INVESTIGATING INHERENCY: INCEPTION TO AIA

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Investigating Inherency: Inception to AIA

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Abstract

The doctrine of inherent anticipation has a long and convoluted history which has evolved within the American court system from the late 1800s through present day, with the advent of the American Invents Act (AIA). The doctrine is typically used to invalidate a claim for lacking novelty over an inherent undisclosed feature present in the prior art. More recently, the Federal Circuit has clarified that this doctrine may also be applied to invalidate a claim as obvious. This paper examines the evolution of inherency, and further examines how inherency may be properly applied within the confines of the obviousness inquiry. This paper concludes with a discussion of whether the doctrine of inherent anticipation will have a place under the new AIA regime.

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Introduction

The doctrine of inherent anticipation has been characterized as “perhaps the most elusive doctrine in all of patent law,”\(^1\) a characterization which stems, in part, from its inconsistent application prior to the landmark Schering v. Genentech\(^2\) decision. Although inherency manifests itself across a broad spectrum of patent-related issues, the doctrine is best known and most often applied within the context of anticipation.\(^3\) Under 35 U.S.C. § 102, a claim is anticipated—and thus unpatentable—only if each and every element as set forth in the claim is found in a single prior art reference.\(^4\) Anticipation does not require the actual creation or reduction to practice of the prior art subject matter, but requires only an enabling disclosure that delivers the claimed invention to the public prior to its critical date.\(^5\)

Of course, establishing anticipation is straightforward if the prior art reference expressly discloses each and every element of the claim.\(^6\) Anticipation becomes more difficult to establish, however, when the prior art reference is silent with regard to a particular claimed element, but where such element simply inheres in the disclosure.\(^7\) Extrinsic evidence—such as data, additional references, and/or expert testimony—may be used, for example, to show that the element not expressly disclosed in the primary prior art reference is inherently disclosed.\(^8\) The mere fact that the primary prior art reference may disparage, teach away, or even expressly exclude the inherent element is not at all relevant to the inherency inquiry under 35 U.S.C. § 102.\(^9\)

The difficulties concerning inherent anticipation that American courts have grappled with over time, but which now appear resolved, are, first, whether an element is inherently disclosed if it is “accidentally” and “unwittingly” produced while in the pursuit of other and different results, and, secondly, whether an element is inherent if there was no knowledge or appreciation of its existence prior to the critical date of the claimed invention.\(^10\) Confusion still remains, however, as to whether the doctrine of inherent anticipation may be properly applied under 35 U.S.C. §103, the obviousness inquiry.\(^11\)

This paper is divided into three parts. Part 1 describes the doctrine of inherent anticipation from its inception up to the Schering decision within the realm of 35 U.S.C. § 102, the novelty regime. Part 2 examines the views of the Schering dissenter within
the context of two subsequent cases, *SmithKline Beecham Corp. v. Apotex Corp*\(^\text{12}\) decided in 2005, and *In re Omeprazole Patent Litigation*\(^\text{13}\) decided in 2008, following and upholding the *Schering* decision. Part 3 explores whether the doctrine is, as some practitioners have put it, impermissibly “merging” within the 35 U.S.C. § 103 obviousness inquiry.\(^\text{14}\) This paper concludes with a discussion of whether the doctrine of inherency will exist post-American Invents Act (AIA).\(^\text{15}\)

## I. Evolution of the Doctrine of Inherent Anticipation

### A. Distinguishing Accidental Anticipation from Inherent Anticipation

The 1880 Supreme Court case *Tilghman v. Proctor*\(^\text{16}\) began the American courts’ captivation with the concept of inherency. In *Tilghman*, the inventor discovered that by pumping a mixture of neutral fat and water through a coil of pipe at high temperature and pressure followed by cooling, glycerine separated as a solid from the solution containing fatty acid by-products.\(^\text{17}\) Tilghman sought and obtained U.S. Patent 11,766 reciting a single claim broadly covering his invention: “I claim . . . the manufacturing of fat acids and glycerine from fatty bodies by the action of water at a high temperature and pressure.”\(^\text{18}\) Tilghman later brought suit against William Proctor, James Gamble, and George Proctor, co-partners of Proctor & Gamble, for infringement of the ‘766 patent.\(^\text{19}\)

Prior to discussing the merits of infringement, the Supreme Court addressed various prior art processes that allegedly also effected decomposition of fat into fatty acids and glycerine.\(^\text{20}\) One such prior art process was the lubrication of a cylinder of a steam engine with tallow which, *via* the combined action of steam and high temperature and pressure on the tallow coating, likely produced the claimed products in the scum on the water issuing from the ejection pipe.\(^\text{21}\) The Court, however, did not regard this process as inherent, and thus novelty destroying, since the formation of the fatty acids and glycerine was “accidental” and “never fully understood.”\(^\text{22}\) The oft-quoted language used by the Court, “[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,”\(^\text{23}\) was later boiled down to a more simplistic slogan: “accidental results not intended and not appreciated, do not constitute anticipation.”\(^\text{24}\)

\(^{12}\) *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331 (Fed. Cir. 2005).

\(^{13}\) *In re Omeprazole Patent Litigation*, 536 F.3d 1361, 1365 (2008).

\(^{14}\) See Dittmann, supra note 11.


\(^{16}\) 102 U.S. 707 (1880).

\(^{17}\) *Id.* at 709.

\(^{18}\) *Id.* (hereinafter “the ‘766 patent”).

\(^{19}\) *Id.* at 707.

\(^{20}\) *Id.* at 708-712.

\(^{21}\) *Id.* at 711.

\(^{22}\) *Id.*

\(^{23}\) *Id.* at 711-712.

The doctrine of “accidental anticipation” is distinguishable from inherent anticipation since accidental anticipation requires, as its name implies, an “accidental or unwitting duplication” of the invention in the prior art. Practitioners Brown and Polyakov comment that the “anticipation” moniker of accidental anticipation “is somewhat of a misnomer because under this doctrine the prior art does not, in fact, anticipate under 35 U.S.C. § 102.”

Unfortunately, as Brown and Polyakov assert, it is often unclear when a prior occurrence falls under the doctrine of accidental anticipation—which is not inherent, and thus does not render the claimed invention anticipated—or the doctrine of inherent anticipation—which is inherent, and does render an invention anticipated—because what constitutes an accident remains undefined, and requires the court to engage in a specific fact-based inquiry.

Courts have made it clear, however, that if there is a “possible” or only occasional occurrence, it is not grounds for anticipation because “[o]ccasional results are not inherent.” In contrast, courts have determined that if the prior art discloses a claimed element which necessarily, inevitably, and always functions in accordance with, or includes, the claimed limitations, in other words, is a natural result flowing from the operations as taught, the prior art disclosure inherently anticipates.

For example, in MEHL/Biophile, the United States Court of Appeals for the Federal Circuit (hereinafter “Federal Circuit”) concluded that a laser manual teaching tattoo removal did not inherently anticipate a claimed hair depilation method of aligning a laser substantially over a hair follicle opening. The prior art manual did not expressly teach the substantial vertical alignment of the laser over a hair follicle as claimed. While there was a possibility that the laser may be aligned substantially vertically over a hair follicle during tattoo removal, the MEHL/Biophile court held such occasional results did not constitute inherent anticipation: “The mere fact that a certain thing may result from a given set of circumstances is not [inherent]. 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 [inherent].”

The fact patterns resulting in a finding of accidental anticipation or inherent anticipation can be quite close, however. Compare, for example, the holding of In re Marshall to In re Cruciferous Sprout Litigation.

In Marshall, the claims at issue recited a weight control process comprising, to paraphrase, administering an anesthetic, such as oxethazaine, prior to eating wherein the

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25 See, e.g., In re Felton, 484 F.2d 495, 500 (C.C.P.A. 1973); In re Marshall, 578 F.2d 301, 303 (C.C.P.A. 1978).
27 Id. at 63.
28 MEHL/Biophile Int’l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999).
29 In re King, 801 F.2d 1324, 1326 (Fed. Cir. 1986).
30 MEHL/Biophile Int’l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999).
31 See also In re Montgomery, 677 F.3d 1375, 1384 (Fed. Cir. 2012) (Lourie, J., dissenting)(“[a]bsent inevitability, inherency does not follow even from a very high likelihood that [the prior art] will result in the claimed invention”).
32 MEHL/Biophile Int’l Corp. v. Milgraum, 192 F.3d 1362 (Fed. Cir. 1999).
33 Id. at 1365.
36 In re Cruciferous Sprout Litigation, 301 F.3d 1343 (Fed. Cir. 2002).
quantity of food consumed passes through the digestive tract rather than being absorbed into the bloodstream.\textsuperscript{37} The United States Patent and Trademark Office Board of Appeals (hereinafter “the Board”) affirmed rejection of the claims as anticipated under 35 U.S.C. § 102 by the \textit{Physician’s Desk Reference} (PDR).\textsuperscript{38} The PDR prescribed oxethazaine for the treatment of various gastrointestinal disorders to be administered before meals and/or at bedtime, but did not describe use of oxethazaine for weight control.\textsuperscript{39}

Regardless, the Board found the PDR prescription of oxethazaine before meals inherently anticipated the claimed weight control process since patients following the prescribed treatment for their gastrointestinal disorder would also achieve weight control.\textsuperscript{40} The United States Court of Customs and Patent Appeals (C.C.P.A.) reversed the Board’s rejection of these claims, reasoning that “[n]othing in the PDR remotely suggests taking oxethazaine to lose weight. If anyone ever lost weight by following the PDR teachings it was an unrecognized accident. An accidental or unwitting duplication of an invention cannot constitute an anticipation.”\textsuperscript{41}

