Inherent Anticipation in the Pharmaceutical and Biotechnology Industries

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Pharmaceutical and biotech research often involves discovering new properties of, or new methods to use, existing compositions. The doctrine of inherent anticipation, however, prevents the issuance and/or validity of a patent for discoveries deemed to have been implicitly disclosed in the prior art. This can be a barrier to patent rights in these technologies. Inherent anticipation therefore creates uncertainty for patent protection in the pharmaceutical and biotech sciences. Despite this uncertainty, Federal Circuit jurisprudence provides guidance on the boundaries of the inherent anticipation doctrine. In view of the case law, certain strategies may be employed to protect inventions that may potentially be viewed as inherent in the prior art.

It is a fundamental principle of patent law that to obtain a valid patent, the invention claimed must be novel and nonobvious over the existing art. Generally, to be novelty-destroying, a prior art reference must disclose all the features of the claimed invention. Explicit disclosure, however, is not always required. The doctrine of inherent anticipation may preclude the issuance of a patent or serve to invalidate a previously issued patent, despite the lack of a reference that explicitly discloses each and every limitation of the claim at issue. The Federal Circuit, the federal appeals court with exclusive jurisdiction over patent issues, has summarized this doctrine as follows:

Humans lit fires for thousands of years before realizing that oxygen is necessary to create and maintain a flame. The first person to discover the necessity of oxygen certainly could not have obtained a valid patent claim for “a method of making fire by lighting a flame in the presence of oxygen.” Even if prior art on lighting fires did not disclose the importance of oxygen and one of ordinary skill in the art did not know about the importance of oxygen, understanding this law of nature would not give the discoverer a right to exclude others from practicing the prior art of making fires (EMI Group North America, Inc. v. Cypress Semiconductor Corp. (268 F.3d 1342) (Fed. Cir. 2001)).

Not all cases of inherent anticipation are as straightforward as the hypothetical example advanced by the Federal Circuit above. In fact, inherent anticipation creates a level of uncertainty on where the line is to be drawn between a patently distinct limitation and an inherent characteristic of a claimed invention. This issue is particularly prevalent in patents related to pharmaceutical and biotech technologies. In that regard, the courts as well as the U.S. Patent and
Trademark Office (USPTO) have provided guidance on the scope and application of the inherent anticipation doctrine. This guidance raises particular issues of interest with respect to pharmaceutical and biotech inventions, as discussed in detail below.

STANDARD FOR INHERENT ANTICIPATION

The express, implicit, and inherent disclosures of a prior art reference may be relied on in the rejection or invalidation of patent claims under 35 U.S.C. §§ 102 (anticipation) and 103 (obviousness) (U.S. Patent and Trademark Office 2007) (Manual of Patent Examining Procedure [MPEP]). Thus, prior art references must be analyzed with respect to both their express and inherent teachings. The basis for the inherent anticipation doctrine has been repeatedly reiterated by the Federal Circuit, noting that the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer (see, e.g., Atlas Powder Co. v. Ireco, Inc. (190 F.3d 1342, 1347, 51 U.S.P.Q.2d 1943, 1947) (Fed. Cir. 1999)).

Inherency arguments are most often encountered for anticipation pursuant to 35 U.S.C. §102; however, the inherent disclosure of a combination of references can also be used under 35 U.S.C. §103, which requires that a claimed invention be nonobvious.1 This is because the inherent teaching of a reference is a question of fact, which may arise under both 35 U.S.C. §§ 102 and 103 (In re Grasselli (713 F.2d 731, 739, 218 U.S.P.Q. 769, 775) (Fed. Cir. 1983)). Moreover, the Federal Circuit has held that it is proper for the USPTO to make separate rejections under 35 U.S.C. §§ 102 and 103 or concurrent rejections for obviousness under 35 U.S.C. §103 and for anticipation by inherency under 35 U.S.C. §102 (In re Best (562 F.2d 1252, 195 U.S.P.Q. 420) (C.C.P.A. 1977)).

