

A HARD PILL TO SWALLOW: DOES *SCHERING V. GENEVA* ENDANGER
INNOVATION WITHIN THE PHARMACEUTICAL INDUSTRY?

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Recently the Federal Circuit has adopted a sweeping new rule of inherent anticipation that essentially bars the patenting of metabolites and other biological degradations of chemical compounds. This new rule, adopted in *Schering v. Geneva*, could substantially affect both the willingness and the ability of pharmaceutical companies to develop in vivo metabolites, and other biological compositions. This result may occur because pharmaceutical companies cannot be assured that patent protection will be available for these discoveries. This paper explores the evolution of the doctrine of inherent anticipation, the manner in which the Federal Circuit has chosen to address this issue in relation to pharmaceuticals, and makes suggestions that will allow pharmaceutical companies to receive a return on their research while also protecting the public's need for generic alternatives of pharmaceutical compositions to quickly come to market.

I. INTRODUCTION

It is hard to dispute the significance of pharmaceuticals in modern society. Numerous drugs have been developed to treat ailments to a degree unimaginable several decades ago.¹ Some of these ground breaking drugs are VIAGRA®, PROZAC®, and

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¹ See Neal Masia, *The Cost of Developing a New Drug*, Focus on Intellectual Property Rights, Jan. 2006, <http://usinfo.state.gov/products/pubs/intelprp/cost.htm>. Masia states:

PAXIL®. Developing new drugs requires a huge investment by pharmaceutical companies;² however, a successful drug can potentially bring its producer billions of dollars.³ Not surprisingly, these drugs often provide the backdrop for contentious litigation, as exemplified by the cases regarding both PROZAC®⁴ and PAXIL®.⁵ The

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.

Id.

² *Id.* (“Estimates about the cost of developing a new drug vary widely, from a low of \$800 million to nearly \$2 billion per drug.”). Masia also states that of “5,000 to 10,000 new chemical inventions that look promising . . . [only around] 250 compounds . . . enter into preclinical laboratory and animal testing. Of those . . . fewer than 10, on average, will show enough potential to qualify for Phase I human testing.” *Id.*

³ *Cf. id.* Neal Masia states:

At current levels 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.

Id. Since almost all initial investments cost at least one billion dollars, *see supra* note 2, for a product to cover its upfront cost it must yield revenue more than that amount.

⁴ *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 (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 fluoxetine hydrochloride.” *Id.* at 968-69 (quoting U.S. Patent No. 4,626,549 col.20 ll.7-9 (filed Mar. 31, 1986)). “Fluoxetine hydrochloride is the active ingredient in . . . Prozac.” *Id.* at 958.

The prior art, U.S. Patent No. 4,590,213 (filed Apr. 8, 1983), was directed at “[a] method of treating anxiety in a human subject in need of such treatment which comprises the administration to such human [of] an effective amount of fluoxetine or a pharmaceutically acceptable salts thereof.” *Id.* at 962 (altered to reflect patent’s original text). Originally, the Federal Circuit invalidated the ’549 patent on the grounds of double patenting. *Id.* The Court subsequently vacated the panel decision and directed a specific revision of the double patenting section. *Id.* at 958. In its final opinion, the Court stated, “[s]erotonin uptake inhibition is a natural biological activity that occurs when fluoxetine hydrochloride is administered to an animal.” *Id.* at 969. Also, the Court noted that Lilly had not disputed the proposition by Barr’s expert that “it is literally impossible to treat someone for anxiety . . . with fluoxetine hydrochloride without at the same time inhibiting serotonin uptake.” *Id.* at 970. Since the Court found that Barr had clearly shown “that the natural result flowing from administration of fluoxetine hydrochloride is inhibition of serotonin uptake,” the Court concluded that “the limitation of claim 7 of the ’549

process that a pharmaceutical company must satisfy to obtain approval from the Food and Drug Administration (FDA) to market a drug is long and cumbersome.⁶ These FDA requirements shorten the commercial life of patented drugs and, by decreasing the profits of pharmaceutical companies, endanger future research and development.⁷ Recognizing

patent directed to blocking serotonin uptake by use of fluoxetine hydrochloride is an inherent characteristic of the administration of fluoxetine hydrochloride for any purpose, including the treatment of anxiety.” *Id.* at 970. Because “[h]umans are a species of the animal genus,” the ’549 patent was inherently anticipated by the ’213 patent. *Id.* at 971.

Further controversy resulted from the Court’s determination that the ’213 patent 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.* at 962. The patent application for the ’549 patent was a continuation-in-part originally filed on March 31, 1986 and issued on December 2, 1986. *Id.* at 960. However, the ’549 patent, as a continuation-in-part application, claimed an effective filing date of January 10, 1974. *Id.* at 973 (Newman, J., dissenting) (challenging the Court’s 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 968-70. The Court was likely moved to its conclusion by the seemingly endless divisional applications, continuation applications, and patents arising from the original patent that, as the Court stated, “rival[ed] 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 (Newton, J., dissenting); *see infra* note 17 and accompanying text.

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), *vacated en banc*, 403 F.3d 1328 (Fed. Cir. 2005); *and abrogated by* 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. In the PAXIL® case the prior art mutated into a “pseudopolymorph” that was more stable and easily manufactured. *SmithKline*, 247 F. Supp. 2d at 1016-20. The new composition was distinct from the prior art but was discovered to have been created when a patient ingested the prior art. *Id.* The Federal Circuit originally invalidated the patent on the basis that the clinical trials constituted public use. *SmithKline*, 365 F.3d at 1318 (“[T]he clinical tests . . . did not involve the claimed features of the invention. [Thus, the tests] do not qualify as an experimental use to negate the statutory bar.”). In his concurrence, Judge Gajarsa stated that because SmithKline failed to limit its patent to “*synthetic or non-naturally occurring*” forms of the polymorph, the patent was invalid under 35 U.S.C. § 101, since without this limitation the patent claimed non-patentable subject matter. *Id.* at 1332 (Gajarsa, J., concurring) (emphasis in original). However, Gajarsa noted that such a limitation would allow Apotex to avoid infringement. *Id.* The original panel decision was subsequently vacated by the Court en banc. *SmithKline*, 403 F.3d at 1328. The PAXIL® patent was then invalidated after a panel rehearing as inherently anticipated. *SmithKline*, 403 F.3d at 1344. *See infra* Part II.C.

⁶ *See generally SmithKline*, 247 F. Supp. 2d at 1017 (“Because it takes a long time for a new drug to be approved by the U.S. 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.* at 1017-18. Discussing a main purpose of the Hatch-Waxman Act, Judge Posner stated:

the unique position that pharmaceuticals play in our society, Congress passed the Hatch-Waxman Act to guarantee pharmaceutical companies a reasonable return on their investment⁸ while allowing generic drug manufacturers to quickly enter the field upon the expiration of a drug patent.⁹

One Congressional incentive for pharmaceutical companies is restoring time lost during the FDA approval process.¹⁰ Congress' willingness to lengthen pharmaceutical patent terms to encourage research and development indicates that patents may be treated differently when the public interest demands it. However, the Federal Circuit's recent determination that courts should aggressively apply the doctrine of inherent anticipation

The compression of the commercially significant patent term by reason of the regulatory process at the FDA is a matter of 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 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 effect of the delay, also due largely to the FDA, between obtaining a patent and actually being able to market the patented drug to the consuming public.

Id. (noting that a drug patented in 1977 had still not been marketed to the public in 1985).

⁸ *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 1326 (Fed. Cir. 2002) (quoting *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting on other grounds)) ("[The] provisions of the Hatch-Waxman Amendments '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.'").

⁹ *Mylan Pharm.*, 268 F.3d at 1325-26. Explaining the benefit of the ANDA, the Court stated:

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 product's bioequivalence with the previously approved drug.

Id. (referring also to portions of the Hatch-Waxman Act relating to generic drugs codified in 21 U.S.C. § 355 (2006)).

¹⁰ Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984 § 201, 35 U.S.C. § 156 (2006). *See infra* note 311.

to the patenting of metabolites significantly endangers related scientific advancement.¹¹ By formulating a broad rule on inherent anticipation, the Federal Circuit appears to have substituted its own policy determination on pharmaceutical research and development in direct contravention of the policy choice that Congress has made.

Inherent anticipation is not a new concept. Originally, it was an abstract concept used to address situations where the court appeared sure of the result but unsure of what reasoning justified the proper outcome.¹² The doctrine of inherent anticipation evolved slowly, and it was not until 1945 that the Court finally set out a workable rule. In *General Electric v. Jewel Incandescent Lamp Co.*,¹³ the court stated that a patent was invalid on inherent anticipation grounds because “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.”¹⁴ 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

¹¹ See *Schering Corp. v. Geneva Pharm., 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 will be discussed. See *infra* Part II.A.

¹² See, e.g., *Tilghman v. Proctor*, 102 U.S. 707, 711 (1880) (disregarding as of no consequence to the inquiry of prior art Tilghman’s process of distilling fat acid the accidental formation of fat acid in Perkins’ steam cylinder from the tallow introduced to lubricate the piston). See also *Edison Elec. Light Co. v. Novelty Incandescent Lamp Co.*, 167 F. 977 (3d Cir. 1909) (finding that a patent was not barred for a new and preferable light bulb that joined platinum and copper wires within the glass where accidental construction previously of light bulbs that read on the patent were deemed imperfect and discarded, so the true value of the invention was not discovered until Edison recognized and patented it).

¹³ *Gen. Elec. Co. v. Jewel Incandescent Lamp Co.*, 326 U.S. 242 (1945). This case concerned the frosting of light bulbs. Clear light bulbs produced unpleasant glare. *Id.* at 243. One method to address glare was to frost the outside of the bulb; however, this frosting became dirty easily and was difficult to clean. *Id.* at 243-44. 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. *Id.* at 244. 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. *Id.* Applying a second treatment to the outside of a bulb had been done many years earlier and was known to give glass a rounded, as opposed to angular and creviced, finish. *Id.* at 244-46. What had not been discovered was that the second treatment ate away at some of the original frosting and would actually strengthen the bulb. *Id.* at 244-45. This phenomenon was referred to as “Pipkin’s paradox” and was the basis of his patent application. *Id.* Additionally, Pipkin was the first to apply a second treatment to the inside of the bulb. *Id.* at 248. Ultimately, the court found his discovery insufficient for a patent. *Id.* at 248-49.

¹⁴ *Id.* at 248 (quoting *Lovell Mfg. Co. v. Cary*, 147 U.S. 623 (1893)).

known, more than a new advantage of the product must be discovered in order to claim invention.¹⁵

To what degree does the standard recognized in *General Electric* apply to biological inventions, especially metabolites?¹⁶ Does the test recited above and largely adopted by the Federal Circuit in *Schering v. Geneva Pharmaceuticals* and *SmithKline Beecham Corp. v. Apotex Corp.* 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 pharmaceutical companies to disclose their inventions in order to obtain patent protection? Does *Schering* limit the ability of pharmaceutical companies 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 prior 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. The effects of this new rule will be felt strongly in the pharmaceutical industry. By not requiring recognition by a PHOSITA, 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 was adopting bright line rules which would stifle the advancement of biological inventions by precluding protection for many metabolites. Judge Newman stated:

[E]very biological property is a 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.¹⁷

The decision in *Schering* was the capstone case in a lengthy split within the Federal Circuit. One view, espoused most forcefully by Judge Newman in *Continental*

¹⁵ *Id.* at 248-49.