\textit{Cruciferous Sprout}\textsuperscript{42} recites a similar fact pattern to \textit{Marshall}— in each case the public was ingesting a known material— but the \textit{Cruciferous Sprout} court instead held the claims inherently anticipated. An exemplary claim at issue in \textit{Cruciferous Sprout} recited a method of “reducing the level of carcinogens in a mammal” by administering a harvested cruciferous sprout food product rich in glucosinolates with Phase 2 enzyme-inducing potential.\textsuperscript{43}

The prior art was a sprouting cookbook espousing the “health giving” benefits of sprouts, such as broccoli and cauliflower sprouts.\textsuperscript{44} The Federal Circuit held the claim inherently anticipated since the newly discovered properties— “the glucosinate content and Phase 2 enzyme-inducing potential”— of such sprouts had necessarily “existed as long as sprouts themselves, which is certainly more than one year before the date of application at issue here.”\textsuperscript{45} The \textit{Cruciferous Sprout} court used public policy rationale under 35 U.S.C. § 101 to support this finding of inherency:

\begin{quote}
[t]he basic provision of Title 35 applicable here is § 101, providing in relevant part: “Whoever invents or discovers any \textit{new} . . . composition of matter, or any \textit{new} . . . improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title . . .” [C]ounsel never came to grips with the real issues: (1) what do the claims cover and (2) is what they cover new? Under the laws Congress wrote, they must be considered. Congress has not seen fit to permit the patenting of an old [material], known to others through a printed publication, by one who has discovered its . . . useful properties.\textsuperscript{46}
\end{quote}

\textsuperscript{37} \textit{In re Marshall}, 578 F.2d 301, 302 (C.C.P.A. 1978) (ingesting oxethazaine prior to eating anesthetizes the nerve endings in the digestive tract, thereby preventing downstream release of pancreatic enzymes necessary for digestion).
\textsuperscript{38} \textit{Id.} at 303.
\textsuperscript{39} \textit{Id.}
\textsuperscript{40} \textit{Id.} at 304.
\textsuperscript{41} \textit{Id.}
\textsuperscript{42} \textit{In re Cruciferous Sprout Litigation}, 301 F.3d 1343 (Fed. Cir. 2002).
\textsuperscript{43} \textit{Id.} at 1345.
\textsuperscript{44} \textit{Id.} at 1350-1351.
\textsuperscript{45} \textit{Id.}
\textsuperscript{46} \textit{Id.} at 1350, quoting \textit{Titanium Metals Corp. v. Banner}, 778 F.2d at 780, 782 (Fed. Cir. 1985)(emphasis in the original).
While the plaintiff in *Cruciferous Sprout* was the first to discover the useful cancer-fighting properties of the sprouts, these newly discovered properties were necessarily present in the sprouts, and the public necessarily benefitted from these properties upon ingestion. Since the newly-discovered property was held inherent and given no patentable weight, the claims at issue—merely encompassing an old method of ingesting sprouts—were invalidated as inherently anticipated.

### B. Should Recognition be Required in the Inherency Analysis?

In addition to the difficulty of distinguishing what is an “accidental” from a “necessarily present” occurrence, there remained doctrinal confusion and inconsistent application over whether a party claiming anticipation need show that a Person Having Ordinary Skill In The Art (hereinafter, a “PHOSITA”) would have recognized or appreciated—either contemporaneously or at least before the critical date of the claimed invention—a necessarily present element in order for the prior art disclosure to rise to the level of inherent anticipation. Professors Burk and Lemley credit *Tilghman* for the source of this doctrinal confusion. According to Burk and Lemley,

> [t]he Court in *Tilghman* offered two different reasons why the invention was not inherently anticipated: those of skill in the art did not understand that it was present in that art [the recognition prong] and the public was not using or benefiting from the prior use of the process [the necessarily present prong]. Were both elements required for inherency to attach? Would either one suffice or prove inherency? Or was one of the factors dominant and other simply playing a supporting role?

While courts have repeatedly cited *Tilghman* as standing for the proposition that inherent anticipation requires both prongs, “courts frequently ignore[d]—or outright contradict[ed]—this standard, appearing, rather at least superficially, to only arbitrarily embrace the requirement of recognition of the inherent element by a skilled artisan.”

For example, in the 1991 *Continental Can* decision, the claims at issue recited a container whose bottom structure contained a plurality of hollow ribs. Such ribs allowed the bottom structure to have sufficient flexibility to impart improved impact resistance, but also sufficient rigidity to resist deformation under internal pressure. The prior art, U.S. Patent 3,468,443 described a similar container containing ribs, but was silent with regard to whether the ribs disclosed were hollow.
The court, in consideration of the ‘443 patent, while mechanically reciting the two-prong standard (“[t]o serve as anticipation when a reference is silent about the asserted inherent characteristic...[the extrinsic] 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”), proceeded to only consider whether the injection blow molding process as described in the ‘443 patent necessarily produced hollow ribs. The court simply did not consider whether the inherent hollowness of these prior art ribs was a feature recognized by a PHOSITA, either contemporaneously or prior to the critical date of the claimed invention.

In the 1999 *Atlas Powder* decision, the Federal Circuit outright rejected the requirement for recognition by a PHOSITA in the inherency analysis:

> [i]nherency is not necessarily coterminous 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 . . . an insufficient prior understanding of the inherent properties of a known composition does not defeat a finding of anticipation.

However, in the 2002 *Rosco* decision, the Federal Circuit fully embraced the requirement for recognition while simultaneously disparaging the necessarily present requirement: “[t]he question is not whether the manufacture of the mirror using this process inherently results in a varying radius of curvature along the major axis, but whether one skilled in the art would read the [prior art disclosure] as inherently disclosing the invention.”

Several lines of cases before and after the *Rosco* decision however, similar to *Atlas Powder*, rejected the requirement for recognition by the PHOSITA.

Professors Mueller and Chisum cite Judge Learned Hand’s opinion in the 1933 *H. K. Regar and Sons* decision as arguably the “most satisfactory reason why contemporaneous recognition should not be required for inherent anticipation.” The claims at issue in *Regar* recited a method for producing a scalloped edge at the top of knitted stockings. The prior art “Wilson stockings” were depicted as scalloped, albeit unintended, since the scalloping was the result of a “tuck” stitch distortion. The plaintiff argued that since the scalloping in the Wilson stockings was not Wilson’s intended result, the plaintiff’s claimed method for producing scalloping was not inherently anticipated. Judge Hand disagreed, finding the Wilson stockings, necessarily produced with scalloping via the intentional “tuck” stitch, were anticipatory under the doctrine:

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56 Id. (emphasis added).
58 Id. at 1347, 1349 (emphasis added).
59 *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373 (Fed. Cir. 2002).
60 Id. at 1381 (emphasis added).
61 See, e.g., *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985); *Verdegaal Bros. Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628 (Fed. Cir. 1987); *MEHL/BioPhile International Corp. v. Milgrum*, 192 F.3d 1362 (Fed. Cir. 1999); *In re Cruciferous Sprout Litigation*, 301 F.3d 1343 (Fed. Cir. 2002).
64 *H.K. Regar & Sons v. Scott & Williams*, 63 F.2d at 229 (2d. Cir. 1933).
65 Id. at 230.
66 Id. at 231.
The plaintiff answers that the effect was not intended in the Wilson stockings, and that the invention was not therefore anticipated. It is quite true that an accidental use will not anticipate a process, if the earlier practiser was not aware of what he was doing, or how he did it. His work must give some assurance that the result can be reached another time, and of this there can be none unless the process is deliberate and the means understood. Nothing else can be called an art; it is merely an accident . . . But when the result is a necessary consequence of what was deliberately intended, it is irrelevant that it was then valueless for the purposes in mind. Were that enough to prevent anticipation, it would be possible to patent a new use for an unchanged process; which is never true. 67

Judge Hand determined it was inconsequential that Wilson (or another PHOSITA) did not recognize or appreciate the scalloping in the Wilson stockings prior to plaintiff’s patent application filing date since the method of Wilson necessarily and always produced the scalloping, intentional or not. The plaintiff’s method was well within the public’s grasp prior to his filing date, and it was therefore not possible for the plaintiff to effectively withdraw from the public a benefit already enjoyed by claiming it.

In seeking to resolve the doctrinal confusion promulgated by Tilghman, Burk and Lemley 68 as well as practitioners Brown and Polyakov 69 similarly dispense with the recognition requirement. Burk and Lemley note that the recognition prong, while often recited as an element in inherency cases, has never been the determinative outcome of an appellate case, and thus should not be a factor in the inherent anticipation analysis. 70

Burk and Lemley, however, further reject the draconian position that the “necessarily present” prong be the sole requirement for a finding of inherent anticipation. 71 They propose, instead, the inherency analysis should require a finding that the public has already gained the benefit of the invention, in addition to the claimed element being necessarily present in the prior product or process. 72 If the public has already benefitted from the invention, even without knowing why, the prior product or process should inherently anticipate; if the public has not benefitted from the invention, the prior product or process should not inherently anticipate. 73

The publication of Brown and Polyakov’s treatise pre-dates Burk and Lemley’s public benefit theory by a few months, but presents the same type of analysis in decision tree form. 74

The first question Brown and Polyakov propose for a finding of inherent anticipation, whether the prior product or process was useful in the art, is akin to asking, similar to Burk and Lemley, whether the public benefitted from the prior art product or process. 75 If the first question is answered in the affirmative, Brown and Polyakov propose the second

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67 Id. (emphasis added) (internal citations omitted).
70 Burk & Lemley, Inherency, 47 Wm. & Mary L. Rev. 371, 379 (2005).
71 Id.
72 Id.
73 Id.
75 Id.
question to ask is whether the product was obtained or process occurred under unusual conditions.\textsuperscript{76} If the public already benefits from the invention, and such an invention was not obtained under unusual conditions, according to Brown and Polyakov, the prior product or process should inherently anticipate.\textsuperscript{77}


The Federal Circuit, in its 2003 \textit{Schering v. Geneva}\textsuperscript{78} panel decision, and with its decision to deny rehearing \textit{en banc},\textsuperscript{79} attempted to settle the debate of whether or not prior recognition by a PHOSITA is required. The patent at issue, U.S. Patent 4,659,716,\textsuperscript{80} claimed descarboethoxyloratadine (DCL), a metabolite of the antihistamine loratadine (Claritin\textsuperscript{TM}). See, \textit{e.g.}, Scheme 1.

