accorded drug patents in these countries has not spread to other industries.

From the experience of Germany and other countries which have similar methods of patent protection for drug products, it is obvious that an excellent record of performance can be achieved in the development of new drugs under a patent system which grants much weaker patent protection than is accorded in the United States.

1962 U.S.C.C.A.N. at 2913–14.

²⁵³ 19 Ct. Cl. 624 (1990).

²⁵⁴ *Id.* at 625.

²⁵⁵ *Id.* (“Plaintiff contends the United States used the process in a heat exchanger at The Geysers geothermal power plant in California The heat exchanger HX103 was a part of EIC’s pilot plant at The Geysers. During its tests, EIC modified HX103, originally designed as a cooling component, to preheat the reactant used to clean steam.”).

²⁵⁶ *Id.* at 631 (“In the case at bar, steps (d) and (f) of claim 57 are absent from the accused HX103 process. Therefore, the heat exchanger did not infringe the ’506 patent.”).

the experimental use exception to patent liability.²⁵⁷ Writing for the court, Judge Rader categorized earlier opinions that declined to impose an experimental use exception, including *Douglas, Pitcairn*, and *Roche*, as applying a “purpose test,” which he defined by use of a quotation from Trial Judge Cooper’s opinion in *Douglas*:

Indeed, the Court of Claims trial judge proceeded to apply a purpose test for application of the doctrine:

At no time were the accused devices used for amusement, to satisfy idle curiosity, or for philosophical inquiry; to the contrary, each use was in keeping with the legitimate business of the using agency and served a valuable governmental and public purpose.²⁵⁸

The “purpose test” was applied in *Pitcairn*, according to Judge Rader, in the following quotation from that court’s opinion:

Use for such purposes is use by or for the Government and is compensable. Obviously every new helicopter must be tested for lifting ability, for the effect of vibration on installed equipment, flight speed and range, engine efficiency, and numerous other factors. Tests, demonstrations and experiments of such nature are intended uses of the infringing aircraft manufactured for the defendant and are in keeping with the legitimate business of the using agency. Experimental use is not a defense in the present litigation.²⁵⁹

With respect to *Roche*, Judge Rader stated that the “Federal Circuit applied the purpose test and determined that Bolar’s use was ‘solely for business reasons and not for amusement, to satisfy idle curiosity or for strictly philosophical inquiry.’”²⁶⁰ The court’s decision in *Roche* was broadly characterized by Judge Rader’s conclusion that “[t]he Federal Circuit declined to apply the experimental exception to unauthorized uses with ‘definite, cognizable, and not insubstantial commercial purposes.’”²⁶¹

Judge Rader framed application of the experimental use defense in terms of whether the activities were “in keeping with the legitimate business of the using agency,” or had “definite, cognizable and not insubstantial commercial purposes,” affirmative answers to which would bar application of the experimental use doctrine.²⁶² However, such analyses do not distinguish between the acts of discovery without otherwise benefiting from an invention, which have never been considered to be infringing activities regardless of commercial intent, and activities that do otherwise benefit from a claimed invention (even if the activities are only

²⁵⁷ *Id.* at 635 (“Finally, the experimental use exception does not apply to the EIC pilot program.”).

²⁵⁸ *Id.* at 631 (quoting *Douglas v. United States*, 181 U.S.P.Q. 170, 177 (Ct. Cl. 1974)).

²⁵⁹ *Id.* at 631–32 (quoting *Pitcairn v. United States*, 547 F.2d 1106, 1125–26 (Ct. Cl. 1976)).

²⁶⁰ *Id.* at 632 (quoting *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984)).

²⁶¹ *Id.* at 632 (quoting *Roche*, 733 F.2d at 863).

²⁶² *Id.*

preparatory, such as in *Roche* and *Pitcairn*), which have always been considered to be infringing uses, even if they are not commercially motivated.²⁶³

*Infigen, Inc. v. Advanced Cell Technology, Inc.*²⁶⁴ appears to be a relatively early case directed to the question of whether use of patented research tools could be considered an exception to infringement under experimental use doctrine.²⁶⁵ The patent, as the court stated, was “directed to a process for activating bovine oocytes (unfertilized eggs) for use in cloning.”²⁶⁶ The defendants argued that it should be for a jury to decide “whether science and mankind benefits when researchers . . . use otherwise patented technology as controls or otherwise in their university-based research laboratories.”²⁶⁷ The court disagreed, stating that “it is up to Congress to decide whether there should be an infringement exception for university-based research laboratories.”²⁶⁸ The court then went further and remarked that, although “[t]here is a common law experimental exception to infringement . . . its scope has never been explored in detail.”²⁶⁹ Nevertheless, the court stated that the defendants’ use of the claimed cloning technique and culture media was “for commercial

²⁶³ *Id.* Judge Rader, nevertheless, correctly stated in a footnote to his discussion of the decision by the court in *Roche*, that Title II of the Drug Price Competition and Patent Term Restoration Act of 1984, specifically 35 U.S.C. § 271(e), “did not disturb the Federal Circuit’s enunciation of the parameters of the experimental use exception.” *Id.* at n.14. In other words, authorization under the statute to “make, use, or sell, a patented invention (other than a new animal drug or veterinary biological product . . .) 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,” carved out, in response to the decision by the court in *Roche*, a statutory exception where, historically, experimental use doctrine would not apply, namely, testing conducted in anticipation of sale; such tests were not conducted for the purpose of discovery, but as a prerequisite to commercial distribution. 35 U.S.C. § 271(e) (2006).

Also, interestingly, Judge Rader addressed a recommendation by the defendant to adopt “the objective standards” employed to negate the prohibition against activities considered to be “public use or on sale in this country, more than one year prior to” an application under 35 U.S.C. § 102(b). *Deuterium*, 19 Ct. Cl. at 632. Judge Rader distinguished between experimental use as an exception to public use or sale from experimental use as an exception to infringing use on the basis that the former “protects an inventor’s intellectual property for the period of development and testing prior to patent application,” while the latter “narrows the scope of intellectual property protection.” *Id.* Judge Rader concluded that “the broader objective standards developed to protect an inventor during experimentation prior to patent application do not apply to experiments by a potential infringer.” *Id.*

Judge Rader’s distinction between the two experimental use doctrines is founded on the premise that discovery, as an activity, is embraced within the inventor’s exclusive right, and so fails to consider the inconsistency inherent in permitting indefinite public experimentation in the course of reducing an invention to practice, and yet denying protection of the same right of discovery to the public after an exclusive right has been granted. *Id.* In other words, both types of experimental use deal with discovery related to an invention; to the extent that experimental use by an inventor is not, even though public, a contribution to the art (because suitability for use has not yet been established), there is a parallel with experimental use by an otherwise infringer because discovery, as a consequence of experimental use, does not confer on the user any benefit of the patented invention other than the opportunity to learn about it. *Id.*

²⁶⁴ 65 F. Supp. 2d 967 (W.D. Wis. 1999).

²⁶⁵ *Id.* at 982.

²⁶⁶ *Id.* at 969.

²⁶⁷ *Id.* at 981.

²⁶⁸ *Id.*

²⁶⁹ *Id.*

purposes” and not “merely to satisfy the curiosity of researchers” and, therefore, did not qualify for exception to infringement under the experimental use doctrine.²⁷⁰

In this case, then, the court, consistent with the previous applications of the experimental use doctrine in the vast majority of cases, declined to apply the experimental use exception when the benefit of the invention claimed was conferred by the accused activities. The defendants’ practice of the claimed cloning techniques and use of the claimed culture media in those experiments was not an investigation of that claimed subject matter, but rather a use, the benefit of which advanced the defendants’ objective of developing transgenic cattle. The fact that development of transgenic cattle was for commercial purposes was immaterial; infringement of the claimed cloning technique and use of the claimed culture media would properly have been found regardless of whether the defendant had a commercial intent.

B. Inherency

1. Benefit in the Prior Art as a Threshold

Inherency is related to the idea that anticipation can only be found by deprivation of the public of the benefit of otherwise patentable subject matter. Accidental or unwitting practice of subject matter that was later independently developed and patented was addressed by the Supreme Court in *Tilghman v. Proctor*.²⁷¹ The Court upheld the validity of a patent, directed to the separation of fatty acids from glycerin by exposure in the presence of water to elevated temperature and pressure, over several patents and known processes, which the Court acknowledged as possibly conducting, albeit “accidentally and unwittingly,” the process claimed in Tilghman’s patent.²⁷² However, in each of these instances, the Court held that, because the process was incidental and went unappreciated, the mere fact of its prior occurrence was insufficient to deprive Tilghman of his right to patent protection.²⁷³

The first instance of accidental anticipation recited by the Court was “Perkins’s steam cylinder,” which employed tallow to lubricate a piston.²⁷⁴ The Court found that the possible earlier presence of fatty acids in “scum which rose on the water issuing from the ejection pipe” of the steam cylinder, although being the result of the

²⁷⁰ *Id.* The court stated, specifically:

It is undisputed that defendants used plaintiff’s patented activation methods and culture media in their cloning experiments and that the purpose of those experiments was to develop transgenic cattle that could be used for commercial purposes, including the production of transgene products. These were not “philosophical” experiments or experiments carried out merely to satisfy the curiosity of researchers; they were done as part of the ongoing business activities of defendant Advanced Cell. No common law research or experimentation exception is applicable.

Id.

²⁷¹ 102 U.S. 707 (1880).

²⁷² *Id.* at 711.

²⁷³ *Id.* at 711–12.

²⁷⁴ *Id.* at 711.

process claimed by Tilghman, would not represent an anticipation because “[t]hose engaged in the art of making candles, or in any other art in which fat acids are desirable, certainly never derived the least hint from this accidental phenomenon in regard to any practicable process for manufacturing such acids.”²⁷⁵

Likewise, the Court held that a water barometer and a method for purifying fats and oils for manufacture of soap did not to anticipate Tilghman’s patented process because, if they produced fatty acids by the method patented by Tilghman, the fact of their production went unappreciated:

The accidental effects produced in Daniell’s water barometer and in Walther’s process for purifying fats and oils preparatory to soap-making, are of the same character [as that of Perkins’s steam cylinder]. They revealed no process for the manufacture of fat acids. If the acids were accidentally and unwittingly produced, whilst the operators were in pursuit of other and different results, without exciting attention and without its even being known what was done or how it had been done, it would be absurd to say that this was an anticipation of Tilghman’s discovery.²⁷⁶

A prior patent, directed to boiling fat in a reduced amount of water and at a significantly lower temperature and pressure than described by Tilghman in his specification, also was considered not to be anticipatory:

Nor do we regard the patent of Manicler, which was taken out in 1826, as anticipating the process of Tilghman. It is true that he directs a mixture of fat with about one-quarter of its weight of water to be placed in a boiler, and subjected to a heat sufficient to create a pressure equal to one atmosphere above the natural atmospheric pressure (to about 250° Fah.) . . . It is probable, therefore, that any decomposition of the fat which may have been produced by this process was due to the steam formed and passing through the fat, as no means appears to have been adopted for keeping up the mixture of the fat and water.²⁷⁷

In parallel to the discussions above with respect to experimental use of patented processes that were held to not anticipate later discovery because the public never benefited as a result, the Court further held that an attempt to put the process described in the Manicler patent into practice was nothing “but an abandoned experiment.”²⁷⁸ The Court did not specify whether production of fatty acids by Tilghman’s patented process was considered a necessary consequence of the earlier known process. Rather, the Court found that the public did not benefit by fatty acids

²⁷⁵ *Id.*

²⁷⁶ *Id.* at 711–12.

²⁷⁷ *Id.* at 712.

²⁷⁸ *Id.* (“But we have no evidence that the process was ever successful in practice. . . . Evidently, therefore, this was but an abandoned experiment, since we never hear any more of it from 1826 down to the trial of this cause.”).

generated in the prior art. Tilghman made an independent discovery,²⁷⁹ and was entitled to an exclusive right to his process under a patent.²⁸⁰

In subsequent cases, inherent anticipation hinged on whether benefit of the patented subject matter was obtained at the expense of the public. Manufacture, use, and even sale required that the benefit of the invention be part of the public domain to constitute anticipation.

Consideration of inherency in holdings of patentability and infringement can be found again in *Carnegie Steel Co. v. Cambria Iron Co.*²⁸¹ There, the Supreme Court held that a process for production of steel that collected molten iron from separate furnaces in a “dominant pool” prior to further processing was not anticipated by earlier patents or activities which also collected molten metal from multiple furnaces, but, unlike the claimed method, did not require or suggest reservation of any portion of the amounts pooled in the reservoir.²⁸² For example, with respect to an earlier patent to Deighton, characterized as “the closest approximation to the principle of the Jones invention,”²⁸³ the Court quoted the object of the process from the Deighton patent, as follows:

Instead of manufacturing Bessemer iron or steel from pig iron, which has to be melted in cupolas, my invention also consists in taking the molten metal directly from the blast furnace to the converter, in which case I prefer to arrange the Bessemer plant in a line at a right angle to a row of two or more blast furnaces, and place a vessel to receive the molten metal tapped from two or more blast furnaces to get a better average of metal which will be more suitable for making Bessemer steel or metal of uniform quality, the vessel or receiver being placed on a weighing machine so that any required weight may be drawn or tapped from it and charged into the converter.²⁸⁴

Even though the Deighton process could be operated in a manner within the scope of the Jones patent, the Court held that there was no such disclosure, whereby a “constant quantity of molten iron should always be kept in such a reservoir to serve as a basis for such mixture and an equalizer of the different discharges.”²⁸⁵ The fact

²⁷⁹ *Id.* at 713 (“We are satisfied Tilghman was the original discoverer of this process.”).

²⁸⁰ *Id.* at 708 (“Upon renewed consideration which has been given to the subject, the court is unanimously of opinion . . . that the patent of Tilghman must be sustained as a patent for a process . . .”).

²⁸¹ 185 U.S. 403 (1902).

²⁸² *See id.* at 415.

²⁸³ *Id.* at 418 (“The English patent to Deighton of 1873, for ‘improvements in the arrangement and mode of working an apparatus for the manufacture of Bessemer steel,’ contains the closest approximation to the principle of the Jones invention. If this does not anticipate, none does.”).

²⁸⁴ *Id.* at 419.

²⁸⁵ *Id.* at 419–20. The Court stated:

While Deighton seems to have conceived the idea that uniformity of product was necessary to the successful use of the direct process, and might be attained by mixing the discharge from several blast furnaces in an open reservoir, standing between the furnaces and the converter, the dominant idea of the Jones invention, that a constant quantity of molten iron should always be kept in such reservoir to serve as a basis for such mixture and an equalizer of the different discharges, does not seem to have occurred to him There is nowhere in the specification a suggestion of supplying to and withdrawing from the reservoir small amounts at a

that some “residuum” of metal would be left in ladles employed by methods of the prior art was considered to be “merely an incident of the operation of the ladle,” which was “of no substantial benefit in securing uniformity of the product” and, therefore, not anticipatory of the Jones patent.²⁸⁶ With respect to inherency, even the mixing necessary to use of a common ladle among several furnaces was not sufficient to defeat the validity of the patent if that mixing was a “matter of indifference or accident.”²⁸⁷

The validity of the Jones patent hinged on the benefit to the art contributed by his discovery:

It should be borne in mind that this process was one not accidentally discovered, but was the result of a long search for the very purpose. The surprise is that the manufacturers of steel, having felt the want for so many years, should never have discovered from the multiplicity of patents and of processes introduced into this suit, and well known to the manufacturers of steel, that it was but a step from what they already knew to that which they had spent years in endeavoring to find out. It only remains now for the wisdom which comes after the fact to teach us that Jones discovered nothing, invented nothing, accomplished nothing.²⁸⁸

time, a constant quantity of metal being retained in the reservoir for the purpose of equalizing the different products of the blast furnaces.

Id.

²⁸⁶ *Id.* at 429. As stated by the Court:

An attempt was made to show that the Jones invention was anticipated by the practice common in steel works prior thereto, of tapping iron from cupola furnaces into a receiving ladle, which became known as the Bessemer cupola ladle, from which it was poured into the converters. Molten iron was tapped from several cupolas into this ladle, from which a charge was drawn and delivered to the converter vessel. Of course, if the ladle were of greater capacity than was necessary to charge a single converter, a residuum of metal would be left in it; but this seems to have been merely an incident of the operation of the ladle, which was used primarily for storage, and to have been of no substantial benefit in securing uniformity of product, which can only be obtained by making the receiver of larger size and retaining a considerable quantity of metal in it after each discharge.

Id.

²⁸⁷ *Id.* at 445. The Court stated:

Discarding now all that does not bear directly upon the validity of the Jones patent, and dropping all superfluity of words, let us determine exactly what Jones has contributed, if anything, to the art of making steel. He undoubtedly found reservoirs of small size in use in which were poured from receiving ladles enough molten metal to fill them, and from which a sufficient amount was discharged to supply a converter, usually about half the size of the reservoir. But in these cases the fact whether any particular amount of metal was left in a reservoir was treated as a matter of indifference or accident, although there must have been necessarily some incidental mixing; and probably the metal as it ran into the converters approximated more nearly to uniformity than when it ran into the reservoir.

Id.

²⁸⁸ *Id.* at 445–46.

Similarly, the possibility of occurrence by actions of an accused infringer would require consideration of whether the benefit of the claimed invention was gained, regardless of intent:

This proposition that the application of this patent depends upon the individual intent of the operator overlooks the essential nature of a process patent. The directions and specifications of such a patent are addressed to those engaged and skilled in the art. It professes to disclose a method of procedure, not the particular instrumentality that may be employed. It may be, as suggested, that one person may, and in ignorance of the patented method, make use of a reservoir *merely as such*, and without any desire to avail himself of the patented process; but such a fact would not deprive the discoverer of the process of the protection of his patent.²⁸⁹

In dissent, Justice White, with whom Chief Justice Fuller and Justices Harlan and Brewer concurred, paraphrased the majority opinion as adopting the views of the circuit court:²⁹⁰

The opinion of this court now, as did that of the Circuit Court, expressly concedes that reservoiring of molten metal was well known in the art at the time the Jones patent was applied for, and that mixing was the inevitable result of such reservoiring, but it is decided that this fact did not operate to deprive the Jones method of novelty or to relieve the defendant from the charge of infringement.²⁹¹

The dissent framed the issue as “whether the defendant, in reservoiring its molten metal, irrespective of the supply and demand, intentionally retained in the reservoir a considerable residuum.”²⁹² However, by hinging the decision on the intent in the prior art or by the accused infringer, while conceding that placing molten metal in a reservoir was well known at the time the Jones patent was issued, the majority conferred, according to the dissent, an exclusive right “to do the very thing which the Court admits was well known at the time the patent to Jones was issued,”²⁹³ with the

²⁸⁹ *Id.* at 441.