An inherent feature need not be recognized by one of ordinary skill in the art at the time of the invention (Schering Corp. v. Geneva Pharmaceuticals, Inc. (339 F.3d 1373, 1377, 67 U.S.P.Q.2d 1664, 1668) (Fed. Cir. 2003)). As set forth by the Federal Circuit, “[a]n inherent structure, composition, or function is not necessarily known” (Atlas Powder Co. v. Ireco, Inc. (190 F.3d at 1348–1349, 51 U.S.P.Q.2d at 1947) (Fed. Cir. 1999)). It is only required that the subject matter is, in fact, inherent in the prior art reference (Schering Corp. v. Geneva Pharmaceuticals, Inc.).2

To establish inherency, the missing descriptive matter must necessarily be present in the thing described in the reference (Continental Can Co. USA, Inc. v. Monsanto Co. (948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1749) (Fed. Cir. 1991), quoting In re Oelrich (666 F.2d 578, 581, 212 U.S.P.Q. 323, 326) (C.C.P.A. 1981)). Inherency may not be established by probabilities or possibilities.3 Moreover, the mere fact that a certain thing may result from a given set of circumstances is not sufficient.4

Defendants in patent cases or the USPTO rely on inherency arguments to challenge patent

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2 Some ambiguity arises with older Federal Circuit cases that make general statements regarding a feature being deemed to anticipate a subsequent claim if 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. These cases often cite Continental Can Co. USA, Inc. v. Monsanto Co. (948 F.2d 1264, 20 U.S.P.Q.2d 1746) (Fed. Cir. 1991) for this proposition. However, the issue of the requirement of contemporary knowledge was specifically addressed in Schering Corp., in which the Federal Circuit stated that Continental Can did not require past recognition of the inherent feature, but only allowed recourse to opinions of skilled artisans to determine the scope of the prior art reference (Schering Corp. (339 F.3d at 1378, 67 U.S.P.Q.2d at 1667–1668)). But see EMI Group North America, Inc. v. Cypress Semiconductor Corp. (268 F.3d 1342, 60 U.S.P.Q.2d 1423) (Fed. Cir. 2001) and Rosco, Inc. v. Mirror Lite Co. (304 F.3d 1373, 64 U.S.P.Q.2d 1676) (Fed. Cir. 2002) (rejection under 35 U.S.C. §102(g), requiring corroborated evidence that the accused infringer recognized and appreciated the varying radius feature).


4 948 F.2d at 1268, 20 U.S.P.Q.2d at 1749.
claims when a relevant prior art reference contains an incomplete description of the subject matter at issue. For example, the prior art may include a description of a claimed invention but may be missing a certain element. The concept of inherency is used to supply the element missing from the description, and inherency can operate to anticipate entire inventions as well as single limitations within an invention (Schering Corp. v. Geneva Pharmaceuticals, Inc. (339 F.3d at 1380, 67 U.S.P.Q.2d at 1669) (Fed. Cir. 2003)). The extent of the inherent disclosure does not limit its anticipatory effect. In other words, a single limitation or the entire invention can be inherent in a prior art reference. However, the concept of “inherent disclosure” does not alter the requirement that all elements must be disclosed in an anticipatory reference in the same way as they are arranged or combined in the claim (Therasense, Inc. v. Becton, Dickinson & Co. (593 F.3d 1325, 1332, 93 U.S.P.Q.2d 1481, 1485) (Fed. Cir. 2010)).

Also, an invitation to investigate is not an inherent disclosure (Metabolite Laboratories, Inc. v. Laboratory Corp. of America Holdings (370 F.3d 1354, 1367, 71 U.S.P.Q.2d 1081, 1091) (Fed. Cir. 2004)). For example, the prior art disclosure of a genus, such as a genus of compounds or a genus of potential applications, does not inherently disclose all species within that broad genus. Rather, one must examine the prior art to see if a disclosure of the claimed species has been made. However, the disclosure of a pattern of preferences in the prior art, which directs one of ordinary skill in the art to the claimed invention, may support an inherency argument (see, e.g., Sanofi-Synthelabo v. Apotex, Inc. (470 F.3d 1368, 81 U.S.P.Q.2d 1097) (Fed. Cir. 2006) [distinguishing older United States Court of Customs and Patent Appeals cases where a pattern of preferences was found]).