The prior art was Schering’s own patent, U.S. Patent 4,282,233,\textsuperscript{81} soon to expire, claiming loratadine. Generic manufacturers, seeking to market loratadine once the ‘233 patent expired, submitted applications to the Food and Drug Administration (FDA). Because Schering included the ‘716 metabolite patent in the Orange Book listing for loratadine, the generic manufacturers also certified that the claim to DCL was invalid. Schering filed suit against the generic manufacturers after receiving notice of the FDA filings. The District Court, on summary judgment, construed claims of the ‘716 patent covered DCL “in all its forms, including “metabolized within the human body” and “synthetically produced in a purified and isolated form,”\textsuperscript{82} and the parties agreed with this claim construction. Applying this construction, the District Court held that while the ‘233 patent did not expressly disclose DCL, since the specification contained boilerplate language contemplating administration, and since the post-filing data submitted during trial established that loratadine necessarily metabolized \textit{in vivo} to its active principle DCL upon its administration, the teachings of the ‘233 patent inherently anticipated the ‘716 patent, rendering the ‘716 metabolite patent invalid.\textsuperscript{83}

On appeal, Schering argued for a prior recognition exception to the inherency doctrine, at least for newly discovered, patentably distinct chemical entities:

\textsuperscript{76} Id.
\textsuperscript{77} Id.
\textsuperscript{79} Schering Corp. \textit{v.} Geneva Pharmaceuticals, Inc., 348 F.3d 992 (Fed. Cir. 2003), petition for review \textit{en banc} denied.
\textsuperscript{80} U.S. Patent No. 4,659,716 (filed Mar. 12, 1986)(hereinafter “the ‘716 patent”).
\textsuperscript{83} Id.
DCL is not an old product or process that Schering sought to re-patent based on some previously unknown property, ingredient or effect that does not distinguish it over the prior art. Rather, DCL is a new composition of matter that is patentably distinct . . . Because DCL is a patentably distinct composition of matter, prior recognition of DCL as existing in the prior art is required to invalidate under § 102(b).

The Federal Circuit acknowledged this was “a case of first impression” since this was the first time the court held inherent the entire recitation claimed. However, the Federal Circuit emphatically rejected the notion that inherent anticipation of the claim to DCL requires knowledge and recognition of its chemical structure by a PHOSITA before the critical date of the invention, citing *Cruciferous Sprout*, *MEHL/Biophile*, and *Atlas Powder* in support. The Federal Circuit determined, based on the post-filing evidence submitted, that DCL did not form accidentally or under unusual conditions, but rather formed necessarily and inevitably *in vivo* from the metabolism of loratadine. The Federal Circuit further held the boilerplate language in the ’233 patent, describing the administration and formulation of loratadine, sufficiently enabled DCL to be within the public’s grasp prior to the critical date of the ’716 patent, stipulating that “[t]o qualify as an enabled reference, the ’233 patent need not describe how to make DCL in its isolated form . . . [but] 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.” In other words, Schering could not later claim the metabolite DCL since the public, following the teachings of the ’233 patent, already fully possessed the DCL upon administration of loratadine, regardless of whether such possession was actual or prophetic, and regardless of whether the public had no knowledge of DCL’s existence.

86 *In re Cruciferous Sprout Litigation*, 301 F.3d 1343 (Fed. Cir. 2002).
87 *MEHL/Biophile Int’l Corp. v. Milagraum*, 192 F.3d 1362 (Fed. Cir. 1999).
90 *Id.* at 1378.
91 *Id.* at 1381.
The Federal Circuit was cognizant of the impact this holding would have on the pharmaceutical industry since claiming metabolites was one way of evergreening a pharmaceutical patent portfolio.\footnote{See, e.g., Alfredo De La Rosa, A Hard Pill to Swallow: Does Schering v. Geneva Endanger Innovation Within the Pharmaceutical Industry? 8 Colum. Sci. & Tech. L. Rev. 37 (2007), http://www.cstlr.org/cite.cgi?volume=8&article=2 (discussing the repercussions the patent community feared would result from the Schering decision).} For example, extending the monopoly over a particular drug by claiming the metabolite of that drug was simply not possible after Schering. The Federal Circuit indicated however, using proper claim language, patent protection may still be available for metabolites of known drugs, such as claiming the pure and isolated form of the metabolite, claiming the pharmaceutical composition of the metabolite, and claiming the method of using the metabolite, if such claims were desirable to the patentee.\footnote{Schering Corp. v. Geneva Pharmaceuticals, Inc., 339 F.3d at 1381.}

Recent case law has seen it fit to modify the Schering court’s advice: a claim to a pure and isolated metabolite is presently deemed unpatentable subject matter under 35 U.S.C. § 101 in light of the recent Myriad decision.\footnote{Association for Molecular Pathology v. Myriad Genetics, Inc., 133 U.S. 2107 (2013).} Myriad held that “isolated” language in a composition of matter claim reciting “isolated DNA” does not render that claim to the natural DNA patentable under 35 U.S.C § 101,\footnote{Id. at 2118.} and the USPTO 2014 Guidance\footnote{U.S. Pat. & Trademark Office, 2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature /Natural Principles, Natural Phenomena, And/or Natural Products (Mar. 4, 2014) (hereinafter “Guidance”), superseded by U.S. Pat. & Trademark Office, 2014 Interim Guidance on Patent Subject Matter Eligibility (Dec. 16, 2014).} in light of Myriad, extended the Supreme Court’s holding to all natural products, including metabolites.

II. After Schering

A. The Schering Dissenters

Judges Newman and Lourie filed separate opinions sharply dissenting the Schering court’s denial of rehearing en banc.\footnote{Schering Corp. v. Geneva Pharmaceuticals, Inc., 339 F.3d 992 (Fed. Cir. 2003), petition for rehearing en banc denied.} Judge Newman primarily objected to the majority’s lack of deference to established precedent, pointing out that all of the inherency cases before Schering found inherency only in situations where a single undisclosed limitation of a claimed invention was necessarily present.\footnote{Id. at 993.} In contrast, the Schering decision extended inherency to claimed subject matter completely undisclosed and unknown in the prior art: “[n]o 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.”\footnote{Id.}

In his dissent, Judge Lourie objected to majority’s finding that the mere description of administering and formulating a pharmaceutical product using boilerplate language enabled disclosure of the product’s unknown metabolites:

\[i f \text{ U.S. Patent 4,282,233 really taught how to make metabolites, it might be another story. However, that patent simply included a minimal boilerplate} \]
statement of how to use the claimed products, sufficient to satisfy the requirements of 35 U.S.C. § 112, but far from the careful and thorough prescribing information required by the FDA... That is hardly an enabling disclosure of how to make any metabolites, whatever they might turn out to be, sufficient to anticipate them by inherency.  

Lourie argued that the metabolite DCL was not in “actual public use” by this boilerplate disclosure, and thus the patentability of DCL should not be precluded under the doctrine of inherent anticipation.

Judges Newman and Lourie have repeatedly dissented in various inherency cases post-Schering, and their dissents following two of these decisions, SmithKline Beecham Corp. v. Apotex Corp decided in 2005, and In re Omeprazole Patent Litigation decided in 2008, are exemplary of their continued disagreement with Schering and its application. Regardless, as of this writing, of the Federal Circuit cases citing the Schering decision, none question its result, i.e., that recognition is no longer required, that inherency may be extended to completely undisclosed or unknown subject matter, and that an enabling disclosure rather than an actual presence may be sufficient for establishing inherent anticipation. Furthermore, at least at the time of this writing, the precepts of Schering remain good law since such panel decisions may only be overruled by the en banc Federal Circuit or the Supreme Court.

**B. SmithKline Beecham Corp. v. Apotex Corp. (2005)**

In the 1970s the chemical company Ferrosan sought and obtained U.S. Patent 4,007,196 claiming 3-substituted-1-alkyl-4-fluorophenyl-piperidines, including a compound later known as the anti-depressant paroxetine. The ’196 patent generally described the preparation of salts of these compounds, such as the hydrochloride and maleate salts, and specifically disclosed and characterized the crystalline maleate salt of paroxetine. See, e.g., Figure 1. Ferrosan later produced the hydrochloride salt form of paroxetine (hereinafter “PHC”), although with some difficulty, as the crystalline hydrochloride salt without bound water molecules (“PHC anhydrate”). After the ’196 patent and related technology were licensed to SmithKline Beecham, during experiments to improve PHC production, SmithKline scientists discovered a new PHC crystalline form with one bound water molecule for every two PHC molecules (“PHC hemihydrate”) which they found more stable, and thus more easily packaged and preserved, than PHC anhydrate. Interestingly, the scientists also found that batches of

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100 Id. at 996.
101 Id. at 996.
103 SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331 (Fed. Cir. 2005).
104 In re Omeprazole Patent Litigation, 536 F.3d 1361, 1365 (Fed. Cir. 2008).
105 Results provided from a Westlaw search of all Federal Circuit cases citing Schering.
107 SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1334 (Fed. Cir. 2005).
108 Id.
109 Id.
110 Id.
PHC anhydrate, when “seeded” (contaminated) with the more stable PHC hemihydrate form, naturally converted to the hemihydrate form. See, e.g., Scheme 2. Furthermore, the scientists found after this initial seeding experiment it became impossible to produce pure PHC anhydrate in the general environment of the laboratory since any anhydrate formed — presumably now exposed to trace PHC hemihydrate crystals— morphed to the hemihydrate over time (later dubbed “the disappearing polymorph theory”). SmithKline rationalized that the PHC hemihydrate was a novel form which did not exist prior to 1984 since there was no evidence of PHC hemihydrate contamination of early batches of PHC anhydrate and the early batches remained stable and did not convert to PHC hemihydrate.