²⁹⁰ *Id.* at 453 (White, J., dissenting) (“This court now reverses the decree of the Circuit Court of Appeals, adopts the views of the Circuit Court, and in effect affirms the decree of that court.”).

²⁹¹ *Id.* at 453–54 (White, J., dissenting).

²⁹² *Id.* at 451 (White, J., dissenting).

²⁹³ *Id.* at 456–57 (White, J., dissenting). Justice White stated in his dissent:

Aside from this, it seems to me the concession that the placing of molten metal in a reservoir for use as required was well known at the time the Jones patent was issued, is inconsistent with the ruling now made, that the Jones patent validly embraced the retention in a reservoir of a mass of such metal, now described by the court as a dominant pool. . . . If it be meant by the court that the right to reservoir carries with it the right to draw off or retain at will, unless the person reservoiring intends to retain a residuum for a particular purpose, the reasoning reduces itself again to the proposition that the Jones patent covers, not the process described therein, but the mind and intention of the individual who may exercise the right to reservoir molten metal. . . . In other words, I fail to see

consequence being “to put the patentee in a position where, without invention on his part, and without the possession by him of lawful letters patent, he is allowed to exact tribute from the steel and iron-making industry, whenever those engaged in such industry desire to increase their plants or to more conveniently and satisfactorily conduct their operations so as to keep pace with the natural evolution of modern industrial development.”²⁹⁴ In other words, the dissent objected to granting a patent for what they viewed as recognition of advantages of a natural result of a well known practice, summarizing their opinion of the majority decision, as follows:

But this is only to say that whilst the Jones method was old, it must be treated as new because of the conduct of individuals in applying the method and their intentions. And this reduces itself to the proposition that the Jones patent as construed covered the mere intention or mind of persons. The reasoning is equally applicable to the distinction which is asserted to exist between storing and the mixing incidental thereto, and mixing with incidental storage. The mere form of expression cannot create a distinction where none exists, or destroy a law of nature.²⁹⁵

In essence, the dissent dismissed the incidental nature of mixing found in prior art methods, as did the majority, but with the opposite result, namely, that the dissent found intent to be the distinction between “incidental” results and Jones claimed method, whereby intent was not, in and of itself, a claim limitation that would distinguish the method from the prior art.²⁹⁶ In contrast, the majority held that intent, as expressed as an objective in the patent specification, conferred a physical distinction on the method, whereby variation in molten metal composition was suppressed, thereby providing an advantage over the prior art that deserved recognition.²⁹⁷ However, for both the majority and the dissent, the crux of the decision was whether the public was being deprived of a benefit that existed prior to the exclusive patent right granted, or whether the inventor had contributed by his invention a benefit to the public that did not previously exist, and for which an exclusive right, therefore, should be granted.

In *Kuehsted v. Farbenfabriken of Elberfeld Co.*,²⁹⁸ the patentable distinction of a therapeutic formulation of acetyl salicylic acid, or “aspirin,” over well-known formulations of the same compound was based on the fact that the patentee, Hoffmann, “produced a medicine indisputably beneficial to mankind — something new in a useful art, such as our patent policy was intended to promote,” whereas the prior art, described by “Kraut and his contemporaries, on the other hand, had produced only, at best, a chemical compound in an impure state.”²⁹⁹ The court

how the exclusive right can be conferred to do the very thing which the court admits was well known at the time the patent to Jones was issued.

Id.

²⁹⁴ *Id.* at 487 (White, J., dissenting).

²⁹⁵ *Id.* at 455 (White, J., dissenting).

²⁹⁶ *See id.* at 446–87.

²⁹⁷ *See id.* at 410–46.

²⁹⁸ 179 F. 701 (7th Cir. 1910).

²⁹⁹ *Id.* at 705.

summarized the distinction as follows: “In the one case the mass is made to yield something to the useful arts; in the other case what is yielded is chiefly interesting as a fact in chemical learning.”³⁰⁰ As in earlier cases, therefore, an exclusive right was contingent upon contribution to the useful arts, and knowledge, in this case “chemical learning,” did not meet that threshold.

Similarly, in *Union Carbide v. American Carbide*,³⁰¹ a claim directed to crystalline calcium carbide was upheld as valid in view of an earlier publication by a German chemist, Woehler.³⁰² The Woehler publication described a method for formation of acetylene from calcium carbide.³⁰³ The court addressed, as two distinct arguments by the defendant, questions of novelty of the claimed invention.³⁰⁴ The first argument by the defense assumed that calcium carbide produced according to the teachings of the Woehler publication was amorphous rather than crystalline, but that, nevertheless, “the patent is not for a new product, but for a new form of an old product, having the same composition, properties and uses as the old.”³⁰⁵ The court stated, in response, that “patentable novelty” can be based on superior properties,³⁰⁶ and that the superior properties were a consequence of the crystalline form.³⁰⁷ Moreover, the court pointed out that the Woehler publication represented no more than a “laboratory experiment” which, although “generally recognized in treatises upon chemistry,” did not result in any “appreciable amount of calcium carbide . . . made by any person before the present patentee came into the field.”³⁰⁸

³⁰⁰ *Id.*

³⁰¹ 181 F. 104 (2d Cir. 1910).

³⁰² *Id.* at 106.

³⁰³ *Id.*

³⁰⁴ *See id.* at 105–06.

³⁰⁵ *Id.* at 106.

³⁰⁶ *Id.* at 106–07. The court stated:

In determining the question of patentable novelty, there can be no hard and fast rule. Each case must be decided upon its own facts. Mere change of form in and of itself does not disclose novelty. A new article of commerce is not necessarily a new article patentable as such. But patentable novelty in a case like the present may be founded upon superior efficiency; upon superior durability, including the ability to retain a permanent form when exposed to the atmosphere; upon a lesser tendency to breakage and loss; upon purity, and, in connection with other things, upon comparative cheapness. So, supplementing other considerations, commercial success may properly be compared with mere laboratory experiments.

Id.

³⁰⁷ *Id.* at 107. The court stated:

Now, broadly comparing amorphous and crystalline carbides, we are convinced that the complainants’ expert was substantially correct in testifying as follows: “Usually speaking the amorphous substance is less dense, more soluble, has a lower melting point and less hardness. That would seem to mean in all probability, even between equally pure compounds, that bulk for bulk . . . the amorphous would be the inferior material”

Id.

³⁰⁸ *Id.* at 106. As stated by the court:

There is nothing to indicate that that [sic] which Woehler did was anything more than to make and describe a laboratory experiment, and, although his work was generally recognized in treatises upon chemistry, it does not appear that any appreciable amount of calcium carbide was made by any person before the present patentee came into the field.

According to the court, the product of the method described by Woehler was “put to no practical use,” in contrast to the claimed crystalline carbide of the patent, which was a “great commercial success.”³⁰⁹ Commercial success, therefore, overcame the argument that crystallinity was a “mere change of form” that should not confer patentability on the claimed product:

For these reasons, it is held that the product possesses the requisite patentable novelty. And we must regard this conclusion as not only well founded in law, but as most just. To hold an important discovery which has given to the world a commercially new product — a product the high utility of which must be conceded — not entitled to protection for want of novelty, would, as it seems to us, be applying the patent statute to defeat its fundamental purposes.³¹⁰

As in *Kuehmsted*, patentability was based on contribution of a practical use, which was contrasted with “chemical learning” in the prior art of *Kuehmsted*, and “mere laboratory experiments” in that of *Union Carbide*.³¹¹ Previous activities of those who did not contribute a therapeutic or practical use, respectively, were inadequate to deny exclusive rights to those who did.

As a second defense, the defendant in *Union Carbide* purported to show that experiments following the teachings of the Woehler reference “demonstrate the crystallinity of the Woehler carbide.”³¹² The court, however, held that novelty was not defeated because there was “little information concerning the process of making calcium carbide” in the Woehler article³¹³ and the defendant had not carried the burden of establishing that crystallinity was a consequence of following its teachings.³¹⁴ “Patentable novelty” of the claimed invention consequent to a practical contribution to the useful arts was considered to be an issue distinct from the potential lack of certainty in producing a crystalline product by following the teachings of a published article; contribution to the useful arts was distinguished from experimental work as a whole, and was a separate consideration from the

Id.

³⁰⁹ *Id.* at 107 (“It is also quite clear that Woehler published a mere result of a laboratory experiment which was put to no practical use. Crystalline carbide, on the other hand, has been a great commercial success, and has furnished the foundation for important industries.”).

³¹⁰ *Id.* at 107–08.

³¹¹ See *Kuehmsted v. Farbenfabriken of Elberfeld Co.*, 179 F. 701, 705 (7th Cir. 1910); *Union Carbide*, 181 F. 104 at 107.

³¹² *Union Carbide*, 181 F. at 108 (“But it is contended that experiments made by the defendant’s witnesses for the purposes of this suit demonstrate the crystallinity of the Woehler carbide.”).

³¹³ *Id.* (“Now, as already pointed out, the Woehler article furnished very little information concerning the process of making calcium carbide.”).

³¹⁴ *Id.* at 108–09. The court stated:

The burden is upon the defendant to establish crystallinity, not upon the complainant to disprove it, and, among other things, we cannot ignore the possibility that the defendant’s witnesses may have attributed the crystallinity of the calcium cyanamide in the product to the calcium carbide. Consequently the Woehler product, whether correctly represented by the earlier compound or by the result of recent experiments, must be held not to anticipate.

Id.

inevitability of inherent results in prior art teachings as a threshold consideration to defeat patentability.³¹⁵ The court also grouped experimental use by others with those of the inventor as activities that were inadequate to obviate the right to patent protection:

We find experimental uses of the product before that time. We find that Lord Kelvin in a foreign country put some of the carbide in water, and lighted the gas which was generated. We find that the patentee gave samples of the product to different persons for experimental purposes. But it is well settled that an inventor has the right to experiment in perfecting his invention and demonstrating its utility, and we are not satisfied that the patentee in this case did anything more. We think that the proof fails to establish that there was any public use of the invention more than two years prior to the application for the patent.³¹⁶

Therefore, “experimental use,” regardless of whether it was conducted by the inventor or another, was not considered by the court to be a “public use” that would prohibit patent protection.

The Supreme Court in *Diamond Rubber Co. of New York v. Consolidated Rubber Tire Co.*³¹⁷ also suggested that the utility of something new could be evidence of novelty.³¹⁸ Again, from the point of view of “substantial” or “patentable” novelty relative to what was known in the art, recognition and contribution to the useful arts were identified as the “tests” of an invention, regardless of the straightforward nature that it may seem to have in retrospect:

Knowledge after the event is always easy, and problems once solved present no difficulties, indeed, may be represented as never having had any, and expert witnesses may be brought forward to show that the new thing which seemed to have eluded the search of the world was always ready at hand and easy to be seen by a merely skillful attention. But the law has other tests of the invention than subtle conjectures of what might have been seen and yet was not. It regards a change as evidence of novelty, the acceptance and utility of change as a further evidence, even as demonstration.³¹⁹

Another embodiment of the principle in *Kuehmsted*, that patentable distinction can be based on achievement of a practical purpose,³²⁰ can be found in the decision of Judge Learned Hand in *Parke-Davis & Co. v. H. K. Mulford*.³²¹ In that case, the claimed invention was directed to adrenaline in a relatively pure state.³²² As in *Kuehmsted*,³²³ the court in *Parke-Davis* upheld patentability of the claimed subject

³¹⁵ *See id.* at 107–10.

³¹⁶ *Id.* at 109.

³¹⁷ 220 U.S. 428 (1911).

³¹⁸ *Id.* at 435.

³¹⁹ *Id.*

³²⁰ *Kuehmsted v. Farbenfabriken of Elberfeld Co.*, 179 F. 701, 705 (7th Cir. 1910).

³²¹ 189 F. 95, 103 (C.C.S.D.N.Y. 1911).

³²² *Id.* at 101–03.

³²³ *Kuehmsted*, 179 F. at 705.

matter over prior art, despite the possibility that the physical product claimed might be the same, but for a difference in purity, because the consequence of the difference in purity made it “available” for use.³²⁴ Therefore, “it became for every practical purpose a new thing commercially and therapeutically.”³²⁵ As was also the case with *Kuehsted*, and with *Union Carbide*, the court in *Parke-Davis* implied that knowledge, without any evidence of a practical result, is insufficient to defeat patentability:

That the change here resulted in ample practical differences is fully proved. Everyone, not already saturated with scholastic distinctions, would recognize that Takamine’s crystals were not merely the old dried glands in a purer state, nor would his opinion change if he learned that the crystals were obtained from the glands by a process of eliminating the inactive organic substances. The line between different substances and degrees of the same substances is to be drawn rather from the common usages of men than from nice considerations of dialectic.³²⁶

The Supreme Court in *Eibel Process Co. v. Minnesota & Ontario Paper Co.*³²⁷ upheld the validity of a patent directed to paper making machinery in view of prior art that achieved the same result, but in a different way and for a different purpose.³²⁸ The inventor, Eibel, discovered the cause of limitations in the speed at which a Fourdrinier machine for making paper could be operated.³²⁹ His

³²⁴ *Parke-Davis*, 189 F. at 103.

³²⁵ *Id.* The court stated:

Nor is the patent only for a degree of purity, and therefore not for a new “composition of matter.” . . . [b]ut, even if it were merely an extracted product without change, there is no rule that such products are not patentable. Takamine [the patentee] was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. That was a good ground for patent.

Id. (citations omitted).

³²⁶ *Id. Modified Park-Davis and Co. v. H. K. Mulford*, 196 F. 496, 497–500 (2d Cir. 1912). The court reversed the portion of Judge Hand’s decision in the lower court as to the validity and infringement of claims that could be considered to be so broad as to embrace substances which have “never been associated with suprarenal gland tissue.” *Id.* The court further stated:

Two important questions then arise: Is there anything in the specification and prior art which indicates that this claim may be sustained without giving it so broad a construction? Giving it the broad construction, was Takamine’s contribution to the art such that he is entitled to make and hold so comprehensive a claim?

. . . .

We are averse to entering into the investigation necessary to answer the second question, until it is seen whether or not the art is going to produce a substance which has never been associated with suprarenal gland tissue and which nevertheless responds to the requirements of these claims

Id. at 499–500.

³²⁷ 261 U.S. 45 (1923).

³²⁸ *Id.* at 56–66.

³²⁹ *Id.* at 52. The court explained:

improvement was to increase the “speed of the stock by substantially tilting up the wire and giving the stock the added force of the downhill flow.”³³⁰ As a consequence, Eibel was successful in increasing the speed at which Fourdrinier machines could be run, from about 500 to in excess of 700 feet per minute.³³¹ Eibel’s improvement was a tremendous commercial success.³³²

The degree of pitch of the wire was not an element of any of the claims in Eibel’s patent.³³³ Instead, the court relied on distinctions in the practice of Eibel’s claimed invention, as described in the specification, in combination with “a different purpose to be accomplished,” in evaluating the invention relative to the prior art:

The Eibel invention is distinguished from the prior art in two ways: First, in that the pitch of the wire was for a different purpose to be accomplished, not at the dandy roll some [twenty] or more feet from the breast roll, but at a point [nine] or [ten] feet from there; and, second, by the fact that to achieve his purpose a high or substantial pitch must be given to the wire, while only a small or trivial pitch was needed for the drainage of the prior art.³³⁴

The defense argued that, regardless of whether the prior art had recognized “the advantage of speeding up the stock to an equality with the wire, yet the necessary effect of their devices was to achieve that result and therefore their machine anticipated Eibel.”³³⁵ In response, the Court stated that “we find no evidence that any pitch of the wire, used before Eibel, had brought about such a result as that sought by him” and that, “if it had done so under unusual conditions, accidental results, not intended and not appreciated, do not constitute anticipation.”³³⁶ The Court also clearly linked patent protection to the significance of the contribution made to the art by a new discovery or invention:

In administering the patent law, the court first looks into the art, to find what the real merit of the alleged discovery or invention is and whether it has advanced the art substantially. If it has done so, then the court is liberal in its construction of the patent, to secure to the inventor the reward he deserves. If what he has done works only a slight step forward, and that which he says is a discovery is on the borderline between mere mechanical

Eibel concluded that this was due to the disturbance and ripples in the stock as it was forming at a point between the breast roll and the first suction box, caused by the fact that at that point the wire was traveling much faster than the stock, and if at that point the speed of the flowing stock could be increased approximately to the speed of the wire, the disturbance and rippling in the stock would cease and the defects would disappear from the paper product.

Id.

³³⁰ *Id.*

³³¹ *Id.* at 55.

³³² *Id.* (“The defendant’s witnesses without exception refer to that disclosure [of Eibel’s discovery] as something that surprised and startled the paper-making trade. It spread, to use the expression of one witness, like wild fire.”).

³³³ *Id.* at 50–51.

³³⁴ *Id.* at 58.

³³⁵ *Id.* at 66.

³³⁶ *Id.*

change and real invention, then his patent, if sustained, will be given a narrow scope and infringement will be found only in approximate copies of the new device. It is this differing attitude of the courts toward genuine discoveries and slight improvements that reconciles the sometimes apparently conflicting instances of construing specifications and the finding of equivalents in alleged infringements.³³⁷

Therefore, the intention, or purpose, to be accomplished was a factor in determining “real merit of the alleged discovery or invention” and “whether it has advanced the art substantially,” to thereby justify patent protection and the scope of protection granted to the discoverer.³³⁸

The claimed invention in *Kansas City Southern Ry. Co., et al. v. Silica Products Co.*³³⁹ was a “waterproof plastic” that included a “gelantinizable ‘reversible colloid,’ such as dry bentonite” disseminated within material such as concrete, stucco, and plaster of Paris.³⁴⁰ The court upheld the validity of the patent to Collings in view of prior art patents that employed bentonite because the mention of bentonite in those references was not for the purposes of waterproofing, and that the “plasticity or plastic condition referred to in the specification and in some of the claims is merely an incident to one stage of the mixture.”³⁴¹ Accordingly, despite technical inclusion in the specification of the prior art patents of all the elements of certain claims, validity was upheld because there was no mention of, nor was there inherent in the teachings of the prior art, the object of Collings patent: the benefit of the invention claimed by Collings was not necessarily obtained by following the teachings of the identified art.³⁴²

With respect to infringement, the defendants contended that “the result of their use of bentonite is to produce a water-tightening and not a waterproofing in the finished product, and, in support of this contention, that they use a different agent for waterproofing . . .”³⁴³ In response, the court stated that “all that need be said is that defendants have followed the process of the patent with substantial closeness.”³⁴⁴ The court hinged infringement on whether the benefit [i.e., waterproofing] of Collings’ patented invention was gained, albeit imperfectly: “[I]f in some slight particular there has been a variance and the result has been a product inferior in waterproofing to the product of the patent, this will not avoid infringement. ‘One does not escape infringement by practicing invention imperfectly.’”³⁴⁵ The court concluded that “[e]ven if the defendants used the bentonite, as is claimed, for plasticity and water-tightening, and not for

³³⁷ *Id.* at 63.