¹⁶ 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.

¹⁷ *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 976 (Fed. Cir. 2001).

Can Company v. Monsanto,¹⁸ states that patenting should only be prevented if a PHOSITA could have recognized the inherent trait that was now being claimed.¹⁹ Judge Randall Rader explicitly disavowed any such notion in *Schering*.²⁰ Judge Newman believes that more lenient and clear standards for pharmaceutical and biological patents are necessary in light of the prevalence of unpredictable breakthroughs.²¹ In contrast, Judge Rader adopts a clear position in *Schering* that sets extremely stringent standards for the patenting of metabolites and other biological inventions.²²

¹⁸ *Cont'l Can Co., Inc. v. Monsanto Co.*, 948 F.2d 1264 (Fed. Cir. 1991).

¹⁹ *Id.* at 1268 (“To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may 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.”).

²⁰ *Schering*, 339 F.3d at 1377 (“[R]ecognition by a person of ordinary skill in the art before the critical date [of the patent] is not required to show anticipation by inherency.”). The court further stated:

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 reference disclosing a plastic bottle. The record contained conflicting expert testimony about whether the ribs of the prior art plastic bottle were solid. The accused infringer’s expert testified that the prior art plastic bottle was made by blow molding, a process that would inherently produce hollow ribs. The patentee’s experts testified that the prior art plastic bottle had solid ribs. The patentee disputed whether the blow molding inherently produced hollow ribs. Given the disputed material fact, this court vacated the 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 supra* note 19 and accompanying text. Subsequently, Judge Newman lamented the Circuit’s refusal to hear the *Schering* case en banc: “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.” *Schering*, 348 F.3d 992, 993 (Fed. Cir. 2003) (Newman, J., dissenting). She went further and quoted her language of *Continental Can*, *see supra* notes 18-19, which required recognition of the inherent characteristic by a PHOSITA. *Schering*, 348 F.3d at 994-95.

²¹ *Eli Lilly*, 251 F.3d at 976.

²² *Schering*, 339 F.3d at 1381. Judge Rader allowed for the patenting of metabolites with “proper claiming.” *Id.* 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 that prevents such recognition. He also stated that the metabolite could be patented in

This paper will examine the split that has developed within the Federal Circuit regarding whether recognition by a PHOSITA is necessary in order to apply the doctrine of inherent anticipation. It will argue that Congress through the Hatch-Waxman Amendments has already recognized that pharmaceuticals occupy a uniquely important position within society. Upon conclusion, the reader will see that it is necessary to give pharmaceutical and biological inventions different treatment when applying inherent anticipation in order to avoid stifling scientific advancement. Finally, suggestions will be made on how to protect pharmaceutical companies to ensure that they maintain sufficient incentives to continue to investigate the biological causes of existing compositions. At the same time, these 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.²³ Among the most basic requirements are that an invention be useful,²⁴ novel,²⁵ and non-obvious.²⁶ Anticipation under § 102(a) occurs if the identical invention has been claimed on a single prior art reference.²⁷ When more than one prior art reference is required to find unpatentability or if patentability revolves around a minor improvement of the prior art, the validity of the patent is evaluated for obviousness under § 103.²⁸ 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.²⁹ As Judge Rader said in *Atlas Powder Co. v. Ireco, Inc.*, “[u]nder the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.”³⁰ Anticipation is a factual determination³¹ that, once established, will

its “pure and isolated form . . . or as a pharmaceutical composition . . . The patent drafter could also claim a method of administering the metabolite or the corresponding pharmaceutical composition.” *Id.*

²³ 35 U.S.C. §§ 101-103 (2006).

²⁴ § 101.

²⁵ § 102.

²⁶ § 103.

²⁷ *Cont’l Can Co., Inc. v. Monsanto Co.*, 948 F.2d 1264, 1267 (Fed. Cir. 1991) (citing *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 780 (Fed. Cir. 1985); *Lindemann Maschinenfabrik GmbH v. Am. Hoist and Derrick Co.*, 730 F.2d 1452, 1458 (Fed. Cir. 1984)).

²⁸ *Id.*

²⁹ *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987).

³⁰ *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

prevent the patenting of an old composition by those who discovered its new properties.³² If a patent has already been issued, then anticipation must be shown by clear and convincing evidence.³³

The doctrine of inherent anticipation is an offshoot of accidental anticipation. Accidental anticipation was first addressed by the Supreme Court in *Tilghman v. Proctor*.³⁴ 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 had not been understood.³⁵ This accidental use had occurred when individuals practicing the prior art introduced tallow to lubricate the piston on a steam cylinder.³⁶ The Court stated:

[i]f the acids were accidentally and unwittingly produced, whilst the operators were in pursuit of other and different results, without exciting attention and without its even being known what was done or how it had been done, it would be absurd to say that this was an anticipation of Tilghman's discovery.³⁷

The Court's determination in *Tilghman* centers on the previous producer's failure to appreciate what had occurred through its actions.³⁸

Today, *Tilghman* and cases following its facts are described as being cases of "accidental anticipation."³⁹ *Tilghman* continues to be valid law although the

³¹ *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1367 (Fed. Cir. 1991) (citing *Ralston Purina Co. v. Far-Mar-Co.*, 772 F.2d 1570, 1574 (Fed. Cir. 1985)).

³² *Atlas Powder*, 190 F.3d at 1347 (citing *Titanium Metals*, 778 F.2d at 782).

³³ *Id.*

³⁴ *Tilghman v. Proctor*, 102 U.S. 707, 707 (1880).

³⁵ *Id.* at 711.

³⁶ *Id.*

³⁷ *Id.* at 711-12.

³⁸ *Id.*

³⁹ Paul G. Alloway has outlined the factors that the Federal Circuit has considered in determining whether "inherent anticipation" or "accidental anticipation" applies to certain sets of facts. The factors he recites are:

whether the prior art intended the claimed composition or process; whether the prior art includes knowledge of the claimed composition or process; 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; whether the prior art includes knowledge of a claimed component

circumstances that lead to a finding of accidental anticipation do not appear common. Courts have long treated inherent anticipation and accidental anticipation as being distinct from one another.⁴⁰ Judge Rader distinguished *Tilghman* from *Schering* by noting that the claimed process in *Tilghman* was not found to be inevitably present in the prior art.⁴¹ 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; thus, the patent was invalid due to inherent anticipation, regardless of whether there was recognition by a PHOSITA.⁴²

in the claimed composition; whether the prior art includes knowledge of the function of a component in a prior art process or composition; whether the prior art performs the claimed process or makes or uses the claimed composition for a different purpose; whether the claimed composition is useful in the prior art; whether the claimed process is useful to achieve the claimed result in the prior art; and 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.

Paul G. Alloway, Note, *Inherently Difficult Analysis for Inherent and Accidental Biotechnology Inventions*, 38 Suffolk U. L. Rev. 73, 91 (2004). 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.

⁴⁰ See, e.g., *Am. 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 incidental use of hydraulic force). 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 the prior art, even though the prior art did not recognize the implications to shelf life). See also Alloway, *supra* note 39, 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 unknowingly produced by the “hot process” but was 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.

⁴¹ *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1378 (Fed. Cir. 2003).

⁴² *Id.* Judge Rader appears somewhat uncertain if the basis of the *Schering* decision will be accepted, as demonstrated by his attempts to distinguish *Tilghman* and find no need for recognition by a PHOSITA. For example, he states: “[a]pplying 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.* After summarizing several additional cases, Judge Rader writes:

Inherent anticipation requires that an event inevitably follow.⁴³ 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.”⁴⁴ 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 a PHOSITA] *would* result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.”⁴⁵ Allowing a patent for 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.⁴⁶

The Supreme Court touched more clearly on inherent anticipation in *General Electric Co.*⁴⁷ In that case, the court made clear that it would require more than the mere discovery of a “new advantage” to an existing product in order to obtain a patent.⁴⁸ The inventor in the case had discovered that a second treatment of frost inside the bulb actually strengthens it by dissolving away additional glass which would otherwise weaken the bulb.⁴⁹ The Court did not believe that the advancement warranted patent protection.⁵⁰ 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.⁵¹ Absent such advancement, the public is merely being deprived of a good for an additional patent term.⁵²

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, DCL.

Id.

⁴³ *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981).

⁴⁴ *Id.* at 581 (quoting *Hansgirk v. Kemmer*, 102 F.2d 212, 214 (C.C.P.A. 1939)) (emphasis added).

⁴⁵ *Id.* (emphasis added).

⁴⁶ *In re Wiseman*, 596 F.2d 1019, 1023 (C.C.P.A. 1979).

⁴⁷ *Gen. Elec. Co. v. Jewel Incandescent Lamp Co.*, 326 U.S. 242, 242 (1945).

⁴⁸ *Id.* at 248-49.

⁴⁹ *Id.* at 244-45.

⁵⁰ *Id.* at 248-49.

⁵¹ *Id.*

⁵² 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 finding

Public policy considerations best explain why the Federal Circuit adopted such a hard line in *Schering* and *SmithKline*. The Federal Circuit's concern is that permitting the consecutive patenting of pharmaceuticals and their *in vivo* biological by-products would substantially lengthen the patent protection of the pharmaceutical without substantially advancing the present frontiers of science.

A. *Schering Corporation v. Geneva Pharmaceuticals*

The *Schering* case concerned two patents.⁵³ The first was “the ’233 patent” (U.S. Patent No. 4,282,233).⁵⁴ The ’233 patent covered loratadine, the active ingredient in an antihistamine marketed by Schering under the brand name CLARITIN™.⁵⁵ CLARITIN™ was unique in the marketplace at the time it was launched because it was an antihistamine that did not cause drowsiness.⁵⁶ The ’233 patent was issued in 1981 and had expired by the time the Federal Circuit considered the case.⁵⁷ The second patent at issue in the case was “the ’716 patent” (U.S. Patent No. 4,659,716).⁵⁸ The ’716 patent covered a metabolite of loratadine called descarboethoxyloratadine (DCL), which is also a non-drowsy antihistamine.⁵⁹ Metabolites form when an “ingested pharmaceutical undergoes a chemical conversion in the digestive process to form a new metabolite

inherency 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. *Cont'l Can Co., Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). 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 v. Proctor*, 102 U.S. 707, 711 (1880); *see also Eibel Process Co. v. Minn. & Ont. Paper Co.*, 261 U.S. 45, 66 (1923). The second portion of the test addresses the fact that if something 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 248-49 (quotation omitted). 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. *Cont'l Can*, 948 F.2d at 1269.

⁵³ *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1375 (Fed. Cir. 2003).

⁵⁴ *Id.* at 1374.

⁵⁵ *Id.* at 1375.

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ *Id.* at 1374.

