I. Introduction

It is hard to dispute the role that pharmaceuticals play in modern society. Numerous drugs have been developed that allow ailments to be treated to a degree that would have been unimaginable several decades ago.[1] Among the groundbreaking drugs to be developed by various pharmaceutical companies are VIAGRA®, PROZAC®, and PAXIL®. New drugs require a huge investment by pharmaceutical companies;[2] however, a successful drug can potentially bring its producer billions of dollars.[3] Not surprisingly, since a successful drug can bring its maker billions of dollars, these same drugs often provide the backdrop for contentious litigation. Both PROZAC®[4] and

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[1] Neal Masia, *The Cost of Developing a New Drug*, Focus on Intellectual Property Rights, January 2006, http://usinfo.state.gov/products/pubs/intelprp/cost/htm.

> Advances in treating cancer, HIV/AIDS, and a broad host of other afflictions have been nearly continuous in recent decades, thanks to -in many instances- new drug discoveries. Economists estimate almost half of the increase in life expectancy achieved over the past 15 years in the industrialized world can be attributed to new drugs. In the United States alone, the economic gains from medical innovations are estimated at $500 billion per year.

[2] *Id*. Neal Masia puts the cost of developing a drug at a low of $800 million to a high of $2 billion. Masia also states that of 5,000 to 10,000 new chemical inventions that look promising, only 250 enter preclinical laboratory and animal testing. Fewer than ten of these will show enough potential to enter Phase I human testing.

[3] *Id*. Neal Masia states that "at the current level of reimbursement, economists estimate that only about 30 percent of new medicines actually earn enough revenue during their patented product lifecycle to cover the average upfront cost of development. If a firm incurred the average cost of drug development and only invented 'average' drugs, it would quickly go out of business."

[4] *Eli Lilly and Company v. Barr Laboratories, et. al.*, 251 F.3d. 955, 968-969 (Fed. Cir. 2001). Eli Lilly attempted to extend its patent on Prozac by patenting a "method of blocking the uptake of serotonin by brain neurons in animals by administering the compound fluoextine hydrochloride." (U.S. Patent No. 4,626,549 ,"the '549 patent"). Fluoextine hydrochloride is the active ingredient in Prozac. *Id*. at 958. The prior art (U.S. Patent No. 4,590,213 ,"the '213 patent") was directed at a method of "treating anxiety in a human by administering an effective amount of fluoxetine or a pharmaceutically-acceptable salt thereof." *Id.* at 962. Originally, the Federal Circuit invalidated the '549 patent on the grounds of double patenting. *Eli Lilly v. Barr Laboratories*, 222 F.3d. 973 (Fed. Cir. 2000). The Court subsequently vacated the panel decision and directed a specific revision of the double patenting section. *Eli Lilly*, 251 F.3d. at 958. In its final opinion the Court stated that "serotonin uptake is a natural biological activity that occurs when fluoxetine hydrochloride is administered to an animal… [And] that it is literally impossible to treat someone with anxiety without at the same time inhibiting serotonin uptake." *Id.* at 969-970. Based on this finding the Court found that Barr Laboratories had provided "ample foundation for the proposition that administration of fluoxetine hydrochloride naturally and inherently inhibits the uptake of serotonin." *Id*. at 970. Because humans are members of the animal genus the '549 patent was inherently anticipated by the

PAXIL®[5] resulted in substantial litigation. In addition, the process that a pharmaceutical company must satisfy to obtain approval from the FDA to market a drug is long and cumbersome.[6] Congress recognized that the regulatory requirements of the FDA shortened the commercial life of patented drugs and, by decreasing the profits of pharmaceutical companies, endangered future research and development.[7] Based on its

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'213 patent. *Id*. at 971. Further controversy resulted from the Court's determination that the '213 was prior art to the '549 patent, despite having a later priority date. The patent application for the '213 patent had priority from April 8, 1983 and issued on May 20, 1986. *Id.* The patent application for the '549 patent was a continuation-in-part originally filed in about April 1986 and issued in December 1986. *Id*. at 968, FN 7. However, the '549 patent, as a continuation-in-part application, claimed an effective filing date of January 10, 1974. *Eli Lilly*, 251 F.3d. at 973, *Newman's dissent to refusal to reconsider the case en banc*. Despite this fact, the Court determined that the '549 patent was obvious in light of the later filed '213 patent. *Id*. at 968-970. The Court was likely moved to its conclusion by the seemingly endless divisional applications, continuation applications and patents which arose from the original patent and, as the Court stated, "rivals the Hapsburg legacy." *Id*. at 959. Newman's dissent will be further discussed later in this paper, as she also notes concern for the effect that this decision could have on future patenting of biological inventions. *Id*. at 977, see pg. 5, *infra*.

[5] *SmithKline Beecham Corp v. Apotex Corp*., 247 F.Supp.2d. 1011 (N.D. Ill. 2003), *aff'd on other grounds*, 365 F.3d. 1306 (Fed. Cir. 2004); *opinion vacated en banc*, 403 F.3d. 1328 (2005); *aff'd on other grounds*, 403 F.3d. 1331 (Fed. Cir. 2005). The PAXIL® case provides another situation where a drug patent was ultimately disposed of on the basis that it was anticipated inherently by the prior art. The PAXIL® case the prior art mutated into a "pseudopolymorph" that was more stable and easily manufactured. *SmithKline*, 247 F.Supp.2d. 1016-1020. The new composition was distinct from the prior art, but was discovered to have been created when a patient ingested the prior art. The Federal Circuit originally invalidated the patent on the basis that clinical trials constituted public use. *SmithKline*, 365 F.3d. at 1316-1317. Judge Gajarsa, *concurring*, states that SmithKline should have limited its patent to "synthetic or non-naturally occurring" forms of the polymorph, in order prevent infringement by using the prior art. *Id*. at 1332. The original panel decision was subsequently vacated by the Court *en banc*. The PAXIL® patent was then invalidated after a panel rehearing as inherently anticipated. *SmithKline*, 403 F.3d. at 1344. *See*, pp 49-53, *infra*.

[6] *SmithKline*, 247 F.Supp.2d. at 1017-1018. Circuit Judge Posner, sitting by designation, states "Because it takes a long time for a new drugs to be approved by the Food and Drug Administration for sale to the American public, the actual period during which the producer has an exclusive right to make, use, and sell the drug is shorter than the statutory term of the patent."

[7] *Id.*

> The compression of the commercially significant patent term by reason of the regulatory process at the FDA is a matter of great concern to the manufacturers of new drugs. The cost of developing such a drug is often very great, in part because attempts to develop a new drug that will be both safe and effective often fail and the cost of these 'dry holes' must be reckoned into the cost of the drugs that succeed, as it is only out of the revenues of those drugs that the costs of the dry holes can be recovered. The greater the upfront cost of developing a product, the more time that is required to recoup the cost and so (other things being equal) the longer is the socially optimal patent term. The costs incurred in running the gauntlet of FDA approval not only increase the manufacturer's upfront development cost but compound the delay, also largely due to the FDA, between obtaining a patent and actually being able to market the patented drug to the consuming public

(noting that a drug patented in 1977 had still not been approved for marketing to the public in 1985).

recognition of the unique position that pharmaceuticals play in our society, Congress attempted to strike a balance- through the Hatch-Waxman Act- that would guarantee the pharmaceutical companies a reasonable return on their investment[8] while allowing generic drug manufacturers to quickly enter the field upon the expiration of a drug patent.[9]

Congress' willingness to lengthen patent terms of pharmaceuticals in order to encourage research and development indicates patents may be treated differently when the public interest demands it. The Federal Circuit's recent determination that the doctrine of inherent anticipation should be aggressively applied to the patenting of metabolites significantly endangers the scientific advancement of pharmaceuticals.[10] By formulating a broad rule on inherent anticipation the Federal Circuit appears to be directly contravening the policy choice that Congress has made, through the Hatch-Waxman Act, relating to pharmaceutical research and development. The Federal Circuit is instead substituting its own policy determination in the place of Congress'.

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[8] *Mylan Pharmaceuticals v. Thompson*, 268 F.3d. 1323, 1326 (Fed. Cir. 2002)(quoting *Abbott Labs v. Young*, 920 F.2d. 984, 991 (D.C.Cir.1990)). "[The] provisions of the Hatch-Waxman Act 'emerged from Congress' efforts to balance two conflicting policy objectives: to induce name brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper generic copies of those drugs to market.'" 35 U.S.C. §156 (relating to the patent restoration term available under the Hatch-Waxman Act to restore some of the time lost during the regulatory process).

[9] *Mylan*, 268 F.3d. at 1325-1326.

> An ANDA [Abbreviated New Drug Application] offers an expedited approval process for generic drug manufacturers. Instead of filing a full NDA [New Drug Application] with new safety and efficacy studies, in an ANDA a generic drug manufacturer may rely in part on the pioneer manufacturer's work by submitting data demonstrating the generic products' bioequivalence with the previously approved drug.

Portions of Hatch-Waxman relating to generic drugs codified in *Title 21 U.S.C. §355*.

[10] *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d. 1373 (Fed. Cir. 2003). This case is central to the debate of the application of inherent anticipation to pharmaceuticals, and its implications are discussed. *See*, pp 11-26, *passim*.

Inherent anticipation is not a new concept although, originally, it was an abstract concept used to address situations where the court appeared sure of the result but unsure of what reasoning it could use to justify that outcome.[11] The evolution of inherent anticipation was slow, and it was not until 1945 that the Court finally set out a workable basic rule. In *General Electric v. Jewel Incandescent Lamp.*[12] the Court stated that "the prior art discloses the method of making the article having the characteristics of the patented product, though all the advantageous properties of the product had not been fully appreciated."[13] The Court went on to state that:

> [The inventor] found latent qualities in an old discovery and adapted it to a useful end. But that did not advance the frontiers of science in this narrow field so as to satisfy the exacting standards of our patent system. Where there has been use of an article or where the method of its manufacture is known, more than a new advantage of the product must be discovered in order to claim invention.[14]

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[11] See *e.g. Tilghman v. Proctor*, 102 U.S. 707, 711(1880) (holding that whether Tilghman's process of distilling fat acid had been practiced before by others was immaterial in determining whether he was entitled to a patent). Paul Galloway, *Inherently Difficult Analysis for Inherent and Accidental Biotechnological Inventions*, Suffolk U. L. Rev., 38 SFKULR 73, 77-78 (2004)(stating that the process had been practiced when tallow was introduced as lubrication for the piston in the machine, the formation of fat acid in the machine was unintended and not understood. This situation is now seen as "accidental anticipation" and is distinct from "inherent anticipation" because the result is not necessarily present within the invention, method, or process). *See also, Edison Electric v. Novelty Incandescent Lamp Co.*, 167 F. 977 (3rd Cir. 1909)(finding that a patent was not barred for a new and preferable light bulb. The bulb had been previously built, but the construction was accidental and those bulbs were discarded as being defective, so the true value of the invention was not discovered until Edison recognized and patented it, so the patent was valid).

[12] *General Electric v. Jewel Incandescent Lamp Co.*, 326 U.S. 242 (1945). This case concerned the frosting of light bulbs. Clear light bulbs produced unpleasant glare. One method to address glare was to frost the outside of the bulb; however, this frosting became easily dirty and was difficult to clean. The natural alternative was to frost the inside of the bulb, but this substantially weakened the bulb, almost to the point that it was unfit for use. Pipkin, the inventor in this case, found that a second treatment of frost made the bulb stronger by eating away the crevices created by the first layer of frost. This treatment had been discovered many years earlier and was known to give glass a rounded, as opposed to angular and creviced, finish. What had not been discovered was that a second finish ate away at some of original frosting and would actually strengthen the bulb. This phenomenon was referred to as "Pipkin's paradox" and was the basis of his patent application. Ultimately, the court found his discovery insufficient for a patent.

[13] *Id*. at 248 (quoting *Lovell Mfg. Co. v. Cary*, 147 U.S. 623).

[14] *Id*. at 248-249.

The question raised by the *GE* case above is to what degree it should be applied to biological inventions.[15] Does the stringent test recited above, and largely adopted by the Federal Circuit in *Schering v. Geneva Pharmaceuticals* and *SmithKline Beecham v. Apotex*, protect the public by ensuring that pharmaceuticals, and their accompanying metabolites, pass to the public domain as soon as possible; or does the *Schering* decision pose a threat to scientific advancement by forcing pharmaceuticals to disclose their inventions in order to obtain patent protection, but limiting their ability to claim metabolites caused by their products, even if they could not have recognized the benefits of their invention prior to the patent's critical date?

The rule enunciated in *Schering* is a new interpretation of the previous case law concerning inherent anticipation. The Federal Circuit's new view- that inherency no longer requires recognition of the trait by a "person having ordinary skill in the art" (PHOSITA) - applies to any situation where one is attempting to gain a patent for a derivative result of a previous patent. However, the effects of this new rule will felt most in the pharmaceutical industry. There is a danger that, by not requiring recognition by PHOSITA to apply the doctrine of inherent anticipation, the ability to patent pre-existing unrecognized biological inventions could be imperiled, regardless of the individual utility that may be garnered from these substances once their value is recognized.

Judge Pauline Newman of the Federal Circuit expressed her concern that the Federal Circuit, in 2001, was adopting bright line rules which, by precluding protection

[15] Metabolites form when an "ingested pharmaceutical compound undergoes a chemical conversion in the digestive tract to form a new metabolite compound." *Schering*, 339 F.3d. at 1375. Biological inventions are similar to metabolites, but the processes that lead to biological compositions are not limited to the digestive tract. Metabolites are merely a specific form of biological invention.

for many metabolites, would stifle the advancement of biological inventions Judge Newman stated:

> [E]very biological property is the natural and inherent result of the chemical structure from which it arises, whether or not it has been discovered. To negate the patentability of a discovery of biological activity because it is 'the natural result' of the chemical compound can have powerful consequences for the patentability of biological inventions.[16]

The decision in *Schering* was the culminating case in a lengthy split within the Federal Circuit. One view, espoused most forcefully by Judge Newman in *Continental Can Company v. Monsanto*,[17] states that patenting should only be prevented if a "person having ordinary skill in the art" could have recognized the inherent trait that was now being claimed.[18] Judge Randall Rader explicitly disavowed any such notion in *Schering*.[19] Judge Newman believes that more lenient and clear standards, with respect to the patenting of pharmaceutical and biological inventions, are necessary in light of the

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[16] *Eli Lilly*, 251 F.3d. at 976.

[17] *Continental Can v. Monsanto*, 948 F.2d. 1264 (Fed. Cir. 1991).

[18] *Id*. at 1269. Judge Newman wrote:

> [T]o serve as anticipation when the reference is silent about the asserted inherent characteristic, such a gap must be filled with recourse to extrinsic evidence. Such 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.

[19] *Schering*, 339 F.3d. at 1377. Judge Rader stated that "recognition by a person of ordinary skill in the art before the critical date [of the patent] is not required to show anticipation by inherency." He went on to further state that:

> *Continental Can* does not stand for the proposition that an inherent feature of a prior art reference must be perceived as such by a person of ordinary skill in the art before the critical date. In *Continental Can* this court vacated summary judgment of anticipation of claims reciting a plastic bottle with hollow ribs over a prior art disclosing a plastic bottle. The record contained conflicting expert testimony about whether the ribs of the prior art plastic bottle were solid. Given the material fact, this court vacated summary judgment as improper.

Id. Judge Rader did sit on the panel that ruled on *Continental Can*, but Judge Newman, the author of the *Continental Can* opinion would likely disagree with his view of that case, see FN 18, *supra*. Subsequently, Judge Newman lamented the Circuit's refusal to hear the *Schering* case *en banc* and stated "no precedent supports the position that a product whose existence was not previously known and is not in the prior art is always unpatentable on the grounds that it existed undiscovered." She went further and quoted her language of *Continental Can*, noted in FN 18, *supra*, which required recognition of the inherent characteristic by PHOSITA. *Schering v. Geneva*, 348 F.3d. 992, 993-995 (Fed. Cir. 2003), *dissent to denial of rehearing en banc*.

unpredictability of the breakthroughs that various discoveries may bring,[20] but in *Schering*, the Federal Circuit, led by Judge Randall Rader, adopted a clear position which sets extremely stringent standards for the patenting of metabolites and other biologicals.[21]

This paper will examine the split that had developed within the Federal Circuit concerning whether it is necessary that there be recognition by PHOSITA in order to apply the doctrine of inherent anticipation. It will then argue that Congress, through the Hatch-Waxman Amendments, has already recognized that pharmaceuticals occupy a uniquely important position within society; and, based upon that, it is necessary that pharmaceutical and biological inventions be given different treatment when applying inherent anticipation to prevent the stifling of scientific advancement which may otherwise occur. Finally, some suggestions will be made on how pharmaceutical companies can be protected, to ensure that they maintain sufficient incentives to continue to engage in the research and development of new drugs, including investigation of the biological causes of existing compositions; but, at the same time, the suggestions will attempt to remove as little as necessary from the public domain.