SmithKline Beecham filed and obtained U.S. Patent 4,721,723, claim 1 simply reciting: “Crystalline paroxetine hydrochloride hemihydrate.” In 1993, SmithKline, after obtaining FDA approval, started marketing and selling PHC hemihydrate under the tradename Paxil™. Following expiration of the ‘196 patent, the generic manufacturer Apotex filed an Abbreviated New Drug Application (“ANDA”) with the FDA seeking approval to market generic PHC as the PHC anhydrate.

The ANDA filing included a certification that Apotex did not infringe the ‘723 hemihydrate patent. SmithKline subsequently filed suit against Apotex on the basis of the ANDA filing, alleging under their “disappearing polymorph theory” that Apotex, by manufacturing and selling anhydrous PHC, infringed claim 1 of the ‘723 patent since “PHC anhydrate tablets inevitably convert to hemihydrate when combined with moisture, pressure, and practically ubiquitous PHC hemihydrate seeds.”

The resulting litigation between Schering and Apotex eventually made its way to the Federal Circuit upon appeal, and a three-judge panel deemed claim 1 of the ‘723 patent inherently anticipated by the prior disclosure of the ‘196 patent. Both parties submit-
ted conflicting evidence, including conflicting expert testimony, concerning whether or not the PHC hemihydrate existed before the critical date of the '723 patent.\textsuperscript{120}

Particularly telling to the Federal Circuit was SmithKline’s failure to offer any evidence that pure PHC anhydrate could be produced in facilities uncontaminated with PHC hemihydrate.\textsuperscript{121} SmithKline’s explanation that it had been manufacturing PHC anhydrate according to '196 patent for years before the hemihydrate was first detected in 1995 did not persuade the Federal Circuit that the hemihydrate was a novel crystalline form, the court noting that “existence and detection are not the same thing.”\textsuperscript{122}

The Federal Circuit pointed to the District Court’s reasoning that “PHC hemihydrate may have existed in undetectable amounts since Ferrosan first produced PHC anhydrate in the 1970s, particularly because the technology to detect PHC hemihydrate in small amounts did not exist until 1985.”\textsuperscript{123} Reconciling conflicting expert testimony in favor of Apotex, the Federal Circuit determined “that it may also be possible for PHC anhydrate to coexist with low levels of PHC hemihydrate without further conversion,” at least when the PHC hemihydrate is present in “small amounts.”\textsuperscript{124}

Applying Schering, the Federal Circuit reasoned the “doctrine of inherent anticipation applies to the entire claimed subject matter just as it does to a single claimed feature” and that “inherent anticipation does not require a person of ordinary skill in the art to recognize the inherent disclosure in the prior art at the time the prior art is created.”\textsuperscript{125} Further following Schering’s reasoning that “[a]nticipation does not require the actual creation or reduction to practice of the prior art subject matter; anticipation requires only an enabling disclosure,”\textsuperscript{126} the Federal Circuit indicated it was irrelevant to speculate on whether the hemihydrate existed prior to the critical date of the '723 patent since the '196 patent provided sufficient enabling and anticipating disclosure.\textsuperscript{127}

Pointing to the record as clear and convincing, the Federal Circuit further reasoned production of PHC anhydrate, following the methods taught in the '196 patent, always

\begin{equation}
\text{paroxetine hydrochloride salt (PHC), anhydrate} \xrightarrow{\text{seeding}} \text{paroxetine hydrochloride salt (PHC), hemihydrate}
\end{equation}

\begin{eqnarray}
\text{more stable form}
\end{eqnarray}

\text{Scheme 2}
and necessarily results in at least trace amounts of the PHC hemihydrate, and thus the ‘196 disclosure rendered the claim to the “bare compound PHC hemihydrate” invalid as inherently anticipated under 35 U.S.C. § 102(b).128 Following Schering’s example, the Federal Circuit concluded “a patentee may obtain patent protection for an inherently anticipated compound through proper claiming.”129

Judge Newman,130 in the order declining to hear the case en banc,131 not surprisingly argued the court’s finding of inherent anticipation in error:

[t]here is no evidence to support the panel’s current finding that the ‘196 patent “discloses in an enabling manner the production of the PHC hemihydrate” . . . The evidence before the District court did not show that disclosure and enablement, and did not show that the hemihydrate was produced in 1975, even inherently and undetected. The discovery of the hemihydrate a decade later, and the “seeding” of subsequent production in this crystal form, does not provide retrospective knowledge of this then-unknown compound. The not-unique situation that the air of the manufacturing plant is now seeded with the hemihydrate crystal form does not mean that this situation existed when the anhydrous product was discovered and the patent application thereon was filed.132

Newman, seeing the Federal Circuit once again straying from long-established precedent, fervently argued for reinstatement of the recognition prong to the inherency analysis, at least with regard to application of inherency to the entire scope of subject matter claimed:

[i]nvalidity based on anticipation under 35 U.S.C. § 102 requires that the identical invention was known or its existence would reasonably have been known to a person of ordinary skill in the field of the invention - not that it might have lain hidden in minuscule amount, undetected, unsuspected, and unknown . . . 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.”133


Omeprazole, better known as the heartburn medication Prilosec®, inhibits gastric acid secretion through a complex mechanism via absorption in the intestinal lining. See, e.g., Figure 2. Omeprazole is, however, quite sensitive to acid, and thus the oral formulation must be designed to protect omeprazole from contact with gastric juices in the stomach prior to absorption in the intestine.134

128Id. at 1346.
129Id.
130Judge Lourie did not participate.
131SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1328 (Fed. Cir. 2005), petition for rehearing en banc denied.
132Id. at 1329-1330 (internal citations omitted).
133Id. at 1330.
134See, e.g., In re Omeprazole Patent Litigation, 536 F.3d 1361, 1365 (Fed. Cir. 2008); In re Omeprazole Patent Litigation, 483 F.3d 1364, 1367 (Fed. Cir. 2007).
A Swedish corporation, Aktiebolaget Hässle, a wholly-owned subsidiary of AstraZeneca AB (hereinafter “Astra”), sought to develop an oral omeprazole formulation which would have sufficient gastric acid resistance and long-term shelf life.\(^{135}\) Such a task, however, proved difficult because the two goals appeared antithetical: protecting omeprazole from gastric acid in the stomach required an enteric coating, but typical enteric coatings contained acidic compounds that would degrade omeprazole over time due to direct contact with the drug core.\(^{136}\) Furthermore, alkaline reacting compounds (“ARCs”), typically added to the drug core to increase stability of the drug product, were found to chemically interact with and degrade the acidic enteric coating.\(^{137}\) After much experimentation, the Astra scientists discovered employing an inert sub-coating between the enteric coating and the drug core solved both goals of increased shelf-life and stability, and subsequently filed and obtained two patents, U.S. Patent 4,786,505\(^{138}\) and U.S. Patent 4,853,230\(^{139}\) covering this three-layer formulation.\(^{140}\)

The Astra scientists later discovered that such an inert sub-coating may be produced \textit{in situ}, during the formulation process, by reaction of two layers, the acidic enteric coating with the basic ARCs in the drug core, to create a third separating (water soluble salt form) layer provided certain conditions were controlled, such as low inlet air temperature (\textit{e.g.}, below 42 °C), air flow, atomizer air flow, and spraying rate.\(^{141}\)

Astra, at the time of this discovery, was aware of a Korean patent application by the Korean company Chong Kun Dan Corporation (CKD) (the “CKD Patent Application”) describing production of an omeprazole formulation (Method A) comprising L-arginine, microcrystalline cellulose, SLS, corn starch and magnesium stearate as the drug core, and an enteric coating containing HPMCAS, ethyl citrate, talc, and sorbitan sesquioleate, and whose stability relied on the zwitterionic amino acids (like L-arginine) within the core.\(^{142}\)

The CKD Patent Application notably expressly disavowed the presence of a sub-coating between the drug core and enteric coating, and did not disclose any enteric coating process conditions.\(^{143}\) Furthermore, after CKD provided Astra with their internal protocol for manufacturing their CKD omeprazole (OMP) product, Astra determined the CKD OMP manufacturing process did not result in an \textit{in situ} sub-coating,

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135 In re Omeprazole Patent Litigation, 536 F.3d at 1373.
136 Id. at 1365.
137 Id.
138 U.S. Patent No. 4,786,505 (filed Apr. 20, 1987)(hereinafter “the ’505 patent”)
139 U.S. Patent No. 4,853,230 (filed Apr. 20, 1987)(hereinafter “the ’230 patent”)
140 In re Omeprazole Patent Litigation, 536 F.3d at 1365.
141 Id. at 1368.
142 Id. at 1368, 1369, 1370.
143 Id. at 1370.
presumably due to the high inlet air temperature (e.g., 70 ºC) used following the CKD protocol. Considering the Astra formulation produced in situ novel and non-obvious over the process described in the CKD Patent Application, Astra filed and obtained U.S. Patent 6,013,281. Claim 1 of the '281 patent, in its entirety, recites:

1. A process for preparing an oral pharmaceutical formulation comprising the steps of:

   forming a core material comprising a proton pump inhibitor and at least one alkaline reacting compound [ARC], wherein the concentration of the alkaline reacting compound is about 0.1 mmol/g dry ingredients in the alkaline containing part of the core material, and

   applying an enteric coating polymer layer so as to surround the core material thereby forming in situ a separating layer as a water soluble salt product between the alkaline compound and the enteric coating polymer.