⁵⁹ *Id.* at 1375.

compound.”⁶⁰ The ’716 patent was issued in April 1987 and would expire in April 2004.⁶¹ Numerous generic drug manufacturers sought to market generic versions of loratadine once the ’233 patent had expired, but were required to assert in their FDA applications that the ’716 patent was invalid or not infringed by their practice of the ’233 patent because of Schering’s listing of the ’716 patent in the “Orange Book” in connection with the ’233 patent.⁶²

Since the earliest priority date of the ’716 patent was February 15, 1984, the ’233 patent was prior art over the ’716 patent.⁶³ After cross-motions for summary judgment, the district court invalidated the ’716 patent as being anticipated under 35 U.S.C. §

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.* at 1376; Memorandum of Law of Federal Trade Commission as Amicus Curiae Concerning Torpharm’s Cross Motion for Entry of an Amended Order, *SmithKline Beecham Corp. v. Apotex Corp.*, 232 F.R.D. 467 (E.D. Pa. 2005) (No. 99-CV-4304), 2003 WL 22023358. Once a New Drug Application (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 Abbreviated New Drug Application (ANDA) 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 Federal Trade Commission (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 that time SmithKline had only one patent listed in the “Orange Book” for PAXIL®. After Apotex commenced its suit, eight additional 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 (Fed. Cir. 2004), *opinion vacated en banc*, 403 F.3d 1328 (Fed. Cir.2005), *aff’d on other grounds*, 403 F.3d 1331 (Fed. Cir 2005). The problem of “Orange Book” listings is further complicated by the Federal Circuit’s rulings in *Andrx Pharm. v. Biovail Corp.*, 276 F.3d 1368 (Fed. Cir. 2001), and *Mylan Pharm. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001). 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 invalid. *Andrx*, 276 F.3d at 1376; *Mylan*, 268 F.3d at 1330-33.

⁶³ *Schering*, 339 F.3d at 1376.

102(b) because DCL was “necessarily formed as a metabolite by carrying out the process disclosed in the ’233 patent.”⁶⁴ 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 apply when evaluating a patent under the doctrine of inherent anticipation. He started by making clear that prior art “may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference.”⁶⁵ Rader then made clear that “this court rejects the contention that inherent anticipation requires recognition in the prior art.”⁶⁶ This decision juxtaposed numerous cases, such as *Continental Can*, which hold that an anticipating reference must be recognized by a PHOSITA to be inherently anticipated.⁶⁷ In rejecting this view, Judge Rader attempted to distinguish *Continental Can* as a summary judgment determination where disputed material facts made any inherent anticipation analysis premature.⁶⁸ 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.

In *Continental Can*, Judge Newman stated that inherent anticipation applies only when “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.”⁶⁹ She found this flexible rule to be necessary to prevent continuing patents for inventions outside the knowledge of judges, but not necessarily outside the knowledge of those skilled in the art.⁷⁰ Summary judgment in the *Continental Can* case was ultimately reversed because the Federal Circuit found that there were questions as to whether the process necessarily

⁶⁴ *Id.* (discussing *Schering Corp. v. Geneva Pharm.*, 275 F. Supp. 2d 534 (D.N.J. 2002)).

⁶⁵ *Id.* at 1377 (citing *Cont’l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991)).

⁶⁶ *Id.*

⁶⁷ *Cont’l Can*, 948 F.2d at 1268.

⁶⁸ *Schering*, 339 F.3d at 1377.

⁶⁹ *Cont’l Can*, 948 F.2d at 1268 (emphasis added).

⁷⁰ *Id.* at 1269. 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 Pharm., Inc. v. Mayo Found. for Med. Educ. and Research*, 346 F.3d 1051 (Fed. Cir. 2003), and her dissent to the Circuit’s refusal to hear *Schering en banc*, *Schering Corp. v. Geneva Pharm., Inc.*, 348 F.3d 992, 993 (Fed. Cir. 2003) (Newman, J., dissenting), 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 function, it seems to be well settled that the disclosure should be regarded as sufficient,” *Cont’l Can*, 948 F.2d at 1269 (quoting *Hansgirk v. Kemmer*, 102 F.2d 212, 214 (C.C.P.A. 1939)), could leave an incorrect impression if taken out of its context.

produced the hollow ribs claimed.⁷¹ 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 a PHOSITA would have recognized the hollow ribs in order to uphold a summary judgment of anticipation by inherency.⁷² 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.⁷³

⁷¹ *Cont'l Can*, 948 F.2d at 1269.

⁷² Since the Court did not reach the issue of whether a 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 that either treat *Continental Can* as binding or use the same general test. See, e.g., *Rosco Corp. v. Mirror Lite Co.*, 304 F.3d 1373, 1380-81 (Fed. Cir. 2002) (finding that a PHOSITA would not read the reference as inherently creating a mirror of varying radius); *Finnigan Corp. v. Int'l Trade Comm'n*, 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, 1480-81 (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) (stating that claims were anticipated because the prior art "placed a person of ordinary skill in the field of the invention in possession" of the claims); *In re Oelrich*, 666 F.2d 578, 581-82 (C.C.P.A. 1981) (holding that if the disclosure is sufficient to show that the claim is the natural result flowing from the operation taught to a PHOSITA, then the disclosure is sufficient); *In re Shetty*, 566 F.2d 81, 86 (C.C.P.A. 1977) (finding that a 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 PHOSITA and is therefore not anticipated). See also *Hansgirg v. Kemmer*, 102 F.2d 212. Cf. *Telmac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1327-28 (Fed. Cir. 2001) (finding anticipation, but citing to *Continental Can*, *Atlas Powder*, and *MEHL/Biophile* despite their different requirements relating to PHOSITA recognition).

⁷³ Fed. Cir. R. 35(a)(1) ("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 decide whether to ask the regular active judges to consider hearing the case en banc.") (emphasis added).

At that point there was already conflicting case law as to whether recognition by a PHOSITA was required. *Continental Can* and its precursors developed the rule that required recognition by a PHOSITA. On the other side of the argument were *Atlas Powder v. Ireco Inc.*, 190 F.3d 1342 (Fed. Cir. 1999), *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362 (Fed. Cir. 1999), and *EMI Group N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342 (Fed. Cir. 2001), all authored by Judge Rader. None of these cases required recognition by a PHOSITA, but the

In *Schering*, the issue presented was one of first impression. The court was asked to find anticipation based not on the absence of a single limitation, but 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 inherently anticipated did not trouble Judge Rader. Rather, he dispensed with any concerns about finding an inherently anticipated structure by explaining that:

Because 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

In an attempt to distinguish the *Schering* case from other precedent, Judge Rader found that DCL would have been detectable after ingestion of loratadine by humans.⁷⁷

requirement was not expressly disavowed until *Schering*. Complicating matters was the fact that Judge Newman expressly rejected the view that there was no need for recognition by a PHOSITA to apply inherent anticipation in *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. and Research*, 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 a 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 Fed. Cir. R. 35(a)(1).

⁷⁴ *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003).

⁷⁵ *Id.*

⁷⁶ *Id.* (citing *Eli Lilly & Co. v. Barr Labs. Inc.*, 251 F.3d 955, 977 (Fed. Cir. 2001)). 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. *Eli Lilly*, 251 F.3d at 959. Previously, Eli Lilly claimed a way to treat anxiety in humans that would naturally block serotonin uptake. *Id.* at 959. The Court originally invalidated the newer patent on the basis of double patenting. *Id.* at 972. A revised opinion found inherent anticipation since humans are part of the animal genus and claiming a patentable non-distinct treatment for a genus member, when the same treatment has been claimed for a species member, renders that claim inherently anticipated. *Id.* at 971. It is clear in that case that Eli Lilly probably recognized that the claims were duplicative, but there was a question as to the order of the priority of the patents. *Id.* at 974. 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 *Schering*, 339 F.3d at 1379. *Contra In re Seaborg*, 328 F.2d 996 (C.C.P.A. 1964). In *Seaborg*, claims involving an isotope of americium were permitted, despite the fact that they would have been present in the Fermi reactor many years prior. *Id.* at 999. However, they would not have been detectable and its presence was merely theoretical. *Id.* Judge Rader's view is confusing since it does appear to place some importance on recognition, but does not place

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

In the dicta of *Schering*, Judge Rader did allow for limited patenting of metabolites.⁸² He stated that patents for the pure and isolated form of a metabolite in compositions with pharmaceutically acceptable carriers, or patents for a method of administering the metabolite or pharmaceutical composition would not be affected by *Schering*.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, Judge Rader attempted to settle the lingering dispute within the Federal Circuit of whether inherent anticipation could apply to a situation where there was no recognition by a PHOSITA.⁸⁵

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 its combined petition for panel rehearing and rehearing en banc, *Schering* states that it had to "develop new, more sensitive testing methods to detect DCL and other metabolites of the '233 patent compounds." See Combined Petition for Panel Rehearing and Rehearing en banc by Plaintiff-Appellant, *Schering Corp. v. Geneva Pharm., Inc.*, 348 F.3d 992, at *5-6 (Fed. Cir. 2003) (No. 02-1540), 2003 WL 24033460.

⁷⁸ *Schering*, 339 F.3d at 1380-81.

⁷⁹ *Id.* at 1381.

⁸⁰ *Id.*

⁸¹ *Id.* at 1379-80 (citing the patent principle that "that which would literally infringe if later in time anticipates if earlier" (quoting *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1378 (Fed. Cir. 2001))).

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 compound."

⁸³ *Id.* (citing *In re Kratz*, 592 F.2d 1169, 1174 (C.C.P.A. 1979); *In re Bergstrom*, 427 F.2d 1394, 1401-02 (C.C.P.A. 1970) (citing both for the proposition that pure and isolated metabolites may be patentable)).

⁸⁴ *Id.*

⁸⁵ The confusion within the Circuit appears to be largely due to three previous panel decisions authored by Judge Rader: *Atlas Powder v. Ireco Inc.*, 190 F.3d 1342 (Fed. Cir. 1999); *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362 (Fed. Cir. 1999); *EMI Group N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342 (Fed. Cir. 2001). The decisions in *Atlas* and *MEHL/Biophile* were issued three weeks apart from one another in late 1999. Judge Rader

Other members of the court objected to the potential effects Judge Rader's opinion 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 both the *Schering* decision and the rejection of an en banc re-hearing.⁸⁶ Judge Newman did not accept Judge Rader's view on the law of inherent anticipation, nor did she 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 (descarbethoxyloratadine or 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

attempted to limit the circumstances where recognition by a PHOSITA would be required in 2001 by stating such recognition:

may be sensible for claims that recite limitations of structure, compositions of matter, and method steps which could be inherently found in the prior art. Such recognition by one of ordinary skill may be important for establishing that the descriptive matter would inherently exist for every combination of a claims limitation. Theoretical mechanisms or rules of natural law that are 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. A person of ordinary skill does not need to recognize that a method or structure behaves according to a law of nature in order to fully and effectively practice the method or structure.

EMI Group, 268 F.3d at 1350-51 (citations omitted). This portion of the *EMI Group* decision was, until *Schering*, Judge Rader's boldest attempt to alter the rule of inherent anticipation. It is unclear where his distinction between structure, composition of matter, and method steps as compared to "natural law" is derived. It is true that natural law cannot be patented, although the Supreme Court nearly considered what limitations may exist when a party actually discovers a natural law that leads to an accompanying correlation. See *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, cert. granted in part, 126 S. Ct. 601 (Nov. 2, 2005), cert. dismissed as improvidently granted, 126 S. Ct. 2921 (June 22, 2006). See also *infra* note 265. However, Judge Rader held in both *Schering* and *SmithKline Beecham Corp. v. Apotex Corp.*, 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.

⁸⁶ *Schering Corp. v. Geneva Pharm. Inc.*, 348 F.3d 992 (Fed. Cir. 2003), *reh'g en banc denied* (Newman, J., dissenting). Fed. Cir. R. 35(a)(1) states that "only the court en banc may overrule a binding precedent." 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 *Schering*, 348 F.3d at 993.