II. Inherent Anticipation

Patents that relate to metabolites must meet all the basic requirements of patentability.[22] Among the most basic requirements are that an invention be useful,[23] novel[24], and non-obvious.[25] Anticipation under §102(a) occurs if the identical invention

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[20] *Eli Lilly*, 251 F.3d. at 976.
[21] *Schering*, 339 F.3d. at 1381. Judge Rader allowed for the patenting of metabolites with "proper claiming." This, of course, would require that the metabolite be recognized prior to the patent's critical date, which is a difficult proposition given that it may be the state of technology which prevents such recognition. He also stated that the metabolite could be patented in its "pure and isolated form … or as a pharmaceutical carrier."
[22] 35 U.S.C. §§101-103 (2005).
[23] 35 U.S.C. §101 (2005).
[24] 35 U.S.C. §102 (2005).

has been claimed on a single prior art reference.[26] When more than one prior art reference is required to find unpatentability, or patentability revolves around a minor improvement of the prior art, then the validity of the patent is evaluated for obviousness under §103.[27] In some cases, a prior art reference may anticipate if all the claimed limitations are not disclosed within the prior art but are deemed to be inherent within it.[28] As Judge Rader said in *Atlas Powder v. Ireco Inc*., "under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates."[29] Anticipation is a factual determination[30] thatwill prevent patenting.[31] If a patent has already been issued then anticipation must be shown by clear and convincing evidence, but if this burden is met the patent will be invalidated.[32]

The doctrine of inherent anticipation is an off-shot of accidental anticipation. Accidental anticipation was first addressed by the Supreme Court in *Tilghman v. Proctor*.[33] In that case the Court found that Tilghman's invention for separating fats and oils was not anticipated because it had only been practiced accidentally and the results, and benefits, were not understood.[34] This accidental use had occurred when individuals practicing the prior art introduced tallow to help lubricate the piston on a steam cylinder.[35] The Court stated that the "acids were accidentally and unwittingly produced,

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[25] 35 U.S.C. §103 (2005).
[26] *Continental Can*, 948 F.2d. at 1267 (citing *Titanium Metals Corp. of America v. Banner*, 778 F.2d. 775, 780 (Fed. Cir. 1985); *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co.*, 730 F.2d. 1452, 1458 (Fed. Cir. 1984)).
[27] *Id*.
[28] *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d. 628, 630 (Fed. Cir. 1987).
[29] *Atlas Powder v. Ireco Co. of Cal.*, 190 F.3d. 1342, 1347 (Fed. Cir. 1999).
[30] *Standard Havens v. Gencor Industries*, 953 F.2d. 1360, 1367 (Fed. Cir. 1991) (citing *Ralston Purina Co. v Far-Mar-Co.*, 772 F.2d. 1570, 1574 (Fed. Cir. 1985).
[31] *Atlas Powder*, 190 F.3d. at 1347 (citing *Titanium Metals*, 778 F.2d. at 782).
[32] *Id.* 35 U.S.C. §282.
[33] *Tilghman*, 102 U.S. 707. See FN 11, *supra*.
[34] *Id*. at 711.
[35] *Id*.

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 it was an anticipation of Tilghman's discovery."[36] The Court's determination that the situation in *Tilghman* did not qualify as anticipation makes sense, but the explanation seems to center on the previous producer's failure to appreciate what had occurred through their actions.[37] Future cases added to the*Tilghman* decision; and, today, *Tilghman* and cases following its fact pattern are described as being cases of "accidental anticipation."[38] *Tilghman* continues to be valid law, although the circumstances that lead to a finding of accidental anticipation do not appear common.

Courtshave long treated inherent anticipation and accidental anticipation as being distinct from one another.[39] Judge Rader distinguished *Tilghman* from *Schering* by

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[36] *Id*. at 711-712.
[37] *Id.*
[38] Paul Galloway has outlined the factors that the Federal Circuit, and its predecessor the Court of Customs and Patent Appeals, have considered in determining whether "inherent anticipation" or "accidental anticipation" applies to certain sets of facts. The factors he recites are:

> 1) whether the prior art intended the claimed process; 2) whether the prior art includes knowledge of the claimed composition or process; 3) whether the prior art includes knowledge of the newly discovered result of the claimed process or knowledge of the newly discovered function of the claimed composition; 4) whether the prior art includes knowledge of the claimed component in the claimed composition; 5) whether the prior art performs the claimed process or makes or uses the claimed composition for a different purpose; 6) whether the claimed composition is useful in the prior art; 7) whether the claimed material is useful to achieve the claimed result in the prior art and; 8) whether the claimed process performs occasionally or under unusual conditions in the prior art or the claimed composition is formed occasionally or under unusual conditions.

Galloway, 38 SFKULR at 91. Accidental anticipation is differentiated from inherent anticipation in that the result, in inherent anticipation, is the naturally occurring and inevitable result of practicing the prior art. A determination that accidental anticipation exists allows for patenting; whereas a finding of inherent anticipation precludes patenting.
[39] *See e.g., The American Original Corp. v. Jenkins Food Corp.*, 696 F.2d. 1053 (4th Cir. 1982)(finding that a patent to eviscerate clams using a "shearing hydraulic force" was valid and had only been accidentally anticipated by the prior art, whose use of hydraulic force was incidental); *But see, Bird Provision Co. v. Owens Country Sausage, Inc.*, 568 F.2d. 369 (5th Cir. 1978)(finding that a method to "hot process" pork sausage to lengthen shelf life was anticipated by prior art, even though the prior art did not recognize the implications to shelf life). *See also,* Galloway, 38 SFKULR at 77-80, development of the doctrines of inherent anticipation and accidental anticipation. The *Bird* case also presents the opportunity to pose an interesting inherent anticipation hypothetical unrelated to pharmaceuticals: assume that a chemical was

noting that the claimed process from *Tilghman* was not found to be inevitably present in the prior art.[40] He then concluded that since the claimed metabolite was inherently present whenever loratadine was ingested, the sale of loratadine resulted in the sale of the patented metabolite; and, regardless of whether there was recognition by PHOSITA, invalidity due to inherent anticipation was applicable.[41]

Inherent anticipation requires that an event inevitably follow.[42] As the Court of Customs and Patent Appeals stated in *In Re Oelrich*, "inherency … 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."[43] The Court went on to state that if it is shown that the "natural result flowing from the operation as taught [in the prior art to PHOSITA] *would* result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient."[44] Allowing a patent for

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unknowingly produced by the "hot process" but never recognized, and, years later, a new method was created that substantially lengthened the shelf life of pork by creating that same chemical (apparently an impressive feat), but this time the chemical was detected. If the company that discovered the new process patented both the process and the resulting chemical could a competitor invalidate the patent on the chemical because it was inherently anticipated by the prior art "hot process." Under *Schering* and *SmithKline*, the answer is almost certainly "yes" since the undetected chemical would be inherent, but undetected, within the prior art. This could make many companies balk when considering whether to obtain a patent or retain a method as a trade secret.

[40] *Schering*, 339 F.3d. at 1378.

[41] *Id.* Judge Rader appears somewhat uncertain if the basis of the *Schering* decision will be accepted, as demonstrated by his attempts in the opinion to distinguish *Tilghman* and find no need for recognition by PHOSITA. For example, he states: "Applying an inherency principle in the context of an on sale bar under *35 U.S.C. §102(b)*, this court has distinguished *Eibel* and *Tilghman*," *Id.* Several sentences later, after summarizing several additional cases, Judge Rader says:

> In those cases the product sold or offered for sale had an inherent, but unrecognized feature that was a limitation of the asserted claims. Thus, this court has distinguished *Eibel* and *Tilghman*, which therefore do not bind this court to find no anticipation because skilled artisans did not recognize that the prior art '233 patent inherently produced the claimed invention.

Id.

[42] *In Re Oelrich*, 666 F.2d 578 (C.C.P.A. 1981).

[43] *Id*. at 581 (emphasis added), (citing *Hansgirg v. Kemmer*, 102 F.2d. 212, 214 (C.C.P.A. 1939).

[44] *Id*. (emphasis added).

a claim that is inherent within the prior art has the practical effect of removing that claim from the public domain, at least for the duration of a new patent.[45]

The Supreme Court touched more clearly on inherent anticipation in the case of *General Electric v. Jewel Incandescent Lamp Co.*[46] In that case the court made clear that more than the mere discovery of a "new advantage" to an existing product is required in order to obtain a patent.[47] In that case the inventor, Pipkin, discovered that a second treatment of frost, inside the bulb, actually strengthens the bulb by dissolving away additional glass which would otherwise weaken the bulb.[48] The Court did not believe that Pipkin's advancement warranted patent protection.[49] However, the Court did leave open the possibility that the discovery of a new quality, which does advance the science in a narrow field, could be entitled to a patent.[50] But, absent such advancement, the public is merely being deprived of a good for an additional patent term.[51]

Public policy considerations best explain why the Federal Circuit adopted such a hardline in *Schering* and *SmithKline*. The Federal Circuit's concern is that permitting the consecutive patenting of pharmaceuticals, and later of their *in vivo* biological by

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[45] *Application of Roy Wiseman, Jr.*, 596. F.2d. 1019, 1023 (C.C.P.A. 1979).
[46] *General Electric*, 326 U.S. 242, see FN 12 *supra*, for facts.
[47] *Id.* at 248-249.
[48] *Id*. at 244-245.
[49] *Id*. at 248-249.
[50] *Id*.
[51] The test espoused by Judge Newman in *Continental Can* and derived from previous cases was meant to address the concerns of undeserved patent extensions. The requirements for inherency to be triggered were that 1) the missing descriptive matter is necessarily present in the thing described in the reference and 2) it would be so recognized by persons having ordinary skill in the art. *Continental Can*, 948 F.2d. at 1268. The first portion of the test attempts to distinguish accidental anticipation from inherent anticipation. As a threshold matter, accidental anticipation may not bar a patent since the public has not derived benefit from the discovery. *Tilghman*, 102 U.S. at 711; *see also*, *Eibel*, 261 U.S. at 66. The second portion of the test addresses the fact that it a thing is inherently present in a prior art reference but not recognized then it is most likely not obvious and its discovery could provide the "[advancement of] the frontiers of science in [a] narrow field" that the Supreme Court alluded to in *General Electric*, 326 U.S. at 248-249. The second portion of the test also prevents claims that, while appearing to advance science in a narrow field, are known to technologists in the field but not to Judges, *Continental Can*, 948 F.2d. at 1269.

products, would have the practical result of substantially lengthening the patent protection of the pharmaceutical, as well as preventing the creation of other pharmaceuticals that may metabolize into the same biological composition, without substantially advancing the present frontiers of science.

A. *Schering Corporation v. Geneva Pharmaceuticals*

The *Schering* case concerned two patents.[52] The first was (U.S. Patent No. 4,282,233, "the '233 patent").[53] The '233 patent covered loratadine, the active ingredient in an antihistamine marketed by Schering under the brand name CLARITIN®.[54] CLARITIN® was unique in the marketplace at the time it was launched because it was an antihistamine that did not cause drowsiness.[55] The '233 patent issued in 1981 and had expired by the time the Federal Circuit considered the case.[56] The second patent at issue in the case was (U.S. Patent No. 4,659,716 ,"the '716 patent").[57] The '716 patent covered a metabolite of loratadine called descarboethoxyloratadine (DCL), which is also a non-drowsy antihistamine.[58] Metabolites form when an "ingested pharmaceutical undergoes a chemical conversion [during the course of] the digestive process to form a new metabolite compound."[59] The '716 patent issued in April 1987 and was set to expire in April 2004.[60] Numerous generic drug manufacturers sought to market generic versions of loratadine once the '233 patent had expired, but were required to assert that the '716 patent was invalid or not infringed by their practice of the '233 patent because of

[52] *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d. 1373, 1375 (Fed. Cir. 2003).
[53] *Id*. at 1374.
[54] *Id*. at 1375.
[55] *Id*.
[56] *Id*.
[57] *Schering*, 339 F.3d. at 1374.
[58] *Id.* at 1375.
[59] *Id*.
[60] *Id*.

Schering's listing of the '716 patent in the "Orange Book" in connection with the '233 patent.[61]

Since the earliest priority date of the '716 patent was February 15, 1984, the '233 patent was prior art over the '716 patent.[62] After cross-motions for summary judgment the District Court invalidated the '716 patent as being anticipated under 35 U.S.C. §102(b) because DCL was "necessarily formed as a metabolite by carrying out the process disclosed in the '233 patent."[63] Schering appealed the District Court's decision.

Judge Rader authored the opinion in *Schering* and took full advantage of the opportunity to lay out the exacting standards to applywhen evaluating a patent under the doctrine of inherent anticipation. He started by making clear that prior art "may

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[61] *Id*. at 1376; *SmithKline v. Apotex, et.al.*, Federal Trade Commission Amicus Curie Concerning Torpharm's Cross Motion for Entry as an Amended Order, 2003 WL 22023358 (E.D. Pa.). Once an NDA is approved the patents related to it are submitted with the NDA and listed. Later, any new patent information relating to the approved drug is submitted to the FDA and listed in the "Orange Book." To be listed, the patent must contain at least one valid product or use claim. However, once the patents are listed, any filing of an ANDA approval for a drug that involves a listed patent will automatically trigger a 30 month stay. During this time the FDA may not approve a drug unless the litigation is concluded sooner in favor of the ANDA applicant. The Orange Book registration has proven problematic because the FDA has stated that it lacks the expertise and resources to scrutinize the listed patents; and must therefore treat its role in Orange Book listings as purely ministerial, so there should be no presumption that a patent was correctly listed. Drug Manufacturers have proven adept at manipulating the Orange Book system to their advantage. Among the methods that Drug Manufacturers have used to prevent the entry of generic drugs into the marketplace is the listing of later issued patents in the Orange Book after a suit has been commenced. This results in either consecutive or overlapping stays that prevent the FDA from considering the ANDA. The FTC singled out SmithKline's orange book listings in relation to PAXIL® as being particularly egregious. Apotex filed an ANDA in March of 1998. At the time SmithKline had only one patent listed in the Orange Book for PAXIL®. After Apotex commenced its suit an additional eight patents were filed in the Orange Book at staggered intervals. Based on these additional filings SmithKline was able to extend its original 30 month stay to a 65 month stay, which was finally set to expire in September of 2003, assuming SmithKline listed no additional patents in the Orange Book.) The Paxil Patent was finally disposed of by the Federal Circuit in *SmithKline Beecham Corp v. Apotex Corp*., 365 F.3d. 1306; *opinion vacated en banc*, 403 F.3d. 1328; *aff'd on other grounds*; 403 F.3d. 1331. The problem of Orange Book listings is further complicated by the Federal Circuit's rulings in *Andrx Pharmaceticals v. Biovail Corp.*, 276 F.3d. 1368 (Fed. Cir. 2001); and *Mylan Pharmaceuticals v. Thompson*, 268 F.3d. 1323 (Fed. Cir. 2002). In these cases the Federal Circuit determined that district courts lacked the power to shorten the 30 month stay and that individuals lacked the ability to commence a private action to require pharmaceuticals to take steps to de-list patents from the Orange Book, even after those patents had been found to be invalid. *Andrx*, 276 F.3d. at 1376; *Mylan*, 268 F.3d. at 1324, 1330-1333.

[62] *Schering*, 339 F.3d at 1376.

[63] *Id*. *Schering Corporation v. Geneva Pharmaceuticals* , 2002 WL 20001552 (D. N.J. 2002).

anticipate without disclosing every feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference."[64] Rader then stated "[a]t the outset, this Court rejects the contention that inherent anticipation requires recognition in the prior art."[65] This is a striking determination because numerous cases, including *Continental Can*, appear to stand for the proposition that an anticipating reference must be recognized by PHOSITA to be inherently anticipated.[66] In rejecting this view, Judge Rader attempts to distinguish *Continental Can* as a summary judgment determination where disputed material facts made any inherent anticipation analysis premature.[67] However, Judge Rader's attempt to minimize the reach of *Continental Can* is unconvincing, based on the clear view expressed by Judge Newman in that case.

Judge Newman, the author of the *Continental Can* opinion, stated that for inherent anticipation to apply "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*" (emphasis added).[68] She found this flexible rule to be necessary to prevent continuing patents for matters that were outside the knowledge of judges, but not necessarily the knowledge of those skilled in the art.[69] Summary judgment in the

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[64] *Id.* at 1377.
[65] *Id*.
[66] *Continental Can*, 948 F.2d. at 1269.
[67] *Id*.
[68] *Continental Can*, 948 F.2d at 1269. *See also*, FN 18 and 19, *supra*.
[69] *Id*. Judge Newman's primary concern appeared to be that technologists in the field would omit basic facts as unnecessary to a reference. It could then be possible for an opportunist to attempt to take advantage of this omission in order to claim something that was already known at the time of patenting, but not expressly included in the reference. Newman's later decisions, such as those in *Elan Pharmaceuticals v. Mayo Foundation* and her dissent to the Circuit's refusal to hear *Schering en banc*, make clear that it was never her intent to preclude all material present from being foreclosed by inherent anticipation. A cursory reading of *Continental Can*, where she says "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

Continental Can case was ultimately reversed because the Federal Circuit found that there were questions as to whether the process necessarily produced the hollow ribs claimed.[70] However, according to Judge Newman's framing of the issue, had there been no question that the process in *Continental Can* inevitably and always produced hollow ribs, the Court would still have had to determine whether PHOSITA would have recognized the hollow ribs in order to uphold a summary judgment of anticipation by inherency.[71] Thus, Judge Rader's view of the limited importance of *Continental Can* does not seem to be supported by Judge Newman's statement of its holding and rationale. It is also possible that Judge Rader may have violated the Federal Circuit's local rules by overruling a binding precedent in a panel decision.[72]

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function, it seems well settled the disclosure should be sufficient," could leave an incorrect impression if taken out of its context.

[70] *Id*.