Astra filed suit against several generic pharmaceutical manufacturers, including Andrx Pharmaceuticals, Inc., asserting infringement of the '281 patent. The District Court found the '281 patent inherently anticipated by the CKD Patent Application and thus invalid under 35 U.S.C. § 102(b), and the Federal Circuit affirmed the District Court’s decision.

Interestingly, this finding of inherency was based primarily on assertions Astra made in prior proceedings in the Korean Intellectual Property Office (KIPO) over infringement of the Korean counterpart to the three-layer '505 patent. The KIPO proceedings turned on whether the omeprazole formulation provided in the CKD Patent Application, and which encompassed the omeprazole product CKD was marketing, contained a sub-coating between the drug core and enteric coating.

CKD pointed out during these proceedings that the method described in the CKD Application (Method A) did not involve a separate third step to make a sub-coating. In response, Astra countered that the omeprazole formulation described in the CKD Patent Application forms an in situ sub-coating layer “each and every time” due to the instantaneous reaction of HPMCAS (provided in the enteric coating) with L-arginine (provided within the drug core).

In the suit at hand, Astra did not attempt to deny their previous assertions. Instead, Astra argued that the CKD Patent Application could not render the claims of the '281 patent inherently anticipated since the claim language “forming an in situ layer” was not explicitly described in the CKD Patent Application; the teachings of the '281 patent required that the claimed invention be performed at a temperature below 42 ºC in order for the in situ sub-coating to form; and such a low temperatures were not specifically taught by the CKD Patent Application.

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144Id. at 1360.
145U.S. Patent No. 6,013,281 (filed Feb. 9, 1996)(hereinafter “the '281 patent”).
146In re Omeprazole Patent Litigation, 536 F.3d. at 1367, 1368. Of note is that claim 1 is not limited to a low inlet air temperature.
147Id. at 1366.
148Id.
149Id. at 1368.
150Id. at 1372.
151Id.
152Id. at 1371.
The Federal Circuit agreed with the District Court that Astra’s arguments were unpersuasive since claim 1 of the ’281 patent was not limited to any temperature and the ’281 patent specification suggested not just below 42 °C but also other variable temperatures for producing the in situ formulation.\(^{154}\) Astra’s argument that the CKD Application did not disclose or perform the method at the low required temperature of 42 °C or below was thus disregarded as irrelevant. Furthermore, citing Schering, the Federal Circuit determined that although the Astra scientists “may not have recognized that a characteristic of CKD’s Method A ingredients, disclosed in the CKD Patent Application, resulted in an in situ formation of a separating layer, the in situ formation was inherent.”\(^{155}\)

The Federal Circuit further agreed with the District Court that, while the CKD Patent Application did not explicitly recite formation of the in situ layer, and even disavowed its formation, the assertions Astra made during the KIPO proceedings provided sufficient basis for a finding of inherency:

> [t]he record shows formation of the in situ separating layer in the prior art even though that process was not recognized at the time . . . Despite CKD’s denials, [Astra’s scientists] realized and explained that CKD’s OMP tablet’s formation of a separating layer was a natural result flowing from the combination of certain ingredients listed in Method A . . . The ingredients and protocols CKD gave to the KIPO and Astra in 1993 and 1994 necessarily resulted in in situ formation of a separating layer. Thus, the trial court correctly found inherent anticipation.\(^{156}\)

Newman again dissented, chalking this inherency finding up to a “flawed analysis”\(^{157}\) since the court invalidated a patent directed to a unknown process as anticipated:

> [t]he Astra process is not described in the prior art, although Astra admitted that it believed that the Korean company Chong Kun Dan Corporation (CKD) had made such a product. It is not disputed that such a sublayer does not form under the conditions in the CKD patent application. No such reaction is described in CKD’s Korean patent application, nor the conditions that could have produced such a product. Nonetheless, my colleagues rule that the process discovered by Astra is “inherently anticipated” by the CKD application. That is not the law of either anticipation or inherency. I must, respectfully, dissent.\(^{158}\)

Newman further argued that in her view the CKD Patent Application lacked sufficient enablement to provide the in situ separating layer since the application did not describe the low temperature required for its formation:

> All parties agree that the closest prior art is the Korean CKD application. It was not disputed that the ingredients of the Astra and the CKD omeprazole formulations are the same standard enteric ingredients . . . However, no reference describes the conditions by which Astra produced an in situ interior

\(^{154}\)Id. at 1372.

\(^{155}\)Id. at 1373.

\(^{156}\)Id.

\(^{157}\)Id. at 1376.

\(^{158}\)Id. at 1377.
III. Inherent Anticipation Applied to Obviousness

In the wake of the *In re Omeprazole Patent Litigation* decision, in which (some argued) enabled subject matter rather than “necessarily present” subject matter was deemed inherent, the patent community expressed concern over whether the doctrine of inherency – by “simply turn[ing] what used to be an obviousness rejection into an inherent anticipation rejection” – was impermissibly expanding into the obviousness inquiry. Such an expansion would indeed be significant because “an applicant or patentee facing an anticipation rejection cannot rebut it with evidence of secondary considerations (such as unexpected results or commercial success) in contrast to an obviousness rejection where such secondary considerations are relevant.” Part of this confusion stemmed from several Federal Circuit cases decided between 1966 to 1993 maintaining a clear distinction between the concepts of inherency and obviousness, repeatedly reversing findings of obviousness which used inherency as part of the rejection, reasoning “[t]hat which may be inherent is not necessarily known; obviousness cannot be predicated on what is unknown.” The Federal Circuit has since clarified its position, first in the “reverse inherency” *In re Dillon* decision, and most recently via a series of cases decided between 2011 and 2014 affirming the doctrine of inherent anticipation may indeed be applicable within the obviousness inquiry: *In re Kao*, *Allergan v. Sandoz*, and *Par Pharmaceutical, Inc. v. Twi Pharmaceuticals, Inc.*

While each of the above-referenced cases will be examined further below, an initial

159 Id. at 1379.
160 As well as other decisions; see, e.g., Upsher-Smith Laboratories Inc. v. PamLab LLC, 412 F.3d 1319 (Fed. Cir. 2005); Perricone v. Medicis Pharmaceutical Corp., 432 F.3d 1368 (Fed. Cir. 2005); and Abbott Laboratories v. Baxter Pharmaceutical Products Inc., 471 F.3d 1363 (Fed. Cir. 2006).
162 Id. at 443.
163 See, e.g., *In re Shetty*, 566 F.2d 81, 86 (C.C.P.A. 1977) (“[T]he inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown” - reversing obviousness rejection(citing *In re Spormann*, 363 F.2d 444, 448 (C.C.P.A. 1966)); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 713 F.2d 731, 739 (Fed. Cir. 1983) (“obviousness cannot be predicated on what is unknown” - reversing obviousness rejection based on erroneous conclusion that prior art reference described a process that inherently would produce the claimed product invention); *In re Grasselli*, 713 F.2d 731, 739 (Fed. Cir. 1983) (“obviousness cannot be predicated on what is unknown” - reversing USPTO’s rejection of the claims as obvious over inherent aspects of the prior art); *Jones v. Hardy*, 722 F.2d 1524, 1529 (Fed. Cir. 1984) (“though anticipation is the epitome of obviousness, [they] are separate and distinct concepts”); *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993) (“[A] retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection” - reversing obviousness rejection because USPTO had failed to establish a *prima facie* case of obviousness).
165 919 F.2d 688 (Fed. Cir. 1990).
166 639 F.3d 1057, 1070 (Fed. Cir. 2011).
167 767 F.3d 1286, 1296 (Fed. Cir. 2013, rehearing *en banc* denied, Dyk, J., dissenting).
168 773 F.3d 1186 (Fed. Cir. 2014).
169 See also *In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995), not discussed, but one of the earliest cases to articulate “an inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness.”
170 See also *Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1369 (Fed. Cir. 2012, rehearing *en banc* denied), not discussed, but, following a similar rationale as laid out in *Kao*, used inherency to render a claim invalid as obvious.
spoiler may be helpful: the Federal Circuit has maintained in these recent decisions that establishing a prima facie case of obviousness first requires a finding of motivation or apparent reason to combine or modify the prior art to arrive at the claimed invention, and that finding a particular claim limitation or newly discovered property of the claimed subject matter as inherent—thus without patentable weight—should only come after that motivation is established. In other words, absent an articulated motivation or reason to combine based within the confines of the prior art, the doctrine of inherent anticipation should not be applied.

A. In re Dillon (1990) and the Concept of “Reverse Inherency”

In re Dillon provides one example of how inherent anticipation can become a significant and troublesome factor in attempting to overcome an obviousness rejection. Dillon filed a patent application encompassing hydrocarbon fuel compositions based upon his discovery that inclusion of a known class of structurally related compounds, triorthoesters and tetraorthoesters, into hydrocarbon fuel compositions reduced soot emission upon combustion.

The claims at issue—directed towards the tetraorthoester hydrocarbon fuel compositions—were initially rejected as obvious by the Board. The primary prior art cited, two U.S. patents, described hydrocarbon fuel compositions containing triorthoesters but did not explicitly teach the use of tetraorthoester hydrocarbon fuel compositions.

A secondary prior art reference taught that the triorthoesters and tetraorthoesters were chemically equivalent, at least when used as water scavengers in hydraulic (e.g., non-hydrocarbon) fluids. Based on a combination of the primary and secondary references, and the close structural and chemical similarity between these two classes of compounds, the Board found that a PHOSITA, acquainted with the prior art of record, would have a reasonable expectation for the tetraorthoesters to have properties similar to the triorthoesters, such as water scavenging properties, sufficient to provide a motivation to make the claimed compositions.