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 biological inventions.⁸⁹ Her primary concern about the substantive effects of the *Schering* decision was that there would no longer be an incentive for pharmaceuticals to invest in the research and development of metabolites that cannot be patented.⁹⁰ She also viewed the

⁸⁸ *Id.*; see Fed. Cir. R. 35(a)(1).

⁸⁹ *Schering*, 348 F.3d at 994.

⁹⁰ *Id.* Judge Newman’s view was echoed by the Washington Legal Foundation in its *amicus curiae* brief in support of SmithKline’s petition for a writ of certiorari. In the Foundation’s brief it states its concern that the rule of *Schering* will not protect material in the public domain, as Rader wants, but rather stifle innovation. The foundation also argues 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. Brief of Washington Legal Foundation as Amicus Curiae in Support of Petitioners, *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, at *8 (Fed. Cir. 2005) (No. 03-1285), *cert. denied*, 126 S. Ct. 2887 (2006), 2005 WL 3114487. The Pharmaceutical Research and Manufacturers of America also filed an *amicus curiae* brief 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 cite as an example of the new rule’s shortcomings that a broad spectrum antibiotic tetracycline was developed by studying Auremycin, a pre-existing antibiotic. Brief of Pharmaceutical Research and Manufacturers of America as Amicus Curiae in Support of Petitioners, *SmithKline Beecham*, 403 F.3d 1331, at *2-3 (Fed. Cir. 2005) (No. 03-1285), 2005 WL 3087521. The Federal Circuit allowed for the patenting of this newly discovered substance in *Glaxo Inc. v. Novopharm, Ltd.*, 52 F.3d 1043 (Fed. Cir. 1995). It may no longer be practical to research such compositions because generic manufacturers will be able to file Abbreviated New Drug Applications (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 could be reinvested in research and development. Pharmaceutical companies could resort to a trade secret approach 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 of 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 *Merck KGaA v. Integra Lifesciences I, Ltd.*, 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 for creating a metabolite during the patent term, with marketing to follow as soon as the term expires. Multiple

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. One situation was where a single piece of prior art taught all the elements of a claim, and in these cases the claim lacked novelty.⁹² The second situation was where a single piece of prior art did not include all the elements of an invention.⁹³ At that point, the question was whether the omitted elements would have been known to a PHOSITA.⁹⁴ If the missing elements would have been known to the a PHOSITA, as demonstrated by reference to extrinsic evidence, then the claim would be anticipated.⁹⁵

Clearly, the first circumstance was not present 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 its creation. The question at that point, according to Judge Newman, was whether a 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 analysis of *Continental Can*, the Federal Circuit adopted a bright line rule precluding all additional patents for metabolites regardless of whether PHOSITA recognition was present.

Judge Newman's second major objection was that Judge Rader's panel exceeded its powers by contradicting existing case law concerning inherent anticipation.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 Judge Newman's 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

methods of creating a metabolite are useful to address the different needs possessed by individuals in society.

⁹¹ *Schering*, 348 F.3d at 994.

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Id.* at 995.

⁹⁶ *Id.*; Fed. Cir. R. 35(a)(1).

⁹⁷ *Schering*, 348 F.3d at 993-94.

⁹⁸ *Id.* at 995.

⁹⁹ Fed. Cir. R. 35(a)(1); *Schering*, 348 F.3d at 995. 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

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 pointed out some of the practical limitations that currently exist and that affect the ability of pharmaceutical

speak to the influence of Judge Rader. The Federal Circuit in *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1328 (Fed. Cir. 2005) (en banc), once again seemed to endorse Judge Rader’s view of inherent anticipation. Judge Rader initially ruled that clinical trials constituted public use that would invalidate the “Paxil” patent, but stated that an alternative ground for invalidating the patent was inherent anticipation due to SmithKline’s claim that the ’723 material was created upon ingestion of the prior art ’196 patent. *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306 (Fed. Cir. 2004), *vacated*, *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1328 (Fed. Cir. 2005) (en banc). The Federal Circuit’s vacating of the previous “Paxil” decision 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, given the opportunity. *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*, 403 F.3d at 1331. Both the vacating of the previous “Paxil” decision and the new “Paxil” decision were released on April 8, 2005. The cases preceding *Schering* indicate that the matter of inherent anticipation in relation to biological and pharmaceutical compositions may have actually been festering for some time. A year before *Schering*, the Federal Circuit reversed a District Court decision in *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. and Research*, 304 F.3d 1221 (Fed. Cir. 2002), where the lower court found that a patent for a “recipe” to make transgenic mice was anticipated. Judge 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 a PHOSITA would not have recognized how to make the mice. Judge Dyk, in a dissent, objected to what he viewed as the patenting of “existing inventions” in light of recent cases, such as *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1350 (Fed. Cir. 2002), that prohibited such patents. *Elan Pharm.*, 304 F.3d at 1331 (Dyk, J., dissenting). The Court issued an order granting a rehearing en banc, which later merely vacated the previous panel decision. *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. and Research*, 314 F.3d 1299 (Fed. Cir. 2002) (en banc). Judge Newman’s later opinion, after the en banc vacating of her previous opinion, rather than concentrating on non-recognition of the missing elements by a PHOSITA, instead stated that the prior art was not sufficiently enabled to allow one to replicate without undue experimentation. *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. and Research*, 346 F.3d 1051 (Fed. Cir. 2003). Nonetheless, even without Judge Newman’s original *Elan* decision, which directly contradicted Judge Rader’s view on the need for recognition by a PHOSITA to trigger inherent anticipation, there still exists a troubling split within the Circuit concerning inherent anticipation. The *Continental Can* line of cases is still good law, as are the cases relied on by *Schering* and *SmithKline* (i.e., *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.*

companies to originally patent metabolites.¹⁰² His primary concern is that 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 would 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 would not be sufficient to enable a metabolite because such administration would "inevitably cause the human body to make the metabolite."¹⁰⁵ Judge Lourie prefers not to allow every metabolite to be patented. However, he does state that he would rule differently if the patent actually taught how metabolites could be made 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 As a result, to hold that a "patent on a product, with minimal disclosure of administering to a human or other subject, anticipates

¹⁰² *Id.*

¹⁰³ *Id.* Judge Lourie takes a strikingly different view on the patenting of metabolites from the view expressed by Judge Rader. Whereas Judge Rader is primarily concerned with the direct and immediate public policy concerns surrounding metabolites, namely that pharmaceutical companies will manage to extend their patent, Judge Lourie is more concerned with how fair the adopted process would be to those seeking patents. Like Judge Newman, he believes 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, but rather will hinder scientific advancement.

¹⁰⁴ *Id.* at 996.

¹⁰⁵ *Id.*

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 limit starting one year from the initial issuing of the patent should be applied to determine whether 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 consistent with *Continental Can*, which holds that a reference does not qualify as prior art unless it is recognized. Judge Newman offered a sensible recommendation that addresses 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*, 348 F.3d at 994 (Newman, J., dissenting). Judge Newman's alternative solution would 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 developing 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.*

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 *SmithKline* can be justified through his concern for the public policy implications of the patenting of metabolites caused by prior art. Despite acknowledging that, unlike the decisions in *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 differently than an inherent characteristic of prior art.¹⁰⁹ Instead, the dispositive issue was whether an anticipatory reference enabled the use of the claims, regardless of whether a PHOSITA recognized the presence of those claims.¹¹⁰ 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 a PHOSITA, creates a situation where a substance that is non-obvious to a 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 for materials that otherwise qualify under 35 U.S.C. §§ 101-103, Judge Rader made a policy determination regarding the desirability of allowing patents that, while advancing the sciences, extend patent protection beyond the reasonable twenty year limit.

Judge Newman, on the other hand, appeared to be solely concerned with patent law and did not address the public policy concern raised by Judge Rader. In her dissent to the denial of the rehearing en banc for *Schering*, Judge Newman’s objections revolved around the Circuit’s apparent denial of 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 held that this new compound was unpatentable on the ground of ‘inherent anticipation.’”¹¹⁴ Judge Newman then succinctly summarized her concern that no precedent supported the finding that a substance is “inherently anticipated” because it previously existed

¹⁰⁸ *Id.*

¹⁰⁹ *Schering*, 339 F.3d at 1378-79.

¹¹⁰ *Id.* at 1381.

¹¹¹ *Id.* at 1379-80.

¹¹² *Id.* at 1378-79.

¹¹³ *Schering*, 348 F.3d at 993.

¹¹⁴ *Id.*

undiscovered.¹¹⁵ Judge Newman also objected to *Schering's* abandonment of the *Continental Can* requirement that there be recognition by a 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 court had previously addressed the issue of whether a party may patent byproducts and, based on the severe differences of opinion that emerged, the case law was predictably mixed. Some, like Judge Newman, thought that a PHOSITA needed to recognize the missing elements in order to find anticipation by inherency. Others, like Judge Rader, recognized 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 within the case law.¹¹⁷

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, *Schering*, 348 F.3d 992, at *5-6 (Fed. Cir. 2003) (No. 02-1540), 2003 WL 24033460. 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 its costs.

¹¹⁷ Dan Burk & Mark Lemley, *Inherency*, 47 Wm. & Mary L. Rev. 371 (2005). Burk and Lemley suggest a theory to reconcile the conflicting views of the Federal Circuit. Their suggestion is that the Court will not grant further protection if the public has already been enjoying the benefit of the unpatented claims. This theory attempts to reconcile decisions that predated Judge Rader's attempts to abandon *Continental Can's* PHOSITA requirement, beginning with *Atlas Powder*, *MEHL/Biophile*, and *EMI Group*, and culminating with the explicit abandonment of the PHOSITA requirement in both *Schering* and *SmithKline*. By attempting to reconcile all of the Federal Circuit's case law on inherent anticipation, Burk and Lemley do not adequately appreciate the seismic shift orchestrated by Judge Rader relating to inherent anticipation. To begin with, they incorrectly claim that the PHOSITA requirement is irrelevant because no cases pass upon the issue, 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 the threshold must be met for the court 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, which 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 F.2d 578, 581 (C.C.P.A. 1981), 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 a PHOSITA may have suspected its presence, no one could sufficiently isolate or recognize Americium with any certainty until *Seaborg*. See, e.g., *Finnigan Corp. v. ITC*, 180 F.3d 1354 (Fed. Cir. 1999) (holding that a PHOSITA would not recognize the non-resonance ejector of the prior art and is therefore not anticipated); *In re Shetty*, 566 F.2d 81, 84-85 (C.C.P.A. 1977) (finding that a PHOSITA would not have recognized that a previous method to treat microbial

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 Corp. v. Apotex Corp.* (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 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

infection in animals also curbed appetite, and therefore the patent is not anticipated). 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." *Gen. Elec. Co. v. Jewel Incandescent Lamp Co.*, 326 U.S. 242, 248-49 (1945). Cases such as *General Electric*, *Titanium Metals*, and *EMI Group* merely claimed ever-present traits within devices whose discovery did not have any 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." *Cont'l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991). This objective test allows a court to ask what was known, or should have been known, by a PHOSITA in relation to a patent application. Unlike the test of obviousness, the PHOSITA requirement is not frozen at the date of patenting. This test thereby protects both the first discoverer 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 a PHOSITA generally recognizes a trait is unjustifiable. Lastly, the rule of *Schering* and *SmithKline* does not limit the inherent anticipation bar on patents to material from which the public is already benefiting. 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 clearer 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. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005). These cases indicate that 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 fails to recognize the Court's recent shift in its approach to inherent anticipation, and it is therefore largely a *post hoc* rationalization of the Court's opinions that is unworkable in practice.