[71] Since the Court did not reach the issue of whether PHOSITA would have recognized the presence of the trait in the reference, the test in *Continental Can* is technically dicta, however it is supported by a host of cases both preceding it, and preceding *Schering, MEHL/Biophile, Atlas Powder, and EMI Group*, that treat *Continental Can* as binding. *See e.g., Rosco Corp. v.Mirror Lite Co.*, 304 F.3d. 1373, 1380-1381 (Fed. Cir. 2002)(finding that PHOSITA would not read the reference as inherently creating a mirror of varying radius); *Finnegan Corporation v. ITC*, 180 F.3d. 1354, 1366 (Fed. Cir. 1999)(holding that one skilled in the art would not necessarily recognize the "nonresonance ejection" disclosed in the prior art and therefore the patent is not anticipated); *In Re Robertson*, 169 F.3d. 743, 745 (Fed. Cir. 1999)(holding that the Board in rejecting a patent failed to show that the disclosed diaper fasteners were either necessary or would have been recognized by an artisan of ordinary skill); *In Re Paulsen*, 30 F.3d. 1475, 1480-1481 (Fed. Cir. 1994)(holding that a prior art reference must be considered together with the knowledge of one skilled in the art and, after doing so, the claim is anticipated); *In Re Spada*, 911 F.2d. 705, 708 (Fed. Cir. 1990)(Judge Newman stating the claim is anticipated because the prior art "put one of ordinary skill in possession" of the claims.); *In Re Oelrich*, 666 F.2d. 578, 581-582 (Fed. Cir. 1981)(holding that if the disclosure is sufficient to show that the claim is the natural result flowing from the operation taught [to PHOSITA] then the disclosure is sufficient); *In Re Shetty*, 566 F.2d. 81, 84-85 (C.C.P.A. 1977)(finding that PHOSITA would not have recognized that prior art method to combat microbial infections also inhibited appetite and the patent is not anticipated); *In Re Seaborg*, 328 F.2d. 996, 999 (C.C.P.A. 1964)(finding that creation of element 95 would require more skill than possessed by PHOISTA and is therefore not anticipated); *see also Hansgirg v. Kemmer*, 26 CCPA 937 (C.C.P.A. 1939); *Cf. Telmac Cellular Corp. v. Topp Telecom*, 247 F.3d. 1316 (Fed. Cir. 2001)(holding that an algorithm for "real time call debiting" was anticipated but citing to *Continental Can, Atlas Powder,* and *MEHL/Biophile* despite their different requirements relating to PHOSITA recognition).

[72] Fed. Cir. R. 35(a)(2).

> Arguing to a panel to overrule a precedent. Although *only the court en banc* may overrule a binding precedent, a party may argue, in its brief and oral argument, to overrule a binding precedent without petitioning for hearing en banc. The panel will

Judge Rader continued, in his *Schering* opinion, to describe how he believed that the issue presented was one of first impression.[73] In *Schering* the court was asked to find anticipation based not on the absence of a single limitation, but rather upon the absence of an entire structure from the prior art.[74] The enormity of the item that would have to be found to be anticipated inherently did not trouble Judge Rader. Rather, he dispensed with any concerns about finding a whole structure inherently anticipated by explaining that:

> inherency places subject matter in the public domain as well as an express disclosure, the inherent disclosure of the entire claimed subject matter anticipates as well as inherent disclosure of a single feature of the claimed subject matter. The extent of the inherent disclosure does not limit its anticipatory effect.[75]

He went on to state that a "'natural result flowing from' the explicit disclosure of the prior art" is normally sufficient to find inherency.[76]

> decide whether to ask the regular active judges to consider hearing the case en banc. (emphasis added).

At this point in time there was already conflicting case law as to whether recognition by PHOSITA was required. *Continental Can* and its precursors developed the rule that required recognition by PHOSITA. On the other side of the argument were *Atlas Powder v. Ireco Inc.*, 190 F.3d. 1342 (Fed. Cir. 1999); *MEHL/Biophile International*, 192 F.3d. 1362 (Fed. Cir. 1999); *EMI Group*, 268 F.3d. 1342 (Fed. Cir. 2001). These cases do not require recognition by PHOSITA. However the requirement for recognition by PHOSITA, while minimized and distinguished by the second line of cases, was not expressly disavowed until *Schering*. Incidentally, the three cases that supported the concept that inherent anticipation did not require recognition by PHOSITA were all authored by Judge Rader in panel decisions, and the oldest case pre-dated *Schering* by only four years. Further complicating matters was the fact that Judge Newman expressly rejected the view that there was no need for recognition by PHOSITA to apply inherent anticipation in *Elan Pharmaceuticals v. Mayo Foundation*, 304 F.3d. 1221 (Fed. Cir. 2002), *opinion vacated en banc and remanded*, 314 F.3d. 1299 (Fed. Cir. 2002), *aff'd on other grounds*, 346 F.3d. 1051 (Fed. Cir. 2003). Rather than resolving en banc the issue of whether recognition by PHOSITA is required, the Court merely vacated Judge Newman's decision and remanded it back to her panel. While this appears to be a rejection of Judge Newman's view, it is not the equivalent of the en banc hearing required by Federal Circuit Rule 35(a)(2).

[73] *Schering*, 339 F.3d. at 1378. Shepard's views *Continental Can* as being of questionable validity.

[74] *Id*. at 1379.

[75] *Id*.

[76] *Id*. (citing *Eli Lilly v. Barr Labs*, 251 F.3d. 955, 977). The *Eli Lilly* case is of questionable value here. In that case Eli Lilly tried to extend its patent on the active ingredient in Prozac by claiming a method of blocking serotonin uptake in animals. Previously, Eli Lilly claimed a way to treat anxiety in humans which would naturally block serotonin uptake. The Court originally invalidated the newer patent on the basis of double patenting. A revised opinion found inherent anticipation since humans are part of the animal genus and claiming a patentably non distinct treatment for a genus member, when the same treatment has been claimed for a species member, renders that claim inherently anticipated. It is clear in that case that Eli Lilly

In an attempt to distinguish the *Schering* case from other precedent, Judge Rader found that, based on the record, DCL would have been detectable after ingestion of loratadine by humans.[77] As a result the '233 patent was found to have enabled the production of loratadine.[78] Judge Rader stated that to be enabling the '233 patent need "only describe how to make DCL in any form encompassed by a compound claim covering DCL, e.g., DCL as a metabolite in a patient's body."[79] In this case, the direction in the '233 patent to administer loratadine to a patient was sufficient to enable a PHOSITA to create DCL.[80] For that reason, the '716 patent claims on DCL were inherently anticipated by the '233 patent for loratadine.[81]

Judge Rader did allow for limited patenting of metabolites.[82] The types of patents that he stated were still possible despite the *Schering* holding were patents for the pure and isolated form of a metabolite, in pharmaceutical compositions with pharmaceutically acceptable carriers, or for a method of administering the metabolite or pharmaceutical

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probably recognized that the claims were duplicative, but there was a question as to the order of the priority of the patents. See FN 4, *supra*. However, the *Eli Lilly* case is a good example of the type of behavior that Judge Rader seemed most concerned with when he issued his ruling in *Schering*.

[77] *Id*. *Contra, In Re Seaborg*, 328 F.2d. 996 (1964). Claims involving an isotope of americium were permitted, despite the fact that they would have been present in the Fermi reactor many years prior. However, they would not have been detectable and its presence was merely theoretical. Judge Rader's view is confusing since it does appear to place some importance on recognition, but does not place importance on whether recognition occurred when the original patent issued, or whether the recognition was actually the impetus for the new patent. Schering's counsel also took issue with Judge Rader's view that DCL would have been detectable upon ingestion of loratadine. In his combined petition for panel rehearing and rehearing *en banc* Schering's states that Schering had to "develop new, more sensitive testing methods to detect DCL and other metabolites of the '233 patent compounds." *Comined Petition for Panel Rehearing and Rehearing en banc by Plaintiff-Appellant*, 2003 WL 24033460 at 5-6.

[78] *Schering*. 339 F.3d. at 1380-1381.

[79] *Id*. at 1381.

[80] *Id*. at 1381.

[81] *Id.* at 1380. Rader also cites to the patent principle that "that which would literally infringe if later in time, anticipates if earlier."

[82] *Id*. at 1381. Judge Rader's statement regarding continuing patentability of metabolites was dicta in this case. Judge Rader did not believe that Schering was entitled to any additional patents since Schering attempted to claim "bare chemical compound."

composition.[83] However, the decision made clear that metabolites may not have protection for broad compound claims because such claims are anticipated by the pharmaceutical composition which causes them.[84] Essentially, what Judge Rader attempted to accomplish with his decision in *Schering* was to settle the lingering dispute within the Federal Circuit of whether inherent anticipation could apply to a situation where there was no recognition by PHOSITA.[85]

Other members of the court recognized the implications of Judge Rader's decision and objected to the potential effects that it would have on both the patenting of metabolites, and the status of the Federal Circuit's case law for inherent anticipation. Perhaps not surprisingly, Judge Newman was the most vociferous in her opposition to

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[83] *Schering*, 339 F.3d. at 1381.
[84] *Id*.
[85] The confusion within the Circuit appears to be largely due to three previous panel decisions authored by Judge Rader. In *Atlas Powder*, 190 F.3d. 1342; *MEHL/Biophile*, 192. F.3d. 1362; and *EMI Group North America*, 268 F.3d. 1342. The decisions in *Atlas* and *MEHL/Biophile* were issued three weeks apart from one another in late 1999. Judge Rader attempted limit the circumstances where recognition by PHOSITA would be required by stating in *EMI Group* that such recognition

> may be sensible for claims that recite limitations of structure, compositions of matter, and method steps which could be inherently found in prior art. Such recognition by one of ordinary skill in the art may be important for establishing that the descriptive matter would inherently exist in every combination of the claims limitation … [t]heoretical mechanisms or rules of natural law that are recited in a claim, that are not themselves patentable, however, do not need to be recognized by one having ordinary skill in the art for a finding of inherency. A person of ordinary skill does not have to recognize that a method or structure behaves according to fully and effectively practice the method or structure.

EMI, 268 F.3d. at 1350-1351. This portion of the *EMI Group* decision was, until *Schering*, Judge Rader's most bold attempt to alter the rule of inherent anticipation. It's unclear where his distinction between structure, composition of matter, and method steps as compared to "natural law" comes from. It is true that natural law cannot be patented, although the Supreme Court is currently considering what limitations may exist when a party actually discovers a natural law that leads to an accompanying correlation (*Laboratory Corporation of America Holdings v. Metabolite Laboratories*, No. 04-607, oral arguments heard March 21, 2006, *see* FN 267, *infra*). However, Judge Rader held in both *Schering* and *SmithKline v. Apotex*, 403 F.3d. 1331 (Fed. Cir. 2005) that when natural processes lead to otherwise patentable material, that material may not be patented if it existed in the prior art, even if such existence was undiscovered and unrelated to the utility of the drug.

both the *Schering* decision and the decision not to hear it *en banc*.[86] Judge Newman did not accept Judge Rader's view on the law of inherent anticipation or approve of how the new precedent was created.[87]

> I write to state my concern for the panel's departure from the established law of anticipation. The court holds "anticipated" a novel chemical compound (DCL), a compound not known to the prior art and that did not previously exist. The Schering inventor discovered it *in vivo* as a degradation product of loratadine, isolated it, determined its structure, and found its biologic properties. The panel nonetheless holds that this new compound is unpatentable on the ground of "inherent anticipation"…The law is that a product is "anticipated" if it is not new. Conversely, it is not anticipated if it is new. A new product may of course be unpatentable based on obviousness, but it is not subject to unpatentability for lack of novelty. No precedent supports the position that a product whose existence was not previously known and is not in the prior art is always unpatentable on the ground that it existed undiscovered. If the law is to be changed in this direction it must be done *en banc*.[88]

Judge Newman cautioned that the panel's decision may have a dire impact on the discovery of biological patents.[89] Her primary concern about the substantive affects of the *Schering* decision is that there is no longer incentive for pharmaceuticals to invest in the research and development of metabolites that cannot be patented.[90] She also viewed

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[86] *Schering v. Geneva*, 348 F.3d. 992, *dissent to decision not to rehear en banc.* Federal Circuit Rule 35(a)(2) states that "only the court en banc may overrule a binding precedent." A party may argue before a panel to overrule a binding precedent, but, before overruling a binding precedent, the panel must decide whether to take a poll of the active Judges. If a majority of the active Judges choose to hear the matter en banc, then the decision may be reviewed en banc as dictated in Federal Circuit Rule 35(a)(1). Judge Newman recognized that the *Schering* decision, when taken together with *Atlas Powder*, *Mehl/Biophile*, and *EMI Group*, had the practical result of overruling *Continental Can* without first holding an en banc hearing.

[87] *Id.* at 993.

[88] *Id.* S*ee* Fed. Cir. R. 35(a)(2).

[89] *Id.* at 994.

[90] *Id*. The Washington Legal Foundation filed an *amicus curiae* brief in support of *SmithKline* petition for a writ of certiorari. In their brief they state their concern that the rule of *Schering* will not protect material in the public domain, as Rader wants, but rather stifle innovation. The foundation states that the best way to increase the flow of useful information is to provide patents that protect the discovery of previously existing, but unappreciated, compositions. *Washington Legal Foundation's Amicus Curiae Brief in Support of Petitioners*, 2005 WL 3114487 at 8. The Pharmaceutical Research and Manufacturers of America also filed an amicus curiae in support of SmithKline's petition for certiorari. They too stated a concern that the *SmithKline* rule would negate any potential incentive to investigate the beneficial uses of existing materials. They also gave an example of the new rule's shortcomings. They state that a broad spectrum antibiotic tetracycline was developed by studying Auremycin, a pre-existing antibiotic. The Federal Circuit allowed for the patenting of this newly discovered substance in *Glaxo v. NovoPharm*, 52 F.3d. 1043 (Fed. Cir. 1995). *Pharmaceutical Research and Manufacturers of America Amicus Curiae Brief in Support of Petitioner*, 2005 WL 3087521 at 2-3. It may no longer by practical to research such compositions because generic manufacturers will be able to file Abbreviated New Drug Applications

the decision as being based on a misunderstanding of the existing precedent on inherency.[91] In Newman's view the precedent on inherency had always dealt in two areas: first, situations where a single piece of prior art teaches all the elements of a claim, and in these cases the claim lacks novelty.[92] The second situation is where a single piece of prior art does not include all elements of an invention.[93] At that point, the question is whether the omitted elements would have been known to PHOSITA.[94] If the missing elements would have been known to the PHOSITA, as demonstrated by reference to extrinsic evidence, then the claim is anticipated.[95]

Clearly, the first circumstance did not exist since DCL was an *in vivo* metabolization not covered by the elements of the loratadine '233 patent. The second situation may have applied since loratadine did not claim DCL, but did lead to the creation of DCL. The question at that point, according to Judge Newman, was whether PHOSITA would have recognized the presence of DCL. If so, no further patent protection is warranted due to the danger that sophisticated patent applicants would omit known claims in order to prolong patent protection. But, rather than engaging in the

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(ANDAs) that will capitalize off both the research and testing undertaken by brand name manufacturers. They will then be able to enter the market with generic forms of the drugs, long before brand name pharmaceutical manufacturers have been able to recoup their investment. Also lost will be any profits that can be reinvested in research and development. Pharmaceutical companies could resort to trade secret to protect metabolites, but there is a danger that one company will be left to discover all alternative ways to create a metabolite. Allowing patents will place the information in the public domain and, because to the expanded experimental use exception under Hatch-Waxman, will allow multiple companies to research alternative methods of creating a metabolite that can be marketed soon after the patent expires. Under *Integra Lifesciences v. Merck KGaA*, 545 U.S. 193 (2005), companies may make fair use of patented products if the use is related to government approval, even if that use is ultimately economic in nature. This allows for approval of alternative methods of creating a metabolite during the patent term, with marketing to follow as soon as the term expires. Multiple methods of creating a metabolite are useful to address the different needs possessed by individuals in society.

[91] *Schering v. Geneva*, 348 F.3d at 994.

[92] *Id.*

[93] *Id.*

[94] *Id*.

[95] *Id.* at 995.

analysis of *Contiental Can*, the Federal Circuit adopted a bright line precluding all additional patents for metabolites regardless of whether PHOSITA recognition was present.

Judge Newman's second major objection is that Judge Rader's panel, in contradicting what she viewed to be the existing case law concerning inherent anticipation, went beyond what a panel could permissibly do.[96] Judge Newman agreed that there was no infringement, but she reached that conclusion because she did not believe that Schering could prevent people from practicing the prior art.[97] In her view, the decision in *Schering* was not only a misunderstanding of previous case law, but ultimately amounted to a full scale rejection of existing precedent.[98] Newman stated, understandably, that "a rejection of precedent requires *en banc* action, not panel disruption."[99]

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[96] *Schering*, 348 F.3d. at 995. Fed. Cir. R. 35(a)(2).
[97] *Id*. at 993-994.
[98] *Id.* at 995.
[99] *Id.* at 995. Fed. Cir. R. 35(a)(2). It is uncertain exactly why the Federal Circuit chose to address the matter of inherent anticipation with a panel decision. That the *Schering* case appears to have been "de facto" adopted by the circuit, after a panel hearing, seems to speak to the influence of Judge Rader. The Federal Circuit in *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d. 1328, once again seemed to endorse Judge Rader's view of inherent anticipation. Initially Judge Rader ruled that clinical trials constituted public use that would invalidate the "Paxil" patent, but stated that an alternative grounds for invalidating the patent was inherent anticipation due to SmithKline's claim that the '723 matierial was created upon ingestion of the prior art '196 patent. *See SmithKline v. Apotex*, 365 F.3d. 1306 (Fed. Cir. 2004), *vacated by SmithKline v. Apotex*, 403 F.3d. 1328 (Fed. Cir. 2005). The Federal Circuit's vacating of the previous "Paxil" decision en banc can be seen as an endorsement of Judge Rader's view of inherent anticipation since he specifically stated in his previous decision which alternative grounds he would use to pass upon the case of given the opportunity, *see SmithKline*, 365 F.3d at 1320. This allowed Judge Rader to invalidate the "Paxil" patent based on his view of inherent anticipation and, since the '723 substance was created by ingesting the prior art '196 substance, it was inherently anticipated regardless of whether it was recognized. *SmithKline v. Apotex*, 403 F.3d. 1331 (Fed. Cir. 2005). Both the vacating of the previous "Paxil" decision and the new "Paxil" decision were released on April 8, 2005. However, the cases preceding *Scherng* indicate that the matter of inherent anticipation in relation to biological and pharmaceutical compositions may have actually been festering for a while. A year before *Schering*, Judge Newman reversed a District Court decision in *Elan Pharmaceuticals v. Mayo Foundation*, 304 F.3d. 1221 (Fed. Cir. 2002) in which the lower court found a patent for a "recipe" to make transgenic mice was anticipated. Newman found the prior art possessed too many alternatives to allow for reliable production of the mice and thus the requirements of anticipation were not met since PHOSITA would not have recognized how to make the mice. Judge Dyk, in a dissent, objected to what he viewed as the patenting of

Judge Lourie also dissented from the decision not to rehear the case *en banc*.[100] His concern was that *Schering* was an "extraordinary decision, effectively precluding virtually all patents on human metabolites of drugs."[101] Judge Lourie also pointed out some of the practical limitations that currently exist and that affect the ability of pharmaceutical companies to originally patent metabolites.[102] Namely, patents covering pharmaceuticals typically issue prior to the completion of clinical trials, which is when the identity and nature of the metabolites are likely to become known.[103] He believed that the *Schering* decision would preclude protection of related metabolites by creating a rule that will find existing patents to be effective prior art against their metabolites *per se*.[104] In Judge Lourie's view, the mere disclosure of a certain chemical composition that should be administered to a patient is not sufficient to enable a metabolite merely because such administration would "inevitably cause the human body to make the metabolite."[105] Judge Lourie would not allow every metabolite to be patented. He stated that he would

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"existing inventions" in light of recent cases (*In Re Cruciferous Sprout Litigation*) that prohibited such patents. The Circuit granted a *rehearing en banc*, which later merely vacated the previous panel decision, *Elan*, 314 F.3d. 1299. Judge Newman's later opinion, rather than concentrating on non recognition of the missing elements by PHOSITA, instead stated that the prior art was not sufficiently enabled to allow one to replicate without undue experimentation, *Elan,* 346 F.3d. 1051. Nonetheless, even without the Judge Newman's original *Elan* decision, which directly contradicted Judge Rader's view on the need for recognition by PHOSITA to trigger inherent anticipation, there still exists a troubling split within the Circuit concerning inherent anticipation. The *Continental Can* line of cases are still good law, as are the cases relied on by *Schering* and *SmithKline* (*Atlas Powder*, *Mehl/Biophile*, *EMI Group*). The two conflicting lines of cases necessitate resolution by the Court *en banc*, even though it appears clear that Judge Rader's view on inherent anticipation is generally accepted within the Court.