Inherency arguments arise in a number of situations. One common type of inherency issue arises when a composition, product, or apparatus is claimed in terms of a property or characteristic or function. If the prior art teaches an identical chemical structure, a party may argue that the claimed characteristic or function is necessarily disclosed (In re Spada (911 F.2d 705, 709, 15 U.S.P.Q.2d 1655, 1658) (Fed. Cir. 1990)). Moreover, if product and apparatus claims are substantially identical to prior art products or produced by substantially identical processes, parties can argue that the claimed properties or functions should be presumed to be inherent. In other words, where a composition is claimed in terms of a function, property, or characteristic and the composition is in the prior art, but the function or property or characteristic is not explicitly disclosed, there may be grounds for an inherency argument under 35 U.S.C. §§ 102 and 103. This same rationale applies to product, apparatus, and process claims claimed in terms of function, property, or characteristic.

Another claim type susceptible to inherency arguments is a process claim using a known device. If a prior art device in its normal and usual operation would necessarily perform the claimed method, then the method is arguably inherently anticipated by the prior art device (In re King (801 F.2d 1324, 1326, 231 U.S.P.Q. 136, 138) (Fed. Cir. 1986)). Yet another claim type susceptible to inherency arguments is a “method of use” claim where the “use” is directed to a result or property of a known composition or structure. For example, in In re May (574 F.2d 1082, 197 U.S.P.Q. 601) (C.C.P.A. 1978), the United States Court of Customs and Patent Appeals held that a method of effecting nonaddictive analgesia was inherently anticipated by a prior art disclosure of the same compounds for effecting analgesia, but silent as to addiction. The court stated that applicants had merely found a new property of the compound and that this discovery did not constitute a new

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539 F.3d at 1380, 67 U.S.P.Q.2d at 1669.
6370 F.3d at 1367, 71 U.S.P.Q.2d at 1091.
7MPEP §2112.01; In re Best (562 F.2d 1252, 1255, 195 U.S.P.Q. 430, 433) (C.C.P.A. 1977); In re Schreiber (128 F.3d 1473, 1478, 44 U.S.P.Q.2d 1429, 1432) (Fed. Cir. 1997) (conical shape of spout for oil can in the prior art is the “same general shape” as the claimed conical top for dispensing popcorn).
8MPEP §2112(III).
9574 F.2d at 1090, 197 U.S.P.Q. at 607.
However, the court reversed the rejection of claims directed to a process of using a new compound, relying on evidence showing that the nonaddictive property of the new compound was unexpected.

CURRENT PHARMACEUTICAL/BIOTECH CASE LAW RELATING TO INHERENCY
Numerous cases have analyzed inherent anticipation related to inventions involving pharmaceutical and biotech applications. The cases have dealt with both inherent properties of compositions as well as inherent uses of particular compounds or methods. Several recent decisions related to these inherent anticipation issues regarding pharmaceutical and biotech technologies are discussed below.

Inherent Properties
A patent may be deemed anticipated if a prior art reference teaches a composition with the same properties. The properties themselves, however, are not required to be disclosed in order for inherent anticipation to apply. There are numerous cases dealing with inherent properties of pharmaceuticals and biotech technologies.

In SmithKline Beecham Corp. v. Apotex Corp. (403 F.3d 1331, 74 U.S.P.Q.2d 1398) (Fed. Cir. 2005), for example, the technology related to paroxetine, which is used to treat depression. The original form of paroxetine was anhydrous paroxetine hydrochloride (PHC). The patent at issue, assigned to SmithKline, covered crystalline paroxetine hydrochloride hemihydrate (Paxil®), a new and more stable crystalline form of PHC.

The case arose out of an Abbreviated New Drug Application (ANDA) by Apotex for an antidepressant including PHC anhydrate as an active ingredient. In response, SmithKline filed an infringement action alleging that Apotex would infringe claim 1 of its patent, directed to crystalline paroxetine HCl hemihydrate, by manufacturing PHC anhydrate that necessarily contains, by a conversion process, at least trace amounts of PHC hemihydrate. The district court interpreted the claim to require the PHC hemihydrate in commercially significant amounts and found the claim valid but not infringed.