³³⁸ *Id.*

³³⁹ 48 F.2d 503 (8th Cir. 1931).

³⁴⁰ *Id.* at 504.

³⁴¹ *Id.* at 505 (“In considering these prior art patents, it should be borne in mind that the prime object sought in the Collings patent, original and reissue, is the waterproofing of concrete, stucco, etc. The plasticity or plastic condition referred to in the [prior art] specifications and in some of the claims is merely an incident to one stage of the mixture.”).

³⁴² *Id.* at 505–06.

³⁴³ *Id.* at 508.

³⁴⁴ *Id.*

³⁴⁵ *Id.* (quoting *Gibbs v. Triumph Trap Co.* (C.C.A.) 26 F.2d 312 (2d Cir. 1928)).

waterproofing, this would not avoid infringement. The purpose and intent of the defendants is immaterial.”³⁴⁶

The link between anticipation and infringement in *Kansas City* was not intent. Rather, stated objects of prior art teachings were indicative of whether the benefit of Collings’ patented invention was gained, just as, with respect to infringement, the test was whether the defendants gained the benefit obtained by practicing the patented invention, regardless of intent. The parallel between anticipation and infringement was not consistency between stated objects in the prior art and intent of the accused infringers, but whether the prior art and the accused infringers obtained the benefit to be achieved by practicing the claimed invention; intent in both cases was immaterial.

Inherency was at issue in *Hansgird v. Kemmer*,³⁴⁷ where adequate support for provoking an interference depended upon inherent disclosure in Kemmer’s application of separating dust from vapor in a process for producing substantially pure magnesium.³⁴⁸ The court agreed with Hansgird that the necessary method step was not inherent in the “possible use of a bound briquette.”³⁴⁹ Relying on several prior cases, the court stated “[i]nherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.”³⁵⁰

The court then went on to state, without citing precedent, that “performance of the questioned function” can be established if it is the “natural result” of the “operation as taught,” and, further, if “the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.”³⁵¹ Therefore, as contemplated by the court in *Hansgird*, a “natural result” is the necessary consequence of a “given set of circumstances.”³⁵²

Contribution to the art as a practical matter was relied upon by Judge Learned Hand in *Dewey & Almy Chemical Co. v. Mimex Co., Inc.*³⁵³ There, Judge Hand for the United States Court of Appeals for the Second Circuit held one patent, directed to use of latex to seal tops of tin cans, to be invalid, and upheld the validity of another, directed to a particular form of latex.³⁵⁴ Judge Hand, in *dicta*, commented on the relevance of teachings that were known in the art, but did not provide “the chance of

³⁴⁶ *Kansas City*, 48 F.2d at 508.

³⁴⁷ 102 F.2d 212 (C.C.P.A. 1939).

³⁴⁸ *Id.* at 214.

³⁴⁹ *Id.* The court stated:

It is contended by Kemmer, and found by the board, that the binding around the briquette acted as a screen through which the vapor passed during the process of vaporizing and that the critical element of the counts was, therefore, disclosed in the meagre sentence relating to the possible use of a bound briquette. . . . [T]his interpretation of the counts is certainly not the meaning which the patentee gave in his application.

Id.

³⁵⁰ *Id.* at 214 (emphasis added).

³⁵¹ *Id.*

³⁵² *Id.*

³⁵³ 124 F.2d 986 (2d Cir. 1942).

³⁵⁴ *Id.* at 986, 990–91.

profit.”³⁵⁵ Specifically, and similarly to his reasoning in *Park-Davis*, Judge Hand suggested that “elements” in the art, if commercially unavailable, should be discounted because they do not offer the opportunity for exploitation that is to be rewarded by grants of a patent:

The difficulty in the case at bar is not therefore that the invention consisted only of a substitution of material, but that the necessary setting did not exist for any invention at all. It is not important that latex had been known for many years, and that a convenient method of shipping it had been known for eight years. We should not count elements that were not commercially available; a substance, long known to chemists, but not upon the market, is practically as impotent upon the art as though it were unknown. The assumption of the law is that the chance of profit from the exploitation of the patent will stimulate discovery, and profit presupposes that the materials are at hand.³⁵⁶

Judge Hand dismissed a prior art reference as nonanticipatory because of lack of consistency in the results obtained by the teachings provided by the reference:

No doctrine of the patent law is better established than that a prior patent or other publication to be an anticipation must bear within its four corners adequate directions for the practice of the patent invalidated. If the earlier disclosure offers no more than a starting point for further experiments, if its teaching will sometimes succeed and sometimes fail, it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of knowledge, and if it is not an anticipation.³⁵⁷

Therefore, utility of knowledge made available to the public was a consideration in determining the anticipatory effect of a reference.

A lower court decision upholding the validity of a patent directed to salts of 1-phenyl-2-aminopropane was affirmed by the Third Circuit of the United States Circuit Court of Appeals, in *Smith, Kline & French Laboratories v. Clark & Clark*.³⁵⁸ An earlier paper authored by a German scientist, Edeleano, and published in 1887, described the equivalent base of the claimed salt.³⁵⁹ Although no clear link was made between the utility and novelty of the claimed invention, it appears that the court took a constrained view of the prior art in order to uphold the patentee’s exclusive right:

While the question of what constitutes anticipation is one of law, as open for determination by this court as by the court below, the facts on which the

³⁵⁵ *Id.* at 987.

³⁵⁶ *Id.*

³⁵⁷ *Id.* at 989.

³⁵⁸ 157 F.2d 725, 726–29 (3d Cir. 1946).

³⁵⁹ *Id.* at 728 (“We think the inference is possible that Edeleano actually prepared betaphenylisopropylamine. In any event Edeleano’s phenylisopropylamine must be taken as the equivalent of Alles’ base, viz., 1-phenyl-2-aminopropane, or amphetamine.”).

legal defense of anticipation is to be based must be found by the court below. . . . We cannot say that the learned trial judge was in error in his conclusions as to Edeleano's disclosures. He found that Edeleano's work did not constitute anticipation of Alles' claim.³⁶⁰

The patent claims, which broadly embraced any salt of 1-phenyl-2-aminopropane, including amphetamine sulfate, a drug that "has proved itself to be of great importance in the treatment of narcolepsy, post-encephalitic parkinsonism, chronic exhaustion, psychoneurosis and depression, acute and chronic alcoholism . . . [and] of singular importance in counteracting the effects of barbiturate poison,"³⁶¹ were upheld as valid, partly as a consequence of a high degree of usefulness of the invention:

That Alles' contribution was of great therapeutic use and value may not be doubted. Following his discovery, physicians had at hand a drug which could affect, even create, mood. Alles' discovery is close to pioneer invention. His patent is entitled to a liberal construction in aid of the claim under consideration. We conclude that the court below committed no error when it found claim 1 of the patent valid. That the defendants have infringed it is clear.³⁶²

Novelty, again, hinged on utility of claimed subject matter, relative to what was known in the art, in *Merck & Co. v. Olin Mathieson Chemical Corp.*³⁶³ The subject patent claimed a "vitamin B(12)-active composition comprising recovered elaboration products of the fermentation of a vitamin B(12)-activity producing strain of Fungi" exhibiting activity of "at least 440 L.L.D. units per milligram and less than 11 million L.L.D. units per milligram."³⁶⁴ The court held that previous development of an assay for "an unidentified substance in liver which stimulated the growth of rats" and employment of a microorganism, *Lactobacillus lactis*, Dorner, ("LLD"³⁶⁵), did not deprive the claimed subject matter of patentability by the mere fact that certain materials tested positive.³⁶⁶ Rather, the activities of Dr. Shorb, who had developed

³⁶⁰ *Id.* at 728–29.

³⁶¹ *Id.* at 729 n.14.

³⁶² *Id.* at 729.

³⁶³ 253 F.2d 156 (4th Cir. 1958).

³⁶⁴ *Id.* at 157–58.

³⁶⁵ *Id.* at 159. The court explained:

Dr. Mary S. Shorb, a bacteriologist employed by the Department of Agriculture, undertook the development of an assay, or test, for "Factor X," an unidentified substance in liver which stimulated the growth of rats. She selected for investigation a microorganism, *Lactobacillus lactis*, Dorner, which has high nutritional requirements. She found that the growth of this organism in an amino acid basal medium to which clarified tomato juice had been added was stimulated by the further addition of liver extracts, yeast, orange juice and other substances. Since she did not know the identity of the active principle in either clarified tomato juice or in growth stimulants, she referred to them, respectively, as the TJ, or tomato juice, factor and the LLD factor, after the name of the organism she was studying.

Id.

³⁶⁶ *Id.* at 164.

the assay, were dismissed by the court for lack of conception of the significance of her discovery,³⁶⁷ which positively identified the presence of what was known at that time as “anti-pernicious anemia factor,” and later classified as vitamin B(12).³⁶⁸ The court considered Dr. Shorb’s failure to recognize the significance of her results as fatal to defendant’s arguments that her work rendered patentees’ claimed invention unpatentable:

The contention that there was lack of invention in the work of the patentees rests principally upon the work of Dr. Shorb. . . . For her provision of a tool of great assistance to them, the patentees must have been grateful to her, but there is nothing to suggest that she ever envisioned anything in the nature of the compositions developed by the patentees, or, indeed, that she ever supposed that anti-pernicious anemia activity might be found in any material other than liver.³⁶⁹

The court summarized the lack of significance of Dr. Shorb’s activities as follows:

No support can be found in the record for a finding that Dr. Shorb told anyone, or even thought, that the anti-pernicious anemia principal might be found in fermentation materials. It is conceivable that some other scientist with the knowledge of the day might have found significance in Dr. Shorb’s observations, which she overlooked, but the record does not show that anyone did.³⁷⁰

³⁶⁷ *Id.* at 160–61. As stated by the court:

Dr. Shorb, in speculating that her assay might be responsive to the anti-pernicious anemia factor in liver, knew it was responsive to some substance or substances. . . . In her search for a stable TJ factor to be substituted for tomato juice, she actually examined fermentation materials. Some of these she found inhibited the growth of *Lactobacillus lactis*, Dorner; others, promoting growth, were found to contain both the TJ factor and LLD activity, but the presence of LLD activity was significant to her only because it required that she discard the material for further investigation as a substitute for tomato juice. From all that appears, such observation of LLD activity in fermentation materials (as her earlier observation of such activity in yeast, a fermentation product, and other materials) did not produce the faintest notion that the anti-pernicious anemia principal might be present. Such observations were merely a disappointment, marking another failure in her search for a stable TJ factor.

Id.

³⁶⁸ *Id.* at 159–60. The court summarized:

Beginning in 1938, employees in Merck’s research laboratories had worked upon the isolation of the anti-pernicious anemia factor in liver.

. . . .

After much additional analysis and investigation, officials of Merck decided the pure material could be classified as a vitamin. Since it was water-soluble, it was placed in the ‘B’ group and was assigned the number 12, all lower numbers having been appropriated.

Id.

³⁶⁹ *Id.* at 160.

³⁷⁰ *Id.* at 161.

Moreover, the court relied on “therapeutic and commercial worth” to distinguish a difference in kind of the patented composition from unpatentable differences in “degree of purity”:

The compositions of the patent here have all of the novelty and utility required by the Act for patentability. They never existed before; there was nothing comparable to them. If we regard them as purification of the active principal in natural fermentates, the natural fermentates are quite useless, while the patented compositions are of great medicinal and commercial value. The step from complete uselessness to great and perfected utility is a long one. That step is no mere advance in the degree of purity of a known product. From the natural fermentates, which, for this purpose, were wholly useless and were not known to contain the desired activity in even the slightest degree, products of great therapeutic and commercial worth have been developed. The new products are not the same as the old, but new and useful compositions entitled to the protection of the patent.³⁷¹

In other words, novelty and utility, as threshold conditions for patent protection, were both contingent upon the existence of a beneficial contribution to the art and value as an item of commerce. The court closed by reciting the portion of the Supreme Court opinion in *Diamond Rubber Co.*, stating that “[the law] . . . regards a change as evidence of novelty, the acceptance and utility of change as further evidence, even as demonstration.”³⁷² Therefore, as in several cases already discussed, beneficial contribution to the art was evidence, and even a demonstration, of novelty prerequisite to grant of patent protection.

In *International Nickel Co., Inc. v. Ford Motor Co.*,³⁷³ the United States District Court for the Southern District of New York confirmed the validity of a patent held by International Nickel Company, Inc. (“INCO”) directed to an improved formulation of iron, whereby a small amount of magnesium was employed to cause graphite to assume a spheroidal rather than flake form.³⁷⁴ Earlier activities by Mack Truck Company, which included formation of valve seat inserts exhibiting “changes in graphite structure attributable to the retention of magnesium . . . [that] produced, though to a lesser degree, the same desirable characteristics present in nodular iron”³⁷⁵ of INCO’s patented product, did not amount to anticipation because Mack was “not merely ignorant of the scientific phenomena underlying nodular iron,” but “in fact Mack never consciously pursued the product here in question for any purpose.”³⁷⁶ Mack’s failure to appreciate what it had produced “merely by chance” nullified any anticipatory affect of its activities:

³⁷¹ *Id.* at 164.

³⁷² *Id.* at 165 (quoting *Diamond Rubber Co. v. Consolidated Rubber Tire Co.*, 220 U.S. 428, 435 (1911)).

³⁷³ 156 F. Supp. 551, 554 (S.D.N.Y. 1958).

³⁷⁴ *Id.* at 554.

³⁷⁵ *Id.* at 559.

³⁷⁶ *Id.* at 560. The court found that:

Mack was not merely ignorant of the scientific phenomena underlying nodular iron. It is not that Mack knew it had a new iron but failed to appreciate that its unique properties were due to an alteration in graphite shape. Not only was

Here Mack never sought to manufacture nodular iron, the product which INCO has discovered. Indeed it was unaware that it had done so and had no idea of the significance of retained magnesium. Where the allegedly anticipating product was produced merely by chance and never recognized nor appreciated, one who later discovers and recognizes the product may patent it.³⁷⁷

The policy behind the court's holding, once again, linked the exclusive rights granted under a patent to contribution to the art. Where prior activity did not make the contribution that was later attributable to a patent applicant, exclusive rights would not be denied:

The Patent Law seeks to reward those who teach the public how to perform, process or construct things which the public theretofore was unable to do because of insufficient information. If a product or process is accidentally produced and unrecognized by the prior art, it is unlikely that the opportunities which it presents would be within the reach of the general public.³⁷⁸

In *In re Seaborg*, the Court of Customs and Patent Appeals reversed a decision by the Board of Appeals of the United States Patent and Trademark Office rejecting claims directed to "element 95" and "the isotope of element 95 having the mass number 241," under 35 U.S.C. § 101 for lack of novelty under what the solicitor of the Patent Office referred to as "inherency doctrine."³⁷⁹ Reflecting the logic of *Merck & Co. v. Olin Mathieson* where patent rights were upheld as "new and useful compositions of matter" within the "meaning of § 101 of the Act,"³⁸⁰ and despite earlier activities that did not recognize the significance of the compositions that were

Mack unaware that it had created a new iron but in fact Mack never consciously pursued the product here in question for any purpose. Nor did it ascribe any meaningful function to retained magnesium. Mack sought merely a means for the degasification of iron.

Id.

³⁷⁷ *Id.* at 561.

³⁷⁸ *Id.* at 562 (citation omitted).

³⁷⁹ 328 F.2d 996, 996–97 (C.C.P.A. 1964). The court summarized the issue as follows:

The issue here arises by application of what both the appellant and the solicitor termed the "inherency doctrine", [sic] which, as we understand it, is a Patent Office doctrine which infers a lack of novelty in a product under 35 U.S.C. § 101 if a comparable process for making the product is found to exist in the art.

Id.

³⁸⁰ *Merck & Co. v. Olin Mathieson*, 253 F.2d 156, 162 (4th Cir. 1958). The court in *Merck & Co. v. Olin Mathieson* stated:

The fact that the product, itself, is not a "new and useful *** machine, manufacture, or composition of matter," within the meaning of § 101, is fatal to the product claims. The facts here, however, are far from the premise of the principle. Until the patentees produced them, there were no such B(12) active compositions. No one had produced even a comparable product. The active substance was unidentified and unknown.

Id.

claimed, the court in *Seaborg* characterized “inherency doctrine” as being “broader” than the analysis conducted to find anticipation, and “establishe[d] a broader basis for refusing a patent than is required by the courts in finding anticipation of an issued patent.”³⁸¹

The court contrasted the facts in *Seaborg* with those of an earlier case of inherency, *In re Wiegand*,³⁸² where patentability was denied on the basis of unspoken production of a claimed product, by distinguishing the appealed claims from the allegedly inherent teachings of U.S. Patent Number 2,708,656 issued to *Fermi, et al.* on the uncertainty that the claimed product was produced and that, even if produced, the presence of the claimed subject matter would be undetectable.³⁸³ The court recited with approval statements regarding patentability by the Board of Appeals in a companion appeal, concluding that, in instances of unpredictability in the result, “conception and reduction to practice are necessarily concurrent.”³⁸⁴

In effect, a parallel was drawn by the court in *Seaborg* between patentability and anticipation as a function of predictability, on one hand, and the necessity of conception, where certainty in the result could not be established, on the other. As a product of the facts in *Seaborg*, the court declined to hold that the uncertain and undetectable result of the teachings of the Fermi patent anticipated the appellant’s claimed invention.³⁸⁵ The court approved of the conclusions of the appellant’s brief, to wit:

There is no positive evidence that americium was produced inherently in the natural uranium fuel by the operation of the reactor for the times and at the intensity mentioned in the exemplary statement relied upon by the Patent Office . . . [i]f the one billionth of a gram were produced, it would have been completely undetectable, since it would have been diluted with the 40 tons of intensely radioactive uranium fuel which made up the

³⁸¹ *In re Seaborg*, 328 F.2d at 997.