The Board held since Dillon did not submit evidence of an unexpected advantage or superiority of the claimed tetraorthoester fuel compositions, the tetraorthoester fuel composition claim was unpatentable as obvious. Dillon and her assignors subsequently appealed the Board’s decision to the Federal Circuit.

The Federal Circuit affirmed the Board’s decision en banc, finding the prior art references provided sufficient motivation to make the claimed tetraorthoester hydrocarbon fuel compositions, albeit based on a different reason taught in the art (water scavenging

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171 See, e.g., Par Pharmaceutical, Inc. v. TWi Pharmaceuticals, Inc., No. CCB-11-2466, slip op. at 26 (D. Md. Feb. 21, 2014) (citing In re Newell 891 F.2d 899 (1989), indicating that if no motivation to combine the prior art other than the inventor’s discovery, reliance on the inherency of the problem or improvement to find the invention obvious is improper).

172 In re Dillon, 919 F.2d 688 (1990).

173 Id. at 690-691.

174 A method of reducing the emissions using tetraorthoester hydrocarbon fuel compositions was also claimed by Dillon, but the Board, and well as the Federal Circuit, reviewed only the merits of the composition claims. See Dillon at 692.

175 Id. at 691.

176 Id.

177 Id.

178 Id.

179 Id.
properties) from the inventor’s discovery (reducing soot emissions). The Federal Circuit held that once a prima facie case of obviousness is established, and where the prior art gives a reason or motivation to make the claimed compositions, “the burden (and opportunity) then falls on the applicant to rebut that prima facie case. Such rebuttal or argument can consist of a comparison of test data showing that the claimed compositions possesses unexpectedly improved properties or properties that the prior art does not have.” Since Dillon did not (and presumably could not) present such rebuttal evidence, the Federal Circuit held the claimed composition obvious.

The rebuttal evidence in Dillon—demonstrating the structurally similar prior art compositions did not have the same properties as the claimed compositions—was later dubbed by Burk and Lemley as “reverse inherency” or “inherent absence.” Such evidence, in essence, requires the applicant to demonstrate the properties of the new composition are not inherently present in the prior art composition. An applicant who discovers a new use of a new but structurally similar composition thus may shoulder a heavier burden than most if the applicant cannot produce sufficiently persuasive evidence of unexpectedly improved properties, since the applicant must then prove the absence of those properties in the prior art.

Dillon, according to Burk and Lemley, can be likened to Cruciferous Sprout, albeit within the context of obviousness rather than anticipation:

Like the patentee there, Dillon identified a previously unknown but inherent property; the difference is that she claimed a new but structurally obvious chemical. Because people would have been motivated to make the new chemical for the same reason as they made the old one, the only way Dillon could show patentability would be to demonstrate a new property of the new chemical. Because it turned out that the old chemical inherently had the property she identified, her chemical was held an obvious variant of the old.

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180 Id. at 692. Note the Federal Circuit and the Board did not find the inventor’s discovery of a new use relevant in examination of the composition claims since these claims were not limited to that use. Furthermore, the Federal Circuit held that the inventor’s discovery of this new use cannot defeat an obviousness rejection over a composition claim, see, e.g., Dillon at 693: “[T]he discovery that a claimed composition possesses a property not disclosed for the prior art subject matter does not itself defeat a prima facie case...the statement that a prima facie obviousness rejection is not supported if no reference shows or suggests the newly-discovered properties and results of a claimed composition is not the law.”

181 Id. at 692-693 (emphasis added).

182 In fact, Dillon’s specification provided data showing the prior art compositions containing triorthoesters had equivalent activity to the tetraorthoesters in reducing particulate emissions. See, e.g., Dillon at 694.

183 See, e.g., Dan L. Burk & Mark A. Lemley, Inherency, 47 Wm. & Mary L. Rev. 371, 396-400 (2005).

184 Id.

185 Id.

B. Recent Application of Inherency to Obviousness: 2011 to present

In re Kao,\textsuperscript{187} Allergan v. Sandoz,\textsuperscript{188} and Par Pharmaceutical, Inc. v. TWI Pharmaceuticals, Inc.\textsuperscript{189} are examples of how inherency may be applied during the obviousness inquiry rather than, as in Dillon, afterwards in rebuttal. Each of the claims at issue relied on functional language as the singular distinguishing feature over the prior art. Furthermore, in each case the court proceeded to determine whether this recited functional claim language was or was not an inherent property. If so found, the functional language was given no patentable weight, thereby rendering the claimed invention obvious.

1. In re Kao (2011) and Par Pharmaceutical (2014)

The facts of Kao\textsuperscript{190} and Par Pharmaceutical\textsuperscript{191} share many similarities. In each case, the inventors were confronted with the problem of poor bioavailability of a particular drug upon administration: oxymorphone in Kao and megestrol acetate in Par Pharmaceutical.\textsuperscript{192} See, e.g., Figure 4.

In each case, the inventors discovered improved drug bioavailability with use of a particular formulation: a controlled release (CR) formulation in Kao and megestrol acetate as a nanoparticulate suspension in Par Pharmaceutical.\textsuperscript{193} In each case, the inventors discovered a particular “food effect” associated with the formulation: in Kao, the inventors found improved bioavailability upon administering the CR formulation with food, while in Par the inventors found improved bioavailability of the nanoparticulate suspension such that no substantial difference was observed in the fed versus fasted state.\textsuperscript{194}

Furthermore, in each case the claims at issue recited the associated “food effect” discovery using functional language.\textsuperscript{195} However, in Kao, the recited functional language was found inherent, while in Par, the recited functional language was not so found. As to be expected, the different outcome of each case turned on whether or not the recited functional limitation was a “necessary result” of what was described in the prior art.\textsuperscript{196}

In re Kao In Kao, the Board rejected claims of three pending U.S. Patent Applications as obvious. Claim 8 of one such pending application, U.S. Patent Application 12/167,859 recites:

8. A method for treating pain in a human subject in need of acute or chronic pain relief, comprising the steps of:

\textsuperscript{187} 639 F.3d 1057, 1070 (Fed. Cir. 2011, rehearing en banc denied).
\textsuperscript{188} 726 F.3d 1286, 1296 (Fed. Cir. 2013, rehearing en banc denied, Dyk, J., dissenting).
\textsuperscript{189} 773 F.3d 1186 (Fed. Cir. 2014).
\textsuperscript{190} In re Kao, 639 F.3d 1057, 1070 (Fed. Cir. 2011, rehearing en banc denied).
\textsuperscript{192} See In re Kao at 1062 and Par Pharmaceutical slip op. at 1.
\textsuperscript{193} Id.
\textsuperscript{194} See In re Kao at 1072 and Par Pharmaceutical slip op. at 2.
\textsuperscript{195} See In re Kao at 1063 and Par Pharmaceutical slip op. at 2.
\textsuperscript{196} See In re Kao at 1069 and Par Pharmaceutical, Inc. v. TWI Pharmaceuticals, Inc., 773 F.3d 1186, 1194-1196 (Fed. Cir. 2014). In fact, in Kao, as discussed in more detail below, there was only one prior art reference that taught each of the non-functional limitations at least for the broadest claim at issue, thus, the claims at issue in Kao might have been properly invalidated as inherently anticipated under 35 U.S.C. §102 rather than as obvious under 35 U.S.C. §103. See, In re Kao at 1069, indicating the prior art Maloney reference taught each non-functional limitation.
(a) providing a solid oral dosage form comprising about 5 mg to about 80 mg oxymorphone or a pharmaceutically acceptable salt thereof in a controlled release delivery system with a release rate profile designed to provide an adequate blood plasma level over at least 12 hours to provide sustained pain relief over this same period, the system comprising a filler and a hydrophilic material, wherein oxymorphone is the sole active ingredient; and

(b) administering the dosage form to the subject, wherein the oxymorphone Cmax is at least about 50% higher when the dosage form is administered to the subject under fed versus fasted conditions.\(^{197}\)

Upon appeal, the Federal Circuit agreed with the Board’s finding of obviousness.\(^{198}\) The Maloney prior art reference expressly taught using controlled release solid dosage formulations of oxymorphone, using both hydrophilic and hydrophobic materials, within the dosage amount claimed, and enabled the claimed 12-hour release rate profile.\(^{199}\) The teachings of Maloney were deficient in reciting the claimed “food effect” limitation, but the Federal Circuit properly relied on the specification of the ‘859 Application\(^{200}\) to confirm that the claimed “food effect” was an inherent property of oxymorphone itself, present both in controlled release and immediate release formulations of the drug.\(^{201}\) The Federal Circuit concluded claim 8 was invalid as obvious over Maloney since the reference provided sufficient motivation to arrive at the claimed controlled release oxymorphone formulation and the inherent “food effect” claim limitation added nothing of patentable consequence.\(^{202}\)

Practitioners at the time of the *In re Kao* decision predicted the end of second medical use patents in the United States if the *In re Kao* decision was not reversed upon ap-


\(^{198}\)In re Kao at 1070-1071.

\(^{199}\)In re Kao at 1071.

\(^{200}\)In re Kao at 1070, citing In re Kubin, 561 F.3d 1353,1357 (”[e]ven if no prior art of record explicitly discusses the [limitation], [applicant’s] application itself instructs that [the limitation] is not an additional requirement imposed by the claims on the [claimed invention], but rather a property necessarily present in [the claimed invention]”)

\(^{201}\)Id.