[100] *Schering*, 348 F.3d. at 995.

[101] *Id.*

[102] *Id.*

[103] *Id*. Judge Lourie seems to take a strikingly different view on the patenting of metabolites from the view expressed by Judge Rader. Whereas Judge Rader seems to be primarily concerned with the direct and immediate public policy concerns surrounding metabolites, namely that pharmaceutical companies will manage to extend their patent, Judge Lourie appears to be more concerned with how fair the adopted process would be to those seeking patents. Like Judge Newman, he appears to believe that metabolites do meet the requirements of patent and seems to feel that a categorical refusal to patent metabolites does nothing to advance the public interests and will hinder scientific advancement.

[104] *Schering*, 348 F.3d. at 996.

[105] *Id*.

rule differently if the patent actually taught how to make metabolites or if the patented material was in "actual public use" prior to the filing of the new patent application. In those cases the metabolite would be unpatentable.[106] According to Judge Lourie, the Federal Circuit should be interested solely in patent law, not policy or equity.[107] To hold that a "patent on a product, with minimal disclosure of administering 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."[108]

Judge Rader's decisions in *Schering*, and later in *SmithKline*, can be justified through his concern for the public policy implications that would have arisen had the Circuit allowed for the patenting of metabolites caused by prior art. Despite acknowledging that, unlike *Atlas Powder*, *MEHL*, and *EMI Group*, the Court was finding subject matter to be anticipated without any express description present, Judge Rader found no reason to conclude that a distinct substance arising from prior art should be treated any differently than an inherent characteristic of prior art.[109] In Judge Rader's view the dispositive issue is whether an anticipatory reference enabled the use of the

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[106] *Id.* Judge Lourie appears willing to apply an on-sale bar to products that produce an unknown metabolite, but does not believe that the standard one year time period from the initial issuing of the patent should be applied in determining whether or not a substance is barred from receiving a further patent. In his view pharmaceutical companies should be allowed to patent any substances discovered during clinical trials or other experimental stages that occur prior to the drugs being marketed to the public. This view is more consistent with the view of *Continental Can* that a reference does not qualify as prior art unless it is recognized. Judge Newman offered a sensible recommendation that would seem to address the concerns of both Judge Rader and Judge Lourie. In her view, Schering erred not by patenting a newly discovered metabolite (DCL) but by attempting to prevent others from practicing prior art in the public domain that could result in the production of the patented metabolite. *Schering v. Geneva*, 348 F.3d. at 994, *dissent to denial of rehearing en banc.* Judge Newman's alternative solution would be to allow for the patenting of a DCL in a limited manner. All competitors would be able to practice the prior art, whether or not it created the patented DCL, but Schering would be able to bar competitors from creating new alternatives ways of creating DCL. In this manner the DCL patent would be valid and capable of being exploited, but nothing would be removed from the public domain.

[107] *Id*.

[108] *Id.*

[109] *Schering*, 339 F.3d. at 1378-1379.

claims at issue, regardless of whether PHOSITA recognized that presence of the claims.[110] Hence allowing the patenting of metabolites that had already been in use unknowingly by the public would amount to the removal of the substance from the public domain, something clearly impermissible under patent law.[111] He went on in *Schering* to state that the "extent of the inherent disclosure does not limit its anticipatory affect," and, coupled with his abandonment of the requirement for recognition by PHOSITA, creates a situation where a substance that is non-obvious to PHOSITA, possesses utility, and is not anticipated in the standard manner is, nonetheless, inherently anticipated and ineligible for patent protection.[112] In denying a patent to materials that otherwise qualify under *35 U.S.C. §§101-103*, Judge Rader has made a policy determination regarding the desirability of allowing patents that, while advancing the sciences, can reasonably be seen as extending patent protection beyond twenty years.

Judge Newman, on the other hand, appears to be solely concerned with patent law and does not address the public policy concern raised by Judge Rader. In her dissent to the denial of rehearing *en banc* for *Schering* Judge Newman's objections revolved around the Circuit appearing to deny protection to patentable material. She focused on DCL's novelty and absence in the prior art.[113] She then explained that the Schering inventor had discovered DCL "*in vivo* as a degradation product of loratidine, isolated it, determined its structure, and found its biologic properties. This panel nonetheless holds that this new compound is unpatentable on the ground of 'inherent anticipation.'"[114] Judge Newman then succinctly summarized her concern that no precedent supports the finding that a

[110] *Id.* at 1381.
[111] *Id.* at 1379-1380.
[112] *Id*. at 1378-1379.
[113] *Schering*, 348 F.3d. at 993.
[114] *Id*.

substance is "inherently anticipated" because it previously existed undiscovered.[115] Judge Newman also objected to *Schering's* abandonment of the *Continental Can* requirement that there be recognition by PHOSITA to trigger inherent anticipation.[116] She objects to the inflexible rule of inherent anticipation in *Schering* because it prohibits the patenting of materials that, in her view, meet all the patentability requirements of *35 U.S.C. §§101-103*.

The Federal Circuit chose to draw a hard line in *Schering* regarding the patenting of metabolites. However, the issue of whether a party may patent byproducts had been addressed by the court before, and, as would be guessed based on the severe differences of opinion that emerged, the case law was mixed. There were those, such as Judge Newman, who thought that PHOSITA needed to recognize the missing elements in order to find anticipation by inherency. Others, such as Judge Rader, realized that the inherent anticipation regimen was open to potential abuse by sophisticated patent holders who sought to stagger patent applications for the byproducts of a single invention in order to extend patent protection as long as possible. Both positions had substantial support for their views within case law.[117]

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[115] *Id.*

[116] *Id.* at 995. According to Schering's counsel Schering had to develop "new, more sensitive testing methods to detect DCL and other metabolites arising out of the '233 patent compounds." *Combined Petition for Panel Rehearing and Rehearing En Banc by Plaintiff-Appellant*, 2003 WL 24033460 at 5-6. If this is true, then denying Schering additional patents for the '233 compounds allows others to capitalize off Schering's research and development, and makes it unlikely that Schering can recoup their costs.

[117] Dan Burk and Mark Lemley, "Inherency," 47 Wm. & Mary L. Rev. 371(2005). Burk and Lemley suggest an interesting theory to reconcile the conflicting views of the Federal Circuit. Their view is that the Court will not grant further protection if the public has already been enjoying the benefit of the unpatented claims. However, in formulating their theory Burk and Lemley attempt to reconcile decisions that predated Judge Rader's attempts to abandon *Continental Can's* PHOSITA requirement, beginning with *Atlas Powder*, *MEHL/Biophile*, *EMI Group*, and, of course, culminating with the full scale explicit abandonment of the PHOSITA requirement in both *Schering* and *SmithKline*. By attempting to reconcile all the Federal Circuit's case law on inherent anticipation, Professors Burk and Lemley do not adequately appreciate the seismic shift orchestrated by Judge Rader relating to inherent anticipation. To begin with, Burke and Lemley incorrectly claim that the PHOSITA requirement is irrelevant because no cases pass upon the issue,

Schering's position has yet to be confirmed by the Federal Circuit *en banc*, but it has received additional support from later panel decisions, including *SmithKline Beecham*

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which is contained in the second prong of the *Continental Can* test. The reason for this is that the first prong of the *Continental Can* case, which requires that the trait be shown to be inherently present, is a threshold issue and a court must reach it in order to determine whether the issue of a case is inherent anticipation or accidental anticipation. Since inherent anticipation is a somewhat convoluted concept, it is not surprising that district courts, who rarely deal with such an issue, would not appreciate the high initial standard of proof that must be reached. It must initially be shown that a trait is present "not by mere possibility or probability," *In Re Oelrich*, 666 at 581, to even reach the second prong of the *Continental Can* test. The *Seaborg* case can be explained on this point because any presence of Americium in the Fermi reactor was only theoretical and, while PHOSITA may have suspected its presence, no one could sufficiently isolate are recognize Americium with any certainty until Seaborg. *See, e.g. Finnegan Corp. v. ITC*, 180 F.3d. 1354 (Fed. Cir. 1999)(holding that PHOSITA would not recognize the non-resonance ejector of the prior art and is therefore not anticipated); *In Re Shetty*, 566 F.2d. at 84-85 (finding that PHOSITA would not have recognized that a previous method to treat microbial infection in animals also curbed appetite, and therefore the patent is not anticipated); *see also*, FN 71, *supra*. Next, there is a need to draw a clear distinction between unpatentable inherent traits and inherent byproducts which still may "advance the frontiers of science in a narrow field," *General Electric*, 326 U.S. at 248-249. Cases such as *General Electric*, *Titanium Metals*, and *EMI Group* merely claimed ever present traits within devices whose discovery, while interesting, did not contribute independent utility. On this ground, the situations in *Schering* and *SmithKline* can be clearly distinguished in that the compositions claimed have utility independent of the original claim, and appear to have been non-obvious even to those in the art. Judge Rader seemed gravely concerned that allowing additional patents on the metabolites of existing substances would serve no purpose other than to lengthen patent protection for pharmaceutical companies. It is the second portion of the *Continental Can* test that is meant to address Judge Rader's concerns because it protects the public by preventing the patenting of things known to "technologists in the field … albeit not to judges," *Continental Can*, 948 F.2d. at 1269. This objective test allows a court to ask what was known, or should have been known, by PHOSITA in relation to a patent application. An interesting facet of the PHOSITA requirement is that, unlike the test of obviousness, it is not frozen at the date of patenting. So, something may not be known to PHOSITA originally and would therefore be eligible for patenting, but once it became known by PHOSITA it would no longer be patentable. This test thereby protects both the first discover and the public by allowing initial patentability but prohibiting it once it became known within the field because, presumably, there had been sufficient time to apply for a patent and to delay until PHOSITA generally recognizes a trait is unjustifiable. Lastly, the rule of *Schering* and *SmithKline* does not seem to limit the inherent anticipation bar on patent to material which the public is "already receiving the benefit." In the *Schering* case there is no indication that the metabolite DCL was the active ingredient in loratadine, rather DCL was an alternative form of a non-drowsy antihistamine. It is true that Schering attempted to prevent competitors from practicing not only DCL but also loratadine after loratadine's original patent expired, but the Schering situation could have been addressed through patent misuse instead of creating a blanket rule prohibiting patents. The *SmithKline* case creates a more clear example of the public not receiving a benefit from the patented material. In that case, *SmithKline* created a hemihydrate form of an original drug that was more easily manufactured because of its more stable form. SmithKline then attempted to prevent all use of the prior art by claiming the hemihydrate form would appear upon ingestion, although the hemihydrate also did not appear to affect the utility beyond its manufacturing advantages. These cases indicate the Court does not view the public's receipt of the benefit of a material to be dispositive when determining inherent anticipation. The theory suggested by Professors Burk and Lemley has some initial appeal but it fails to recognize the Court's recent shift in its approach to inherent anticipation, and it seems to be largely a *post hoc* rationalization of the Court's opinions that is unworkable in practice.

Corporation v. Apotex Corporation (the "PAXIL case").[118] In that case the Federal Circuit vacated a previous panel decision that invalidated a patent based on the finding that clinical trials constituted public use and remanded the case back to the Judge Rader's panel for further proceedings.[119] The basis of Judge Rader's second opinion in the "Paxil" case did not likely surprise the Circuit since his first opinion in *SmithKline* found inherent anticipation would be alternative ground for invalidating the "Paxil" patent.[120] Thus, when the Circuit vacated Judge Rader's first opinion, it could be said to have endorsed both his view of inherent anticipation and his determination to use his revised version of the doctrine to pass upon the "Paxil" patent.

Had *Schering* been decided *en banc*, the questions surrounding the legitimacy of an appellate panel ignoring circuit precedent could have been avoided. But it is likely the issue of whether unrecognized metabolites should be precluded from receiving separate patents would have been a persistent issue because, as explained in greater detail *infra*, the Court's view of public policy appears, in some respects, to contravene the general policy created by Congress through the Hatch-Waxman Act.

B. *Cases Supporting Judge Newman's View of Inherent Anticipation*

Judge Newman's view that inherent anticipation requires recognition from PHOSITA is consistent with the policy that was slowly developed by the courts regarding anticipation by inherency. The Supreme Court first addressed some form of inherent anticipation in 1890 with the *Tilghman v. Proctor* case.[121] Later cases, such as *Edison*

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[118] *SmithKline Beecham Corporation v. Apotex Corporation*, 403 F.3d. 1331 (Fed. Cir. 2005).
[119] *SmithKline*, 365 F.3d. 1306 (Fed. Cir. 2004), *vacated en banc by SmithKline*, 403 F.3d. 1328 (Fed. Cir. 2005).
[120] *Id.* at 1320.
[121] *Tilghman*, 102 U.S. 707. See FN 11, *supra*. Inherent anticipation would become an offshoot of accidental anticipation. The Court in Tilghman recognized that Tilghman was entitled to a patent and developed a doctrine of non recognized anticipation that would allow them to issue Tilghman a patent.

Electric Light Co. v. Novelty Incandescent Light Co.[122] and *Eibel Process Co. v. Minnesota and Ontario Paper*[123] reiterated the view that a creation whose value was not recognized nor appreciated did not constitute prior art.[124] These cases are now categorized as incidences of "accidental anticipation," but it is notable that originally a threshold question when considering anticipation was whether PHOSITA recognized the value of the invention.[125]

The case of *In Re Seaborg* supports Judge Newman's position.[126] In *Seaborg* the material being patented was Americium, also known as element 95, as well as the accompanying isotopes and methods of producing and purifying the element.[127] Difficulty in the patenting process arose because Americium had almost certainly been produced in the prior art Fermi reactor.[128] However, the presence of Americium was impossible to prove because the maximum amount that could have been produced had the reactor ran for 100 days at 500 kilowatts was no more than one-billionth of a gram, which would be interspersed with 40 tons of highly radioactive reactor fuel.[129] Even if it had been possible to safely measure the amount of Americium present, the technology of the time would not have allowed for certain confirmation of its presence.[130] The *Seaborg* court ultimately concluded that the prior art would not allow for the creation of

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Courts later recognized that their focus on non-recognition was capable of being expanded to situations where the unrecognized trait is always present. Allowing the Tilghman rule to be applied to these cases would extend patent protection and potentially encourage willful blindness. As a result inherent anticipation was developed to deny patents in those situations.

[122] *Edison Electric Light Co.*, 167 F. 977. See FN 11, *supra*.
[123] *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923).
[124] *Id.* at 66.
[125] *See* FN 38, *supra*, for a list of factors to differentiate "accidental anticipation" from "inherent anticipation."
[126] *In Re Seaborg*, 328 F.2d. 996 (C.C.P.A. 1964).
[127] *Id.*
[128] *Id.*
[129] *Id.* at 997.
[130] *Id.*

Americium "without the exercise of more than ordinary skill in the art."[131] Based on the conclusion that PHOSITA would not have been able to create Americium from the prior art a patent was granted over the examiner's original denial.[132]

The precedent seemed well established by the time the C.C.P.A. considered the case of *In re Shetty*.[133] The *Shetty* case pertained to a method of "curbing appetite in animals by administering certain adamantane compounds."[134] The Patent and Trademark Board of Appeals originally denied all claims as "analogous" to the prior art and therefore obvious or anticipated.[135] The Court affirmed the Appeals Board's decision as to one claim, but reversed the Board on the other five claims.[136] In the case of the five claims that were allowed to issue, the C.C.P.A. stated that they were not convinced that

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[131] *Seaborg*, 328 F.2d. at 999.