¹¹⁸ *SmithKline*, 403 F.3d 1331.

¹¹⁹ *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306 (Fed. Cir. 2004), *vacated*, 403 F.3d 1328 (Fed. Cir. 2005) (en banc), *cert. denied*, 126 S. Ct. 2887 (2006).

would be alternative grounds 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 a PHOSITA is consistent with the policy that was slowly developed by the courts. The Supreme Court first addressed some form of inherent anticipation in 1890 with *Tilghman v. Proctor*.¹²¹ Later cases, such as *Edison 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 neither 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 a PHOSITA recognized the value of the invention.¹²⁵

The case of *In re Seaborg* supports Judge Newman's position.¹²⁶ In *Seaborg*, the patent covered Americium (also known as element 95), the accompanying isotopes, and

¹²⁰ *Id.* at 1320.

¹²¹ *Tilghman v. Proctor*, 102 U.S. 707 (1880). 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. 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 such situations.

¹²² *Edison Elec. Light Co. v. Novelty Incandescent Light Co.*, 167 F. 977 (3d Cir. 1909).

¹²³ *Eibel Process Co. v. Minn. & Ont. Paper Co.*, 261 U.S. 45 (1923).

¹²⁴ *Id.* at 66.

¹²⁵ See *supra* note 39, for a list of factors that differentiate between "accidental anticipation" and "inherent anticipation."

¹²⁶ *In re Seaborg*, 328 F.2d 996 (C.C.P.A. 1964).

the 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 could not have confirmed its presence.¹³⁰ The *Seaborg* court ultimately concluded that the prior art would not allow for the creation of Americium “without the exercise of more than ordinary skill in the art.”¹³¹ Based on the conclusion that a PHOSITA would not have been able to create Americium from the prior art, a patent was granted over the examiner’s original denial.¹³²

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *Id.* at 997.

¹³⁰ *Id.*

¹³¹ *Id.* 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 patent 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 1024-25. There was also testimony at the trial court that once a facility was seeded it would be almost impossible to “unseed” it. *Id.* at 1021. Judge Rader, in *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306 (Fed. Cir. 2004), *vacated*, 403 F.3d 1328 (Fed. Cir. 2005) (en banc), *cert. denied*, 126 S. Ct. 2887 (2006), rejected the view that policy may affect claim construction and rejected the suggestion of a *de minimus* exception to infringement. However, he did 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

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 just because 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 a 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

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. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the

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 to combat microbial infestation, but such actions can arguably inhibit appetite.

¹³⁶ *Id.* at 86.

¹³⁷ *Id.*

¹³⁸ *Id.* at 86.

¹³⁹ *In re Oelrich*, 666 F.2d 578 (C.C.P.A. 1981).

¹⁴⁰ *Id.* at 580.

¹⁴¹ *Id.* at 579-80.

¹⁴² *Id.*

performance of the questioned function, it seems to be 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 a PHOSITA would have recognized the claim.¹⁴⁵ Based on the parallel analysis of the C.C.P.A. with *Shetty*, the Court would have addressed recognition by a 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 a 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

¹⁴³ *Id.* at 581 (citing *Hansgirk v. Kemmer*, 102 F.2d 212, 214 (C.C.P.A. 1939)).

¹⁴⁴ *Id.* at 580.

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 a PHOSITA in possession of it. *Id.* at 708.

¹⁴⁷ *Id.*

¹⁴⁸ *Id.* at 706.

¹⁴⁹ *Id.* at 707.

¹⁵⁰ *Id.* at 707-08 n.3.

¹⁵¹ *Id.* at 708.

¹⁵² *Id.* 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 was issued in 1978 (U.S. Patent No. 4,128,658, “the ’658 patent”), Glaxo used a new, more efficient method to manufacture the ’658 material.¹⁵⁵ The new process created the ’658 material in a crystalline version, a polymorphed 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 the new version of manufacturing 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 inherently, if all the limitations are contained within a single piece of prior art.¹⁶¹ 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

¹⁵⁴ *Id.* at 1046.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ *Id.* 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 with 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 a PHOSITA, which was not shown to be the case in either *Schering* or *SmithKline*.

¹⁶¹ *Id.* at 1047.

¹⁶² *Id.*

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 that where 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 critical date."¹⁶⁸ Instead, he 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.¹⁷²

¹⁶³ *Id.* at 1047-48.

¹⁶⁴ *Cont'l Can Co. v. Monsanto Co.*, 948 F.2d 1264 (Fed. Cir. 1991).

¹⁶⁵ *Id.* at 1268-69.

¹⁶⁶ *Id.* at 1268 (emphasis added).

¹⁶⁷ *Id.* at 1269.

¹⁶⁸ *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003).

¹⁶⁹ *Id.*

¹⁷⁰ *Cont'l Can*, 948 F.2d at 1268.

¹⁷¹ *Id.*

¹⁷² *Id.* See also *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1380-81 (Fed. Cir. 2002); *Finnigan Corp. 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, 1480-81 (Fed. Cir. 1994); *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990); *In re Oelrich*, 666 F.2d 578, 581-82 (Fed. Cir. 1981); *In re Shetty*, 566

Subsequent to *Continental Can*, the Federal Circuit required recognition by a 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 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 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 mirror lens.”¹⁷⁶ Rosco’s ’357 design patent was filed in April 1992 and predated the Mirror Lite patent, which had a priority date of September 1992.¹⁷⁷ Both companies sued one another for 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 persons 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 whether “one skilled in the art would read the ’357 patent as showing a mirror of varying radius of curvature along the major axis.”¹⁸² The record did not show that a PHOSITA would have recognized the ’357 design patent as inherently disclosing the ’984 patent, so summary judgment was inappropriate.¹⁸³

F.2d 81, 84-85 (C.C.P.A. 1977); *In re Seaborg*, 328 F.2d 996, 999 (C.C.P.A. 1964); *Hansgirk v. Kemmer*, 102 F.2d 212, 214 (C.C.P.A. 1939).

¹⁷³ *Rosco*, 304 F.3d 1373.

¹⁷⁴ *Id.* at 1376.

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

¹⁷⁸ *Id.* at 1376.

¹⁷⁹ *Id.* at 1380.

¹⁸⁰ *Id.*

¹⁸¹ *Id.* (emphasis added) (quoting *Cont’l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991)).

¹⁸² *Id.* at 1380-81.

¹⁸³ *Id.* at 1381.

Crown Operations v. Solutia Inc., decided less than a year before *Schering*, confirms that inherent anticipation requires recognition by a PHOSITA.¹⁸⁴ *Crown Operations* involved layered films in glass that improve the safety and performance of the glass in, for instance, windshields and other products.¹⁸⁵ The patented films resisted shattering while also ensuring that visible light reflection was limited to two percent or less, whereas prior solar films permitted reflection of at least three percent.¹⁸⁶ The district court found Solutia's patent (U.S. Patent No. 4,973,511, "the '511 patent") to be valid on summary judgment and rejected a claim of inherent anticipation.¹⁸⁷ The Federal Circuit affirmed: "[i]f 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 had to be established, as a preliminary matter, as something that is more than "probabilities or possibilities."¹⁸⁹ The Court found that Crown had failed to carry its evidentiary burden of showing the two percent limitation to be necessarily present in the prior art patent.¹⁹⁰

The case of *Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education and Research* may have represented the first moment of open conflict between the two schools of inherent anticipation as represented by Judges Newman and Rader.¹⁹¹ Judge Newman authored the opinion in this case, which dealt with a "recipe" to make transgenic mice.¹⁹² The district court invalidated Elan's patents (U.S. Patent No. 5,612,486, "the '486 patent," and U.S. Patent No. 5,850,003, "the '003 patent") as being anticipated by the Mullan patent (U.S. Patent No. 5,455,169, "the '169 patent").¹⁹³ The Federal Circuit originally reversed this decision because the legal requirements of

¹⁸⁴ *Crown Operations Int'l., 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.

¹⁸⁵ *Id.* at 1370.

¹⁸⁶ *Id.* at 1370-71.

¹⁸⁷ *Id.* at 1371.

¹⁸⁸ *Id.* at 1377 (emphasis added) (citations omitted).

¹⁸⁹ *Id.* at 1377.

¹⁹⁰ *Id.*

¹⁹¹ *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. 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 1221.

¹⁹³ *Id.* at 1223.

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 However, Mullan never produced a transgenic animal.¹⁹⁶ The Elan '486 and '003 patents encompassed the characteristics of transgenic mice and the unpredictable method of production.¹⁹⁷ Judge Newman once again stated that a finding of inherent anticipation requires that the limitation be inherently present *and* that the missing elements in a reference be recognized by a PHOSITA as present in a single reference.¹⁹⁸ Judge Newman's opinion pointed out that the Mullan patent did nothing but repeat 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 inherently anticipated.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 simply has not invented anything new."²⁰¹ Furthermore, Judge Dyk 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 may not have recognized these inherent characteristics.'"²⁰² Judge Dyk's opinion recognized that the Federal Circuit's position regarding inherency appeared to be shifting and the court's subsequent en banc order 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

¹⁹⁴ *Id.*

¹⁹⁵ *Id.* at 1224.

¹⁹⁶ *Id.* at 1226.

¹⁹⁷ *Id.*

¹⁹⁸ *Id.* at 1227-28 (emphasis added).

¹⁹⁹ *Id.* at 1228.

²⁰⁰ *Id.* at 1229.

²⁰¹ *Id.* at 1229-31.

²⁰² *Id.* at 1231.

²⁰³ *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. and Research*, 314 F.3d 1299 (Fed. Cir. 2002).

²⁰⁴ *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. and Research*, 346 F.3d 1051, 1054 (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

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 case was remanded for a determination of whether the Mullan patent *enabled* a PHOSITA to create a transgenic mouse without undue experimentation, while avoiding the issue of whether the Mullan patent was inherently anticipated.²⁰⁷

Judge Newman's position in her *Schering* dissent that inherent anticipation required recognition by a PHOSITA seems to be well supported by precedent, but it also appears that she did not recognize the Federal Circuit shift concerning inherent anticipation.²⁰⁸ Her position is quite sensible from a case law standpoint. Judge Newman focused on whether the subject matter could have been patented sooner. If so, then an additional patent should not be permitted without a terminal disclaimer; but if a PHOSITA could not, and did not, recognize the subject matter then science has been advanced and a patent is appropriate. Judge Newman's was driven primarily out of a concern for patent law, in contrast to Judge Rader's public policy objectives.

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 a PHOSITA need not recognize an inherent property to disqualify that invention are fairly recent.

Titanium Metals Corp. of America v. Banner is arguably the oldest case that could stand for the proposition that recognition by a PHOSITA is unnecessary to support a finding of inherent anticipation.²⁰⁹ This case involved a patent for a titanium base alloy

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 resolved the conflict. The fact that such divisions could occur within a Circuit 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 implored 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. Combined Petition for Panel Rehearing and Rehearing en banc by Plaintiff-Appellant, *Schering Corp. v. Geneva Pharm. Inc.*, 348 F.3d 992, at *4 (Fed. Cir. 2003) (No. 02-1540), 2003 WL 24033460. This is confusing since the court's decision en banc was 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 *Elan Pharm.*, 346 F.3d at 1054.