³⁸² 182 F.2d 633, 638 (C.C.P.A. 1950).

³⁸³ *In re Seaborg*, 328 F.2d at 998–99. The court stated:

The record before us, unlike the record in the *Wiegand* case, is replete with showings that the claimed product, if it was produced in the Fermi process, was produced in such minuscule amounts and under such conditions that its presence was undetectable. There was no question in the *Wiegand* case but that carbon black had been produced by the furnace process of the prior art . . .

Id.

³⁸⁴ *Id.* at 999. The court referred to this companion board decision, as follows:

In the companion appeal . . . the board . . . stated what we consider to be the fact here, that:

. . . The exhibits submitted, considered in the most favorable light, do not show that appellant could predict with any degree of definiteness the properties or characteristics of the new elements or specify with any certainty the exact procedures which could be followed, without the exercise of more than the ordinary skill of the art, to prepare these elements. Indeed, in view of the unpredictability both as to the character of the product elements and of the processes by which they might be achieved, it is particularly reasonable to hold, as the court did in *Smith v. Bousquet* that conception and reduction to practice are necessarily concurrent for an invention of this kind.

Id. (citation omitted).

³⁸⁵ *Id.*

reactor. The possibility that although a minute amount of americium may have been produced in the Fermi reactor, [the fact that] it was not identified (nor could it have been identified), would preclude the application of the Fermi patent as a reference to anticipate the present invention.³⁸⁶

The court, therefore, followed the policy stated by Judge Learned Hand, requiring that prior teachings enrich “the store of common knowledge” as a prerequisite to anticipation under patent law.³⁸⁷ The court quoted Judge Hand from his opinion in *Dewey & Almy*, discussed above, as follows:

No doctrine of the patent law is better established than that a prior patent or other publication to be an anticipation must bear within its four corners adequate directions for the practice of the patent invalidated. If the earlier disclosure offers no more than a starting point for further experiments, if its teaching will sometimes succeed and sometime fail, if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation.³⁸⁸

Therefore, a result that is uncertain in the prior art, combined with a lack of conception of that result in the art, would not bar grant of a patent right for lack of novelty.

“Benefit to mankind” was the criterion necessary to establish anticipation by the United States District Court for the Southern District of Florida in *Chas. Pfizer & Co., Inc. v. Barry-Martin Pharmaceuticals, Inc.*³⁸⁹ There, the court stated that a demonstration that “prior art fermentation procedures [which] did not produce the recoverable amounts of tetracycline in which the Examiner was interested, but only trace amounts of no practical significance,”³⁹⁰ was not sufficient to negate the validity of later patent claims: “Since the prior art Aureomycin fermentation broths and antibiotics contained insufficient tetracycline to be of any benefit to mankind, they do not as a matter of law negate the validity of Conover’s patent claims.”³⁹¹

The court relied on the holdings in *Keuhmsted*, *Parke-Davis*, and *Merck v. Olin Mathieson*, to assert that production of the claimed compound only in a laboratory, where, “if produced naturally, would decompose within minutes,”³⁹² and, regardless, only produced in “trace amounts, unrecognized and of no use,” did not invalidate a patent directed to that product.³⁹³ The court stated that there was “[n]o evidence to sustain the defendant’s contention that tetracycline is a natural product that was

³⁸⁶ *Id.*

³⁸⁷ *Id.* at 997.

³⁸⁸ *Id.*

³⁸⁹ 241 F. Supp. 191, 194 (S.D. Fla. 1965).

³⁹⁰ *Id.* at 193.

³⁹¹ *Id.* at 194.

³⁹² *Id.* at 193 (“There is no evidence that tetracycline has ever been recovered, produced, isolated or even identified other than in a laboratory. The defendant witness, Dr. Wallis, testified that tetracycline, Aureomycin and terramycin, if produced naturally, would decompose within minutes due to their sensitivity to alkali.”).

³⁹³ *Id.* at 194.

produced. The prior existence of tetracycline in Aureomycin in trace amounts, unrecognized and of no use does not invalidate the patent.”³⁹⁴

The court appeared unwilling to defeat patentability, especially in view of the significance of the discovery made by the inventor, which the court characterized as “of unquestioned benefit to mankind”:

The discovery of tetracycline by Dr. Conover was, as described by Dr. Wallis, a “marvelous” and “great” discovery. This discovery, which was most unobvious and involved scientific imagination, perseverance and skill, has been of unquestioned benefit to mankind. Tetracycline is now considered the best of the broad spectrum antibiotics and has largely replaced Aureomycin due primarily to a much lower incidence of toxic side effects in its use.³⁹⁵

At least with respect to the court’s opinion in *Chas. Pfizer*, even certainty of production of a claimed compound, where the compound was present only in “trace amounts, unrecognized and of no use,” and, therefore, of no “benefit to mankind,” would not invalidate patent claims.³⁹⁶

Inherency was also the issue in *In re Marshall*.³⁹⁷ The Court of Customs of Patent Appeals held that a claim directed to a method for weight control that included anesthetizing nerve endings in the digestive tract was not anticipated by entries in the Physicians’ Desk Reference (“PDR”) teaching the anesthetic oxethazaine, which was disclosed by the patent applicant as a suitable anesthetic for practicing the claimed invention, because “the primary reference, the PDR, does not disclose every material element of the claimed subject matter.”³⁹⁸ The PDR taught use of oxethazaine to treat various disorders, including esophagitis, gastritis, peptic ulcer and irritable colon syndrome.³⁹⁹ The court specifically held that “[i]f anyone ever lost weight by following the PDR teachings it was an unrecognized accident” and, therefore, the claimed method was not anticipated by the PDR because “[a]n accidental or unwitting duplication of an invention cannot constitute anticipation.”⁴⁰⁰ Consistent with earlier holdings, establishment of certainty, or, at least, recognition, were prerequisite in *In re Marshall* to establishing a contribution to the art sufficient to constitute an antecedent benefit in the public domain that would deprive a later inventor of the right to patent his discovery.⁴⁰¹

Similarly, in another case, *Coordinated Pretrial Proceedings in Antibiotic Antitrust Actions v. Pfizer Inc.*,⁴⁰² co-production of a claimed antibiotic, tetracycline,

³⁹⁴ *Id.*

³⁹⁵ *Id.* at 193.

³⁹⁶ *Id.*

³⁹⁷ 578 F.2d 301 (C.C.P.A. 1978).

³⁹⁸ *Id.* at 304 (“Applying this rule of law to the present case, we must reverse the board’s rejection of claims 1–4 under 35 U.S.C. § 102 since the primary reference, the PDR, does not disclose every material element of the claimed subject matter.”).

³⁹⁹ *Id.* (“The PDR, however, teaches using drugs containing the anesthetic oxethazaine to inhibit release of the acid-stimulating hormone, gastrin, in order to treat esophagitis, gastritis, peptic ulcer and irritable colon syndrome.”).

⁴⁰⁰ *Id.*

⁴⁰¹ *Id.*

⁴⁰² 498 F. Supp. 28 (E.D. Pa. 1980).

in prior art processes for the production of chlortetracycline (Aureomycin) was not to be anticipatory, because the claimed tetracycline was produced only in “small amounts” and was “unrecognized at the time.”⁴⁰³ The court accepted both the examiner’s statement during the course of prosecution that “it appeared that tetracycline and tetracycline hydrochloride were inherently produced by the prior art fermentation processes described in the Duggar and Niedercorn patents”⁴⁰⁴ and a summary of an interview with the examiner in which the applicant stated:

The Examiner made it clear that he would not insist on a categorical averment that the fermentation broths prepared according to cited patents contained no tetracycline whatsoever. He evidently appreciates the impossibility of proving its non-existence and is not concerned about useless trace amounts which cannot be separated from the broths by methods now recommended for recovery of the new antibiotic.⁴⁰⁵

The court found that “[n]o evidence has been presented to this Court that anyone prior to the Conover invention had any knowledge of the therapeutic benefits of tetracycline,”⁴⁰⁶ and concluded that the patent claims directed to tetracycline were valid, despite trace amounts having been “coproduced during the preparation of the earlier antibiotic Aureomycin according to the prior art Duggar and Niedercorn fermentation processes.”⁴⁰⁷ The court referenced several cases as precedent for “the basic principle that prior unrecognized co-production or use will not bar a patent on a later invention of the same product or process.”⁴⁰⁸

The United States Court of Customs and Patent Appeals in *In re Oelrich*⁴⁰⁹ reversed a decision by the Board of Patent Appeals and Interferences rejecting claims

⁴⁰³ *Id.* at 35. This case is directed to related patents, but is otherwise distinct from *Chas. Pfizer v. Barry-Martin Pharmaceuticals, Inc.*, 241 F. Supp. 191 (S.D. Fla. 1965). In *In re Coordinated Pretrial Proceedings*, the court stated:

The government has contended that information that small amounts of tetracycline may have been produced under the prior art Duggar and Niedercorn processes was withheld from the Patent Office because it would have barred issuance of the Conover Patent. That contention is incorrect. Coproduction of small amounts of tetracycline in the prior art which was unrecognized at the time of the Conover invention could not act as a bar to a patent on tetracycline.

In re Coordinated Pretrial Proceedings, 498 F. Supp. at 35.

⁴⁰⁴ *Id.* at 31.

⁴⁰⁵ *Id.* at 34. The court made clear its acceptance of the summary provided by the applicants:

Rule 2 of the Patent Office specifies that all business with that Office must be transacted in writing, and that the actions of the Patent Office will be based exclusively on the written record. . . . [The Examiner] Lidoff’s failure to indicate any disagreement with the statement can only mean that he accepted them as accurate.

Id.

⁴⁰⁶ *Id.* at 36.

⁴⁰⁷ *Id.* at 32.

⁴⁰⁸ *Id.* at 36 (“There have been many other adjudications which have confirmed the basic principal that prior unrecognized coproduction or use will not bar a patent on a later invention of the same product or process.” (footnote omitted)). The court cited, as an example, *Chas. Pfizer & Co. v. Barry Martin Pharmaceuticals, Inc.* 384 F. Supp. 191 (S.D. Fla. 1965), as also affirming the validity of the Conover patent.

⁴⁰⁹ 666 F.2d 578 (C.C.P.A. 1981).

because the express teachings of the prior art reference relied upon as being inherently anticipatory did not inevitably result in “means for generating a . . . carrier frequency . . . less than the minimum system resonant frequency.”⁴¹⁰ The court relied on language from *Hansgirk*, discussed above, which stated that “[i]nherency, however, may not be established by probabilities or possibilities If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.”⁴¹¹ The language of *Hansgirk* was applied by the court to equate “the natural result flowing from the operation” with inevitability:

The relationship between the carrier frequency and the system critical frequency — the former below the latter . . . — cannot be said to be “the natural result flowing from the operation as taught.” The Oelrich patent instructs that the device is “adapted to receive a carrier frequency substantially in excess of the particular system critical or resonant frequency” Given this express teaching, a ‘means for generating a . . . carrier frequency . . . less than the minimum system resonant frequency’ is not inevitably present.⁴¹²

2. *The Role of Recognition*

Judge Newman for the Court of Appeals for the Federal Circuit in *Continental Can Co., U.S.A. v. Monsanto Co.*⁴¹³ vacated a lower court summary judgment of anticipation under 35 U.S.C. § 102(a) of a patent claim directed to a container having hollow ribs.⁴¹⁴ Judge Newman asserted that a finding of inherent anticipation can rely on extrinsic evidence, but that “[s]uch evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.”⁴¹⁵ *In re Oelrich* was cited by Judge Newman for support, which quoted *Hansgirk* to the effect that, although the “mere fact that a certain thing *may* result from a given set of circumstances is not sufficient,” if “the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function,” then “the disclosure should be regarded as sufficient.”⁴¹⁶ Therefore, Judge Newman in *Continental Can*, like the court in earlier decisions addressing inherent anticipation, filled the “gap in the reference,” created by silence with respect to a specific teaching, by resorting to a determination of whether the teaching was, although silent, nevertheless part of the public domain.⁴¹⁷ As phrased in the quotation from *Hansgirk*, and relied upon by Judge Newman in *Continental*

⁴¹⁰ *Id.* at 581.

⁴¹¹ *Id.* (quoting *Hansgirk v. Kemmer*, 102 F.2d 212, 214 (C.C.P.A. 1939)).

⁴¹² *Id.* at 581–82.

⁴¹³ 948 F.2d 1264 (Fed. Cir. 1991).

⁴¹⁴ *Id.* at 1269.

⁴¹⁵ *Id.* at 1268.

⁴¹⁶ *Id.* at 1269.

⁴¹⁷ *Id.* at 1268.

Can, the factor overriding whether “a certain thing may result from a given set of circumstances” in an assessment of inherency was whether the critical teaching was a “natural result flowing from the operation as taught.”⁴¹⁸ For Judge Newman, apparently, a determination of the “natural result” sufficient to inherently anticipate a patent claim was contingent upon the necessary presence of missing descriptive matter in combination with recognition by persons of ordinary skill in the art that the missing teaching was present.⁴¹⁹ In essence, to be properly a part of the prior art and, therefore, in the public domain, the test required by Judge Newman was not merely presence, but recognition of presence of missing teachings by those skilled in the art. Only then could an inventor be deprived of a grant of an exclusive right in exchange for his contribution to the public of the knowledge of his discovery.

The CAFC in *Atlas Powder Co. v. Ireco, Inc.*⁴²⁰ held invalid U.S. Patent No. 4,111,727, issued to Clay, and its reissue, U.S. Re. 33,788, as being anticipated by either of two U.S. patents.⁴²¹ The patents that were held invalid (the original patent and its reissue) were both directed to ammonium nitrate and fuel oil (“ANFO”) blasting compositions.⁴²² The lower court held, in two separate decisions, that the limitation of “sufficient aeration . . . to enhance sensitivity” was an inherent property of the compositions taught by earlier patents to Egly and Butterworth and that, therefore, the claimed patent and its reissue were anticipated by their teachings.⁴²³

Judge Rader, in affirming the lower court decisions, referenced *Titanium Metals Corp. v. Banner*⁴²⁴ for the proposition that “[i]nherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art,” and that “[a]rtisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.”⁴²⁵ The court in *Titanium Metals* relied on *In re Wilder*⁴²⁶ and *In re Legrice*,⁴²⁷ which required an anticipatory reference to be “enabling,” to uphold the subject patent.⁴²⁸ “The implication” of the lower court, according to Judge Rich in

⁴¹⁸ *Id.* at 1269.

⁴¹⁹ *Id.* at 1268.

⁴²⁰ 190 F.3d 1342 (Fed. Cir. 1999).

⁴²¹ *Id.* at 1343.

⁴²² *Id.* at 1344.

⁴²³ *Id.* at 1345. The court summarized the two lower court decisions, in part, as follows:

The only element of the Clay patent claims which is arguably not present in the prior art compositions is “sufficient aeration . . . entrapped to enhance sensitivity to a substantial degree.” The trial court determined that “sufficient aeration” was an inherent element in the prior art blasting compositions within the overlapping ranges.

. . . .

After the reissue patent issued, the district court conducted a second bench trial, in January 1996, on the issues of phase two. . . . Despite the PTO’s consideration of the Egly and Butterworth references during prosecution of the reissue, the district court concluded that IRECO had overcome the Clay reissue patent’s presumption of validity under 35 U.S.C. § 282 (1994) by clear and convincing evidence.

Id.

⁴²⁴ 778 F.2d 775, 782 (Fed. Cir. 1985).

⁴²⁵ *Atlas Powder Co.*, 190 F.3d at 1347.

⁴²⁶ 429 F.2d 447, 451 (C.C.P.A. 1970).

⁴²⁷ 301 F.2d 929, 944 (C.C.P.A. 1962).

⁴²⁸ *Titanium Metals*, 778 F.2d at 778.

Titanium Metals, “being that the Russian article perhaps does not enable one to know all the things that the plaintiff’s inventors disclosed in their application, such as the range limits of the alloying ingredients Mo and Ni and the corrosion resistance.”⁴²⁹ The court in *Titanium Metals* reversed the lower court’s decision because “it is immaterial, on the issue on their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties.”⁴³⁰ The CAFC in *Titanium Metals* quoted *Wilder* as follows:

However, recitation, in a claim to a composition, of a particular property said to be possessed by the recited composition, be that property newly-discovered or not, does not necessarily change the scope of the subject matter otherwise defined by that claim. . . . We start with the proposition that claims cannot be obtained to that which is not new.⁴³¹

Summarizing, the court on appeal in *Titanium Metals* stated that “[i]t is also an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is ‘anticipated’ if *one* of them is in the prior art.”⁴³²

Reflecting the reasoning of *Titanium Metals*, Judge Rader in *Atlas Powder* asserted inherency as a function of public freedom to “make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate.”⁴³³ Judge Rader summarized that, “[a]n inherent structure, composition, or function is not necessarily known,”⁴³⁴ and that “[i]nsufficient prior understanding of the inherent properties of a known composition does not defeat a finding of anticipation.”⁴³⁵

In *Titanium Metals* and *Atlas Powder*, therefore, the issue was whether claimed subject matter could be considered novel on the basis of properties present but not made explicit in teachings of the prior art. The holding by the CAFC in each case was that discovery and explicit identification of properties inherent in compositions otherwise fully disclosed in a prior art reference could not confer novelty in a patent

⁴²⁹ *Id.*

⁴³⁰ *Id.* at 782.

⁴³¹ *Id.* (quoting *In re Wilder*, 429 F.2d at 450).

⁴³² *Id.* (citing *In re Petering*, 49 C.C.P.A. 993 (1962)).

⁴³³ *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1348 (Fed. Cir. 1999). Judge Rader stated:

This court concluded [in *Titanium Metals*] that the claimed alloy was not novel, noting that “it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties.” This same reasoning holds true when it is not a property, but an ingredient, which is inherently contained in the prior art. The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle.

Id. (citation omitted).

⁴³⁴ *Id.* at 1348–49.