[132] *Id.* An interesting question arises- what if Americium could have been proved, during the life of the *Seaborg* patent, to be produced by the Fermi patented reactor? At that point is it possible to invalidate the patent as inherently anticipated? If not, does anyone using the Fermi reactor become an infringer? The natural answer would be that, if the patent is valid, a patent holder should not be permitted to prevent others from using prior art that has passed into the public domain. This was the view that Judge Newman suggested in *Schering*, but appears to have been rejected by Judge Rader. A second view would be to allow for *de minimus* use of the patented product. This second view was suggested by Judge Posner, sitting by designation, in *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F.Supp. 2d. 1011 (N.D. Ill. 2003), in a case involving the "seeding" of a patented product in prior art. "Seeding" could have occurred in this case if anyone attempting to experiment with the prior art '196 patent used the '723 in experimentation. *SmithKline*, 247 F.Supp. 2d. at 1024. Seeding can occur if the '723 material is handled roughly or dropped, and molecules break off. Once a seed of '723 material enters the manufacturing facility of the '196 material it begins to convert the '196 substance to the '723 substance, *Id.* at 1023. However, the '196 substance would reach a saturation point at a percentage points, but any manufacturing advantage would require results in the "high double digits." *Id.*, at 1024-1025 There was also testimony at the trial court that once a facility was seeded it would almost be impossible to "unseed" it. *Id.*, 247 F.Supp. 2d. at 1021. Judge Rader, in *SmithKline Beecham Corp v. Apotex Corp.*, 365 F.3d. 1306, 1314 (Fed. Cir. 2004), *vacated en banc*, *SmithKline*, 403 F.3d 1328, rejected the view that policy may affect claim construction and rejected the suggestion of a *de minimus* exception to infringement. He did however leave open the possibility that a claim, which would make infringers of those using the prior art, may be invalid for indefiniteness in violation of 35 U.S.C. §112. This case presents a somewhat analogous situation to the one addressed in this paper, but there is a significant difference…in the *Seaborg* case the Americium is a byproduct that is probably unrelated to the utility of the prior art and its presence was theoretical. In the *SmithKline* situation, the previously unknown byproduct is related to the utility of the prior art, not to the consumer but in the manufacturing process. Furthermore, SmithKline wanted to prevent all creation of the hemihydrate, including creation that occurred by practicing the prior art.

[133] *In re Shetty*, 566 F.2d. 81 (C.C.P.A. 1977).

[134] *Id.* at 81.

[135] *Id.* at 84-85. The prior art had actually been used combat microbial infestation, but such actions can arguably inhibit appetite.

[136] *Id.* at 86.

since Shetty's method corresponded or inhered to the prior art that it was obvious.[137] The Court went on to state that "inherency is quite immaterial if, as the record establishes here, one of ordinary skill in the art would not appreciate or recognize the inherent result."[138] Once again, more than a dozen years after *Seaborg* the Court's primary concern when considering inherency was whether PHOSITA would have recognized the inherent result.

A similar situation arose in *In Re Oelrich* four years later.[139] Like *Shetty*, the *Oelrich* case dealt with the patenting of a process that was arguably anticipated by the prior art.[140] In *Oelrich*, the patent claims involved a means for generating a "low inertia" carrier frequency to steer the fins of guided missiles.[141] The prior art involved "high inertia" carrier frequencies that *Oelrich* admitted would occasionally fall within the range of his stated frequencies.[142] The Court approved the patent and declared that

> [inherency] could not be established by probabilities or possibilities. The mere fact that a thing might occur is not sufficient … [but] if the disclosure is sufficient to show that the natural result flowing from the operation … of the questioned function, it seems well settled that the disclosure should be regarded as sufficient.[143]

In *Oelrich*, the major issue concerned the inherency of an unknown function that Oelrich claimed to discover.[144] The court, in determining that the claims were not inherent within the prior art did not reach the issue of whether PHOSITA would have recognized the

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[137] *Id.* at 86.
[138] *Shetty*, 566 F.2d. at 86..
[139] *In Re Oerlich*, 666 F.2d. 578 (C.C.P.A. 1981).
[140] *Id.* at 580.
[141] *Id.* at 579-580.
[142] *Id.*
[143] *Id.* at 581, (citing *Hansgirg v. Kemmer*, 102 F.2d. 212, 214 (C.C.P.A. 1939)).
[144] *In re Oelrich,* 666 F.2d at 580.

claim.[145] Based on the parallel analysis of the C.C.P.A. with *Shetty*, the Court would have addressed recognition by PHOSITA if inherency had been found.[146]

Judge Newman authored the Federal Circuit's decision for *In Re Spada*.[147] The *Spada* case dealt with "pressure sensitive adhesives and manufactured articles."[148] These adhesives were created by using "polymers of the same monomers, in overlapping ratios of components" as the prior art, but created a product "quite different" from the prior art.[149] Based on the prior art Smith reference the examiner determined that a *prima facie* case existed that Spada's invention was unpatentable as anticipated.[150] Newman found that the virtual identity of the monomers was disclosed in the prior art, as was the procedure necessary to create the monomers, and the reference described the applicant's claimed invention "sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it."[151] Since the products were described sufficiently to enable PHOSITA to be in possession of them, the claimed invention was anticipated notwithstanding the differences in the final products.[152]

In 1995 the Federal Circuit considered the case of a polymorph version of a previously patented composition.[153] In *Glaxo Inc. v. Novopharm Ltd.*, Glaxo created and received a patent on ranitidine hydrochloride, a "powerful histamine blocker, inhibiting

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[145] *Id.*
[146] *See, e.g., In Re Spada*, 911 F.2d. 705, 708 (Fed. Cir. 1990). Judge Newman outlines the anticipation analysis as 1) all the elements of a claimed invention must be described in a single reference, and 2) the reference must be sufficient to place PHOSITA in possession of it. *See also* FN 71, *supra*.
[147] *In Re Spada,* 911 F.2d. 705.
[148] *Id.* at 706.
[149] *Id.* at 707.
[150] *Id*. at 707-708 and FN 3.
[151] *Id.* at 708.
[152] *In Re Spada*, 911 F.2d. at 708.
[153] *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d. 1043 (Fed. Cir. 1995).

the secretion of stomach acid."[154] Two years after the original patent issued in 1978 (U.S. Patent No. 4,128,658, "the '658 patent") Glaxo used a more efficient new method to manufacture the '658 material.[155] The new process, at one point, created the '658 material into a crystalline version, or polymorph version of the original ranitidine hydrochloride.[156] This version was better suited for commercial production and a second patent was issued covering this new composition (U.S. Patent No. 4,521,431, "the '431 patent").[157] Further tests showed that practicing the new version of manufacture for the '658 material did not always produce the '431 material.[158] In 1991 Novopharm, a Glaxo competitor, filed an ANDA seeking to practice the '431 patent in December of 1995, which was the expiration of the '658 patent, but well before the 2002 expiration of the '431 patent.[159] Novopharm asserted that the '431 patent was anticipated by the '658 patent, and Glaxo sued for technical infringement as permitted by 35 U.S.C. §271(e)(2).[160] In *Glaxo*, the court held that a claim is only anticipated, either expressly or

[154] *Id.* at 1046.
[155] *Id.*
[156] *Id.*
[157] *Id.*
[158] *Glaxo,* 52 F.3d. at 1047.
[159] *Id.* at 1047.
[160] *Id.* In this case it appears that Novopharm had no interest in practicing the '658 patent, but hoped that it would provide it a basis to invalidate the '431 patent. Glaxo does not appear to have had any objection to Novopharm practicing the '658 patent, perhaps because it was aware that Novopharm had no interest in actually practicing the '658 patent. However, compare Glaxo's behavior to that of Schering and SmithKline in *Schering* and *SmithKline.* In those cases Schering and SmithKline attempted to completely prohibit the practice of the prior art, and both found their patents to be invalidated through inherent anticipation. In this case Glaxo did not attempt to prevent practice of the '658 patent despite the knowledge that at some point it would likely morph into the '431 form, and the legal outcome for the '431 patent was much better than for the patents covering DCL and Paxil. The Federal Circuit may have been partly reacting in those cases to the overreaching of both Schering and SmithKline, or it may have taken time to develop a new view on inherency. It is also possible that the facts dictated a different outcome. In both Schering and SmithKline the claimed compositions were metabolites inherent within the claimed composition upon ingestion, whereas that was not the situation in this case. However, the court does go on to require, in dicta, that inherency be recognized by PHOSITA, which was not shown to be the case in either *Schering* or *SmithKline*.

inherently, if all the limitations are contained within a single piece of prior art.[161] But, in order to be anticipated by inherency, it is necessary that the inherency would "be appreciated by one of ordinary skill in the art."[162] The district court had concluded that the '658 patent did not inevitably result in the creation of the polymorph covered by the '431 patent, so anticipation did not exist. The Federal Circuit found this holding not to be clearly erroneous.[163]

Continental Can marked the last occasion where Judge Rader and Judge Newman agreed on a case of inherency, although they would later vociferously disagree as to the actual scope of the case's holding.[164] In *Continental Can*, the controversy concerned whether a prior art process to produce cans necessarily produced "hollow" ribs, even though all sides agreed that the ribs were not shown as hollow in the patent.[165] Judge Newman stated thatwhere inherency is to be found it is necessary to refer to extrinsic evidence, but such 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."[166] The Court vacated summary judgment on the issue of inherency because there was conflicting expert testimony as to whether "hollow" ribs were necessarily created.[167] Later, in *Schering*, Judge Rader claimed that "*Continental Can* does not stand for the proposition that an inherent feature of a prior art reference must be perceived as such by a person of ordinary skill in the art before the

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[161] *Id.* at 1047.
[162] *Id.*
[163] *Id.* at 1047-1048.
[164] *Continental Can Company USA, Inc. v. Monsanto Company*, 948 F.2d. 1264 (Fed. Cir. 1991). For more on Newman's and Rader's subsequent disagreement as to the holding of the *Continental Can* case *see* FNs 18, 19, and 69, *supra*.
[165] *Id.* at 1268-1269.
[166] *Id.* at 1268 (emphasis added).
[167] *Id.* at 1269.

critical date."[168] He instead stated that the holding of the case was that summary judgment was inappropriate when there was conflicting expert testimony.[169] Technically, Judge Rader is correct; the case was remanded for a determination on the first part of the articulated test, so Judge Newman's two part test for inherent anticipation is dicta.[170] Ultimately, the *Continental Can* case was remanded for a determination of whether the "hollow" ribs would be inevitably created since inherency cannot be established by "possibilities or probabilities."[171] However, Judge Newman's test, which required PHOSITA recognition of the inherent presence of the missing descriptive matter to trigger inherent anticipation, is well supported by the prior case law, discussed *supra*.[172]

Subsequent to *Continental Can*, the Federal Circuit required recognition by PHOSITA in order to find anticipation by inherency in *Rosco, Inc. v. Mirror Lite Company*.[173] The *Rosco* case concerned convex school bus "cross-view" mirrors.[174] Rosco owned the '357 design patent (U.S. Design Patent No. 346,357, "the '357 design patent") which covered an "oval, highly convex cross-view mirror with a black, flat metal backing."[175] Mirror Lite's '984 utility patent (U.S. Patent No. 5,589,984, "the '984 patent") covered an "oval cross-view mirror with a varying radius of curvature along the major axis of the convex ellipsoid mirrorlens."[176] Rosco's '357 design patent was filed in

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[168] *Schering*, 339 F.3d. at 1377.
[169] *Id.*
[170] *Continental Can*, 948 F.2d. at 1268.
[171] *Id.*
[172] *Id. See, Rosco Corp. v.Mirror Lite Co.*, 304 F.3d. 1373, 1380-1381 (Fed. Cir. 2002); *Finnegan Corporation v. ITC*, 180 F.3d. 1354, 1366 (Fed. Cir. 1999); *In Re Robertson*, 169 F.3d. 743, 745 (Fed. Cir. 1999); *In Re Paulsen*, 30 F.3d. 1475, 1480-1481 (Fed. Cir. 1994); *In Re Spada*, 911 F.2d. 705, 708 (Fed. Cir. 1990); *In Re Oelrich*, 666 F.2d. 578, 581-582 (Fed. Cir. 1981); *In Re Shetty*, 566 F.2d. 81, 84-85 (C.C.P.A. 1977); *In Re Seaborg*, 328 F.2d. 996, 999 (C.C.P.A. 1964); *Hansgirg v. Kemmer*, 26 CCPA 937 (C.C.P.A. 1939); *see also*, FN 71, *supra*.
[173] *Rosco, Inc. v. Mirror Lite Company*, 304 F.3d. 1373 (2002).
[174] *Id.* at 1376.
[175] *Id*.
[176] *Id*.

April of 1992 and issued in April of 1994 and predated Mirror Lite's patent that had a priority date of September of 1992.[177] Both companies sued one another based on infringement of each other's respective patents.[178] Rosco also alleged that Mirror Lite's '984 patent was inherently anticipated by its own '357 design patent because anyone practicing their design patent would create a mirror with a varying radius of curvature.[179]

The district court granted summary judgment to Rosco on its claim of inherent anticipation, but the Federal Circuit reversed.[180] The Court stated that in order for inherent anticipation to apply, it must be shown that the missing element is "necessarily present in the thing described in the reference, *and* that it would be so recognized by a person of ordinary skill."[181] The relevant question was not whether the use of a "vacuum thermoforming process" inherently resulted in a "varying radius of curvature along the major axis," but rather whether "one skilled in the [would] art read the '357 design patent as showing the varying radius of curvature."[182] The record did not show that PHOSITA would have recognized the '357 design patent as inherently disclosing the '984 patent, so summary judgment was inappropriate.[183]

Crown Operations v. Solutia Inc, decided just a year before *Schering*, confirms that inherent anticipation requires recognition by PHOSITA.[184] *Crown Operations* involved layered films in glass that improve the safety and performance of the glass, most

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[177] *Id*.
[178] *Rosco*, 304 F.3d. at 1376.
[179] *Id.* at 1380.
[180] *Id.*
[181] *Id.* (emphasis added).
[182] *Id.* at 1380-1381.
[183] *Rosco,* 304 F.3d. at 1381.
[184] *Crown Operations International. Ltd. v. Solutia Inc.*, 289 F.3d. 1367 (Fed. Cir. 2002). Crown sued Solutia seeking declaratory relief that Solutia's patent was invalid because it both lacked novelty and was obvious.

notably windshields.[185] The patented films resist shattering while also limiting visual distortion by ensuring that visible light reflection was limited to two percent or less, whereas prior solar films permitted reflection of three percent or greater.[186] The District Court found Solutia'spate nt (U.S. Patent No. 4,973,511, "the '511 patent") to be valid on summary judgment against an invalidity argument of inherent anticipation.[187] The Federal Circuit affirmed: "if the two percent reflectance limitation is inherently disclosed by the [prior art] patent, it must be necessarily present *and* a person of ordinary skill in the art would [be presumed to] recognize its presence."[188] Also, the inherent presence must be established, as a preliminary matter, as something that is more than a "possibility or probability."[189] In this case the Court found that Crown had failed to carry its evidentiary burden of showing the two percent limitation to be necessarily present in the '661 patent.[190]

Finally, the case of *Elan Pharmaceuticals v. Mayo Foundation* may havebeen the initial moment that the two schools of thought regarding inherent anticipation, as represented by Judges Newman and Rader, came into open conflict.[191] Judge Newman authored the opinions in this case, which dealt with a "recipe" to make transgenic mice.[192] The District Court invalidated Elan's '486 and '003 patents (U.S. Patent No. 5,612,486, "the '486 patent" and U.S. Patent No. 5,850,003, "the '003 patent") as being

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[185] *Id.* at 1370.
[186] *Id*. at 1370-1371.
[187] *Id*. at 1371.
[188] *Id.* at 1377 (emphasis added).
[189] *Crown Operations*, 289 F.3d. at 1377.
[190] *Id*.
[191] *Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education and Research*, 304 F.3d. 1221 (Fed. Cir. 2002); *vacated en banc and remanded to panel*, 314 F.3d. 1299 (Fed. Cir. 2002); *aff'd on other grounds*, 346 F.3d. 1051 (Fed. Cir. 2003).
[192] *Id.* at 1223.

anticipated by the Mullan '169 patent (U.S. Patent No. 5,455,169, "the '169 patent).[193] The Federal Circuit originally reversed this decision because the legal requirements of anticipation had not been met.[194] The '169 patent was granted to Mullan after he located a Swedish family susceptible to Alzheimer's disease, isolated the mutated gene and its protein and expressed the mutation.[195] Mullan, however, never produced a transgenic animal.[196] The Elan '486 and '003 patents encompass the method of production, which experts agreed was unpredictable, and the characteristics of transgenic mice.[197] Judge Newman once again states that a finding of inherent anticipation requires that the limitation be inherently present *and* that the missing elements in a reference be recognized by PHOSITA as being present.[198] Judge Newman's opinion pointed out that the Mullan patent did nothing but point out broad recitations of known procedures to make transgenic mice, and, to support the finding of no inherency, pointed out that the mouse produced by Mayo using the Mullan patent technology was the 2,576th mouse screened.[199] Based on the shortcomings of the Mullan patent, Judge Newman determined that Mayo had failed to support its contention that the Elan patents were anticipated inherently.[200]

Judge Dyk dissented expressing concern that the Court was allowing for the patenting of "existing inventions." He said "[while] Elan may have recognized something quite interesting… it has simply not invented anything new."[201] Furthermore, Judge Dyk

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[193] *Id*.
[194] *Id*.
[195] *Id.* at 1224.
[196] *Elan*, 304 F.3d at 1226.
[197] *Id.*
[198] *Id.* at 1227-1228 (emphasis added).
[199] *Id.* at 1228.
[200] *Id.* at 1229.
[201] *Elan* at 1229-1231.

believed that the decision contradicted case law "recently recognized in *In Re Cruciferous Sprout Litigation* … On the issue of inherency 'it matters not that those of ordinary skill heretofore have not recognized these inherent characteristics.'"[202] Either Judge Dyk was extremely persuasive, or he recognized that the Federal Circuit's position regarding inherency appeared to be shifting, because the court granted a rehearing *en banc*, which subsequently vacated Judge Newman's first *Elan* decision.[203] In her second panel decision Judge Newman carefully avoided the issue of inherent anticipation.[204] Instead, she chose to base her decision on a lack of enablement.[205] She stated that prior art must be enabling to inherently anticipate, although, in Newman's opinion, enablement by itself is not sufficient to find inherent anticipation.[206] The Mullan patent, while citing numerous possible methods to produce a mouse, did not suggest which method might reasonably be expected to successfully produce a transgenic mouse.[207] The case was remanded for a determination of whether the Mullan patent *enabled* PHOSITA to create a

[202] *Id.* at 1231.
[203] *Elan Pharmaceuticals v. Mayo Foundation*, 314 F.3d. 1299 (Fed. Cir. 2002).
[204] *Elan Pharmaceuticals v. Mayo Foundation*, 346 F.3d. 1051 (Fed. Cir. 2003). It is also interesting to note that this decision was issued several months after the *Schering* decision. Completely contradictory sets of precedent would have emerged within the Federal Circuit had Judge Newman reissued a decision that upheld the patent for failure to prove anticipation by inherency. Undoubtedly, an *en banc* hearing would have really been held this time to resolve the matter. The fact that such divisions could occur within a Circuit that was created by Congress, to ensure the uniformity of patent opinions would have been troubling. *Federal Courts Improvement Act of 1982*, §402 Pub. L. 97-164. Also, Schering's counsel later implores the court to grant a hearing *en banc* because, he says, the panel should not have ruled on issues similar to those of *Elan* while the *en banc* determination was still pending. *Schering v. Geneva,* Combined Petition for Panel rehearing and Rehearing *en banc* by Plaintiff-Appellant at 4, 2003 WL 24033460 (2003). This is confusing since the court's decision *en banc* is dated December 18, 2002, eight months prior to Schering counsel's request for rehearing, and there is no indication that the *en banc* decision was amended at any point.
[205] *Id.* at 1055-1056.
[206] *Id*. at 1052.
[207] *Id.* at 1056.

transgenic mouse without undue experimentation, while avoiding the issue of whether the Mullan patent was inherently anticipated.[208]

Judge Newman's position in her *Schering* dissent that inherent anticipation requires recognition by PHOSITA seems to be well supported by precedent, but it would also appear that she did not recognize the shift that was occurring within the Federal Circuit regarding matters of inherent anticipation.[209] However, her position seems quite sensible from a case law standpoint. Judge Newman's focus is on whether the subject matter could have been patented sooner. If it could have been, then an additional patent, without a terminal disclaimer, should not be permitted; but if PHOSITA could not, and did not, recognize the subject matter then science has been advanced and a patent is appropriate. This position seems to be driven primarily out of a concern for patent law, in contrast to Judge Rader's position, which appears to be dictated primarily by public policy concerns.