²⁰⁶ *Id.* at 1055.

²⁰⁷ *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.

²⁰⁸ *Schering*, 348 F.3d at 993. Judge Newman viewed such a substantial shift in precedent as only appropriate after a hearing en banc.

²⁰⁹ *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985).

in which the applicants claimed that their invention was the recognition of the preferable qualities of corrosion resistance, strength, and “ductility,” which improved the welding properties of the alloy in hot brine environments.²¹⁰ Both the examiner and the board rejected the patent application as being obvious to a PHOSITA in light of a Russian article that predated the patent application by five years.²¹¹ The applicants then commenced a civil action and the U.S. District Court for the District of Columbia ordered the patent to issue.²¹² The Federal Circuit reversed: “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.”²¹³

The Court seemed to acknowledge, *arguendo*, that the applicants were the first to specifically discover these inherent properties in the alloys.²¹⁴ 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.²¹⁵ By acknowledging that the applicants did discover the properties inherent within the alloys but were nonetheless prohibited from receiving a patent, the Court seemed to downplay the importance of recognition by a PHOSITA in the inherent anticipation analysis.²¹⁶

Soon after *Titanium Metals*, the court reached a finding of inherency without reference to a PHOSITA in *Verdegaal Brothers v. Union Oil Co. of California*.²¹⁷ *Verdegaal Brothers* involved the infringement of a process for making liquid fertilizer by first mixing the elements in a “nutritive heat sink,” known as a “heel,” to absorb heat.²¹⁸

²¹⁰ *Id.* at 776.

²¹¹ *Id.*

²¹² *Id.*

²¹³ *Id.* at 782.

²¹⁴ *Id.* at 782.

²¹⁵ *Id.* (quoting *In re Thuau*, 135 F.2d 344, (C.C.P.A. 1943)).

²¹⁶ Both the examiner and the Board relied on a finding that a PHOSITA would have known of the properties based on the Russian publication to justify their denial of a patent originally. 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, the titanium alloys in question would have been completely removed from the public domain without contributing anything distinctly patentable in themselves. The facts of this case are analogous to those of *General Electric*, 326 U.S. 242 (1945), where the court specifically found that discovery of a pre-existing trait within a prior art reference does not impart patentability.

²¹⁷ *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628 (Fed. Cir. 1987).

²¹⁸ *Id.* at 630.

A “heel” is a previously mixed batch of liquid fertilizer.²¹⁹ Verdegaal Brothers owned a patent (U.S. Patent No. 4,310,343, “the ’343 patent”) on the process of making liquid fertilizer by adding sulfuric acid rapidly to the heel.²²⁰ The prior art Stoller patent (U.S. Patent No. 4,315,763, “the ’763 patent”) also called for the creation of a heel.²²¹ 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.”²²² 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.”²²³ The Court went further to declare “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.”²²⁴ Once again, the Court seemed to shy away from the importance of recognition by a 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.²²⁵ 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.²²⁶

Knowledge by a PHOSITA was also unnecessary to prevent patenting in *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*²²⁷ In *Abbott*, Byron Chemical Company, Inc. sold at least three lots of anhydrous terazosin hydrochloride between 1989 and 1992.²²⁸ Two lots were sold to Geneva Pharmaceuticals and one lot to Warner Chilcott Laboratories.²²⁹ Abbott Labs subsequently developed the same anhydrous terazosin hydrochloride (“Form IV”) to treat hypertension and “benign prostatic hyperplasia.”²³⁰

²¹⁹ *Id.*

²²⁰ *Id.*

²²¹ *Id.* at 632.

²²² *Id.* at 633.

²²³ *Id.*

²²⁴ *Id.*

²²⁵ *Id.*

²²⁶ *Id.* at 633-34.

²²⁷ *Abbott Labs. v. Geneva Pharm., Inc.*, 182 F.3d 1315 (Fed. Cir. 1999).

²²⁸ *Id.* at 1317.

²²⁹ *Id.*

²³⁰ *Id.* at 1316.

The patent application for Abbott's "Form IV" anhydrous terazosin hydrochloride was filed on October 18, 1994 (U.S. Patent No. 5,504,207, "the '207 patent").²³¹ 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.²³² 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 'invention' on sale."²³³ The Court rejected this argument and focused on the three commercial sales before the critical date occurred; the knowledge of the parties was irrelevant: "[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."²³⁴ *Abbott Labs* was consistent with Judge Rader's view that recognition by a PHOSITA of inherent properties is not relevant for issuing patents.²³⁵

Judge Rader himself explained his view quite clearly in *Atlas Powder Co. v. IRECO Inc.*, which was decided a month after *Abbott Labs*.²³⁶ *Atlas Powder* 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").²³⁷ 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").²³⁸ Neither of the prior art patents cited the specific composition of the Clay patent or of the reissue patent, but the prior art patents disclosed the same chemical compositions as the Clay and reissue patents in overlapping amounts.²³⁹ In affirming the district court, Judge Rader stated that the only limitation not arguably within the prior art patents was the requirement that there be "sufficient aeration" in the

²³¹ *Id.* at 1317.

²³² *Id.*

²³³ *Id.* at 1318.

²³⁴ *Id.* at 1319. 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.

²³⁵ Between *Abbott Labs*, *Atlas Powder*, and *MEHL/Biophile* (decided three weeks after *Atlas Powder*), Judge Rader assembled a string of cases that would support his view that there was no requirement of recognition by a PHOSITA to trigger inherent anticipation. *EMI Group* would follow two years later and this string of case law ultimately formed the substantive basis for the decisions in *Schering* and *SmithKline*.

²³⁶ *Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

²³⁷ *Id.* at 1343.

²³⁸ *Id.*

²³⁹ *Id.* at 1345.

composition.²⁴⁰ 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.”²⁴¹ Even assuming that the applicants did initially discover the property of the prior art composition, that trait was unpatentable regardless of the lack of recognition by a PHOSITA because the properties were inherently present within the prior art.²⁴² Nonetheless, Judge Rader explicitly found that “those of ordinary skill in the art at the time the patent application was filed knew [of the importance of aeration].”²⁴³ Judge Rader concluded 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].”²⁴⁴ Rader made it clear in *Atlas Powder* that the claimed invention was inherent in the prior art, and that there was recognition by a PHOSITA of the claimed “aeration.” However, he believed that this recognition by a PHOSITA was unnecessary in order to trigger anticipation by inherency.

Judge Rader’s apparent discomfort with explicitly abandoning the requirement for recognition by a PHOSITA resurfaced again a month after *Atlas Powder* in *MEHL/Biophile International Corp. v. Milgraum*.²⁴⁵ In *MEHL*, the plaintiffs sued the defendants for infringing their patent (U.S. Patent No. 5,059,192, “the ’192 patent”) covering a method to remove hair using a laser that destroys “the papilla, thereby preventing hair regrowth.”²⁴⁶ The district court granted summary judgment of invalidity based on a manual that anticipated all claims.²⁴⁷ 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.²⁴⁸ 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 to be well settled that the disclosure should be regarded as sufficient.”²⁴⁹ Judge Rader went on to state that “where, as here, the result is a necessary consequence of what was deliberately intended,

²⁴⁰ *Id.*

²⁴¹ *Id.* at 1347.

²⁴² *Id.* at 1348-49.

²⁴³ *Id.* at 1347.

²⁴⁴ *Id.* at 1348.

²⁴⁵ *MEHL/Biophile Int’l Corp. v. Milgraum*, 192 F.3d 1362 (Fed. Cir. 1999).

²⁴⁶ *Id.* at 1364.

²⁴⁷ *Id.*

²⁴⁸ *Id.*

²⁴⁹ *Id.* at 1365 (quoting *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981)).

it is of no importance that the article's authors did not appreciate the results."²⁵⁰ He added that "[i]nherency is not necessarily conterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art."²⁵¹ But, once again, Judge Rader covered his bases: "[i]t 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."²⁵² Judge Rader predicated his decision upon the inevitability of the claimed results of the invention and the presence of PHOSITA recognition, while maintaining in dicta that PHOSITA recognition was unnecessary.

After *Atlas* and *MEHL*, Judge Rader's next opportunity to address the issue of inherent anticipation came in *EMI Group North America v. Cypress Semiconductor*.²⁵³ *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").²⁵⁴ 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."²⁵⁵ Manufacturers "blow" dysfunctional links in a chip using a laser beam to sever the connectors, and chips are built with redundant circuits to allow this action.²⁵⁶ 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.²⁵⁷ 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.²⁵⁸ 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, though the previous inventors had not recognized the trait.²⁵⁹ It was enough that the prior art disclosed the

²⁵⁰ *Id.* at 1366.

²⁵¹ *Id.* at 1365 (citing *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986)).

²⁵² *Id.* at 1366.

²⁵³ *EMI Group N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1342 (Fed. Cir. 2001).

²⁵⁴ *Id.* at 1344.

²⁵⁵ *Id.*

²⁵⁶ *Id.*

²⁵⁷ *Id.* at 1346.

²⁵⁸ *Id.* at 1347.

²⁵⁹ *Id.* at 1349-50 (citing *Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999)). Perhaps the most interesting portion of Judge Rader's opinion in *EMI* is that he makes

structure of the fuse because doing so “inherently discloses the law of nature by which such fuses rupture under the heat of a laser.”²⁶⁰

While not written by Judge Rader, the case of *In re Cruciferous Sprout Litigation* is an example of the type of policy matters that Judge Rader was most concerned with in his attempt to abandon the requirement that a PHOSITA recognize an inherent trait for anticipation to be triggered.²⁶¹ This case revolved 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”).²⁶² The patent applicants discovered that sprouts induced Phase 2 enzymes, which in turn reduced the level of carcinogens.²⁶³ The panel agreed with Judge Rader’s position that recognition by a PHOSITA was not necessary for inherent anticipation to apply.²⁶⁴ They stated that the carcinogen reducing characteristics of a sprout were “inherent characteristics” and it did not matter that those of ordinary skill had not recognized the traits.²⁶⁵

his first clear attempt to partially abandon the PHOSITA recognition requirement of inherent anticipation. He stated:

[the] requirement, that a person of 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 law that are 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 1350-51. Therefore, Rader would still require recognition by a PHOSITA in cases of patents covering structural matter, compositions, and methods, while not requiring recognition by a PHOSITA for theory or rules of natural law that are not themselves patentable. 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 through *in vivo* metabolization.

²⁶⁰ *Id.* at 1351.

²⁶¹ *In re Cruciferous Sprout Litig.*, 301 F.3d 1343 (Fed. Cir. 2002).

²⁶² *Id.* at 1345.

²⁶³ *Id.*

²⁶⁴ *Id.* at 1350.