\(^{202}\)Id.
While rehearing of *In re Kao en banc* was subsequently denied, second medical use patents in the United States are still alive and well, at least by avoiding functional inherent language. For example, the claims at issue in *Kao* may have been upheld as patentable and non-obvious had the inventor’s “food effect” discovery been claimed using non-functional language.204

**Par Pharmaceutical**  Par Pharmaceutical filed suit against TWi Pharmaceuticals alleging infringement of U.S. Patent 7,101,576205 covering Par’s FDA approved nanoparticulate megestrol acetate oral suspension, Megace® ES. TWi, in defense, asserted the claims at issue were invalid as obvious. Claim 1 of the ’576 patent recites a method of treatment using a nanoparticulate megestrol acetate suspension:

1. A method of increasing the body mass in a human patient suffering from anorexia, cachexia, or loss of body mass, comprising administering to the human patient a megestrol formulation, wherein:

   (a) the megestrol acetate formulation is a dose of about 40 mg to about 800 mg in about a 5 mL dose of an oral suspension;

   (b) the megestrol acetate formulation comprises megestrol particles having an effective average particle size of less than about 2000 nm, and at least one surface stabilizer associated with the surface of the megestrol particles; and

   (c) the administration is once daily;

   *wherein after a single administration in a human subject of the formulation there is no substantial difference in the Cmax of megestrol when the formulation is administered to the subject in a fed versus a fasted state,*

   wherein fasted state is defined as the subject having no food within at least the previous 10 hours, and wherein fed state is defined as the subject having a high-calorie meal within approximately 30 minutes of dosing.206

TWi submitted substantial evidence supporting the District Court’s finding of obviousness. In particular, TWi submitted a reference that specifically found that a 160 mg dose of micronized megestrol acetate exhibited higher bioavailability than a 160 mg dose of non-micronized megestrol acetate.207 A second submitted reference taught that reducing particle size, either to nanoparticulate or microparticle size, could increase the bioavailability of poorly soluble drugs.208

A third submitted reference taught the nanocrystalline technology used in the formulation Megace® ES touted the potential to increase bioavailability, reduce fed-fasted effects, allow higher dose loading with smaller dose volume, decrease time to therapeutic levels, and reduce viscosity in poorly soluble drugs.209 Other references submitted


204 Such as requiring administering the CR oxymorphone formulation to the subject in a fed state.


206 Id. (disputed functional language emphasized).

207 Par Pharmaceutical, Inc. v. TWi Pharmaceuticals, Inc., CCB-11-2466, slip op. at 12.

208 Id.

209 Id. slip op. at 11.
by TWi supplied additional motivation in the art to arrive at the claimed invention, but were silent with regard to the recited “food effect” limitation.

Regardless, the District Court, relying on TWi’s expert testimony that “an improvement in bioavailability necessarily results in a reduction in any food effect, whether previously known or not” determined the claimed pharmacokinetic parameters inherent properties of the obvious nanoparticulate formulation—citing In re Kao— which added “nothing of patentable consequence.”

The Federal Circuit found the District Court “erred in its inherency analysis under our precedent.” In particular, the Federal Circuit reminded the District Court that while “inherency may supply a missing claim limitation in an obviousness analysis...the concept of inherency must be limited when applied to obviousness, and is present only when the limitation at issue is the “natural result” of the combination of prior art elements...A party must, therefore, meet a high standard in order to rely on inherency.”

A claim limitation which is described in the prior art or the patent specification as a “property that is necessarily present” (as in Kao) meets this high standard. A claim limitation derived from administering an obvious formulation, such as claiming the formulation’s serum concentration, also meets this high standard, and cannot render that formulation non-obvious. Citing Kao, the Federal Circuit reiterated that if a claimed limitation meets this high standard, the claimed “inherent property” of the formulation simply “adds nothing of patentable consequence.”

In particular, the Federal Circuit found that the District Court’s analysis completely ignored the metes and bounds of the functional claim limitation at issue: “[w]hile it may be true that a reduction in particle size naturally results in some improvement in the food effect, the district court failed to conclude that the reduction in particle size naturally results in “no substantial difference” in the food effect...Inherency...may not be established by probabilities or possibilities. There mere fact that a certain thing may result from a given set of circumstances is not sufficient.” Since the Federal Circuit could not conclude, based on the proffered evidence, that the food effect as claimed was necessarily present in the prior art, the District Court’s judgment was vacated and remanded for further analysis.


In the early 1990’s Allergan began marketing a new single-agent anti-glaucoma medication, Alphagan®, containing the alpha-2 agonist brimonidine. See, e.g., Figure 5. Unlike many anti-glaucoma medications, which are dosed once or twice daily, the FDA only approved Alphagan® for dosing three times daily due to a low efficacy of twice-a-day brimonidine. This recommended third dose, along with a high rate of ocular
allergy to the drug, prompted Allergan to begin working on developing a better product as soon as Alphagan® was approved.221 For patients whose glaucoma could not be effectively controlled with a single drug, the most common form of treatment at the time was using a combination of two or more drugs, either serially - in separate formulations - or fixed in the same formulation.222

Serial formulations were generally viewed as beneficial because the two or more drugs are kept separate and stable and the dosing of each may be controlled or varied depending upon the patient’s needs.223 Fixed formulations were generally viewed as beneficial by ensuring patient compliance.224 Furthermore, at the time of this development, the single agent medication Timoptic® containing the beta-blocker timolol (see, e.g., Figure 5) was also on the market for the treatment of glaucoma.225

Allergan formulators began experimenting with certain fixed formulations of brimonidine with other anti-glaucoma medications, and discovered the combination of 0.2% brimonidine and 0.5% timolol improved the efficacy of brimonidine so much so that the difference between twice-a-day brimonidine and three-times-a-day brimonidine was minimized, and allowed for a twice-a-day brimonidine product with lowered ocular allergy incidence. The twice-a-day combination formulation, later approved by the FDA, was christened Combigan®.226

Allergan filed a patent application describing the combination formulation which culminated into four issued patents, two of which are the subject of the inherency discussion.227 Claim 1 of U.S. Patent 7,323,463 encompasses the Combigan® formulation composition of matter:

1. A composition comprising about 0.2% brimonidine by weight and about 0.5% timolol by weight as the sole active agents, in a single composition.228

Claim 4 of U.S. Patent 7,030,149 encompasses the corresponding method of use as follows:

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221 Id. at 979.
222 Id. at 981.
223 Id.
224 Id.
225 Id. at 982.
226 Id. at 998.
4. A method of reducing the number of daily topical ophthalmic doses of brimonidine administered topically to an eye of a person in need thereof for the treatment of glaucoma or ocular hypertension from 3 to 2 times a day without loss of efficacy, wherein the concentration of brimonidine is 0.2% by weight, said method comprising administering said 0.2% brimonidine by weight and 0.5% timolol by weight in a single composition.229

Sandoz Inc., Alcon Laboratories, Inc., Falcon Pharmaceuticals, Ltd., Apotex, Inc., Apotex Corp., and Watson Laboratories, Inc. (collectively “Sandoz”) each sought approval to market a generic version of Combigan®, filed an ANDA asserting the claims of the ‘463 patent and the ’149 patent invalid as anticipated and obvious, and Allergan promptly filed suit against each party alleging infringement.230 In a consolidated action at the district court level the claims at issue were found valid and non-obvious, and Sandoz timely appealed to the Federal Circuit.231

Sandoz’s obviousness argument was based upon the teachings of a prior U.S. patent, the DeSantis reference, describing fixed combinations of alpha-2 agonists and beta-blockers for the treatment of glaucoma.232 DeSantis explained a significant number of patients require more than one drug to achieve efficacy in treating glaucoma, and that serial administration often resulted in poor patient compliance.233 As a solution to this problem, DeSantis proposed fixed formulations containing the beta-blocker timolol, preferably in a concentration of 0.01 to 3.0% by weight (meeting the 0.5% claim limitation), with an alpha-2 agonist, preferably 0.2 to 2.0% by weight (meeting the 0.2% claim limitation).234

While DeSantis did not expressly teach brimonidine, DeSantis incorporated by reference certain alpha-2 agonists described in a literature publication, which disclosed brimonidine.235 Sandoz submitted an additional publication describing serial administration of 0.2% brimonidine with 0.5% timolol, and submitted additional evidence demonstrating it was common at the time of invention to dose brimonidine and timolol serially twice per day rather than three times per day for the treatment of glaucoma.236

The District Court found each of the claims at issue not obvious, and deemed the motivation within the DeSantis reference, espousing fixed formulations to increase patient compliance, insufficient and “did not motivate a person of skill in the art to develop fixed combinations with a reasonable expectation of success, because the FDA did not consider improving patient compliance as a factor in its approval decision.”237 While agreeing that FDA approval may be relevant to the obvious analysis, the Federal Circuit found clear error in the District Court’s conclusion, stating “[t]here is no requirement in patent law that the person of ordinary skill be motivated to develop the claimed invention based on a rationale that forms the basis for FDA approval. Motivation to combine may be found in many different places and forms; it cannot be limited to those reasons the FDA sees fit to consider in approving drug applications.”238 The Federal Circuit thus concluded

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232Id. at 1289-1290.
233Id.
234Id. at 1290.
235Id.
236Id.
237Id. at 1291.
238Id.
that the evidence submitted established sufficient motivation to combine brimonidine and timolol in a fixed combination product, and there was a reasonable expectation of success, as suggested by DeSantis, in so doing.\textsuperscript{239}

Moreover, in light of the extensive body of evidence submitted by Sandoz, the Federal Circuit held Allergan’s unexpected results demonstrating an increased efficacy of brimonidine when combined with timolol and decreased ocular allergy incidence did not tilt the balance in favor of a finding of nonobviousness, at least for the fixed formulation of claim\textsuperscript{1}\textsuperscript{240} The Federal Circuit thus held claim 1 of ‘463 patent, encompassing the Combigan® formulation, unpatentable as obvious.\textsuperscript{241} The Federal Circuit held, however, method claim 4 of the ‘149 patent, reciting the functional language “administered...without loss of efficacy”, not obvious.\textsuperscript{242}