C. *Cases Supporting Judge Rader's View of Inherent Anticipation*

Judge Rader's position also enjoys substantial support. However the cases that most support his contention that PHOSITA need not recognize an inherent property to disqualify that invention from patenting are fairly recent.

An oldest case that can arguably stand for the proposition that recognition by PHOSITA is unnecessary to support a finding of inherent anticipation is *Titanium Metals Corp. of America v. Banner*.[210] This case involved a patent for titanium alloy in which the applicants claimed that their invention was the recognition of the preferable qualities

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[208] *Id*. at 1057. It was still possible that, had the District Court found the Mullan patent enabling, the matter of inherent anticipation could have been brought to the forefront once again.
[209] *Schering*, 438 F.3d at 992. Judge Newman viewed such a substantial shift in precedent as only appropriate after a hearing *en banc*. Fed. Cir. R. 35(a)(2).
[210] *Titanium Metals Corporation of America v. Banner*, 778 F.2d. 775 (Fed. Cir. 1985).

of corrosion resistance, strength, and "ductility" which improves the welding properties of the alloy.[211] Both the examiner and the board rejected the patent application as being obvious to PHOSITA in light of a Russian article that predated the patent application by five years.[212] The applicants then commenced a civil action and the District Court for the District of Colombia ordered the patent to issue.[213] The Federal Circuit reversed the lower court and stated that "Congress has not seen fit to permit the patenting of an old alloy…by one who has discovered its corrosion resistance or other useful properties."[214] The Court seems to acknowledge, *arguendo*, that the applicants were the first to specifically discover these inherent properties in the alloys.[215] However, it stated that "claims cannot be obtained to that which is not new" and the Russian article was found to be sufficient to disclose the alloys, regardless of whether all accompanying properties were also disclosed.[216] By acknowledging that the applicants did discover the properties inherent within the alloys, but are nonetheless prohibited from receiving a patent, the Court seems to downplay the importance of recognition by PHOSITA in the inherent anticipation analysis.[217] It should be noted that this case revolved around recognition of a trait of the prior art without creating anything new. Had a patent been granted then the titanium alloys in question would have been completely removed from the public domain without contributing anything that is, in itself, distinctly patentable. The facts of this case are analogous to those of *General Electric v. Jewel Incandescent Lamp Co.* where the

[211] *Id.* at 776-777.
[212] *Id*. at 781.
[213] *Id.* at 776.
[214] *Id*. at 782.
[215] *Titanium Metals*, 778 F.2d. at 782.
[216] *Id*.
[217] Both the examiner and the Board relied on a finding that PHOSITA would have known of the properties based on the Russian publication to justify their denial of a patent originally.

court specifically found that discovery of a pre-existing trait within a prior art reference does not impart patentability.[218]

Soon after *Titanium Metals* the Court ruled, in *Verdegaal Brothers v. Union Oil Company of California*, that recognition by PHOSITA was not necessary to reach a finding of inherency.[219] *Verdegall Brothers* involved the infringement of a process for making liquid fertilizer by first mixing the elements in a "nutritive heat sink" to absorb heat- known as a "heel."[220] A "heel" is nothing more than a previously mixed batch of liquid fertilizer.[221] Verdegall Brothers owned a patent on the process of making liquid fertilizer by adding sulfuric acid rapidly to the heel (U.S. Patent No. 4,310,343, "the '343 patent").[222] The prior art Stoller patent (U.S. Patent No. 4,315,763, "the '763 patent") also called for the creation of a heel.[223] Verdegaal Brothers attempted to distinguish their patent as novel by claiming that the Stoller patent did not "recognize the 'inventive concept' that the heel functioned as a heat sink."[224] The Court rejected this argument and stated that Union Oil's burden "was limited to establishing that Stoller disclosed the same process. It did not have the additional burden of proving that Stoller recognized the heat sink capabilities of using a heel."[225] The Court went further and declared "even assuming Stoller did not recognize that the heel of his process functioned as a heat sink, that property was inherently possessed by the heel in his disclosed process, and, thus, his process anticipates the claimed invention."[226] Once again, the Court seems to shy away

[218] *General Electric*, 326 U.S. 242. *See* FN 12, *supra*.
[219] *Verdegaal Brothers, Inc. v. Union Oil Company of California*, 814 F.2d. 628 (Fed. Cir. 1987).
[220] *Id.* at 630.
[221] *Id*.
[222] *Id*. at 632.
[223] *Id*.
[224] *Verdegaal Brothers*, 814 F.2d. at 633.
[225] *Id*.
[226] *Id*.

from the importance of recognition by PHOSITA and stated a willingness to invalidate the '343 patent even if the prior art reference did not recognize that the heel functioned as a heat sink.[227] Ultimately, the Federal Circuit reversed the jury's verdict of infringement as being unsupported by substantial evidence since the '763 patent inherently anticipated all the properties of the '343 patent.[228]

Another example of knowledge by PHOSITA not being necessary to prevent patenting of a product can be found in *Abbott Laboratories v. Geneva Pharmaceuticals*.[229] In this case Byron Chemical Company, Inc., an Australian company, sold three lots of anhydrous terazosin hydrochloride between 1989-1991.[230] Two lots were sold to Geneva Pharmaceuticals and one lot to Warner Chilcott Laboratories.[231] Abbott Labs subsequently developed the same anhydrous terazosin hydrochloride independently and began to market it as "Form IV" of a medication to treat hypertension and "benign prostatic hyperplasia."[232] The patent application for Abbott's "Form IV" anhydrous terazosin hydrochloride was filed October 18, 1994 (U.S. Patent No. 5,504,207, "the '207 patent").[233] Geneva Pharmaceuticals, Novopharm Ltd., and Invamed, Inc. filed ANDAs to market generic versions of Form IV and alleged that the '207 patent was invalid as being on sale for more than one year.[234] Abbott countered that neither Byron Chemical nor the defendants knew that they were dealing with "Form IV", and since they "did not 'conceive' the subject matter [of the transaction] … there was no

[227] *Id.* at 633.
[228] *Id.* at 633-634.
[229] *Abbott Laboratories v. Geneva Pharmaceuticals*, 182 F.3d. 1315 (Fed. Cir. 1999).
[230] *Id*. at 1317.
[231] *Id*.
[232] *Id*. at 1316.
[233] *Id*. at 1317.
[234] *Abbott Labs*, 182 F.3d. at 1318; 35 U.S.C. §102(b).

invention on sale."[235] The Court rejected this argument and said what is important is that the three commercial sales before the critical date occurred, and the knowledge of the parties is irrelevant.[236] "[I]f a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the transactions recognize that the product possesses the claimed characteristics."[237] *Abbot Labs* is consistent with Judge Rader's view that recognition by PHOSITA of inherent properties is not relevant in determining whether a patent may issue. Judge Rader himself explained this view quite clearly in *Atlas Powder Company v. Ireco Inc*., which was decided a month after *Abbott Labs*.[238]

Atlas Powder Case involved two patents for explosive compositions (U.S. Patent No. 4,111,727, "the Clay patent;" and U.S. Patent No. RE 33,788, "the reissue patent").[239] The district court found the patents to be invalid as anticipated by either the '551 patent (U.S. Patent No. 3,161,551, "the Egly patent") or by the foreign '546 patent (U.K. Patent No. 1,306,546, "the Butterworth patent").[240] Neither of the prior art patents cited the specific composition of the Clay or of the reissue patent, but the prior art patents disclosed the same chemical compositions as the Clay and reissue patents in overlapping amounts.[241] In affirming the district court, Judge Rader stated that the only limitation not arguably within the prior art patents is the requirement that there be "sufficient aeration"

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[235] *Abbott Labs*, 182 F.3d. at 1318. Between *Abbott Labs*, *Atlas Powder*, *MEHL/Biophile* (decided three weeks after *Atlas*) Judge Rader had begun assembling a recent string of cases that would support his view that there was no requirement of recognition by PHOSITA to trigger inherent anticipation. *EMI Group* would follow two years later, and this string of case law would form the substantive basis for the decisions in *Schering* and *SmithKline.*

[236] *Id*. The parties in this case clearly possessed "ordinary skill in the art." The court's rejection of the importance of their knowledge underscores that PHOSITA knowledge is an objective inquiry.

[237] *Id*. at 1319.

[238] *Atlas Powder Company v. IRECO Inc.*, 190 F.3d. 1342, 1347 (Fed. Cir. 1999).

[239] *Id*. at 1343.

[240] *Id*.

[241] *Id*. at 1345.

in the composition.[242] This limitation was found to be "inevitably and inherently" present within the prior art and the claims were unpatentable because the discovery of a "previously unappreciated property of a prior art composition … does not render the old composition patentably new."[243] Thus, even assuming that the applicants in this case did initially discover the property of the prior art composition, that trait is unpatentable regardless of the fact that there was no recognition by PHOSITA because the properties were inherently present within the prior art.[244] It is worth noting, however, that Judge Rader, while attempting to make clear that recognition by PHOSITA is not necessary to trigger inherent anticipation, explicitly found that "those of ordinary skill in the art at the time the patent application was filed knew [of the importance of aeration]."[245] Judge Rader's conclusion was that since "sufficient aeration was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the claimed invention]."[246] So in the *Atlas Powder* case Judge Rader made it clear that the claimed invention was inherent in the prior art, and there was recognition by PHOSITA of the claimed "aeration"; but also believed that there was no need to find recognition by PHOSITA of the inherent trait in order to trigger anticipation by inherency.

Judge Rader's apparent discomfort with explicitly abandoning the requirement for recognition by PHOSITA comes to fore again a month after *Atlas Powder* in *MEHL/Biophile International Corp. v. Milgraum*.[247] In this case the plaintiffs sued the defendants for infringing their patent (U.S. Patent No. 5,059,192, "the '192 patent")

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[242] *Id*.
[243] *Atlas Powder*, 190 F.3d. at 1347.
[244] *Id*. at 1348.
[245] *Id.* at 1347.
[246] *Id.* at 1348.
[247] *MEHL/Biophile International Corp. v. Milgraum*, 192 F.3d. 1362 (Fed. Cir. 1999).

covering a method to remove hair using a laser that destroys "the papilla, thereby preventing hair regrowth."[248] The District Court granted summary judgment of invalidity based on a manual that anticipated all claims.[249] Judge Rader affirmed the invalidity of the patent, but based his holding on "the Polla article," which disclosed all elements of the patent, rather than the manual cited by the district court. He stated that 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 well settled that the disclosure should be regarded as sufficient."[250] Rader goes on to state "where, as here, the result is a necessary consequence of what was deliberately intended, it is of no importance that the article's authors did not appreciate the results."[251] He added that "inherency is not necessarily conterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of prior art."[252] But, once again, Judge Rader covers his bases and states that "it is not a question of probabilities as to whether a person of ordinary skill following the teachings of the article will align the laser light applicator over a hair follicle," because the Polla article dealt with guinea pigs and "[n]o one disputes that guinea pigs have hairy backs."[253] So, while attempting, in dicta, to claim that no recognition by PHOSITA is necessary Judge Rader ensures, in making his finding of inherent anticipation, that everyone understands the claimed results of the invention are inevitable and recognition by PHOSITA is present.

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[248] *Id*. at 1364.
[249] *Id*.
[250] *Id*. at 1365.
[251] *Id*. at 1366.
[252] *MEHL*, 192 F.3d. at 1365. (citing *In Re King*, 801 F.2d. 1324 (Fed. Cir. 1986).
[253] *Id*.

After *Atlas* and *MEHL/Biophile*, Judge Rader's next opportunity to address the issue of inherent anticipation was *EMI Group North America v. Cypress Semiconductor.*[254] *EMI* concerned two patents owned by EMI for metallic fuses for semi-conductor chips (U.S. Patent No. 4,826,785, "the '785 patent" and U.S. Patent No. 4,935,801, "the '801 patent").[255] The '801 patent "claims a structure for a metallic fuse with an optically absorptive upper layer, and the '785 patent claims a method for fabricating and blowing a fuse."[256] Manufacturers "blow" dysfunctional links in a chips using a laser beam to sever the connectors, and chips are built with redundant circuits to allow for this.[257] An expert testified at trial that the claimed method of a theoretical vapor-induced explosion was impossible because the metal would expand under the heat of the laser and crack the corners of the fuse, destroying the chip.[258] The expert believed that if he was wrong, and such an explosion was possible without destroying the chip, then the explosive mechanism claimed in the fuse would be inherent in all similar prior art fuses.[259] Judge Rader found that several prior art fuses disclosed the claimed fused structure that would make such a severing process possible without destroying the chips, although the previous inventors had not recognized the trait.[260] It was enough that the

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[254] *EMI Group North America v. Cypress Semiconductor*, 268 F.3d. 1342.
[255] *Id.* at 1344.
[256] *Id.*
[257] *Id.*
[258] *Id.* at 1346.
[259] *EMI*, 268 F.3d. at 1347.
[260] *Id.* at 1349-1350 (citing *Atlas Powder v. Ireco*, 190 F.3d. at 1347, also authored by Judge Rader). Perhaps the most interesting portion of Judge Rader's opinion in *EMI* is that he makes his first clear attempt to partially abandon the PHOSITA recognition requirement of inherent anticipation. He stated

> [the requirement] that a person having ordinary skill in the art must recognize that the missing descriptive matter is necessarily present in the reference, may be sensible for claims that recite limitations of structure, composition of matter, and method steps which could be inherently found in prior art. Such recognition by one of ordinary skill may be important for establishing that the descriptive matter would inherently exist in every combination of a claim's limitation … theoretical mechanisms or rules of natural that are

prior art disclosed the structure of the fuse because doing so "inherently discloses the law of nature by which the fuses are able to rupture under the heat of a laser."[261]

The case of *In re Cruciferous Sprout Litigation* is a great example of exactly the type of policy matters that Judge Rader seems most concerned with in his attempt to abandon the requirement that PHOSITA recognize an inherent trait for anticipation to be triggered.[262] This case, which involved neither Judge Rader nor Judge Newman, revolves around method patents for growing and eating sprouts to reduce the risk of cancer (U.S. Patent No. 5,725,895, "the '895 patent"; U.S. Patent No. 5,968,567, "the '567 patent"; and U.S. Patent No. 5,968,505, "the '505 patent").[263] The patent applicants discovered that sprouts induce Phase 2 enzymes, which in turn reduce the level of carcinogens.[264] The panel agreed with Judge Rader's position that recognition by PHOSITA was not necessary for inherent anticipation to apply.[265] They stated that the carcinogen reducing characteristics of a sprout are "inherent characteristics" and it does not matter that those of ordinary skill have not recognized the traits.[266]

> recited in a claim, that themselves are not patentable, however, do not need to be recognized by one of ordinary skill in the art for a finding of inherency.

Id. at 1350-1351. So Rader would still require recognition by PHOSITA in cases of patents covering structural matter, compositions, and methods; while not requiring recognition by PHOSITA for matter that is not patentable to start with. In the case of metabolites, they are brought about through the body's natural digestive process, but the metabolites themselves are compositions or structural in nature; yet Judge Rader is later unwilling to allow for the patenting of newly discovered metabolites brought about due *in vivo* metabolization.

[261] *Id*. at 1351.

[262] *In Re Cruciferous Sprout Litigation*, 301 F.3d. 1343 (Fed.Cir. 2002).

[263] *Id*. at 1345.

[264] *Id*.

[265] *Id*. at 1350.