⁴³⁵ *Id.* at 1349.

claim.⁴³⁶ The court in both cases required novelty in the composition, regardless of whether properties identified in the claims were made explicit in the reference, or were even otherwise recognized by one skilled in the art, as a prerequisite to patent protection.⁴³⁷ Judge Rich, in *Titanium Metals*, and Judge Rader, in *Atlas Powder*, further implied that patent protection cannot be granted where the public would be excluded from the right to make, use, or sell compositions otherwise known in the art.

In both cases, therefore, the question was whether discovery of existing properties could bestow patentability. However, there is a difference between failing to recognize an inherent property of a composition in the prior art that is within the scope of a claimed composition, and failure of a component in the prior art, either alone or as part of a composition, to contribute any properties to the composition. In other words, whether claimed subject matter can properly be found to be within the public domain can depend not simply on its existence in the prior art, but also whether the public benefited by its presence. Failure of a property of a component of a composition in public use to confer an effect on the public, in combination with failure to recognize the existence of that component in that composition, should not defeat a later claim to that component, or to a composition that benefits from that property.

*MEHL/Biophile v. Sandy Milgraum*⁴³⁸ distinguishes between “occasional” and “natural” results, and provides a basis for making this distinction in view of the benefit conferred on the public.⁴³⁹ Judge Rader, for the CAFC, held that U.S. Patent No. 5,059,192 (“the ’192 patent”) directed to a “method of hair depilation,” by substantial vertical alignment of laser light over a hair follicle opening “to damage its papilla so that hair re-growth is prevented and scarring of the surrounding skin is avoided,”⁴⁴⁰ to be invalid as being inherently anticipated by the teachings of a prior art published article to Polla⁴⁴¹ that “inherently teaches substantially vertical alignment over hair follicle openings.”⁴⁴² The patent owners argued that, in addition to failing to disclose “substantially vertical alignment” or “hair depilation,” there could be no damage to papilla by the teachings of the article because guinea pigs, which were the subject of testing by the method taught in the article had been epilated [i.e., hair removed by the roots] prior to treatment.⁴⁴³ The court disagreed, quoting a portion of the Polla article, which stated that “disruption of melanosomes deep in the hair papillae was observed.”⁴⁴⁴ Vertical alignment was held by the court to be a “natural result flowing from the operation as taught” by the Polla article.⁴⁴⁵ The court considered depilation [i.e., removal of hair] to be the necessary result of the teaching of the article, regardless of the author’s intent, stating that “to the extent

⁴³⁶ *Id.* at 1350; *Titanium Metals*, 778 F.2d at 783.

⁴³⁷ *Atlas Powder*, 190 F.3d at 1350; *Titanium Metals*, 778 F.2d at 783.

⁴³⁸ 192 F.3d 1362 (Fed. Cir. 1999).

⁴³⁹ *Id.* at 1365–66.

⁴⁴⁰ *Id.* at 1364.

⁴⁴¹ *Id.* at 1366 (referring to Luigi L. Polla et al., *Melanosomes Are a Primary Target of a Switched Ruby Laser Irradiation in Guinea Pig Skin*, J. INVESTIGATIVE DERMATOLOGY (1987)).

⁴⁴² *Id.*

⁴⁴³ *Id.* at 1365.

⁴⁴⁴ *Id.* at 1366.

⁴⁴⁵ *Id.* (quoting *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981)).

the embodiment in the patent achieves hair depilation, so does the Polla method. Where, as here, the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results."⁴⁴⁶

In contrast, the teachings of another reference, the "RD-1200 Manual," which was directed to a method of removing tattoos, was held by the court in *MEHL/Biophile* not to be inherently anticipatory because "[t]he record discloses no necessary relationship between the location of a tattoo and the location of hair follicles," and, therefore, "an operator of the RD-1200 laser could use the laser according to the manual without necessarily aligning the laser 'substantially vertically over a hair follicle opening.'"⁴⁴⁷ The court held "[t]he possibility of such an alignment does not legally suffice to show anticipation Occasional results are not inherent."⁴⁴⁸

As discussed previously, cases directed to accidental or occasional anticipation have not made clear whether lack of inherent anticipation is based on lack of certainty in the results of the method taught in a reference or on the inconsequential nature of the results of the method presumed to fall within the scope of a patent claim. Application of a benefit analysis distinguishes between the RD-1200 Manual and Polla article as references. Specifically, regardless of whether following the teachings of the RD-1200 manual would inevitably result in at least occasional substantially vertical alignment of a laser over a hair follicle opening, there was no evidence of the damage to papillae that, according to the claims in the subject patent, was the measure of depilation in the treated subject.⁴⁴⁹ The teachings of the Polla article, by way of contrast, clearly identified damage to papillae.⁴⁵⁰ Therefore, despite the fact that in neither reference was it evident that hair was present at the treatment site, and the fact that substantial vertical alignment of the laser was arguably an occasional occurrence according to the teachings of both references, it was only in the Polla article that the benefit of the claimed method, that of damage to papillae consequent to the laser treatment, was clearly obtained.

C. Benefit as the Link Between Experimental Use and Inherency Doctrines

A parallel can be drawn between infringement by use of a device that occasionally, or accidentally, infringes claims and the effect of occasional or accidental occurrence in the prior art on claimed subject matter. The claim at issue in *Embrex, Inc. v. Service Engineering Corp.*⁴⁵¹ was directed to a method which, unintentionally, was performed by an apparatus designed by Service Engineering Corp. ("SEC") to inject vaccine into the chorioallantoic sac ("CAS") through the eggshell of chicken embryos.⁴⁵² As stated by the *per curiam* opinion of the CAFC, the trial record indicated that tests conducted by a professor at the University of

⁴⁴⁶ *Id.*

⁴⁴⁷ *Id.* at 1365.

⁴⁴⁸ *Id.*

⁴⁴⁹ *See, e.g., id.* at 1365.

⁴⁵⁰ *Id.* at 1366.

⁴⁵¹ 216 F.3d 1343 (Fed. Cir. 2000).

⁴⁵² *Id.* at 1346.

Delaware, Dr. Rosenberger, who was retained by SEC, “showed that . . . most injections penetrated beyond the CAS and into the amnion/yolk sac — areas covered by the ‘630 patent,” which was the subject patent of litigation.⁴⁵³ During testing of the prototype, SEC, as alleged by Embrex, offered the device for sale.⁴⁵⁴

The majority opinion upheld the lower jury verdict of infringement and reversed in part a holding by the lower court that “an offer to sell a device cannot infringe a method patent without evidence of the device’s actual use to carry out the method.”⁴⁵⁵ In view of the commercial purpose of tests conducted by SEC, the court categorically dismissed experimental use as a defense to infringement, and implied that an experimental use defense was equivalent to one of de minimis damages:

In this case, SEC’s acts of hiring Drs. Davis and Rosenberger, and the doctors’ acts injecting eggs with vaccine cannot be deemed experimental use or de minimis. While SEC tries to cloak these tests in the guise of scientific inquiry, that alone cannot immunize its acts. The district court determined on the record before it that SEC performed the tests expressly for commercial purposes. SEC’s chief commercial purpose was to demonstrate to its potential customers the usefulness of the methods performed by its in ovo injection machines. Just because SEC was unsuccessful in selling its machines does not confer infringement immunity upon SEC for its infringing acts. This court therefore affirms the district court’s denial of JMOL on infringement.⁴⁵⁶

Judge Rader, in a concurring opinion, broadly condemned both de minimis and experimental use as “excuses” for infringement, stating that “[b]ecause the Patent Act confers the right to preclude ‘use,’ not ‘substantial use,’ no room remains in the law for a de minimis excuse. Similarly, because intent is irrelevant to patent infringement, an experimental use excuse cannot survive.”⁴⁵⁷ Judge Rader used the holding by the Supreme Court in *Warner-Jenkinson Co. v. Hilton-Davis Chemical Co.*⁴⁵⁸ to assert that experimental use, as a defense to infringement, should be precluded even in the “extraordinarily narrow form recognized in Roche.”⁴⁵⁹ To the extent that experimental use might survive, Judge Rader further stated that “the slightest commercial implication will render the ‘philosophical inquiry/experimental use’ doctrine inapplicable, as occurs in the court’s resolution today.”⁴⁶⁰

⁴⁵³ *Id.* at 1347.

⁴⁵⁴ *Id.*

⁴⁵⁵ *Id.* at 1352.

⁴⁵⁶ *Id.* at 1349.

⁴⁵⁷ *Id.* at 1352 (Rader, J., concurring).

⁴⁵⁸ 520 U.S. 17 (1997) (holding that the doctrine of equivalents continues to exist and that this question is for a jury to decide).

⁴⁵⁹ *Embrex*, 216 F.3d at 1353 (Rader, J. concurring) (“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.”).

⁴⁶⁰ *Id.* (Rader, J., concurring).

Judge Rader, in discounting experimental use as a defense on the basis of the legal maxim that “[i]ntent is not an element of infringement,”⁴⁶¹ did not recognize the irony in his consequent use of commercial intent to restrict application of that doctrine. Experimental use, by definition, is a statement of intent, as is the phrase “commercial implication,” and related phrases, such as those employed by Trial Judge Cooper (e.g., “for the purpose of furthering the legitimate business interests of the infringer,”)⁴⁶² and in *Roche* (the phrase, e.g., “commercial purposes”).⁴⁶³ Even Justice Story in *Whittemore* made reference to infringement as “a design to use it for profit,” with the “limitation” that “it could never have been the intent of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.”⁴⁶⁴ Both “commercial” and “experimental” uses, as characterizations, inherently carry with them statements of intent.

Although intent is inherent in any assessment of use as “experimental,” it is also inherent in assessing use as “commercial.” The distinction, however, between an infringing use, and one that is not infringing because it is experimental, is not whether there are “commercial implications,” which historically have been present in almost all successful applications of the experimental use defense, but whether the benefit of the claimed invention made available by the patentee has been gained by its use. If the benefit of the invention has been obtained, then there is infringement. On the other hand, if use of the claimed invention is limited to discovery or “ascertainment of sufficiency of its described use,” then there is no infringement; protection afforded to the patentee is limited to the benefit provided to the public, and does not extend to the public’s right of discovery, because such an extension would preclude, or retard, further contribution to the public weal of improvements. Subsequent improvement may be the subject of distinct exclusive rights.

In *Embrex*, use of a device, although intended to avoid infringement of a patent directed to injection of vaccines into chick embryos, obtained the benefit of the claimed method because, in fact, “most injections penetrated beyond the CAS and into the amnion/yolk sac — areas covered by the ‘630 Patent.”⁴⁶⁵ Offer for sale of the device was, in itself, insufficient; benefit of the claimed method, in violation of *Embrex*’s exclusive right, could only be found by “the devices’ actual use to carry out the method.”⁴⁶⁶ Therefore, a holding of infringement would be consistent with case precedent, including cases where the experimental use doctrine was successfully invoked despite the presence of commercial intent in experimental activities conducted.

The link between possibility of occurrence and inherency in prior art teachings was made clear in *Elan Pharmaceuticals, Inc. v. Mayo Foundation* (“*Elan I*”)⁴⁶⁷ where

⁴⁶¹ *Embrex*, 216 F.3d at 1353 (Rader, J. concurring) (quoting *Hilton Davis Chem. Co. v. Warner-Jenkins Co.*, 62 F.3d 1512, 1519 (Fed. Cir. 1995)).

⁴⁶² *Roche*, 733 F.2d at 863.

⁴⁶³ *Id.*

⁴⁶⁴ *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600).

⁴⁶⁵ *Embrex*, 216 F.3d at 1347.

⁴⁶⁶ *Id.* at 1352 (“This court also reverses-in-part because, as a matter of law, an offer to sell a device cannot infringe a method patent without evidence of the device’s actual use to carry out the method.”).

⁴⁶⁷ 304 F.3d 1221 (Fed. Cir. 2002) [hereinafter *Elan I*].

Judge Newman held that a prior art patent, U.S. Patent No. 5,455,169 to Mullan, did not anticipate claims of two patents, U.S. Patent Nos. 5,612,486 and 5,850,003 directed to transgenic rodents carrying a genetic mutation, known as the “Swedish mutation,” that causes abnormal enzymatic cleavage in the brain of a protein, amyloid precursor protein (“APP”).⁴⁶⁸ The result of the abnormality is accumulation of plaques in the brain principally composed of a protein fragment called beta-amyloid peptide (“betaAP”).⁴⁶⁹ The district court held that the teachings of the Mullan patent were anticipatory because they would, as summarized by the CAFC, “be expected to produce a statistically small percentage of transgenic mice, and some of these mice would be expected to produce detectable [amino terminal fragment] on enzymatic cleavage.”⁴⁷⁰ Reversal by the CAFC was based on the propositions that, “[w]hen anticipation is based on inherency of limitations not expressly disclosed in the assertedly anticipating reference, it must be shown that the undisclosed information was known to be present in the subject matter of the reference,” and that “[a]n inherent limitation is one that is necessarily present; invalidation based on inherency is not established by ‘probabilities or possibilities.’”⁴⁷¹ For support, Judge Newman quoted Judge Learned Hand:

If the earlier disclosure offers no more than a starting point for further experiments, if its teaching will sometimes succeed and sometimes fail, if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation.⁴⁷²

Judge Dyk dissented from the majority opinion on the premise that there “is simply no basis in our law to support the proposition that the source of proof for inherency must be found in the prior art and cannot be found in the patentee’s own disclosure or other source” and concluded that “the majority’s contrary conclusion is incorrect as a matter of law.”⁴⁷³

The following year, the decision was vacated and substituted with a new opinion also written by Judge Newman (“Elan II”).⁴⁷⁴ Instead of holding that the Mullan reference was not anticipatory, Judge Newman rephrased the issue in the new opinion as one of enablement,⁴⁷⁵ whereby “[t]he disclosure in an assertedly anticipating reference must be adequate to enable possession of the desired subject matter.”⁴⁷⁶ Accordingly, the question of anticipation was reversed and remanded back to the district court for a determination “of whether the Mullan reference enabled persons of ordinary skill in the field of the invention to make the desired

⁴⁶⁸ *Id.* at 1223–24.

⁴⁶⁹ *Id.*

⁴⁷⁰ *Id.* at 1228.

⁴⁷¹ *Id.*

⁴⁷² *Id.* at 1229 (quoting *Dewey & Almy Chem. Co., v. Mimex Co.*, 124 F.2d 986, 989 (2d Cir. 1942)).

⁴⁷³ *Id.* at 1233 (Dyk, J., dissenting).

⁴⁷⁴ *Elan Pharms. v. Mayo Found.*, 346 F.3d 1051 (Fed. Cir. 2003) [hereinafter *Elan II*].

⁴⁷⁵ *Id.* at 1054 (“We conclude that Elan’s arguments are more properly characterized as enablement arguments rather than as inherency arguments.”).

⁴⁷⁶ *Id.* at 1055.

mutated mouse without undue experimentation.”⁴⁷⁷ Therefore, despite the fact that only occasional success could be expected, a prior art reference could be anticipatory as an inherent teaching of a claimed invention if the reference could be considered enabling, thereby constituting possession and benefit of the invention by the public prior to an inventor’s subsequent discovery.

In *In re Cruciferous Sprout Litigation*,⁴⁷⁸ the CAFC affirmed a lower court decision holding invalid three patents directed to cultivating and consuming sprouts to reduce carcinogen levels in animals and thereby diminish the risk of cancer.⁴⁷⁹ The plaintiff, and licensee of the patents, Brassica Protection Products LLC (“Brassica”) argued that the claims of the subject patent were not inherently anticipated by prior art descriptions of the same sprouts and their consumption because “at most, one following the prior art would have a possibility or probability of producing a food product high in Phase 2 enzyme-inducing potential.”⁴⁸⁰ As stated by Brassica, the “fact that one following the prior art might have selected seeds meeting the limitations of the claims is not sufficient to establish inherent anticipation.”⁴⁸¹

In response, the court discounted Brassica’s argument of a lack of certainty by stating that the prior art taught selection of sprouts rich in glucosinates and high in Phase 2 enzyme-inducing potential, because all the sprouts in that art were identified as “suitable for eating.”⁴⁸² The court held that, because the sprouts were all in the public domain and described as suitable for consumption, it was “unnecessary for purposes of anticipation for the person sprouting these particular cultivars to have realized that they were sprouting something rich in glucosinates and high in Phase 2 enzyme-inducing potential.”⁴⁸³ In other words, the court disregarded Brassica’s argument that inherency, as a doctrine of anticipation, requires certainty of presence, and instead relied on an over-riding certainty that the public had been benefiting by ingestion of sprouts selectively cultivated and consumed by the method of Brassica’s claims. To uphold the patents in the face of such evidence would deprive the public of the right to continue to benefit from the anti-carcinogenic effect of certain sprouts, the discovery of which was the basis for obtaining patent protection:

Thus, according to Brassica, the prior art fails to meet the “identifying” steps of the claims because it does not specify which cultivar should be sprouted. However, all of the appropriate cultivars that are identified in Brassica’s patents are in the public domain. . . . Brassica cannot credibly

⁴⁷⁷ *Id.* at 1057.

⁴⁷⁸ 301 F.3d 1343 (Fed. Cir. 2002).

⁴⁷⁹ *Id.* at 1345.

⁴⁸⁰ *Id.* at 1349.

⁴⁸¹ *Id.*

⁴⁸² *Id.* at 1351 (“Numerous prior art references identify these same sprouts as suitable for eating. . . . These references therefore meet the claim limitations of identifying seeds to use in order to have sprouts with the inherent properties of glucosinates and high Phase 2 enzyme-inducing activity.”).

⁴⁸³ *Id.*

maintain that no one has heretofore grown and eaten one of the many suitable cultivars identified by its patents.⁴⁸⁴

Therefore, application of both the experimental use defense and the doctrine of inherency are linked in these cases by whether the benefit of the claimed invention is obtained by its use.