The Federal Circuit rejected the district court’s claim interpretation and held that the claim covered PHC hemihydrate without further limitation. As a factual matter, the court held that PHC anhydrate made in accordance with a cited prior art patent converts into at least trace amounts of PHC hemihydrate. However, based on this claim interpretation and factual finding, the Federal Circuit found the claim inherently anticipated by the earlier patent to the method of making PHC anhydrate. The court held that Apotex did not need to prove that it was impossible to make PHC anhydrate that contained no PHC hemihydrate, but merely that the disclosure of the prior art was sufficient to show that the natural result flowing from the operation as taught would result in the claimed product. Whether it was actually possible to make pure PHC anhydrate before the critical date was held to be irrelevant. Rather, the court stated that the prior art suffices as an anticipatory prior art reference if it discloses in an enabling manner the production of PHC hemihydrate. Moreover, the court emphasized that the first known existence of PHC hemihydrate resulted from an attempt to produce PHC anhydrate according to the prior art method.

Similarly, in Schering Corp. v. Geneva Pharmaceuticals, Inc. (339 F.3d 1373, 67 U.S.P.Q.2d 1664) (Fed. Cir. 2003), the Federal Circuit ap-
plied the inherent anticipation doctrine to invalidate a patent based on the formation of a metabolite as anticipated based on prior art disclosure of administering the base compound. The technology at issue related to the antihistamine loratadine (Claritin®). The patent involved in this case, which was assigned to Schering Corporation, covered a metabolite of loratadine called descarboethoxy-loratadine (DCL), its fluorine analog, and their salts. Schering Corporation also owned a patent covering a class of compounds including loratadine itself, which was prior art to the DCL patent. This prior art patent did not expressly disclose DCL and did not refer to metabolites of loratadine.

This case arose after Geneva Pharmaceuticals, Inc. and others sought to market generic versions of loratadine, alleging invalidity of Schering’s DCL patent. Schering filed suit for infringement. The district court found that the claims covered DCL in all of its forms, including forms metabolized in the human body. However, the district court found that Schering’s prior patent for loratadine inherently anticipated the metabolite claim.

A Federal Circuit panel affirmed. In particular, the court held that the prior art reference showing administration of loratadine to a patient inherently anticipated claims to a metabolite. At the outset the court specifically rejected the contention that inherent anticipation requires recognition in the prior art. Rather, the court held that recognition by a person of ordinary skill in the art before the critical date of the patent at issue was not required to show anticipation by inherency. In addition, the court distinguished cases dealing with “accidental, unwitting, and unappreciated” anticipation, stating that DCL is not formed accidentally or under unusual conditions when loratadine is ingested.

Moreover, the Federal Circuit found inherent anticipation even though the prior art patent did not expressly disclose the claimed metabolite or refer to metabolites of loratadine. The Federal Circuit held that the inherent disclosure of the entire claimed subject matter anticipates as well as inherent disclosure of a single feature of the claimed subject matter. Further, the court noted that, in contrast to In re Seaborg (328 F.2d 996, 51 C.C.P.A. 1109) (C.C.P.A. 1964), in which the prior art process produced at most one-billionth of a gram of the claimed isotope in 40 tons of radioactive material, in this case DCL formed in readily detectable amounts upon ingestion of loratadine.

The Federal Circuit also held that anticipation does not require the actual creation or reduction to practice of the prior art subject matter (i.e., it was irrelevant if actual administration of loratadine to patients occurred before the critical date of the patent at issue). All that was required for the prior art patent to suffice as an anticipatory prior art reference was an enabling disclosure.

Another Federal Circuit decision made clear that statements made by the prior art inventor or owner regarding the inherent disclosure in its prior art may be used to establish inherency. In Astra Aktiebolag v. Andrx Pharmaceuticals, Inc. (In re Omeprazole Patent Litigation) (483 F.3d 1364) (Fed. Cir. 2007), the technology at issue related to omeprazole (Prilosec®). Omeprazole is a proton pump inhibitor that inhibits gastric acid production. However, omeprazole degrades in acidic and neutral environments. Therefore, an omeprazole formulation needs a protective coating to prevent contact with gastric juices. The patent at issue, assigned to Astra, covered a process for preparing an oral pharmaceutical formulation including a protective enteric coating around a core containing a proton pump inhibitor and an active alkaline reacting compound and a separating layer between the

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27. 339 F.3d at 1378, 67 U.S.P.Q.2d at 1668.
29. 339 F.3d at 1379, 67 U.S.P.Q.2d at 1669.
core and coating. In particular, the process involved creating an in situ separating layer in the gastric acid–inhibiting drug.