[266] *Id*. The Supreme Court has recently heard arguments in a case very similar to *In Re Cruciferous Sprout Litigation*. The case is *Laboratory Corporation of America Holdings v. Metabolite Laboratories*, No. 04-607, oral arguments held March 21, 2006. In this case a patent was gained for a process that 1) measured the body's fluid for an elevated level of total homocysteine and 2) correlated the result with an accompanying deficiency of cobalamin or folate, (U.S. Patent No. 4,940,658, "the '658 patent"). Originally Lab Corp received a license from Metabolite to use a patented test to measure the body's level of homocysteine, however, Lab Corp soon switched to a test developed by Abbott Labs that was cheaper

The Court in the *Cruciferous Sprout* case was grappling with the troubling corollary of Judge Newman's PHOSITA rule: if someone finds an inherent trait that was specifically unrecognized but whose end result was known, that individual should technically, under the PHOSITA rule, be entitled to a patent. In this case, people know that it is healthy to eat sprouts, but did not know that cruciferous sprouts induced Phase 2 enzymes that reduced carcinogens and, in turn, cancer. Yet, despite being technically qualified for a patent under the PHOSITA rule, something did not seem right about granting a patent in this instance, and doing so could make potential infringers of anyone attempting to practice the prior art. Likewise, in the *Schering* case, which followed *Cruciferous Sprout* by a year, anyone practicing the prior art loratadine could have been infringing on the new DCL patent.[267] To address this problem Rader attempted to abandon the PHOSITA rule altogether in *Schering* and instead prohibit patents for inherent results regardless of whether there was, or could have been, recognition by PHOSITA prior to the patent application.[268] This rule serves public policy by ensuring that the public is never threatened with infringement from practicing the prior art and ensures that material in the public domain remains in the public domain. But the rule also bypasses several alternative, less severe methods of ensuring this goal, like Judge

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and more efficient. Metabolite then sued Lab Corp claiming that whenever someone received a test result that showed elevated homocysteine, and then correlated the result to a deficiency in cobalamin or folate, the mere correlation in their minds constituted infringement. The Supreme Court seemed most interested in whether such a scientific correlation is patentable under §101. All sides agreed that the patent holders clearly discovered the correlation and, in doing so, overturned what had been for decades the "conventional wisdom" relating to elevated levels of homocysteine. But complicating matters is the fact that Lab Corp never explicitly raised §101 until after the Supreme Court asked the Government to address the issue of patentability. After the Supreme Court inquired into §101 it quickly became the linchpin of Lab Corp's case. Both Metabolite and the Justice Department took the view that the issue of §101 patentability was not properly before the court, and it is possible that the Supreme Court could use this ground to dismiss the case.

[267] *Schering*, 339 F.3d. at 1375.

[268] *Id.* at 1377.

Newman's suggestion that Schering may not prevent others from practicing the prior art.[269]

Judge Rader's view rejecting the need for recognition by PHOSITA was well received in the subsequent decision of *The Toro Company v. Deere & Company*.[270] In the *Toro* case the Federal Circuit made clear that the new rule, that recognition by PHOSITA was no longer required to find anticipation by inherency, was applicable across the board and not limited to situations concerning metabolites.[271] The *Toro* case involved a method to treat turf by aerating the turf with sporadic injections of liquid fertilizer (U.S. Patent No. 5,207,168, "the '168 patent").[272] John Deere alleged that Toro's patents were anticipated by the prior art patent (U.S. Patent No. 4,907,516, "the '516 patent") which also dealt with pulse injections.[273] John Deere alleged that practicing the '516 patent would lead to infringement of the Toro patents because the prior art taught all the spacing and pressure parameters that would lead to the aeration Toro claimed.[274] The District Court denied John Deere's motion for summary judgment because, among other reasons, it found that PHOSITA would not have recognized the Toro characteristics at the time the '516 patent was filed.[275] The Federal Circuit corrected the district court on this subject and stated "the fact that a characteristic is a necessary feature or result of a prior art embodiment … is enough for inherent anticipation, even if that fact was unknown at the time prior to invention."[276] Ultimately, the Court upheld the district court's denial of summary judgment because John Deere did

[269] *See Schering*, Judge Newman's dissent to denial of rehearing *en banc*, 348 F.3d. at 993-994.
[270] *The Toro Company v. Deere & Company*, 355 F.3d. 1313 (Fed. Cir. 2004).
[271] *Id*. at 1320.
[272] *Id*. at 1314, 1317.
[273] *Id*.
[274] *Id*. at 1318.
[275] *Toro*, 355 F.3d. at 1320.
[276] *Id*. at 1321.

not supply adequate evidence to support such a judgment, but the matter was remanded for a determination of the validity of the '168 patent.[277]

Another Federal Circuit panel also endorsed *Schering's* holding in the pharmaceutical context and found that recognition by PHOSITA is not necessary to find invalidity due to inherent anticipation. *SmithKline Beecham Corp. v. Apotex Corp.* involves the antidepressant drug PAXIL®. The case was originally tried before Circuit Court Judge Richard Posner, sitting by designation.[278] PAXIL® was developed over a long period of time. The initial patent for paroxetine was first obtained in 1977 by a British company called Ferrosan (U.S. Patent No. 4,007,196, "the '196 patent").[279] Ferrosan then licensed the '196 patent to SmithKline.[280] The '196 patent covered an "anhydrous" form of the paroxetine. Because they can become "soggy", anhydrous materials are difficult to manufacture because of the special care that must be taken to maintain their viability.[281] In 1985, however, a SmithKline researcher realized the material had naturally morphed into a "pseudo polymorph," known as a hemihydrate, which is much more stable and easily manufactured than the original anhydrous version of the drug.[282] SmithKline received a second patent for this new version of paroxetine (U.S. Patent No. 4,721,723, "the '723 patent").[283] This second patent began to be marketed as PAXIL® in 1993.[284]

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[277] *Id.*
[278] *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d. 1011, 1013 (N.D. Ill. 2003).
[279] *Id*. at 1015.
[280] *Id*.
[281] *Id*. at 1017.
[282] *Id*.
[283] *SmithKline*, 247 F.Supp at 1017.
[284] *Id*.

Complications soon arose due to the nature of the anhydrous version of paroxetine.[285] The original '196 patent on peroxetine expired in 1992; however, when Apotex announced plans in 1998 to work with the '196 patent to make a generic version of anhydrous peroxetine, SmithKline sued them.[286] SmithKline's complaint was that any version of the '196 material was likely to contain some ammount of the '723 hemihydrate, whose patent would not expire until 2006.[287] The basis for SmithKline's claims were that, first, the '196 patent is likely morph into the protected hemihydrate form of peroxtine, which is how SmithKline originally discovered the '723 material.[288] Second, even if the '196 material did not morph into the '723 material it is highly likely that any Apotex manufacturing location would be "seeded" with PAXIL®.[289] The "seeding" phenomenon is likely to occur anytime that the '723 material is handled roughly and small crystals come lose and then implant in the '196 material; the '723 material will then multiply within the '196 material to a saturation point, within pharmaceutical manufacturing plants, of several percent.[290] Lastly, SmithKline claims that even if Apotex can prevent any of the '196 material from morphing into the '723 material, infringement will occur when a patient ingests the '196 material because small amounts of the '723 material will invariably be created within their damp, wet stomachs.[291]

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[285] *Id.* at 1020.
[286] *Id*. at 1023.
[287] *Id.*
[288] *SmithKline*, 247 F.Supp 2d, at 1017.
[289] *Id.* at 1020-1021.
[290] *Id*. at 1020-1023. Within areas of high heat and humidity it is possible that the '196 material would fully convert to the '723 hemihydrate. It is also standard practice to experiment with related compounds in an attempt to determine what differences may exist. In this case Apotex would likely experiment with the '723 material when producing the '196 material.
[291] *Id.* at 1014-1015. The previous Judge on the case had already excluded evidence of contributory infringement brought on by ingestion of the '196 patent, Posner agreed that a finding of contributory

Judge Posner addressed the concern of natural morphing of the '196 material to a hemihydrate by limiting protectability of the '723 patent to "commercially significant amounts."[292] He then limited the ability of SmithKline to allege infringement due to "seeding" by creating an equitable defense that the patent holder caused the infringement.[293] Posner further justified this defense by stating that to hold otherwise would allow SmithKline more protection for the '723 patent than patent law intended.[294] Judge Posner also ruled that Apotex had not shown to his satisfaction that the '196 patent will inherently contain the '723 material, thereby allowing the '723 patent to be valid over a claim of anticipation by inherency.[295] Judge Posner's ultimate conclusion was that the '723 patent was valid but not infringed.[296]

Judge Rader authored the two subsequent opinions in *SmithKline*. In the initial panel decision, Judge Rader rejected nearly all of Judge Posner's conclusions but ultimately found the patent to be invalid for public use.[297] Among Rader's conclusions were that it was error to limit the claims in the '723 patent to commercially significant amounts because claim construction is "not a policy driven inquiry," and the proper claim

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infringement based on those facts would be inappropriate since Apotex had no desire to produce such a result. Additionally, Judge Posner found that under normal manufacturing conditions the growth of the '723 material would occur quickly but level off at "a few percentage points," *Id.* at 1023. Judge Posner also accepted expert testimony that the '723 material would have to be present "in the high double digits to contribute any commercial value to the production of the '196 material" since the two products are bioequivalent the only advantage gained is through the more efficient production allowed by the '723 material, *Id.* at 1024-1025.

[292] *Id*. at 1029-1030. The testimony at trial indicated that hemihydrate needed to be present in amounts in the "high double digits" in order to be of any commercial significance. This was highly unlikely in the carefully controlled environment of a pharmaceutical plant, and Judge Posner stated that creation at such levels would have to be intentional and would serve only to expose a drug manufacturer to clear liability for infringement.

[293] *SmithKline*, 247 F.Supp at 1043.

[294] *Id*. at 1046.

[295] *Id*. at 1035-1036.

[296] *Id*. at 1052.

[297] *SmithKline*, 365 F.3d. 1306, 1333 (Fed. Cir. 2004).

construction of the '723 patent encompassed all hemihydrate.[298] Also, he concluded that the previous Judge, from whom Judge Posner took over the case but by whose procedural decisions Posner was bound, abused his discretion in failing to hear evidence on SmithKline's claims of contributory infringement through ingestion.[299] Additionally, while he understood that Posner was concerned about the implications of finding Apotex liable for infringement that occurred by practicing something in the public domain, Posner's equitable defense was not necessary since the patent could be dispensed with on alternative grounds.[300] Rader then invalidated the patent for being in public use under §102(b) by reasoning that the individuals taking part in the clinical tests were not bound by confidentiality.[301] Amazingly, Rader passed on the initial opportunity to invalidate the '723 patent for inherent anticipation despite the fact that SmithKline alleged infringement through *in vivo* degradation, and despite his specifically warning SmithKline that success on that allegation would result in invalidation of the patent for inherent anticipation.[302]

The Circuit then vacated the panel decision *en banc* and remanded the matter back to Judge Rader's panel, knowing his likely decision would be to hold the patent invalid as inherently anticipated.[303] In writing his second *SmithKline* decision Rader once again corrected the original mistakes made in Judge Posner's district court decision,

[298] *Id*. at 1313-1314. Judge Rader specifically rejected Judge Posner's claim construction limiting the '723 material to "commercially significant amounts," *SmithKline* at 1029-1030. Judge Rader stated that "claim construction is not a policy driven inquiry … [and] the scope of patent claims can neither be broadened nor narrowed based on abstract policy considerations regarding the effect of a particular claim meaning." *SmithKline Beecham v. Apotex*, 365 F.3d. 1306, 1314 (Fed. Cir. 2004); *opinion vacated en banc by* 403 F.3d. 1328 (Fed. Cir. 2005); *aff'd on other grounds* 403 F.3d. 1331 (Fed. Cir. 2005).
[299] *Id.* at 1311.
[300] *Id*. at 1316.
[301] *Id*. at 1317.
[302] *SmithKline*, 365 F.3d. at 1320.
[303] *SmithKline Beecham v. Apotex*, 403 F.3d. 1328 (Fed. Cir. 2005). *See SmithKline*, 365 F.3d. at 1320.

but then went on to invalidate the '723 patent based on inherent anticipation.[304] Rader found the '196 patent was enabled and, if practiced, would inevitably result in at least trace amounts of hemihydrate.[305] Thus, he concluded that the record had shown by clear and convincing evidence that the '196 patent inherently anticipated the '723 patent since, under *Schering*, inherent anticipation did not require PHOSITA to "recognize the inherent disclosure at the time the prior art is created."[306] Additionally, the Court refused to save the patent by requiring that Apotex take extraordinary measures to practice the prior art without infringing the '723 patent.[307] In invalidating the '723 patent, Judge Rader reiterated his dicta from *Schering* that some protection could be allowed for the '723 hemihydrate, but that SmithKline could not receive a patent over the "bare compound."[308]

SmithKline signals the Federal Circuit's wholehearted acceptance of Judge Rader's position on inherent anticipation. The only exception was Judge Newman, who once again dissented to the denial of a rehearing *en banc*. Judge Newman objected to the Circuit's decision to reverse the panel regarding public use during clinical trials, while leaving the panel's enlargement of inherent anticipation in place.[309] Judge Newman saw this as an even larger expansion of inherent anticipation because there was "no evidence whatsoever that the hemihydrate existed at the time that the anhydrate application was filed, and no evidence that such existence would have been recognized by a person of

[304] *SmithKline*. 403 F.3d. at 1335-1343.
[305] *Id.* at 1344.
[306] *Id*. at 1343.
[307] *Id.* at 1345.
[308] *SmithKline*, 403 F.3d. at 1346. *Schering,* 339 F.3d. at 1381. See *also*, pg. 17, *supra*.
[309] *SmithKline v. Apotex*, 403 F.3d. at 1329, *Judge Newman's dissent from the order declining rehearing en banc*.

skill in the field of the invention."[310] Newman contended *Continental Can* was still good law, and the question should still be whether a substance's existence would have been known by PHOSITA, not whether "it might have lain hidden in minuscule amount, undetected, unsuspected, and unknown."[311] "[O]nly after a compound is identified does it become subject to patenting; if its existence is not reasonably known to persons of skill in the field, its later discovery cannot be retrospectively "inherently anticipated."[312]

SmithKline makes sense from a public policy standpoint, but it also appears that the Federal Circuit went further than necessary to protect the public. The new question is whether the Court's new doctrine on inherent anticipation is consistent with the goals of patent law, or is it drawing a categorical limitation that refuses patents to discoveries that significantly advance science? The *Seaborg* case suggested that something which is inherently present, but unknowable, is still patentable if it meets all the other eligibility requirements of patents. Judge Newman also made a reasonable suggestion that patents be interpreted in a manner that does not prevent the practicing of the prior art. This issue is especially relevant in the area of pharmaceuticals, where it is not always possible to understand all the metabolites that may possess utility. The Hatch –Waxman Act acknowledges that pharmaceuticals play a special role in our society. That special role can lead to statutoryrevisions that recognize , not only the role of pharmaceuticals in our society, but also the difficulty in claiming metabolites that can possess actual utility and offer value to a patent holder.

III. Hatch-Waxman

[310] *Id.*
[311] *Id.* at 1330.
[312] *Id.*

Congress attempted to address the concerns of both brand name pharmaceutical companies and the public through the passage of the "Hatch-Waxman Act."[313] The goal of the act was to provide sufficient protection to pharmaceutical companies to spur the research and development of new drugs, while also allowing generic drug manufactures to quickly bring their drugs to market.[314]

Pharmaceutical manufacturers were protected by the Hatch-Waxman Act by becoming eligible for a patent term restoration.[315] Patent extension under §156 is limited to a single instance for the active ingredient of a new drug product, and the extension is limited to "the time equal to the regulatory review period for the approved product."[316] The extension restoration period for the patent was capped at five years, and total patent protection was not permitted to extend beyond fourteen years from the date that the FDA approved the new drug application.[317] Pharmaceutical manufacturers are entitled to list any patents related to a drug in the "Orange Book", and a generic drug manufacturer must address the validity of each of those patents before FDA approval of an abbreviated new drug application (ANDA) can be finalized.[318] Should a pharmaceutical company sue a generic manufacturer for technical infringement after their filing of an ANDA, a thirty month stay is granted to the FDA approval process pending the outcome of litigation.[319] Subsequent listings in the "Orange Book" can result in consecutive stays which often

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[313] *The Hatch Waxman Act* (The Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), Codified at *21 U.S.C. §355* (generic drugs) and *35 U.S.C. §156 (c)* (patent term restoration).
[314] *Andrx Pharmaceuticals v. Biovail Corporation*, 276 F.3d. 1368, 1371 (Fed. Cir. 2002).
[315] *Arnold Partnership v. Dudas*, 362 F.3d. 1338, 1340-1341 (2005).
[316] *Id.* at 1340-1342. 35 U.S.C. §156.
[317] *Merck & Co. v. Kessler*, 80 F.3d. 1543, 1547 (Fed. Cir. 1996). 35 U.S.C. §156(g)(6)(B)(limiting extension to five years), and 35 U.S.C. 156(c)(3)(limiting overall protected time period after FDA approval to fourteen years).
[318] *Adrx*, 276 F.3d. at 1371. 21 U.S.C. §355(b)(1) and (c)(2).
[319] *Id*. 35 U.S.C. 271(e)(2)(2005). This section makes the filing of an ANDA technical infringement if the patents covering a drug are still valid, regardless of whether any drug is ever sold.

have the affect of delaying final approval to proposed generic drugs for periods much longer than the originally intended thirty months.[320] This unintended extension was rendered virtually immune from judicial review by the Federal Circuit's decision in *Mylan*, which held that district courts have no statutory authority to shorten the thirty month stay granted by an Orange Book listing, but did suggest administrative relief could be sought under the Administrative Procedure Act.[321] Additionally, the court subsequently found in *Mylan v. Thompson* that no private right of action existed to secure the delisting of a questionable patent from the "Orange Book."[322] Although antitrust action exists, pharmaceuticals companies have proven adept at avoiding such liability.[323]

The provisions of the Hatch-Waxman Act that were intended to protect brand-name pharmaceutical companies were meant to spur further research and development by allowing these companies to maximize their investments in various drugs, however, the act was a tradeoff. The benefit that the brand-name pharmaceuticals received was that the patent term of their drugs were tolled for the time required to receive regulatory

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[320] *See* FN 61, *supra*.