D. Application of Experimental Use and Inherency Doctrines in the Absence of Benefit

The CAFC again roundly criticized any attempt to defend use of a claimed invention as experimental, except in the very narrow form articulated in *Roche* and *Embrex*, in *Madey v. Duke University*.⁴⁸⁵ The dispute arose as a consequence of use by Duke University (“Duke”) of laser equipment patented by Dr. John M. J. Madey (“Madey”) without his consent.⁴⁸⁶ The lower court held that use of the patented technology by Duke did not infringe because the uses “were solely for research, academic, or experimental purposes,”⁴⁸⁷ and, therefore, embraced by the doctrine of experimental use which, according to the district court, includes uses that are solely “for experimental, non-profit purposes.”⁴⁸⁸ The CAFC, quoting *Roche* and *Embrex*, severely narrowed the experimental use defense from the interpretation given to it by the district court, stating that “use does not qualify for the experimental use defense when it is undertaken in the ‘guise of scientific inquiry’ but has ‘definite, cognizable, and not insubstantial commercial purposes,’”⁴⁸⁹ and that “use is disqualified from the [experimental use] defense if it has the ‘slightest commercial implication.’”⁴⁹⁰ Duke, according to the CAFC, had “legitimate business objectives, including educating and enlightening students and faculty” and that, “so long as the act is in furtherance of the alleged infringer’s legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.”⁴⁹¹ The CAFC further held that “the profit or non-profit status of the user is not determinative.”⁴⁹²

The district court had relied, in part, on *Ruth v. Stearns-Roger Mfg. Co.*,⁴⁹³ which applied the experimental use defense in the context of an academic setting.⁴⁹⁴ The CAFC in *Madey* dismissed the holding in *Ruth* as that of “a case that is not

⁴⁸⁴ *Id.*

⁴⁸⁵ 307 F.3d 1351 (Fed. Cir. 2002).

⁴⁸⁶ *Id.*

⁴⁸⁷ *Id.* at 1361 (quoting *Madey v. Duke Univ.*, No. 1:97 CV 1170, slip op. (M.D.N.C. Dec. 1, 1999)).

⁴⁸⁸ *Id.* at 1355 (quoting *Madey v. Duke*, slip op., at 10)).

⁴⁸⁹ *Id.* at 1362 (quoting *Roche v. Bolar*, 733 F.2d 858, 863 (Fed. Cir. 1984)).

⁴⁹⁰ *Id.* (quoting *Embrex, Inc. v. Serv. Eng’g Corp.*, 216 F.3d 1343, 1353 (Fed. Cir. 2000)).

⁴⁹¹ *Id.*

⁴⁹² *Id.*

⁴⁹³ 13 F. Supp. 697 (D. Colo. 1935).

⁴⁹⁴ *Madey*, 307 F.3d at 1362 (noting the district court cited *Ruth*, which held that the experimental use defense applied in the educational context, to support its decision).

binding precedent for this court,”⁴⁹⁵ but nevertheless went on to explain how the holding in *Ruth* was inconsistent with *Embrex*, *Roche* and *Pitcairn*:

Thus, the combination of apparent lack of commerciality, with the non-profit status of an educational institution, prompted the court in *Ruth*, without any detailed analysis of the character, nature and *effect* of the use, to hold that the experimental use defense applied . . . This is not consistent with the binding precedent of our case law postulated by *Embrex*, *Roche* and *Pitcairn*.⁴⁹⁶

Ruth, however, can be construed in a manner that is, in fact, consistent with *Embrex*, *Roche* and *Pitcairn*, as well as other cases where experimental use was applied as a defense, both successfully and unsuccessfully. Specifically, the court in *Ruth* stated that the “machines were all used in the laboratory and were cut up and changed from day to day. Their use was experimental.”⁴⁹⁷ The court in *Ruth* did not base application of experimental use as a defense on the fact that the Colorado School of Mines was an academic institution. Rather, consistent with the definition of the “experimental use” exception recited in *Embrex*, *Roche*, and *Pitcairn*, and discussed above, the court held that, where “the sole purpose” was that of “gratifying a philosophical taste or curiosity or for instruction and amusement,” the “making or using of a patented invention merely for experimental purposes, without any intent to derive profits or practical advantage therefrom, is not an infringement.”⁴⁹⁸ It is not clear from the statement of facts in *Ruth* whether practical advantage of the claimed subject matter was gained by the Colorado School of Mines’ use of the machines purchased from Stearns-Roger, the defendant in the case, or whether the uses were conducted as “philosophical experiments, or for the purpose of ascertaining sufficiency of the machine to produce its described effects,” as stated by Justice Story in *Whittemore*.⁴⁹⁹ However, neither is it clear from the facts in *Madey* whether use of the patented laser technology was in pursuit of discovery related to operation of the claimed technology or, instead, to obtain the practical advantage of the technology in pursuit of other research goals. Relying on a distinction between philosophical inquiry into the operation of a patented device and exploitation of the benefit provided by operation of the device, the holding in *Ruth*, which arguably was limited to philosophical inquiry into the operation of claimed subject matter (in that the machines were “cut up and changed from day to day”), is consistent with the holding in *Madey*, where Duke, in contrast, at least appeared to benefit by operation of the patented laser to conduct research.

In *Schering Corporation v. Geneva Pharmaceuticals, Inc.*,⁵⁰⁰ Judge Rader, for the CAFC, held that a patent directed to descarbethoxyloratidine (“DCL”) was anticipated by a patent that taught loratidine (which differed from DCL only in that loratidine substituted a hydrogen on DCL with a carbethoxyl group), because DCL

⁴⁹⁵ *Id.* (“The district court supported its conclusion with a citation to *Ruth* . . . a case that is not binding precedent for this court.”).

⁴⁹⁶ *Id.* (citation omitted) (emphasis added).

⁴⁹⁷ *Ruth*, 13 F. Supp. at 703 n.155.

⁴⁹⁸ *Id.* at 713.

⁴⁹⁹ *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600).

⁵⁰⁰ 339 F.3d 1373 (Fed. Cir. 2003).

was a metabolite of loratidine.⁵⁰¹ Judge Rader further stated that “this court rejects the contention that inherent anticipation requires recognition in the prior art.”⁵⁰² Rather, according to Judge Rader, “inherency places subject matter in the public domain” and “a limitation or the entire invention is inherent and in the public domain if it is the ‘natural result flowing from’ the explicit disclosure of the prior art.”⁵⁰³ Judge Rader at least implicitly tied inherency to the benefit provided by “the natural result flowing from” prior art teachings by stating that, in addition to being a “necessary consequence of administering loratidine to patients,” DCL, as a metabolite, “provides a useful result, because it serves as an active non-drowsy antihistamine.”⁵⁰⁴ Interestingly, Judge Rader distinguished *Seaborg*, which upheld patent validity, not on the basis of uncertainty, but “because the process would have produced at most one billionth of a gram of the isotope in forty tons of radioactive material, i.e., the isotope would have been undetectable,”⁵⁰⁵ whereas, “[i]n this case, DCL forms in readily detectable amounts as shown by the extensive record evidence of testing done on humans to verify the formation of DCL upon ingestion of loratidine.”⁵⁰⁶ In other words, the presence of an anticipatory material in the prior art at levels so low as to be undetectable was not enough to defeat the patent claims for lack of novelty, not because presence of the material was undetectable, as such, since, according to Judge Rader, inherency does not require recognition in the art, but, rather, because such low levels would not produce a “useful result,” as was evidenced by the presence of “readily detectable amounts” of DCL in humans consequent to ingestion of loratidine.⁵⁰⁷ The presence of “at most one billionth of a gram of the isotope in forty tons of radioactive material” under the facts of *Seaborg*, as a “natural result flowing from” the prior art teachings, was not only unrecognized, but conferred no benefit to the public in contrast to the “useful result” provided by the unrecognized presence of DCL as a metabolite of loratidine.⁵⁰⁸

Judge Newman dissented from an order issued later that year that denied petitions for a panel rehearing and for a rehearing en banc.⁵⁰⁹ In her dissent, she argued strenuously that, “[w]hen all of the elements of the claim are not shown in the prior art, precedent requires that the missing element was nonetheless known to be

⁵⁰¹ *Id.* at 1382. The court stated:

The district court did not err in finding that the ‘233 patent discloses administering loratidine to a patient, and that DCL forms as a natural result of that administration. The district court correctly concluded that DCL is inherent in the prior art. Without any genuine issues of material fact, the district court correctly granted summary judgment that claims 1 and 3 are invalid as anticipated by the ‘233 patent.

Id.

⁵⁰² *Id.* at 1377.

⁵⁰³ *Id.* at 1379.

⁵⁰⁴ *Id.* at 1378 (“DCL is a necessary consequence of administering loratidine to patients. The record also shows that DCL provides a useful result, because it serves as an active non-drowsy antihistamine.”).

⁵⁰⁵ *Id.* at 1379.

⁵⁰⁶ *Id.*

⁵⁰⁷ *Id.* (“In sum, this court’s precedent does not require a skilled artisan to recognize the inherent characteristic in the prior art that anticipates the claimed invention.”).

⁵⁰⁸ *Id.* (distinguishing its facts from those of *In re Seaborg*, 328 F.2d 996, 996–97 (C.C.P.A. 1964)).

⁵⁰⁹ *Schering Corp. v. Geneva Pharms., Inc.*, 348 F.3d 992 (Fed. Cir. 2003).

present in the subject matter of the reference, and that the claim is directed to the known subject matter.”⁵¹⁰ Judge Newman concluded that “[p]recedent is directly contrary to the panel’s holding that although no one knew of the existence of DCL, it is unpatentable because it in fact existed.”⁵¹¹ Judge Lourie also dissented from the denial of petition for rehearing en banc “because it is an extraordinary decision, effectively precluding virtually all patents on human metabolites of drugs.”⁵¹² According to Judge Lourie, the panel decision “holds that an enabling disclosure of ‘how to make’ metabolites is provided by the mere recitation that one can administer a prior art compound to humans,”⁵¹³ precluding them from patent protection without any of those metabolites ever being identified. Moreover, Judge Lourie asserted the issue to be a matter of law, rather than public policy:

In any event, we deal here with issues of patent law, not policy or equity, and to hold that a patent on a product, with a minimal disclosure of administering it to a human or other subject, anticipates a later application on a metabolite, of which no mention appears whatsoever in the patent, cannot be correct.⁵¹⁴

In effect, both Judges Newman and Lourie viewed the panel decision as a sweeping denial of exclusive rights to compounds that, although present as metabolites, had yet to be recognized.⁵¹⁵

As can be seen from *Madey* and *Schering*, lack of consideration of benefit in application of experimental use and inherency doctrines has resulted in widely divergent opinions about the scope of patent protection that is to be afforded as a matter of law.

⁵¹⁰ *Id.* at 994 (Newman, J., dissenting).

⁵¹¹ *Id.* at 995 (Newman, J., dissenting).

⁵¹² *Id.* (Lourie, J., dissenting).

⁵¹³ *Id.* at 996 (Lourie, J., dissenting).

⁵¹⁴ *Id.* (Lourie, J., dissenting).

⁵¹⁵ The debate continues over the requirement of recognition in inherency analyses. On April 23, 2007, the CAFC rendered an opinion in *In re Omeprazole Patent Litigation* in which Judge Rader for the majority held that claim 1 of U.S. 6,013,281, directed to a process for preparing an oral formulation of a gastric acid inhibiting drug (an FDA approved version of which is known as Prilosec®), was inherently anticipated by the teachings of a published Korean patent application. *In re Omeprazole Patent Litigation*, Nos. 04-1562, 04-1563, 04-1589, 2007 U.S. App. LEXIS 9233, at *21-23 (Fed. Cir. Apr. 23, 2007). Inherency was found, despite the fact that the Korean applicant “disavowed a subcoating and disclosed no process conditions to form a separating layer *in situ*.” *Id.* at *19. Judge Newman in her dissent bluntly stated: “What is unknown cannot ‘anticipate.’” *Id.* at *35. Assuming agreement could be reached as to whether the critical *in situ* formation of a separating layer resulted from following the teachings of the Korean patent application, the question of inherent anticipation might be facilitated by determining whether the separating layer forms in an amount sufficient to provide a benefit. In such an analysis, only if benefit cannot be established would recognition of *in situ* formation of a separating layer “when viewed by persons experienced in the field of the invention,” as dictated by Judge Newman, be required. *Id.* at *37.

II. CONSIDERING BENEFIT IN SOME RECENT CASES

Three recent decisions by the Court of Appeals for the Federal Circuit, two of which have been appealed and decided upon by the Supreme Court, illustrate the effects of current interpretations of the inherency and experimental use doctrines, and how modifications of these doctrines to incorporate considerations of benefit could alter the decision in each case. These cases, *SmithKline Beecham Corp. v. Apotex*,⁵¹⁶ *Metabolite Laboratories, Inc., v. Laboratory Corporation of America Holdings*⁵¹⁷ and *Integra LifeSciences I, Ltd. v. Merck KGaA*⁵¹⁸ are distinct from each other in that *SmithKline Beecham* and *Metabolite* come to opposite decisions in view of the facts under the doctrine of inherency, while the CAFC in *Integra* held that safe harbor under 35 U.S.C. § 271(e) (1) “does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process.”⁵¹⁹ Each of these cases, nevertheless, presents fundamental problems that are rooted in misconceptions of the scope of protection to be provided in exchange for making an inventive contribution to the public domain.

A. SmithKline Beecham v. Apotex

In *SmithKline Beecham*, the court held that, the presence of paroxetine hydrochloride (“PHC”) hemihydrate, although undetected and even undetectable, in a PHC anhydrate composition of the prior art, was an inherent and invalidating anticipation of a later claim to the hemihydrate.⁵²⁰ As a corollary,⁵²¹ the court held

⁵¹⁶ 403 F.3d, 1331 (Fed. Cir. 2005), *cert. denied*, 126 S. Ct. 2887 (2006).

⁵¹⁷ 370 F.3d 1354 (Fed. Cir. 2004), *cert. dismissed*, 126 S. Ct. 2921 (2006).

⁵¹⁸ 331 F.3d 860 (Fed. Cir. 2003), *vacated*, 125 S. Ct. 2372 (2005).

⁵¹⁹ *Id.* at 867.

⁵²⁰ *SmithKline Beecham*, 403 F.3d at 1344–48. The court stated:

The record shows, and SmithKline admits through its proffered arguments, that producing PHC anhydrate according to the ‘196 patent inevitably results in the production of at least trace amounts of anticipatory PHC hemihydrate.

...
 . . . SmithKline would have the court infer from this argument that it is possible to make pure PHC anhydrate according to the ‘196 patent in unseeded conditions. The district court, however, properly dismissed this logic noting that ‘existence and detection are not the same thing.’ The district court went on to explain that PHC hemihydrate may have existed in undetectable amounts since Ferrosan first produced PHC anhydrate in the 1970’s, particularly because the technology to detect PCH [sic] hemihydrate in small amounts did not exist until 1985.

...
 . . . Because the record contains clear and convincing evidence that production of PHC anhydrate in accordance with the ‘196 patent inherently results in at least trace amounts of PHC hemihydrate, this court holds that the ‘196 patent inherently anticipates claim 1 of the ‘723 patent under 35 U.S.C. § 102(b).

...
 In summary, this court reverses the claim construction of the district court and holds that claim 1 of the ‘723 patent covers any amount of crystalline paroxetine hydrochloride hemihydrate without further limitations.

Id. (citations omitted).

⁵²¹ *Id.* at 1341. The court made the connection between anticipation and infringement explicit:

that production by Apotex of PHC anhydrate would infringe claims directed to the hemihydrate, even if the amount of the hemihydrate were not present in “commercially significant amounts,” as required by the district court,⁵²² and even if the amount of hemihydrate present were undetectable, thereby affirming the lower court holding of infringement.⁵²³ Accordingly, certainty of presence, albeit undetectable, of a compound in the prior art inherently anticipated later claims to the compound, and, by the same token, if the claim were valid, production of compositions that include certain, but undetectable amounts, of the claimed compound would be held to be an infringement of such claims. Both inherent anticipation and infringement would be found as a matter of law, regardless of detectability, and regardless of any consideration of the effect of the presence of the compound in either the anticipated prior art or the infringing composition. However, consideration by the court of whether any benefit of PHC hemihydrate was obtained by the “trace amounts” consequent to prior art methods of manufacture of PHC anhydrate, or in later production of PHC anhydrate by Apotex, may have impacted the outcome if one of those activities, but not the other, were sufficient to affect the properties of the product.⁵²⁴

B. *Metabolite Laboratories, Inc. v. Laboratory Corporation of America Holding*

The CAFC in *Metabolite* upheld a district court holding that denied a motion for judgment as a matter of law (“JMOL”), awarding enhanced damages and granting a permanent injunction against Laboratory Corporation of America Holding (“LabCorp”) for infringing a claim directed to a method for detecting a deficiency of cobalamin or folate in warm-blooded animals.⁵²⁵ The claimed method of U.S. Patent

Because Apotex seeks to practice the prior art, and because that practice infringes, the next logical inquiry involves anticipation. That is, if the prior art infringes now, logically the prior art should have anticipated the claim before filing of the ‘723 patent. See *Bristol-Myers Squibb Co. v. BenVenue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001) (restating the maxim that “that which would literally infringe if later in time anticipates if earlier”).

SmithKline Beecham, 403 F.3d at 1341.

⁵²² *Id.* at 1335 (“On the question of claim construction, the district court limited claim 1 to PHC hemihydrate in commercially significant amounts.”).

⁵²³ *Id.* at 1341 (“Having interpreted claim 1 to cover PHC hemihydrate without further limitation, this court turns to infringement . . . This court, therefore affirms the district court’s finding that Apotex’s product will infringe under this court’s claim construction.”).

⁵²⁴ At least one benefit of PHC hemihydrate was articulated, but then never further considered, by the court:

In March 1985, Alan Curzons, a chemist in SmithKline’s Worthing, England laboratory, discovered a new crystalline form of PHC while attempting to improve PHC production. Curzon’s test results established that the new product was the hemihydrate form of PHC (PHC hemihydrate). Ferrosan’s original form was anhydrous PHC (PHC anhydrate). PHC anhydrate comprises crystals of PHC without bound water molecules. PHC hemihydrate comprises PHC crystals with one bound water molecule for every two PHC molecules. PHC hemihydrate proved more stable, and thus more easily packaged and preserved, than PHC anhydrate.

Id. at 1334.

⁵²⁵ *Metabolite Labs., Inc., v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1358 (Fed. Cir. 2004).