²⁶⁵ *Id.* The Supreme Court has recently heard a case very similar to *In re Cruciferous Sprout Litigation*. The case is *Metabolite Labs. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354 (Fed. Cir. 2004), *cert. granted in part*, 126 S. Ct. 601 (2005), *cert. dismissed as improvidently granted*, 126 S. Ct. 2921 (2006)). In this case a patent was gained for a process that 1) measured the body’s

A year after *Cruciferous Sprout*, the *Schering* court asked whether anyone practicing the prior art loratadine could have been infringing on the new DCL patent.²⁶⁶ To address this problem, Rader's opinion abandoned the PHOSITA rule altogether, opting to prohibit patents for inherent results regardless of recognition by a PHOSITA prior to the patent application.²⁶⁷ This rule serves public policy interests by ensuring that the public is never threatened with infringement from practicing the prior art, and ensures that material in the public domain remains freely available. At the same time, the rule also bypasses several alternative, less severe methods, like Judge Newman's suggestion that Schering may not prevent others from practicing its expired patent.²⁶⁸

Judge Rader's view rejecting the need for recognition by a PHOSITA was well received in the subsequent decision of *Toro Co. v. Deere & Co.*²⁶⁹ In *Toro*, the Federal Circuit made clear that recognition by a PHOSITA was no longer required to find anticipation by inherency. This new rule was applied across the board, and not limited to situations concerning metabolites.²⁷⁰ *Toro* involved a method to treat turf by aerating it with sporadic injections of liquid fertilizer (U.S. Patent No. 5,207,168, "the '168 patent").²⁷¹ 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.²⁷² John Deere asserted that practicing the '516 patent would lead to infringement of the *Toro* patent because the prior art taught all the spacing and pressure

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 and more efficient. *Metabolite Labs.*, 370 F.3d at 1359. 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. *Id.* at 1361. 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. However, complicating matters is the fact that Lab. Corp. never explicitly raised 35 U.S.C. § 101 until after the Supreme Court asked the Government to address the issue of patentability. Both Metabolite and the Justice Department took the view that the issue of § 101 patentability was not properly before the court, and the Court ultimately used this as grounds to dismiss certiorari as improvidently granted.

²⁶⁶ *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1375-76 (Fed. Cir. 2003).

²⁶⁷ *Id.* at 1377.

²⁶⁸ *Schering Corp. v. Geneva Pharm. Inc.*, 348 F.3d 992, 993-94 (Fed. Cir. 2003) (Newman, J., dissenting from denial of petition for rehearing en banc).

²⁶⁹ *Toro Co. v. Deere & Co.*, 355 F.3d 1313 (Fed. Cir. 2004).

²⁷⁰ *Id.* at 1320-21.

²⁷¹ *Id.* at 1314, 1317.

²⁷² *Id.* at 1317.

parameters that would lead to the aeration Toro claimed.²⁷³ The district court denied John Deere's motion for summary judgment because it found that a PHOSITA would not have recognized the Toro characteristics at the time the '516 patent was filed.²⁷⁴ The Federal Circuit corrected the district court on this subject: "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 of the prior invention."²⁷⁵ Ultimately, the Federal Circuit upheld the district court's denial of summary judgment, but the matter was remanded for a determination of the validity of the '168 patent.²⁷⁶

In *SmithKline Beecham Corp. v. Apotex Corp.*, another federal circuit panel endorsed *Schering's* holding in the pharmaceutical context, and found that recognition by a PHOSITA was not necessary to find invalidity due to inherent anticipation. The case was originally tried before Judge Richard Posner, sitting by designation.²⁷⁷ The case involved the antidepressant drug PAXIL®. 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").²⁷⁸ Ferrosan then licensed the '196 patent to SmithKline.²⁷⁹ The '196 patent covered an "anhydrous" form of the paroxetine. Anhydrous materials are difficult to manufacture because they can become "soggy" and therefore require special care to maintain their viability.²⁸⁰ In 1985, however, a SmithKline researcher realized the material had naturally morphed into a "pseudopolymorph," known as a hemihydrate, which is much more stable and can be more easily manufactured than the original anhydrous version of the drug.²⁸¹ SmithKline received a second patent for this new version of paroxetine (U.S. Patent No. 4,721,723, "the '723 patent").²⁸² This second patent began to be marketed as PAXIL® in 1993.²⁸³

²⁷³ *Id.* at 1318.

²⁷⁴ *Id.*

²⁷⁵ *Id.* at 1321.

²⁷⁶ *Id.*

²⁷⁷ *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1013 (N.D. Ill. 2003).

²⁷⁸ *Id.* at 1015.

²⁷⁹ *Id.*

²⁸⁰ *Id.* at 1017.

²⁸¹ *Id.* at 1016-17.

²⁸² *Id.* at 1017.

²⁸³ *Id.*

Complications soon arose due to the nature of the anhydrous version of paroxetine.²⁸⁴ The original '196 patent on paroxetine expired in 1992. However, when Apotex announced plans in 1998 to make a generic version of anhydrous paroxetine, SmithKline sued them.²⁸⁵ SmithKline's complaint was that any version of the '196 material was likely to contain some amount of the '723 hemihydrate, a patent that would not expire until 2006.²⁸⁶ First, SmithKline claimed that the '196 patent would likely morph into the protected hemihydrate form of paroxetine, which is how SmithKline originally discovered the '723 material.²⁸⁷ Second, even if the '196 material did not morph into the '723 material, SmithKline argued that it was highly likely that any Apotex manufacturing location would be "seeded" with PAXIL®.²⁸⁸ The "seeding" phenomenon is likely to occur anytime the '723 material is handled roughly and small crystals come loose and then implant in the '196 material; the '723 material will then multiply within the '196 material to a saturation point of several percentage points.²⁸⁹ Lastly, SmithKline claimed that even if Apotex could prevent any of the '196 material from morphing into the '723 form, infringement would occur when a patient ingested the '196 material due to its transformation into '723 form within the warm, humid stomach.²⁹⁰

Judge Posner addressed the concern of natural morphing of the '196 material to a hemihydrate by limiting protections of the '723 patent to commercially significant

²⁸⁴ *Id.* at 1020.

²⁸⁵ *Id.* at 1023.

²⁸⁶ *Id.*

²⁸⁷ *Id.* at 1017.

²⁸⁸ *Id.* at 1020-21.

²⁸⁹ *Id.* at 1020-23. 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 (i.e., PAXIL®) when producing the '196 material.

²⁹⁰ *Id.* at 1014-15. The previous judge in the case had already excluded evidence of contributory infringement brought on by ingestion of the '196 patent. Posner agreed that a finding of contributory 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 '723 material would grow 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 1024-25.

amounts.²⁹¹ He then restricted the ability of SmithKline to allege infringement due to “seeding” by creating an equitable defense that the patent holder had caused the infringement.²⁹² Judge Posner justified this defense by stating that to hold otherwise would allow SmithKline more protection for the ’723 patent than patent law intended.²⁹³ Judge Posner also ruled that Apotex had not shown to his satisfaction that the ’196 patent would inherently contain the ’723 material, thereby allowing the ’723 patent to be valid over a claim of inherent anticipation.²⁹⁴ Judge Posner’s ultimate conclusion was that the ’723 patent was valid but not infringed.²⁹⁵

On appeal, Judge Rader authored two subsequent opinions. In the initial panel decision, Judge Rader rejected nearly all of Judge Posner’s conclusions, and ultimately found the patent to be invalid for public use.²⁹⁶ Rader concluded that it was an 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 construction of the ’723 patent encompassed all hemihydrates.²⁹⁷ Additionally, while Rader understood that Posner was concerned about the implications of finding Apotex liable for infringement by practicing prior art in the public domain, he opined that Posner’s equitable defense was not necessary since the patent could be dispensed on alternative grounds.²⁹⁸ 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.²⁹⁹ Amazingly, Judge Rader did not rule based on inherent anticipation despite the fact that

²⁹¹ *Id.* at 1029-30. 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.

²⁹² *Id.* at 1043.

²⁹³ *Id.* at 1046.

²⁹⁴ *Id.* at 1035-36.

²⁹⁵ *Id.* at 1052.

²⁹⁶ *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306, 1333 (Fed. Cir. 2004), *vacated en banc*, 403 F.3d 1328 (Fed. Cir. 2005), *aff’d on other grounds*, 403 F.3d 1331 (Fed. Cir. 2005).

²⁹⁷ *Id.* at 1313-14. Judge Posner’s claim construction had limited the ’723 material to “commercially significant amounts.” *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1029-30 (N.D. Ill. 2003). Rejecting this approach, Judge Rader stated that “claim construction is not a policy driven inquiry [and t]he scope of patent claims can neither be broadened nor narrowed based on abstract policy considerations regarding the effect of a particular claim meaning.” *SmithKline*, 365 F.3d at 1314.

²⁹⁸ *Id.* at 1316.

²⁹⁹ *Id.* at 1317.

SmithKline alleged infringement through *in vivo* degradation, and despite his specific warning to SmithKline that success on that allegation would result in invalidation of the patent for inherent anticipation.³⁰⁰

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.³⁰¹ In writing his second *SmithKline* decision, Rader once again corrected the original mistakes made in Judge Posner's district court decision, but then went on to invalidate the '723 patent based on inherent anticipation.³⁰² Rader found the '196 patent was enabled and, if practiced, would inevitably result in at least trace amounts of hemihydrate.³⁰³ 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 a PHOSITA to "recognize the inherent disclosure at the time the prior art is created."³⁰⁴ 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.³⁰⁵ 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."³⁰⁶

SmithKline appears to signal 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 undisturbed.³⁰⁷ 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 skill in the field of the invention."³⁰⁸ Newman contended that *Continental Can* was still good law, and that the question should still be whether a substance's

³⁰⁰ *Id.* at 1320.

³⁰¹ *SmithKline*, 403 F.3d at 1328.

³⁰² *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1335-43 (Fed. Cir. 2005).

³⁰³ *Id.* at 1344.

³⁰⁴ *Id.* at 1343.

³⁰⁵ *Id.* at 1345.

³⁰⁶ *Id.* at 1346; see also *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1381 (Fed. Cir. 2003).

³⁰⁷ *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1328, 1329 (Fed. Cir. 2005) (Newman, J., dissenting from the order declining rehearing en banc).

³⁰⁸ *Id.* at 1329.

existence would have been known by a PHOSITA, not whether “it might have lain hidden in minuscule amount, undetected, unsuspected, and unknown.”³⁰⁹ “Only 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.’”³¹⁰

SmithKline makes sense from a public policy standpoint, but it seems that the Federal Circuit went further than necessary to protect the public. Is the Court’s new doctrine on inherent anticipation consistent with the goals of patent law, or does it draw 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 statutory revisions 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. THE HATCH-WAXMAN ACT

Congress attempted to address the concerns of both brand name pharmaceutical companies and the public in the “Hatch-Waxman Act.”³¹¹ 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.³¹²

Pharmaceutical manufacturers were protected by the Hatch-Waxman Act by becoming eligible for a patent term restoration.³¹³ 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.”³¹⁴

³⁰⁹ *Id.* at 1330.

³¹⁰ *Id.*

³¹¹ The Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Amendments” to the Federal Food, Drug and Cosmetic Act (“FFDCA”)), Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355, 360cc (2003) (generic drugs) and 35 U.S.C. §§ 156, 271 (2004) (patent term restoration)).

³¹² *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002).

³¹³ *Arnold P’ship v. Dudas*, 362 F.3d 1338, 1340-41 (Fed. Cir. 2004).

³¹⁴ *Id.* at 1340-42.