Judge Dyk, in dissent, railed against the majority’s decision—that method claim 4 was not obvious while composition claim 1 was—as wrongly decided.\textsuperscript{243} Judge Dyk agreed with the majority that the composition claim 1 was obvious even though it had the unexpected property of being dosed twice a day without loss of efficacy, but would have drawn the same conclusion with regard to claim 4 using similar reasoning, citing Cruciferous Sprout:

\begin{quote}
[w]hile a new and nonobvious method of using an existing (or obvious) composition may itself be patentable...a newly-discovered result or property of an existing (or obvious) method of use is not patentable. In this case, the method of claim 4 consists of a single step: applying a fixed combination of 0.2% brimonidine and 0.5% timolol twice a day. This method was surely obvious to try. The majority recognizes that “it was common at the time of the invention to dose the serial application of brimonidine and timolol twice per day,” and that “the prior art shows concomitant administration of brimonidine and timolol...dosed twice per day.” Moreover, the record shows that reducing the number of daily doses of anti-glaucoma drugs was seen as valuable for improving patient compliance and for reducing exposure to toxic ingredients. The method of applying a fixed combination of 0.2% brimonidine and 0.5% timolol twice a day would therefore have been obvious over the prior art. The majority’s outcome appears to rest, therefore, on the notion that claim 4 was not obvious because it claims the result of twice-a-day dosing—avoiding “a loss of efficacy in the afternoon.” Avoiding a “loss of efficacy” is not a separate step, but rather a result of the claimed method. We should recognize in this case, as we did [previously], that “[n]ewly discovered results of known processes directed to the same purpose are not patentable.”\textsuperscript{244}
\end{quote}

The majority agreed with Judge Dyk that the inherency doctrine may apply to an otherwise obvious claim, but rationalized that use of inherency to render this functional language moot was inappropriate since there was no additional evidence of record (unlike Kao), either in the prior art or in the ‘149 patent specification, establishing the dose

\begin{footnotesize}
\begin{enumerate}
\item Id. at 1292.
\item Id. at 1293.
\item Id. at 1295.
\item Id.
\item Id. at 1295-1296.
\item Id.
\end{enumerate}
\end{footnotesize}
reduction “without loss of efficacy” was an inherent property always and necessarily resulting when combining 0.2% brimonidine and 0.5% timolol.\textsuperscript{245}

C. Inherent Obviousness Deconstructed

Invalidation of a claim as anticipated is different from invalidation of that same claim as obvious. Anticipation requires a single prior art reference disclosing the claimed invention either expressly or inherently, and is fairly black and white—the claimed invention is disclosed in that single reference or it is not.\textsuperscript{246} Establishing a \textit{prima facie} case of obviousness, in contrast, may require a combination of two or more references to demonstrate “that a skilled artisan would have reason to combine the teaching of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so.”\textsuperscript{247} Despite certain incredulity expressed within the patent community,\textsuperscript{248} in the context of obviousness, once this motivation has been established, the doctrine of inherent anticipation is then applicable.

The following decision tree, proposed in view of Dillon, Kao, Par Pharmaceutical, and Allergan, depicts how inherent anticipation can fit within the obviousness inquiry.

\begin{center}
\begin{tikzpicture}
  \node (obviousness) {Obviousness Inquiry};
  \node[below of=obviousness] (is_motivation) {Is there motivation absent the functional property to arrive at the claimed invention?};
  \node[below right of=is_motivation, anchor=west] (is_functional) {Is a functional property claimed?};
  \node[below right of=is_functional, anchor=west] (is_inherent) {Is the functional property also an inherent feature?};
  \node[below right of=is_inherent, anchor=west] (inherent) {Inherent Anticipation};
  \node[below of=inherent, anchor=north] (functional_property) {Functional property given no patentable weight};
  \node[below of=obviousness, anchor=north] (no_motivation) {No};
  \node[below of=no_motivation, anchor=north] (no_functional) {No};
  \node[below of=no_functional, anchor=north] (no_inherent) {Inherency should not be applied};
  \node[below of=obviousness, anchor=north] (yes_motivation) {Yes};
  \node[below of=yes_motivation, anchor=north] (yes_functional) {Yes};
  \node[below of=yes_functional, anchor=north] (yes_inherent) {Yes};
  \node[below of=obviousness, anchor=north] (some_motivation) {Yes};
  \node[below of=some_motivation, anchor=north] (some_functional) {Yes};
  \node[below of=some_functional, anchor=north] (some_inherent) {Yes};
  \node[below of=some_inherent, anchor=north] {Inherency should not be applied};
\end{tikzpicture}
\end{center}

For example, if a functional property has been claimed, the first question to ask is whether there is a motivation to arrive at the claimed invention, absent the functional property. If the answer to that question is yes, a \textit{prima facie} case of obviousness has been established, and inherency may then be applied. If that claimed functional property is also an inherent feature of the invention (as in \textit{Kao}), the functional property is given no patentable weight. If the claimed functional property is not an inherent feature, or if it is

\begin{footnotesize}
\textsuperscript{245}Id. at 1294, note 1 (“Of course, it may be true that the mere administration of 0.2% brimonidine and 0.5% timolol twice daily in any fixed combination formulation inherently produces the claimed result. Alternatively, it may also be true that only certain fixed-combination formulations produce this result. On the present record, we cannot draw a conclusion in favor of either proposition”).
\textsuperscript{246}See, e.g., MPEP (8th ed., Mar. 2014) § 2131.
\textsuperscript{247}In re Cyclobenzaprine, 676 F.3d at 1068-69.
\textsuperscript{248}See, e.g., Dittmann, \textit{supra} note 11.
\end{footnotesize}
not possible to determine whether the claimed functional property is an inherent feature (as in Par and Allergan), inherency is not applicable.

Furthermore, if no functional property has been claimed, as in Dillon’s composition, the first question to ask, as above, is whether there is a motivation to arrive at the claimed invention. If the answer to that question is yes, a prima facie case of obviousness has been established, and inherency may then be applied, albeit in the form of rebuttal evidence.

**Conclusion**

Inherency has been characterized in dissent as presently “unbounded” and which “threatens to stymie innovation by withdrawing from the realm of patentability that which has not before been known, used, or benefitted from.” While such language might be viewed as overly-dramatic, the results of Schering, Dillon, and their successors have certainly made the life of the patent applicant more difficult: once an Examiner rejects a claim or claim limitation as inherent over a reference, and the Examiner presents sufficient reasoning showing this inherency, the burden shifts to the patent applicant to demonstrate the lack thereof or an unobvious, patentable, difference.

Post-Schering, the patent applicant cannot argue that the claims are novel and non-obvious because none prior to the date of invention knew, recognized, or appreciated the claimed subject matter. Of course, thoughtful claim drafting may allow a patent applicant to avoid a potential inherency challenge in order to obtain an issued patent.

Conversely, however, in the context of invalidating an issued patent, as blogger-practitioner-professor Dennis Crouch of Patently-O puts it: “Proving Anticipation-by-Inherency: It is Hard.” The litigant attempting to invalidate a patent claim using the inherency doctrine must establish the claimed subject matter is necessarily, always, and inevitably present under a high burden of proof—by clear and convincing evidence. A claimed invention may thus experience both negatives, such as where the doctrine poses a significant hurdle to overcome during patent prosecution; and positives, such as where the doctrine poses a shield to invalidation when asserting rights under an issued patent, of this “unbounded” doctrine.

The enactment of the American Invents Act (AIA) marked the most dramatic change in United States patent law since the 1952 Patent Act. With its enactment, and in an effort to harmonize U.S. patent law with the rest of the world, the United States moved from a first-to-invent patent system to a first-to-file patent system on March 16, 2013. Newly codified 35 U.S.C. § 102(a)(1) (AIA) includes language remarkably similar to Article 249

In re Montgomery, 677 F.3d 1375, 1383-1384 (Fed. Cir. 2012) (Lourie, J., dissenting).


Applications filed prior to March 15, 2013 are examined under the old law, and, with some exceptions, applications claiming priority to or benefit from a date after March 15, 2013 are examined under the new law.

35 U.S.C. § 102(a)(1) (AIA): (a) NOVELTY; PRIOR ART. A person shall be entitled to a patent unless –

(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention. EPC Art. 54(1)(2): (1) An invention shall be considered to be new if it does not form part of the state of the art.
54 of the European Patent Convention (EPC)\textsuperscript{255}— prior art is that which is “otherwise available to the public.” Practitioners Bjorkman, Voortmans and Block warn, however, that this linguistic similarity is deceptive since “otherwise available to the public” will be interpreted very differently depending upon the jurisdiction.\textsuperscript{256} For example, EPC decisions have consistently rejected the doctrine of inherency, and have specifically found “available to the public” incompatible with inherency.\textsuperscript{257} In contrast, AIA legislative history indicates “otherwise available to the public” is intended to include inherent disclosures found within the prior art.\textsuperscript{258} Thus, following and understanding the nuances of the doctrine of inherent anticipation as it evolves within the U.S. court system, within the context of novelty as well as obviousness, remains essential to patent practitioners and litigators working within the confines of the new AIA regime.

\textsuperscript{255}EPC Art. 54(1)(2): (1) An invention shall be considered to be new if it does not form part of the state of the art.


\textsuperscript{257}Id. at 215-217.

\textsuperscript{258}Id. at 216, 217 (quoting Senator Kyl: “Another important aspect of public availability or accessibility is the doctrine of inherency . . . This doctrine applies to products sold to the public as well as published references. Thus, once a product is sold on the market, any invention that is inherit to the product becomes publicly available prior art and cannot be patented”. 157 Cong. Rec. S1360, at 1370 (daily ed. Mar. 8, 2011)).