No. 4,940,658 (“the ‘658 patent”), the patent in suit, included the steps of “assaying a body fluid for an elevated level of total homocysteine,” and “correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.”⁵²⁶ The court found that the “prosecution history [of the ‘658 patent] ties the preamble directly to the ‘correlating’ step,” whereby the “recitation of the intended use in the preamble makes this invention a method for detecting a vitamin deficiency.”⁵²⁷ An allegation of invalidity for inherent anticipation in view of a prior art reference by Refsum disclosing, according to the court, “that total homocysteine should be used to investigate ‘perturbations of homocysteine metabolism in humans during disease or pharmacological interventions that affect metabolism of one-carbon compounds,’” was dismissed.⁵²⁸ Specifically, the court held that Refsum “simply invites further experimentation” and that “an invitation to investigate is not an inherent disclosure.”⁵²⁹

A per curiam opinion by the Supreme Court, without further explanation, dismissed a writ of certiorari as improvidently granted.⁵³⁰ In dissent, Justice Breyer, with Justices Stevens and Souter, argued that the question on which certiorari was granted, of “[w]hether a method patent . . . directing a party simply to ‘correlate’ test results can validly claim a monopoly over a basic scientific relationship . . . such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result,” should be decided, despite the fact that the legal basis for the question, that of utility under 35 U.S.C. § 101, was not raised by LabCorp in the lower courts.⁵³¹ On the issue of patentability of the claimed subject matter, Justice Breyer stated that “the correlation between [total] homocysteine and vitamin deficiency set forth in claim 13 is a ‘natural phenomenon,’” and, therefore, “respondents have simply described the natural law at issue in the abstract patent language of a ‘process.’”⁵³² According to Justice Breyer, “that correlation is an unpatentable ‘natural phenomenon,’ and I can find nothing in claim 13 that adds anything more of significance.”⁵³³

⁵²⁶ *Id.* at 1358–59.

⁵²⁷ *Id.* at 1362.

⁵²⁸ *Id.* at 1367.

⁵²⁹ *Id.* (“Rather than necessarily containing the correlation between homocysteine and cobalamin or folate deficiencies, Rufsum further invites further experimentation to find such associations. An invitation to investigate is not an inherent disclosure.”).

⁵³⁰ *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921 (2006) (stating the “[w]rit of certiorari is dismissed as improvidently granted.”).

⁵³¹ *Id.* at 2925 (Breyer, J., dissenting.) Justice Breyer stated, for the dissent:

The question before us is whether claim 13, as construed and applied in the way I have described in part I-B, is invalid in light of the “law of nature” principal, described in part I-A. I believe that we should answer that question. There is a technical procedural reason for not doing so, namely, that LabCorp did not refer in the lower courts to § 101 of the Patent Act, which sets forth subject matter that is patentable, and within the bounds of which the “law of nature” principal most comfortably fits. See 35 U.S.C. § 101 (“patent may be obtained for “any new and useful process, machine, manufacture, or composition of matter”); . . .

Lab. Corp., 126 S. Ct. at 2925.

⁵³² *Id.* at 2927–28 (Breyer, J., dissenting).

⁵³³ *Id.* (Breyer, J., dissenting).

The presumption, of course, is that determination of validity of claim 13 of the '658 patent properly hangs on the patentability of discovering a "natural phenomenon." To do so, however, arguably gainsays the issue of whether claim 13, in fact, claims nothing more than a natural phenomenon. As just discussed, the question of the petition filed by LabCorp, on which certiorari was granted, loads the question as a foregone conclusion by inquiring "[w]hether a method patent . . . directing a party simply to 'correlate' test results can validly claim a monopoly over a basic scientific relationship . . ."⁵³⁴ Judge Rader, in writing the majority decision for the CAFC noted that, during the course of prosecution of the '658 patent, the United States Patent and Trademark Office addressed the same issue in the context of a rejection under 35 U.S.C. § 102 because "[i]n the absence of a correlation step, the preamble of claim 13 merely recites an intended use of the invention."⁵³⁵ As recited by Judge Rader, amending claim 13 to include a "correlating" step put the application into condition for allowance,⁵³⁶ thereby imposing on the preamble a meaning beyond that of an intended use.⁵³⁷ In other words, insertion of the "correlating" step in response to the examiner's rejection for lack of novelty narrowed the scope of the claim by imparting to the preamble the real limitation of conducting the test on a population suspected of having, or to be screened for, a cobalamin or folate deficiency. Interpreted in this way, the method, as claimed, is no longer inherently anticipated by the prior existence of assays to determine an elevated level of total homocysteine, as required in the first step of the method of claim 13, since such elevated levels do not always mean that there is a deficiency in cobalamin or folate,⁵³⁸ and until the discovery of the correlation by the inventors, the population to which the test was administered could not have been limited to those suspected of, or to be screened for, cobalamin or folate deficiency. Therefore, the prosecution history of claim 13 strongly suggests that the method is novel, despite the fact that it is based, like all claimed subject matter, on natural phenomena. From the point of view of a benefit analysis, even though the correlation between elevated level of total homocysteine and a deficiency in cobalamin or folate

⁵³⁴ *Id.* at 2925.

⁵³⁵ *Metabolite Labs., Inc., v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1362 (Fed. Cir. 2004).

⁵³⁶ *Id.* ("At that point, the applicant added the recommended "correlating" step. The examiner then allowed claim 13.")

⁵³⁷ *Id.* ("The prosecution history ties the preamble directly to the "correlating" step. Specifically, the recitation of the intended use in the preamble makes this invention a method for detecting a vitamin deficiency.")

⁵³⁸ *See, e.g.*, Brief for Petitioner at 7–8, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921 (2006) (No. 04-607). The brief stated:

Although elevated homocysteine has been linked to various medical conditions, a test result showing elevated homocysteine levels, standing alone, is of limited practical utility to physicians screening for a vitamin deficiency. That is because homocysteine may be elevated in cases of cobalamin *or* folate deficiency, *or* as the result of other conditions, and a test *only* for homocysteine therefore cannot itself diagnose or distinguish between vitamin deficiencies.

Id. (emphasis in original). *See also* Brief for the United States as Amicus Curiae at 11, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921 (2006) (No. 04-607) ("The specification then provides an example of tests conducted by the applicants in which total homocysteine levels were elevated above normal levels for 99% of the patients with cobalamin deficiency and 95% of those with folate deficiency."). Additionally, "[p]etitioner had argued that the assays were used primarily to diagnose other conditions, especially heart disease." *Id.* at 23.

existed as a natural phenomenon, the inventors made a contribution to the public domain by providing a method that more accurately assesses the likelihood of deficiency in cobalamin or folate in a selected population. Contrary to the question posed in the petition by LabCorp, claim 13 does not direct “a party simply to ‘correlate’ test results,” but, rather, directs a party to assay a specific population for total homocysteine and to correlate those results as a method for detecting a deficiency in cobalamin or folate in that population.⁵³⁹ Targeting an assay of total homocysteine content to a population suspected of having a deficiency in cobalamin or folate, or to be screened for such a deficiency, did not exist prior to discovery by the inventors of the correlation. Therefore, the benefit contributed by the inventors pursuant to their method entitles them to a limited period of exclusivity in its application.

C. Merck KGaA v. Integra LifeSciences I, Ltd.

In *Integra LifeSciences I, Ltd. v. Merck KGaA*, the CAFC held that safe harbor under 35 U.S.C. § 271 (e)(1),⁵⁴⁰ enacted under the Drug Price Competition and Patent Term Restoration Act of 1984,⁵⁴¹ did not extend to testing considered by the court to be “only general biomedical research to identify new pharmaceutical compounds,” because “the FDA does not require information about drugs other than the compound featured in an Investigational New Drug application.”⁵⁴² Therefore, according to the court, such testing could not be “reasonably related to the development and submission of information” to the FDA.⁵⁴³ In *dicta*, the court effectively limited application of safe harbor to submission of information “facilitating expedited approval of patented pioneer drugs already on the market,” because “[e]xtending § 271 (e)(1) to embrace new drug development activities would ignore its language and context with respect to the 1984 Act in an attempt to exonerate infringing uses only potentially related to information for FDA approval.”⁵⁴⁴ The court did not expressly preclude activities that “do not directly produce information for the FDA,” stating that “[t]he term ‘reasonably’ permits some activities that are not themselves the

⁵³⁹ Brief for Petitioner at 1, *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 126 S. Ct. 2921 (2006) (No. 04-607).

⁵⁴⁰ 35 U.S.C. § 271(e)(1) (2000) states:

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 used in the Federal Food, Drug, and Cosmetic Act and the 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.

Id.

⁵⁴¹ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

⁵⁴² *Integra LifeSciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 866 (Fed. Cir. 2003).

⁵⁴³ *Id.* at 867.

⁵⁴⁴ *Id.*

experiments that produce FDA information to qualify as ‘solely for uses reasonably related’ to clinical tests for the FDA.”⁵⁴⁵ However, expansion of safe harbor under § 271(e)(1) to “reach any exploratory research that may rationally form a predicate for future FDA clinical tests,”⁵⁴⁶ according to the court, “would swallow the whole benefit of the Patent Act for some categories of biotechnological inventions,”⁵⁴⁷ such as “biotechnology tool patents.”⁵⁴⁸ In a footnote, Judge Rader, for the court, categorically dismissed interjection by Judge Newman in her dissent of any relevance of the common law experimental use doctrine to § 271(e)(1):

In her dissent, Judge Newman takes this opportunity to restate her dissatisfaction with this court’s decision in *Madey v. Duke Univ.*, 307 F.3d 1351, 64 USPQ2d 1737 (Fed. Cir. 2002). However, the common law experimental use exception is not before the court in the instant case. . . . Judge Newman’s dissent, however, does not mention that the Patent Act does not include the word “experimental,” let alone an experimental use exemption from infringement. *See* 35 U.S.C. § 271 (2000).⁵⁴⁹

For her part, Judge Newman characterized the majority decision as holding that “there is no right to conduct such [“discovery-based”] research, under either the common law research exemption or the statutory immunity established in 35 U.S.C. § 271(e)(1).”⁵⁵⁰ According to Judge Newman, “today the court disapproves and essentially eliminates the common law research exemption,” and she dissented from that portion of the majority decision.⁵⁵¹ As stated by Judge Newman:

The purpose of a patent system is not only to provide a financial incentive to create new knowledge and bring it to public benefit through new products; it also serves to add to the body of published scientific/technologic knowledge. The requirement of disclosure of the details of patented inventions facilitates further knowledge and understanding of what was done by the patentee, and may lead to further technologic advance. The right to conduct research to achieve such knowledge need not, and should not, await expiration of the patent.⁵⁵²

Therefore, “disclosure of the details of patented inventions” has, as its purpose, at least in part, public benefit by facilitating “further technologic advance” through research:

⁵⁴⁵ *Id.* at 866.

⁵⁴⁶ *Id.* at 867 (“The safe harbor does not reach any exploratory research that may rationally form a predicate for future FDA clinical tests.”).

⁵⁴⁷ *Id.* (“Thus, exaggerating § 271(e)(1) out of context would swallow the whole benefit of the Patent Act for some categories of biotechnological inventions.”).

⁵⁴⁸ *Id.* (“For example, expansion of § 271(e)(1) to include the Scripps-Merck activities would effectively vitiate the exclusive rights of patentees owning biotechnology tool patents.”).

⁵⁴⁹ *Id.* at 863 n.2.

⁵⁵⁰ *Id.* at 873 (Newman, J., dissenting).

⁵⁵¹ *Id.*

⁵⁵² *Id.*

The patent statute requires full disclosure of the invention, including details of enabling experiments and technical drawings and best modes and preferred embodiments, even commercial sources of special components. Such details would be idle and purposeless if this information cannot be used for 17-20 years. Indeed, there would be little value in the requirement of the patent law that patented information must be removed from secrecy in consideration of the patent right to exclude, if the information is then placed on ice and protected from further study and research investigation.⁵⁵³

Judge Newman's view of the common law exemption to infringement for experimental use is consistent with its historical application, which limits exclusion to the "threshold invention" made possible by "providing the initial knowledge, without which there would be nothing to improve":

Of course, the common law exemption is not unlimited. Indeed, it is a narrow exemption, for it must preserve the patentee's incentive to innovate, an incentive secured only by the right to exclude. It is the patentee who opened the door by providing the initial knowledge, without which there would be nothing to improve It is the initial inventor whose rights must receive primary consideration in an effective patent law, for the public interest starts with the threshold invention. However, while that threshold invention may (as here) exact tribute from or enjoin commercial and pre-commercial activity, the patent does not bar all research that precedes such activity.⁵⁵⁴

Contrary to previous suggestions in *dicta* of earlier cases, such as *Roche*, *Embrex* and *Madey*, Judge Newman recognized that a "goal" or "purpose" of commercialization or profit should not disqualify activities under experimental research doctrine:

The panel majority states that because the Scripps/Merck research had the goal of curing cancer and commercializing the cure, this purpose moved the research outside of any common law exemption. However, an ultimate goal or hope of profit from successful research should not eliminate the exemption. The better rule is to recognize the exemption for research conducted in order to understand or improve upon or modify the patented subject matter, whatever the ultimate goal. That is how the patent system has always worked: the patent is infringed by and bars activity associated with development and commercialization of infringing subject matter, but the research itself is not prohibited, nor is comparison of the patented subject matter with improved technology or with designs whose purpose is to avoid the patent.⁵⁵⁵

⁵⁵³ *Id.* at 875 (Newman, J., dissenting).

⁵⁵⁴ *Id.* at 876 (Newman, J., dissenting).

⁵⁵⁵ *Id.*

For Judge Newman, interpretation of the common law exemption of infringement as experimental use should at least dovetail, if not overlap, with that of 35 U.S.C. § 271(e)(1), and the price of failing to do so would be to create a “kind of limbo, between exploratory research subject to exemption, and the FDA statutory immunity, where the patent is infringed and the activity can be prohibited,” and that “the law does not favor such an illogical outcome.”⁵⁵⁶

On appeal, Justice Scalia, for a unanimous Supreme Court, vacated the CAFC decision and remanded the case.⁵⁵⁷ The Court, like the CAFC, did not disagree with the jury instruction at trial⁵⁵⁸ that, to qualify for the exemption under § 271(e)(1), the defendant “must prove by a preponderance of the evidence that it would be objectively reasonable for a party in [petitioner’s] and Scripps’ situation to believe that there was a decent prospect that the accused activities would contribute, relatively directly, to the generation of kinds of information that are likely to be relevant in the processes in which the FDA would decide whether to approve the product in question.”⁵⁵⁹ The Court also did not disagree with the conclusion by the CAFC that exemption under § 271(e)(1) “does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process.”⁵⁶⁰ With respect to the CAFC’s position that, because “the FDA does not require information about drugs other than the compound featured in [IND] application . . . Scripps’ work sponsored by [petitioner] was not ‘solely for uses reasonably related to’ clinical testing for FDA,”⁵⁶¹ the Court held that, “not to protect research conducted on patented compounds for which an IND is ultimately filed is effectively to limit assurance of exemption to activities necessary to seek approval of a generic drug,”⁵⁶² contrary to the Court’s interpretation of § 271(e)(1), whereby “all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA” are exempt.⁵⁶³ The Court did not address experimental use as a doctrine when making the few statements limiting the scope of § 271(e)(1):

Basic scientific research on a particular compound, performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce, is

⁵⁵⁶ *Id.* at 877 (Newman, J., dissenting).

⁵⁵⁷ *Merck KGaA v. Integra LifeSciences I, Ltd.*, 545 U.S. 193, 208 (2005).

⁵⁵⁸ *Id.* (“Thus, the evidence presented at trial has yet to be received under the standards set forth in the jury instruction, which we believe to be consistent with, if less detailed than, the construction of § 271(e)(1) that we adopt today.”).

⁵⁵⁹ *Id.* at 200.

⁵⁶⁰ *Id.* at 205 (quoting *Integra*, 331 F.3d at 867) (“Second, the court concluded that the exemption ‘does not globally embrace all experimental activity that at some point, however attempted, may lead to an FDA approval process.’ . . . We do not quibble with the latter statement.”).

⁵⁶¹ *Id.*

⁵⁶² *Id.* at 206.

⁵⁶³ *Id.* at 202 (“As an initial matter, we think it apparent from the statutory text that § 271(e)(1)’s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA.”).

surely not “reasonably related to the development and submission of information” to the FDA.⁵⁶⁴

Consequently, the Court also did not reach the question of biotechnology tool patents which, according to Judge Rader, would be embraced by any broad interpretation of the safe harbor provision, as discussed *supra*.

The opinion of the Supreme Court in *Merck* provides general guidance that, as suggested by one commentator, could have “potentially vast” implications and “could lead to chaotic results in the lower courts.”⁵⁶⁵ The same commentator suggests that application of § 271(e)(1) by the lower courts in the context of other decisions, such as the threshold requirement of providing laboratory data to establish conception of a specific “practical utility,” an interference practice, may severely limit availability of the safe harbor provision under section § 271(e)(1), thereby potentially manifesting the limbo forewarned by Judge Newman in her dissenting opinion.⁵⁶⁶ The Supreme Court does not provide any language that would exclude practice of patented subject matter, the benefit of which is generation of data, from the safe harbor of § 271(e)(1).

Application of § 271(e)(1) within the guidelines provided by the Supreme Court in *Merck* could be relatively straightforward if done in consideration of an historic interpretation of common law experimental use doctrine. The decision in *Roche*, which, by all accounts, prompted, at least in part, enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, held that “limited use of a patented drug for testing and investigation strictly related to FDA drug approval requirements during the last 6 months of the term of the patent constitute[s] a use which, unless licensed . . . [is] actionable.”⁵⁶⁷ The issue decided by *Roche* is closely tracked by the safe harbor provision of § 271(e)(1), which states that “[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States a

⁵⁶⁴ *Id.* at 205–06.

⁵⁶⁵ K. Burchfiel, *Merck KGaA v. Integra: More Answers than Questions?*, 6 J. HIGH TECH. L. 79, 83–84 (2006).

If the subject matter limitations of the exception for uses of “patented compounds” is expanded to include any “patented invention,” at any stage of drug development, the scope of the safe harbor becomes potentially vast.

....

If this principle is applied to inventions other than specific potential drug candidate compounds such as those at issue in *Merck*, the Court’s unrestricted endorsement of a broad exemption could lead to chaotic results in the lower courts.

Id.

⁵⁶⁶ *Id.* at 89. Mr. Burchfiel states:

In the hands of the lower courts, the inquiry into whether a researcher has a “reasonable basis” for believing that a patented compound may work “through a particular biological process, to produce a particular physiological effect” may lead to elaborate analysis invoking interference law concepts such as conception of a specific “practical utility,” as a prerequisite for the safe harbor exemption. In general, the Federal Circuit has required laboratory data confirming an expected and plausible but disputed utility, in the interference context. Does this requirement limit the availability of the safe harbor exemption, and if so, how will Judge Newman’s limbo be avoided?