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.³¹⁵ 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.³¹⁶

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.³¹⁷ Subsequent listings in the “Orange Book” can result in consecutive stays which often have the effect of delaying final approval to proposed generic drugs for periods much longer than the originally intended thirty months.³¹⁸ This unintended extension was rendered virtually immune from judicial review by the Federal Circuit’s decision in *Andrx*, 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.³¹⁹ 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.”³²⁰ Although antitrust action exists, pharmaceutical companies have proven adept at avoiding such liability.³²¹

³¹⁵ 35 U.S.C. § 156(g)(6)(B) (2005) (limiting extension to five years); 35 U.S.C. § 156(c)(3) (2005) (limiting overall protected time period after FDA approval to fourteen years); *Merck & Co. v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1996).

³¹⁶ 21 U.S.C. §§ 355(b)(1), (c)(2) (2003); *Andrx*, 276 F.3d at 1371.

³¹⁷ *Andrx*, 276 F.3d at 1371. *Cf.* 35 U.S.C. § 271(e)(2) (2005) (making filing of an ANDA technical infringement if the patents covering a drug are still valid, regardless of whether any drug is ever produced or sold).

³¹⁸ *See supra* note 62 and accompanying text.

³¹⁹ *Andrx*, 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 de-list patents from the “Orange Book” because *Andrx* failed to plead the 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 the *Andrx* complaint “had [implied] certain procedural facts that may give rise to an APA claim” if properly pleaded. *Id.* at 1374.

³²⁰ *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 1332-33 (Fed. Cir. 2001).

³²¹ *See, e.g., SmithKline Beecham Corp. v. Apotex Corp.*, 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

The provisions of the Hatch-Waxman Act that 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 overall protection accorded to the pharmaceutical companies could not extend beyond fourteen years from the date that the FDA approved the new drug application. This extension could only be granted once and had to be filed prior to the expiration of the original patent.³²²

In exchange, the generic companies received an extended experimental use privilege so that they could more quickly market generic versions of drugs.³²³ 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.³²⁴ Hatch-Waxman allows generic drug manufacturers to rely on the clinical trial data provided to the FDA by the original marketer of a drug, to fulfill the FDA regulatory requirements.³²⁵ Such applications are known as ANDAs,³²⁶ and need only show that the drug the generic drug manufacturers seek to market is the bioequivalent of the originally approved drug.³²⁷ Also, generic drug manufacturers are permitted to “make and use the patented product, even though the patent had not yet expired, in order to demonstrate bioequivalence.”³²⁸ 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 generic and original manufacturers co-exist as “duopolists.”³²⁹ The Hatch-Waxman Act aimed to expedite the marketing of

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 tortious 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 company 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.

³²² *Arnold P’ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004).

³²³ *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1018 (N.D. Ill. 2003).

³²⁴ *Merck & Co. Inc. v. Kessler*, 80 F.3d 1543, 1546 (Fed. Cir. 1996).

³²⁵ *Id.* (citing 21 U.S.C. § 355(j)(7)(B) (2003)).

³²⁶ *Merck*, 80 F.3d at 1547.

³²⁷ *SmithKline*, 247 F. Supp. 2d at 1018.

³²⁸ *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). 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.

³²⁹ *SmithKline*, 247 F. Supp. 2d at 1023 (citing 21 U.S.C. § 355(j)(4)(B)(iv) (2003)).

generic versions of brand name drugs.³³⁰ However, pharmaceuticals have proven 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 recognizes that pharmaceuticals possess unique qualities, within themselves and to the public, that necessitate special treatment. The patent extension compensating for lost marketing time during the 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.

In line with Congress’ willingness 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 in light of *Schering* and *SmithKline*. The primary problem with the *Schering* and *SmithKline* cases is that the Federal Circuit has foreclosed patents for metabolites that are unrecognized and provide utility. The *Schering* case ultimately prevents *any* type of patent protection for the *true* scientific advancement of a chemical composition. This view is inconsistent with the goals of patent law, which is intended to encourage and protect innovation. The new rule of inherent anticipation will make research and development of metabolites impractical due to the danger that resulting patents may be invalidated if any prior art is found to have produced that metabolite, regardless of whether the metabolite was previously known or related to the utility of the prior art. However, a full term patent may not prove to be the preferred solution. Congress has determined, as demonstrated by Hatch-Waxman, that pharmaceutical compositions need to be treated differently from other patented materials because of their importance to society’s overall quality of life.³³¹ As a result, a statutory compromise is necessary.

IV. POLICY SUGGESTIONS

Both *Schering* and *SmithKline* are instances where a useful metabolite was discovered, but later found to be anticipated because the discovery was made after the original patent’s critical date.³³² 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 prohibit the public from practicing an invention without advancing science in return. Absent a finding to this effect, patent applications for

³³⁰ *Merck*, 80 F.3d at 1547.

³³¹ See 35 U.S.C. §§ 154, 156 (2005). The statute allows for patent term restoration equal to the 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.

³³² *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1381 (Fed. Cir. 2003); *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005).

metabolites and other biological inventions must be examined on a case-by-case basis. I will make recommendations on how to incentivize pharmaceutical companies' discoveries of metabolites, which do meet all the requirements of patentability, while ensuring that the passing of these discoveries into the public domain is not unduly delayed.

A review of both the *Schering* and *SmithKline* case will help 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 was appropriate because the discovered metabolite may have provided some utility to the patent, although it was not certain to what degree.³³³ 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.³³⁴ Upon the expiration of the '233 patent, generic manufacturers wished to manufacture generic versions of this patent, but were first 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.³³⁵ Through the "Orange Book" listing, Schering attempted to prevent generic drug manufacturers from practicing the '233 patent, even after it had entered the public domain.

The Federal Circuit was understandably troubled by this notion. However, in attempting to rectify the situation the Circuit used a sledgehammer to crack a nut. Although listing the '716 patent in the "Orange Book" in connection with the '233 patent was questionable, Schering's other actions did not necessarily lead to a conclusion of bad intent. Most notably, the '716 patent application was filed in 1984, a mere three years after the '233 patent. If Schering's intention was to extend the term of the '233 patent, the company would have been far better served by delaying the application for several more years. Moreover, the court never addressed whether the '716 patent advanced science. If the '716 patent did advance science, then the patent should not have been categorically invalidated. This view receives support from Judge Lourie's dissent, which points out the difficulty of finding all metabolites prior to clinical trials, which themselves may take years to receive FDA approval.³³⁶

Furthermore, if discoveries such as DCL are denied patent protection, it is likely that companies like Schering will choose in the future to maintain these 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 *Schering* encourages recourse to trade secrets, then the policy goals of patent law have not been

³³³ *Schering*, 339 F.3d at 1375. See also *supra* Section II.A. It is not clear if DCL was the non-drowsy antihistamine within CLARITIN™ or merely another non-drowsy metabolite created upon ingestion.

³³⁴ *Id.* at 1376.

³³⁵ *Id.*

³³⁶ *Schering Corp. v. Geneva Pharm. Inc.*, 348 F.3d 992, 995-96 (Fed. Cir. 2003).

served because scientific advancement will not become readily accessible to the public.³³⁷ Despite the complications brought on by *Mylan*³³⁸ and *Andrx*,³³⁹ the simplest solution to these problems is to refuse to permit a pharmaceutical company to block generic manufacturers' production of drugs that have passed into the public domain. This position, advanced 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.³⁴⁰

SmithKline provides an example of the potential pitfalls of the *Schering* rule. In this case, SmithKline received one patent for paroxetine (the '196 patent), and later a second for the hemihydrate form of paroxetine (the '723 patent).³⁴¹ 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.³⁴² The value of the hemihydrate form of the drug was not an increase in its utility to patients, but 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.³⁴³ The court ultimately concluded that the inevitable creation of small amounts of '723 material within

³³⁷ 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, *Schering*, 348 F.3d 992, at *12 (Fed. Cir. 2003) (No. 02-1540), 2003 WL 24033460. 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.

³³⁸ *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001).

³³⁹ *Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368 (Fed. Cir. 2002).

³⁴⁰ 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 993-94.

³⁴¹ *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1334-37 (Fed. Cir. 2005).

³⁴² *Id.*

³⁴³ *Id.*

a patient's stomach, invalidated the patent as inherently anticipated.³⁴⁴ This decision is once again understandable given SmithKline's unreasonable position in the litigation, but 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's stomach, but rather the efficiency of manufacture as compared to the '196 material.

Through its ruling in *SmithKline*, the Federal Circuit has created a substantial danger to innovation. Consider the following hypothetical: Company A discovers a metabolite that proves extremely valuable for 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 would be invalidated. Thus, Company A is likely to be dissuaded from investing in the research and development of metabolites, because they will not be able to patent their discoveries and recoup their investment. The deterrence caused by generic companies piggybacking on the work of brand-name pharmaceuticals is certainly not anticipated or intended by The Hatch-Waxman Act. Therefore, the ruling in *SmithKline* undercuts the purpose of patent law and encourages recourse to trade secrets, assuming pharmaceutical corporations invest in metabolite research at all.

We must balance the public's desire for generic drugs, against the need to incentivize continued research and development in this area. In this vein, 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. A court should first ask whether a metabolite would be patentable but for inherent anticipation, then determine whether the party acted promptly to patent the metabolite upon its discovery. This would prevent the gamesmanship that concerned Judges Newman and Rader by holding a party accountable if they had knowledge superior to that of a PHOSITA. If the company acted diligently, the court should ask whether a PHOSITA would have recognized the trait prior to the critical date of the original patent. If so, the appropriate step would have been for the applicant to receive a patent with a terminal disclaimer, and further protection should be refused.

If a PHOSITA would not have recognized the discovery, then additional protection is appropriate, provided science is sufficiently advanced. I suggest this protection run conterminously with the length of the original patent, plus an additional

³⁴⁴ *Id.*

five years after the termination of the protected term under Hatch-Waxman. Applicants for this patent should not be limited to the original patent owner. This would encourage publicly beneficial research and development using the patented material. However, this patent should be limited in scope so as not to brand anyone as an infringer who is unknowingly practicing the metabolite or the prior art. Only one five-year extension should be obtainable, and it should not run consecutively with 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 methods of administration, since this a limited exception to the double patenting rule, and obviousness should be judged from the original patent, not from the limited five-year patent.

Congress must address the fact that the discovery of metabolites is not analogous to the situation in *General Electric*, where a party attempted to obtain an additional patent on an invention that had already passed into the public domain.³⁴⁵ The discovery of a metabolite constitutes a substantial discovery that advances science, and could hasten the development of alternative medications. The suggested rules would allow pharmaceutical companies that discover useful metabolites to more fully exploit their discovery, generating further resources for research and development. Other companies would perceive the metabolite's desirable results and begin their own research and development to determine other ways to practice the patented metabolite, and generic companies would be able to practice the protected metabolite after a delay of only five years, as opposed to the twenty years granted to a full patent.

V. CONCLUSION

The problems associated with the patenting of metabolites are fairly new because the technology and incentives to develop such inventions have 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, the time has come to create a sound policy that directly addresses the patenting of metabolites. This policy needs to balance the interests of the public in accessing generic pharmaceuticals against the financial incentives of the pharmaceutical companies to continue producing new drugs that improve public health. I believe that a minor extension to an existing patent to cover recently discovered metabolites is an ideal compromise. The revised rule will improve pharmaceutical companies' ability to fully exploit a discovery with only minor delays in public access to generic drugs. While this view will not allow either side to claim victory, it will address the major underlying concerns raised by both Judges Newman and Rader that new discoveries be protected and that public policy be secured.

³⁴⁵ See *supra* note 13 and accompanying text.