[321] *Mylan*, 276 F.3d. at 1376. The District Court in this case refused to consider Andrx's claim that the APA could be used to require the FDA to delist patents from the orange-book because Andrx failed to plead an APA in their complaint, thus violating the FDA's right to notice. Judge Dyk agreed with the District Court's determination that the APA violation could not be considered, but stated that Adrx complaint "had [implied] certain procedural facts that may give rise to an APA claim" if properly pleaded, *Id.* at 1374.

[322] *Mylan v. Thompson*, 268 F.3d. 1323, 1327-1333 (Fed. Cir. 2001).

[323] *See, e.g. SmithKline Beecham v. Apotex*, 383 F.Supp.2d. 686 (E.D. Penn. 2004). In this case SmithKline was sued by Torpharm for antitrust violations arising out of their consecutive listings of patents in the "Orange Book" relating to their anti-depressant PAXIL®. Under the Hatch-Waxman Act the first company to file an ANDA that proves the invalidity of a patent receives a 180 day exclusive marketing period, during which other generic companies may not market their own generic versions of a drug. SmithKline entered into a licensing agreement with a generic drug company in order to destroy Torpharm's ability to receive the exclusive 180 day marketing period. The district court found that this agreement alone did not constitute an anti-trust injury, although the court did leave in place Torpharm's tortuous interference claims arising under Pennsylvania law. A problem that still remains is that, due to the lengthy nature of anti-trust actions, it is possible that a pharmaceutical may still repeatedly file consecutive patents in the orange book that delay the approval of generic drugs until after the original patents have expired. This alone would frustrate Hatch-Waxman's goal of making generic drugs quickly available to the public.

approval, but their overall protection could not extend beyond fourteen years.[324] This extension could only be granted once and had to be filed prior to the expiration of the original patent.[325]

In exchange the generic companies received an extended experimental use privilege so that they could more quickly market generic versions of drugs.[326] Prior to Hatch-Waxman, pharmaceutical companies received a de facto extension on expired patents because generic drug manufacturers were required to conduct their own testing program to demonstrate safety and efficacy to the FDA for marketing approval.[327] Hatch-Waxman allows generic drug manufacturers to rely on the clinical trial data provided to the FDA by the original marketer of a drug in order to fulfill the FDA regulatory requirements.[328] These applications that rely on a third party's proof of safety and efficacy are known as ANDAs.[329] ANDA applicants need only show that the drug they seek to market is the bioequivalent of the originally approved drug.[330] Also, generic drug manufacturers are permitted to "make and use the patented product, even though the patent hadn't yet expired, in order to demonstrate bioequivalence."[331] To further encourage the entry of generic drugs into the marketplace, the first generic manufacturer to successfully apply for an ANDA receives a 180 day exclusive marketing period, during which time this manufacturer and the original manufacturer would exist as

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[324] *SmithKline*, 247 F.Supp.2d at 1019. 35 U.S.C. §156 (2004).
[325] *Arnold Partnership*, 363 F.3d. at 1340 (2004).
[326] *SmithKline*, 247 F.Supp. 2d. at 1018.
[327] *Merck*, 80 F.3d at 1546.
[328] *Id.* 21 U.S.C. §355(j)(7)(B).
[329] *Merck*, 80 F.3d. at 1547.
[330] *SmithKline*, 247 F.Supp. 2d. at 1018.
[331] *Id.* The "fair use" exemption for testing under 35 U.S.C. §271(e) was recognized by the Supreme Court in *Integra Lifesciences v. Merck KGaA*, 545 U.S. 193 (2005), 125 S.Ct. 2372. This protection was found to extend to any activities "reasonably related" to obtaining government approval of a device or composition, even if the ultimate goals are economic in nature.

"duopolists."[332] Through these steps the Hatch-Waxman Act aimed to expedite the marketing of generic versions of brand name drugs.[333] However, as previously discussed, pharmaceuticals have still proved adept at using orange book patent listings to delay the entry of generic drugs into the market.

The provisions of Hatch-Waxman demonstrate that Congress already recognizes that pharmaceuticals possess unique qualities, within themselves and to the public, that necessitate special treatment. The patent extension for time lost marketing a drug because of lengthy regulatory approval processes is a great example of the extreme lengths to which Congress will go to ensure continued research and development. Additionally, Congress arguably permits pharmaceutical companies to abuse the "Orange Book" listing regimen intended to prevent the FDA from approving the manufacture of a generic drug still protected by a patent.

Due to the seeming willingness by Congress to take all reasonable steps to allow pharmaceutical companies to maximize the value of drug patents, so as to encourage future research and development, it is time for Congress to reevaluate the patent law, as related to biological and pharmaceutical inventions, in light of *Schering* and *SmithKline*. The primary problem with the *Schering* and *SmithKline* cases is that the Federal Circuit in adopting a hard-line rule, which is sensible in light of public policy, has foreclosed patents for metabolites that are unrecognized but that provide utility. The *Schering* case ultimately prevents *any* type of patent protection for the *true* scientific advancement of a chemical composition. This view is not consistent with the goals of patent law because patent law is intended to encourage and protect innovation. There is a significant danger

[332] *SmithKline*, 247 F.Supp.2d. at 1023. 21 U.S.C. §355(j)(4)(B)(iv) (2003).
[333] *Merck*, 80 F.3d. at 1547.

that the new rule of inherent anticipation adopted by the Federal Circuit will make research and development into metabolites impractical due to the danger that any patents gained may be held invalid if any prior art is found have produced that metabolite, regardless of whether the metabolite was previously known or in any way related to the utility of the prior art. However, based upon the importance of pharmaceutical and biological inventions in society a full term patent may not prove be the preferred solution. Congress has determined, as demonstrated by the policy choices made by Hatch-Waxman, that pharmaceutical compositions need to be treated differently from other patented materials due their importance to society though the benefits accorded to the overall quality of living.[334] Due to these considerations a statutory compromise is necessary.

IV. Policy Suggestions

The cases of both *Schering* and *SmithKline* (Paxil) demonstrate instances where a useful metabolite was discovered, but found to be anticipated because the discovery was made after the original patent's critical date.[335] However, the Federal Circuit's adoption of a rigid prohibition on metabolites fails to address the complexities that go into the discovery of a patentable biological or pharmaceutical invention. The law of anticipation was meant to prevent extensions of patents that would, in turn, prohibit the public from practicing an invention without advancing science in return. Absent a finding that a patent applicant is attempting to extend their patent without further advancing science, there is a need to examine patent applications for metabolites and other biological

[334] *See* 35 U.S.C. §154, §156 (2005). The statute allows for a patent term restoration equal to period of regulatory review and approval of a new drug, but capping the total period of protection at fourteen years even if a longer term remains on the patent.
[335] *Schering*, 339 F.3d. 1373; *SmithKline*, 403 F.3d. 1331 (Fed. Cir. 2005).

inventions on a case by case basis. Towards thisgoal I will make recommendations on how to protect pharmaceutical companies' discoveries of metabolites, while still protecting the public by ensuring that the passing of these discoveries into the public domain is not unduly delayed. A review of the practical implications of both the *Schering* case and the *SmithKline* (Paxil) case helps to demonstrate the necessity for a new statutory regimen for such patents.

In the case of *Schering*, an argument can be made that a finding of inherency is appropriate because the discovered metabolite, DCL, may have provided some utility to the patent, although it is not certain to what degree.[336] DCL is a type of antihistamine that does not cause drowsiness, and it was covered by the '716 patent which issued three years after the '233 patent.[337] The '233 patent covers the chemical makeup of Claritin, Schering's antihistamine that was attractive in the market because it did not cause drowsiness.[338] Upon the expiration of the '233 patent, generic manufactures wished to manufacture generic versions of this patent, but they were required to assert the invalidity of the '716 patent because of Schering's "Orange Book" listing of that patent in connection with the '233 patent.[339] The practical implication of the "Orange Book" listing was that Schering was attempting to prevent generic drug manufacturers from practicing the '233 patent, even after it had entered the public domain.

The Federal Circuit was, quite understandably, troubled by this notion. However, in attempting to rectify the situation the Circuit chose to use a sledgehammer against a fly. The listing by Schering in the "Orange Book" of the '716 patent in connection with

[336] *Id.* at 1375. *See also*, Section II. A., pp.11-26, *supra*.
[337] *Id.* at 1376.
[338] *Id.* at 1375.
[339] *Id.* at 1376.

the '233 patent was quite questionable, but Schering's other actions do not necessarily lead to a conclusion of bad intent. Most notably, the '716 patent was applied for in 1984, a mere three years after the '233 patent. If Schering's intent was to extend the patent of the '233 patent, they would have been much better served by delaying the application for several more years. Secondly, the court never addressed whether the '716 patent advanced science. If the '716 patent did advance science, then the notion that a patent should be denied categorically is misplaced. This view receives support from Judge Lourie's dissent, which points out the difficulty of finding all metabolites prior to clinical trials, which in themselves may take years to receive approval for.[340]

Furthermore, if discoveries such as DCL are denied patent protection it is likely that companies, such as Schering, will choose in the future to maintain such unpatentable advancements as trade secrets, lest a competitor be handed a starting point to reverse engineer a competing product before the expiration of the original patent. If the practical result of the *Schering* decision is to encourage recourse by pharmaceutical companies to trade secret, then the policy goals of patent law have not been served because scientific advancement will not become readily accessible to the public.[341] Lastly, despite the complications brought on by *Mylan v. Thompson*[342] and *Andrx v. Biovail*,[343] the simplest

[340] *Schering*, 348 F.3d at 995-996.
[341] Schering's counsel alludes to this in their combined request for panel and en banc rehearing. They state their belief that protection for the purified forms of a drug would be insufficient because "copyists will design pro-drugs to convert into DCL *in vivo* after administration." *Combined Petition for Panel Rehearing and rehearing En Banc by Plaintiff-Appellant*. 2003 WL 24033460 at 12. The concern stated by counsel is that others will find a way to administer DCL without infringing the patent for the pure substance allowed by Judge Rader. However, the greater danger is that pharmaceutical manufacturers will not investigate metabolites because no protection can be afforded through patents. This will therefore not bring the metabolites into the public knowledge, and no alternative methods of creating such a metabolite will be created because they will be unprotectable. Judge Newman's suggestion of allowing the patenting of DCL, without permitting the patent to cover prior art that may result in the DCL, would allow Schering to have limited protection over all new compositions that may create DCL and still allow competitors to practice all prior art in the public domain that results in DCL.
[342] *Mylan*, 268 F.3d. 1323.

solution to problems such as these is to refuse to permit a pharmaceutical company to block generic manufacturers' production of drugs that have passed into the public domain. This position, put forward by Judge Newman, is consistent with the current statute that permits the FDA to approve an ANDA once successful litigation has been concluded by generic drug manufacturers, so rapid summary dismissals of such claims are the best solution to this complicated problem.[344]

The *SmithKline* Paxil case provides an example of the potential pitfalls of the *Schering* rule. In this case *SmithKline* originally received a patent for paroxetine (the '196 patent), but later received a second patent for the hemihydrate form of paroxetine (the '723 patent).[345] The '723 patent was received after the '196 material "morphed" into a more stable hemihydrate state, from the less stable anhydrous form of the drug.[346] The primary value of the hemihydrate form of the drug was not to the patient because the record did not indicate that the hemihydrate form of the drug contributed to its utility. Rather, the utility of the hemihydrate was that it was more easily manufactured in a stable pseudo-polymorph form.

However, SmithKline's position in litigation was that generic manufacturers should not be permitted to practice even the '196 patent because it would invariably contain '723 material, due to seeding, and that ingesting the '196 material would inevitably lead to small amounts of the '723 material in metabolite form.[347] The court ultimately concluded that the inevitable creation of small amounts of '723 material within

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[343] *Andrx*, 276 F.3d. 1368.
[344] The problem is further complicated by consecutive listings of patents in the "orange book" which results in consecutive stays. *See Schering*, 348 F.3d. at 993-994.
[345] *SmithKline*, 403 F.3d. at 1334-1337.
[346] *Id.*
[347] *Id.*

a patient's stomach made that patent invalid as inherently anticipated.[348] This position, once again, is understandable given SmithKline's unreasonable position in the litigation, but it fails to grant SmithKline protection for the advancement that the '723 patent recognized. The value of the '723 patent was not the metabolite formed in the patient' stomach but, rather, the value was in the efficiency of manufacture as compared to the '196 material.

Through its ruling in the *SmithKline* case the Federal Circuit has created a troubling situation that presents a substantial danger to innovation. Consider the following hypothetical: Company A discovers a metabolite that proves extremely valuable at treating a common condition. This metabolite is patentable under 35 U.S.C. §§101-103, and Company A is granted a patent. After the FDA has approved Company A's New Drug Application (NDA) the drug is marketed and becomes extremely popular. Generic Company B then files an ANDA asserting that the patent for the metabolite is invalid. Company B's basis for their claim of invalidity is that prior art Z has been found to have produced the patented metabolite as a byproduct. The metabolite in question in no way contributed to the utility of prior art Z and was undetected in the prior art until Company B recently began scouring all prior art for a way to invalidate Company's A patent on the new blockbuster metabolite. Under the Federal Circuit's inherent anticipation rule in *Schering* and *SmithKline* the new patent on the metabolite should be invalidated. The practical result of this rule is that Company A will not invest in the research and development of metabolites because they will not be able to patent such discoveries, making it highly unlikely that they can recoup their investment. Instead, a windfall will be had by the generic companies who will be permitted to piggyback on the

[348] *Id.*

work of brand-name pharmaceuticals to a degree not anticipated or intended by Hatch-Waxman. In this way the ruling in *SmithKline* undercuts the purposes of patent law and encourages recourse to trade secret, if pharmaceuticals choose to invest in metabolite research at all.

There currently exists a need to balance the public's right to have access to generic drugs, while still ensuring that pharmaceuticals receive an adequate return on their investment so that they will continue research and development. My first suggestion is simple: alter the law to prevent consecutive listings in the Orange Book, while also granting district courts the power to order delisting. Hopefully, courts will also begin to dismiss as meritless cases that attempt to prevent parties from practicing inventions that have fallen into the public domain, even if their use leads to the production of a patented product.

Secondly, I suggest a middle ground for the patenting of metabolites by creating a limited exception to the double-patenting rule. First it should be asked whether a metabolite would be patentable but for inherent anticipation. Then it should be determined whether the party acted promptly to patent the metabolite upon its discovery. This would prevent the gamesmanship that both Judges Newman and Rader are concerned about by holding a party accountable if they had knowledge superior to that of PHOSITA. If the company acted diligently, it should then be asked whether PHOSITA would have recognized the trait prior to the critical date of the original patent. If PHOSITA would have recognized the trait prior to the critical date of the original patent then the appropriate step would have been for the applicant to receive a patent with a

terminal disclaimer; and further protection should be refused because to allow otherwise would merely extend a patent without reciprocal benefit to the public.

If PHOSITA would not have recognized the discovery, then additional protection is appropriate if science is sufficiently advanced. I suggest that a patent be granted that will run for the length of the original patent, plus an additional five years after the termination of the protected term under Hatch-Waxman, and applicants for this patent would not be limited to the original patent owner. This would encourage research and development by others of patented material and any discovery would likely benefit the public. However, this patent would be limited in scope so as not to render anyone who is unknowingly practicing the metabolite, or practicing the prior art, an infringer; and only one five year extension could be obtained, but this extension could run consecutive to an extension under Hatch-Waxman if the patents are owned by the same party. The patent could be used to prevent future competitors from entering the market if they had not already developed their composition at the time the extension patent was filed. Such an extended patent also need not affect the ability of pharmaceutical companies to receive the patents Judge Rader spoke of in *Schering* over pure forms, pharmaceutical compositions, or for a method of administering, since this a limited exception to the double patenting rule, and obviousness should be judged from the original patent, not the limited five year patent.

Congress needs to address the fact that the discovery of metabolites is not analogous to the situation in *General Electric*, where a party attempted to receive an additional patent on an invention that had already passed to the public domain.[349] The discovery of a metabolite constitutes a substantial discovery that advances science and

[349] *See* FN 12, *supra*.

holds the potential of leading to the development of alternative medications that bring about the preferred metabolites. The new rules suggested would allow pharmaceutical companies who discover useful metabolites to more fully exploit their discovery so that the resources will exist for further research and development. The benefit to the public would be that the metabolite that causes a desirable result would become generally known so that other companies could begin their own research and development to determine other ways to practice the patented metabolite; as well as allowing generic companies to practice the protected metabolite after a delay of five years, as opposed to the twenty years that they would normally endure were a full patent given to such a discovery.

V. Conclusion

The problems associated with the patenting of metabolites are fairly new because the technology and incentive to develop such inventions only appeared within the past several decades. As science comes to better understand the function of the human body and its reactions to foreign agents such as pharmaceuticals, the time has come to create a sound policy that directly addresses the patenting of metabolites. This policy needs to balance both the interest of the public to receive generic versions of pharmaceuticals, as well as the needs of pharmaceutical manufacturers to continue producing the new drugs that will improve the general standard of public health. I believe that a minor extension to an existing patent, to cover recently discovered metabolites, makes sense and will serve both these goals by creating only a minor delay in receiving generic drugs, but improving pharmaceutical companies' ability to fully exploit a discovery. I believe that while this view will not allow either side claim to victory, it will address the major

underlying concerns addressed by both Judge Newman and Judge Rader that new discoveries be protected and that public policy be secured.