Id. This author’s response to Mr. Burchfiel’s question, employing a benefit analysis, appears in the Appendix to this article.

⁵⁶⁷ *Roche v. Bolar*, 733 F.2d 858 (Fed. Cir. 1984).

patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates manufacture, use, or sale of drugs . . .”⁵⁶⁸ As discussed above, experimental use doctrine has never been applied to exempt activities conducted in preparation for sale of protected subject matter, including testing to ensure compliance with production standards, or even demonstrations of suitability of claimed subject matter for a prospective customer. These activities, which arguably embrace Government submission requirements under the FDA, were properly held by the court in *Roche* to be infringing activities, and outside the scope of exemption under the experimental use doctrine. Intervention by Congress under the Drug Price Competition and Patent Term Restoration Act of 1984 and, specifically, provision of § 271(e)(1), was required to exempt activities “reasonably related” to Government submission requirements from infringement. In essence, § 271(e)(1) of Title 35 was born out of the shortfall recognized by the courts of the exemption to infringement provided by the doctrine of experimental use. The “intervening kind of limbo, between exploratory research subject to exemption, and the FDA statutory immunity, where the patent is infringed and the activity can be prohibited,” referred to by Judge Newman in her dissenting opinion to *Integra*,⁵⁶⁹ should not exist under any interpretation of the experimental use doctrine or § 271(e)(1) because, properly interpreted, § 271(e)(1) was enacted specifically to fill the gap between permissible experimental use and commercialization that, in the absence of § 271(e)(1), would, effectively, extend patent term. As stated by Judge Rader in *Integra*:

The second reason for the 1984 Act responded to this court’s decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 221 USPQ 937 (Fed. Cir. 1984). Specifically, the Act sought to ensure that a patentees rights did not *de facto* extend past the expiration of the patent term because a generic competitor also could not enter the market without regulatory approval.⁵⁷⁰

Contrary to statements made by the court in *Roche*, *Embrex*, *Madey* and *Merck*, successful application of the experimental use doctrine has never been dependent on any commercial purpose of those activities. Rather, as has been discussed, the doctrine has always hinged on whether the benefit of claimed subject matter, beyond discovery of its operation, has been obtained by its manufacture, use or even sale.⁵⁷¹ Like routine testing to control quality, preparation of submissions mandated by the government as a prerequisite to sale of patented subject matter provides a benefit of that patented subject matter beyond discovery of its operation and, therefore, is not, and historically has not, been exempt from infringement under the doctrine of experimental use.

⁵⁶⁸ Drug Price Competition and Patent Term Restoration Act of 1984 § 202, 98 Stat. 1585 (as amended 35 U.S.C. § 271(e)(1) (2000)).

⁵⁶⁹ *Integra LifeSciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 877 (Fed. Cir. 2003) (Newman, J., dissenting).

⁵⁷⁰ *Id.* at 865.

⁵⁷¹ *See, e.g., Sawin v. Guild*, 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391) (finding that the sale of a patented item in foreclosure was not an infringing deprivation of a patent owner’s lawful reward for his discovery).

Consistent application of experimental use doctrine potentially reduces the prospect of an “intervening limbo” between experimental use doctrine and § 271(e)(1) envisioned by Judge Newman.⁵⁷² In particular, the issue of biotechnology tools posed by Judge Rader in the majority decision of *Integra*,⁵⁷³ and left open by the Supreme Court in *Merck*,⁵⁷⁴ is easily resolved, both with respect to patented tools that have as their only use generation of data in compliance with Federal regulations and, more interestingly, chemical compounds that, depending upon their use, can be candidates for regulatory approval or research tools. By avoiding the gross parameter of “commercial purpose,” and instead focusing on the benefits of claimed subject matter exclusive of discovery of its operation, the scope of exemption under § 271(e)(1) becomes straightforward. A research tool, by definition, provides information about a workpiece and, therefore, the data generated is the benefit provided by the research tool. Garnering the benefit of patented subject matter causes the activity to be infringing and, consequently, outside the scope of experimental use doctrine. Moreover, despite the broad language of the statute, § 271(e)(1) does not apply to a research tool, not because its use is not “reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs,” but because it is not the “patented invention”⁵⁷⁵ that is the subject of regulatory approval,⁵⁷⁶ and, therefore, does not pose the threat of extended patent term that was the impetus for exemption under the statute.

⁵⁷² *Integra*, 331 F.3d at 877 (Newman, J., dissenting).

⁵⁷³ *Id.* at 867. Judge Rader posed the issue with respect to research tool patents as follows:

For example, expansion of § 271(e)(1) to include the Scripps-Merck activities would effectively vitiate the exclusive rights of patentees owning biotechnology tool patents. After all, patented tools often facilitate general research to identify candidate drugs, as well as downstream safety-related experiments on those new drugs. Because the downstream clinical testing for FDA approval falls within the safe harbor, these patented tools would only supply some commercial benefit to the inventor when applied to general research. Thus, exaggerating § 271(e)(1) out of context would swallow the whole benefit of the Patent Act for some categories of biotechnological inventions.

Id.

⁵⁷⁴ *Merck KGaA v. Integra LifeSciences I, Ltd.*, 545 U.S. 193, 205 n.7 (2005). Justice Scalia stated:

The Court of Appeals also suggested that a limited construction of § 271(e)(1) is necessary to avoid depriving so-called “research tools” of the complete value of their patents. Respondents have never argued the RGD peptides were used at Scripps as research tools, and it is apparent from the record they were not. We therefore need not – and do not – express a view about whether, or to what extent, § 271(e)(1) exempts from infringement the use of “research tools” in the development of information for the regulatory process.

Id. (citation omitted).

⁵⁷⁵ 35 U.S.C. § 271(e)(1) (2000).

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 . . . 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 . . .

Id.

⁵⁷⁶ § 271(e)(1) extends to patented inventions that are not necessarily chemical compounds, such as medical devices. *See, e.g.* *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, *reh'g en banc denied*, 879 F.2d 849 (Fed. Cir. 1989), *aff'd*, 496 U.S. 661 (1990).

Whether a compound, for example, is a “patented invention,” under § 271(e)(1) will depend upon whether data generated by its use is in contemplation of its approval or that of another compound under Federal law. For example, with respect to screening assays, thousands or millions of compounds may be assayed, and the same compound alternatively may be employed to target a candidate or may be the candidate compound targeted. Use of that compound may be either as a research tool or as an object of research, and the nature of use, either as a research tool or an object of research, will determine whether experimental use doctrine should be applied. Regardless, as part of the search for candidate compounds, § 271(e)(1) should not apply because, as stated by the Supreme Court, and recited above, “[b]asic scientific research on a particular compound, performed without the intent to develop a particular drug or reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce, is surely not ‘reasonably related to the development and submission of information’ to the FDA.”⁵⁷⁷

IV. CONCLUSION

Both inherency and experimental use doctrines in patent law are based on an equitable exchange between an inventor and public benefit. Just as a patentee is not permitted to embrace within his limited period of exclusivity subject matter of which the public has had the advantage, discovery of phenomena, including the manner in which an inventor’s patented contribution operates, has been reserved to the public, so long as the inventor’s right to exclusivity over the benefit provided by manufacture, use, or sale of the invention is maintained.

The link between these doctrines is a common understanding that an inventor’s exclusive right is coterminous with the benefit of his invention, and that the fundamental right of philosophical inquiry can only be limited to the extent that it deprives the inventor of his exclusive right to that benefit. Issues raised in *Smith-Kline Beecham*, *Metabolite*, and *Merck*, although apparently disparate, can all be substantially resolved by focusing on the scope of the bargain between the public and the inventor. In *Smith-Kline Beecham*, for example, despite allegations of the certainty of the presence of PHC hemihydrate prior to the critical date of Smith-Kline Beecham’s patent directed to that compound, the fact that its presence was so small as to be undetectable and, therefore, by definition, failing to provide benefit to the public, should disqualify it as prior art. Likewise, the theoretical presence of PHC hemihydrate in compositions of PHC anhydride prepared by Apotex, if undetectable, should not be grounds for a holding of infringement of a claim to the hemihydrate since, arguably, an undetectable presence, by definition, cannot provide a public benefit.

Metabolite presents another example where novelty can properly be found in view of prior art that did not provide the benefit of the claimed invention. In *Metabolite*, the inventors’ discovery of a correlation between elevated levels of total homocysteine and deficiencies in cobalamin or folate provided a benefit, captured as a method for detecting deficiency of cobalamin or folate in a warm-blooded animal. Despite the presence in the prior art of the assay employed by the claimed method,

⁵⁷⁷ *Merck*, 545 U.S. at 205–06 (quoting 35 U.S.C. § 271(e)(1)).

the public, without the discovery of the correlation provided by inventors, would be without a method to detect the deficiency. The claimed method, in effect, is a limitation of a known assay to a population of warm-blooded animals suspected of, or to be screened for, a deficiency in cobalamin or folate, and targeted application of the method to that limited population is the only embodiment of the use of the known assay that would infringe the claim. Once again, the inventor's exclusive right is limited by the benefit provided to the public.

In *Merck*, the statutory provision of 35 U.S.C. § 271(e)(1), which was enacted to prevent effective extension of patent term as a consequence of Federal regulatory requirements prior to commercialization, has been given potentially vast scope by the Supreme Court. Recognition of the scope of the well-established doctrine of experimental use as historically applied would facilitate application of the guidelines enunciated by the Court in *Merck*. Specifically, by disregarding commercial purpose in favor of philosophical inquiry as the lynchpin for exemption from infringement under the experimental use doctrine, and by applying § 271(e)(1) with a view to experimental use doctrine, courts can provide for essentially all Federally mandated submissions without creating Judge Newman's limbo and without abrogating the exclusionary rights of the holders of research tool patents.

Like *SmithKline Beecham* and *Metabolite*, the lower court under *Merck* could find guidance in the fundamental premise articulated by Renouard and recited by Phillips, that patent protection is commensurate with the contribution made to the public domain by an inventor's irretrievable disclosure and consequent common benefit. Further, the bargain granted by the public of patent protection stops short of an exclusive right by the patentee over use of the invention to discover the natural principles on which it is based, regardless of the ultimate purpose motivating the philosophical inquiry into those principles, unless by doing so the inventor is otherwise deprived of the benefit of the contribution he has made by his invention.

APPENDIX

The significance of benefit provided by a reference as an enabling description in the public domain, and the distinction of that enabling reference from entitlement by a patent applicant to a priority document having the same enabling description was made apparent in *Rasmusson v. Smith-Kline Beecham, Corp.*⁵⁷⁸ The CAFC affirmed a decision by the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office denying benefit of a priority date to patent applicant Rasmusson in an interference proceeding on the basis that, as of the necessary filing date:

[A] person of ordinary skill in the art would have had no basis . . . for believing that finasteride [the subject matter of the interference] could be used to treat prostate cancer in light of the state of the art and in light of Rasmusson's failure to provide any data to demonstrate the effects of finasteride in treating prostate cancer.⁵⁷⁹

As a prior art reference, however, a published European application corresponding to and disclosing the same subject matter as the priority document was found to be sufficiently enabling to constitute a prior art reference with respect to the patent application of the other party to the interference, Smith-Kline Beecham, Corp.

The distinction between an inability to claim priority to the document while that same document can successfully be used as a prior art reference, derives from conflation of the enablement requirement under 35 U.S.C. § 112 paragraph 1, with that of utility under 35 U.S.C. § 101:

In explaining what constitutes a sufficient showing of utility in the context of the enablement requirement, this court has stated that an applicant's failure to disclose how to use an invention may support a rejection under either § 112, paragraph 1 for lack of enablement or "§ 101 for lack of utility 'when there is a complete absence of data supporting the statements which set forth the desired results of the claimed invention.'"⁵⁸⁰

Because Rasmusson had not provided any supporting data, the court affirmed the Board's denial of entitlement to any filing date that preceded evidence that "a person of ordinary skill in the art would have believed that the 5αR inhibition [provided by finasteride] could play a role in treating prostate cancer . . ." ⁵⁸¹ With

⁵⁷⁸ *Rasmusson v. Smith-Kline Beecham, Corp.*, 413 F.3d 1318 (Fed. Cir. 2005).

⁵⁷⁹ *Id.* at 1322.

⁵⁸⁰ *Id.* at 1323 (quoting *In re Cortright*, 165 F.3d at 1356 and *Environtech Corp. v. Al George, Inc.*, 730 F.2d 753, 762 (Fed. Cir. 1984)).

⁵⁸¹ *Id.* at 1324. The court stated:

In order to obtain a priority date earlier than June 27, 1990, Rasmusson needed to provide experimental proof that his invention could be effective in treating cancer. Because Rasmusson failed to do so and obtained a priority date only as of the

respect to the same published document constituting an effective prior art reference, despite an inability to rely on that document in a priority contest, the court stated “[t]he reason is that § 112 ‘provides that the specification must enable one skilled in the art to ‘use’ the invention whereas [section] 102 makes no such requirement as to an anticipatory disclosure.’”⁵⁸²

The court, however, also stated that an anticipating prior art reference must be enabling:

A patent claim “cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled.” . . . The standard for what constitutes proper enablement of a prior art reference for purposes of anticipation under § 102, however, differs from the enablement standard under § 112.⁵⁸³

The distinction, according to the court in *Rasmusson*, is a statutory requirement of utility in patent applications that is lacking as a threshold requirement for an anticipating reference.⁵⁸⁴

The court agreed with *Rasmusson*, that “proof of efficacy is not required in order for a reference to be enabled for purposes of anticipation.”⁵⁸⁵ In essence, therefore, the court imposed on *Rasmusson* a requirement of “proof of efficacy” in the priority document asserted to establish a filing date prior to that of Smith-Kline.⁵⁸⁶ The same document, however, in the form of a published European application, did not require any such proof, but rather only that the teachings be enabling, in order to anticipate the claimed subject matter of Smith-Kline’s later filed application.⁵⁸⁷

The utility requirement imposed by the court in *Rasmusson*, which extends beyond enablement, at least as enablement is applied as a requirement of anticipatory references, arguably extends beyond disclosure necessary to form part of the public domain. In fact, the Supreme Court decision in *Brenner v. Manson*,⁵⁸⁸ was heavily criticized on this point by Judges Rich and Smith in extensive dissents to two subsequent decisions by the Court of Customs and Patent Appeals, namely, *In re*

filing date of his ‘296 application, the Board was correct to find that all applications prior to that application were not enabled.

Id.

⁵⁸² *Id.* at 1325 (quoting *In re Hafner*, 410 F.2d 1403, 1405 (C.C.P.A. 1969)).

⁵⁸³ *Id.* (quoting *Elan Pharm., Inc., v. Mayo Found. for Med. Educ. Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003)).

⁵⁸⁴ *Id.* (“Since *In re Hafner*, this court has continued to recognize that a prior art reference need not demonstrate utility in order to serve as an anticipating reference under § 102.”).

⁵⁸⁵ *Id.* at 1326. As stated by the court:

Rasmusson . . . asserts that the case [*Bristol-Myers Squibb Co. v. BenVenue Labs., Inc.* 246 F.3d 1368 (Fed. Cir. 2001)] stands for the broader proposition that proof of efficacy is not required in order for a reference to be enabled for purposes of anticipation.

We agree with *Rasmusson*.

Id.

⁵⁸⁶ *Id.*

⁵⁸⁷ *Id.* The court did not hold that the published European application was enabling, instead it remanded the case to the Board for a determination of whether the published European application was “an enabling reference for purposes of anticipation.” *Id.*

⁵⁸⁸ 383 U.S. 519 (1966).

*Kirk*⁵⁸⁹ and *In re Joly*.⁵⁹⁰ Judge Rich argued that statutory utility, even as applied under a careful review of *Brenner v. Manson*, requires only that “some specific use be mentioned (as *Brenner* said), at least in the absence of evidence that a specific use is obvious.”⁵⁹¹ Judge Rich further stated that use of certain terms, including “practical,” “substantial,” “specific” and “currently available,” to establish statutory utility under 35 U.S.C. § 101, are “nothing but troublemakers as time will amply demonstrate.”⁵⁹² Conflation of the threshold requirement for patentability of statutory utility under 35 U.S.C. § 101 with enablement under 35 U.S.C. § 112, paragraph 1, in combination with application of a standard of practical, substantial, specific, and currently available use, imposes an obligation on patent applicants, whereby enabling contributions are made to the public domain sufficient to operate as anticipatory references under 35 U.S.C. § 102, without providing, in exchange, benefit of limited exclusive rights to these contributions as patentees.

The application by the court of a “practical utility” requirement in *Rasmusson*, therefore, deprives would-be patentees of exclusive rights in a manner that is inconsistent with improvements they contribute to the public domain. As discussed in Section III. C. above, Burchfiel *suggests* that this interpretation of utility may contribute to the gap between experimental use doctrine and safe harbor under 35 U.S.C. § 271(e)(1) first identified by Judge Newman in her dissent in *Integra LifeSciences I Ltd. v. Merck KGaA*.⁵⁹³ Partition of statutory utility under 35 U.S.C. § 101 from 35 U.S.C. § 112, paragraph 1, by recognizing the threshold for utility as understood by Judge Rich, would permit the enablement requirement to be applied with parity between establishment of priority dates and of sufficiency of prior art references. As such, availability of the safe harbor exception would not be hobbled by the possibility of linking a “reasonable basis’ for believing that a patented compound may work through a particular biological process, to produce a particular physiological effect,” with an inordinate standard for “practical utility.”⁵⁹⁴

⁵⁸⁹ 376 F.2d 936 (C.C.P.A. 1967).

⁵⁹⁰ 376 F.2d 906 (C.C.P.A. 1967).

⁵⁹¹ *In re Kirk* 376 F.2d at 955 (Rich, J., dissenting).

⁵⁹² *Id.* at 960 (Rich, J., dissenting). Judge Rich stated that “we come to the practical problem posed by the rule being promulgated by the majority — a rule of great vagueness and no definite limits by reason of reliance on the terms ‘practical,’ ‘substantial,’ ‘specific’ and ‘currently available.’ They are nothing but trouble-makers, as time will amply demonstrate.” *Id.*

⁵⁹³ *Integra LifeSciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 877 (Fed. Cir. 2003).

⁵⁹⁴ Burchfiel, *supra* note 565, at 89.