This case arose out of an attempt by Andrx to market a generic version of Prilosec. The district court found the claims of Astra's patent infringed, but inherently anticipated by or obvious over a published Korean patent application by Chong Kun Dan Corporation (CKD). CKD’s Korean patent application described an omeprazole composition with no enteric coating process conditions. Moreover, the court noted that the specification suggested variable temperatures, not a 42°C requirement.

On appeal, Astra argued that its patent contained an additional limitation requiring performance of the claimed process at a temperature below 42°C. The Federal Circuit noted that the 42°C “limitation” was only an example from the specification and held that reliance on a nonclaimed distinction was inappropriate. Moreover, the court noted that the specification suggested variable temperatures, not a 42°C requirement.

In addition, Astra argued that prior art did not disclose “forming in situ a separating layer.” However, the Federal Circuit relied on statements made by Astra in a Korean litigation regarding another Astra patent that the process in the CKD application resulted in the in situ formation of a separating layer. “Despite CKD’s denials, [Astra] 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...”

Moreover, the court noted that Astra neither denied the statements made in the Korean litigation nor provided scientific proof to rebut or refute its prior admissions of inherency. Relying on the fact that the record showed formation of the in situ separating layer in the prior art even though that process was not recognized at the time, the Federal Circuit held that the trial court correctly found inherent anticipation.

**Intended Use**

The Federal Circuit has also rejected claims under inherent anticipation where the claims relate to a method of use directed to a known property.

In *King Pharmaceuticals, Inc. v. Eon Labs, Inc.* (616 F.3d 1267, 95 U.S.P.Q.2d 1833) (Fed. Cir. 2010), the technology at issue related to metaxalone, which is a muscle relaxant that is used to treat musculoskeletal conditions. Metaxalone was first discovered in the 1960s. There were two patents assigned to King Pharmaceuticals, Inc. at issue in this case. The patents covered methods of increasing the bioavailability of metaxalone. The first patent required the administration of an oral dosage form of metaxalone with food. In the specification of the patent, administration with food was shown to increase both the rate and extent of absorption. The second patent required a step of informing that taking metaxalone with food increases the drug’s bioavailability. Certain independent claims the informing step was recited as a method step, and in certain claims, including one independent claim, a container provided information that administration of metaxalone with food increases the drug’s bioavailability. Certain independent
claims also required administering/ingesting metaxalone.

This case arose out of an ANDA by Eon Labs, Inc. alleging noninfringement and invalidity of King’s patents. In response to the ANDA, King filed suit against Eon alleging infringement of King’s two patents. Before the district court, Eon presented six references to invalidate King’s patents, three of which were relied on by the district court and disclosed administration of metaxalone with food to reduce gastric upset or nausea. The district court found the independent claims of the first patent inherently anticipated by the three prior art references and stated that “an increase in the bioavailability of metaxalone is inherent when the drug is taken with food.”45 The dependent claims were also found anticipated or obvious. The district court found the independent claims of the second patent invalid under 35 U.S.C. §101 (the requirement for patentable subject matter), stating that the “informing” limitation was not patentable under In re Bilski (545 F.3d 943, 88 U.S.P.Q.2d 1385) (Fed. Cir. 2008) (affirmed sub nom., Bilski v. Kappos (130 S. Ct. 3218, 177 L. Ed. 2d 792) (2010); (616 F.3d at 1273, 95 U.S.P.Q.2d at 1837)), and, for the independent claim requiring a container providing information regarding bioavailability, this claim was held to be anticipated (inclusion of written material with a known compound did not make the claim patentably distinct from the prior art).46

On appeal, King argued that the prior art disclosure was vague as to the conditions under which the food was administered, such that the court could not assume that an increase in bioavailability was necessarily disclosed.47 In contrast to the cited prior art, King’s written description included specific conditions for food consumption. The Federal Circuit held that reliance on a nonclaimed distinction was inappropriate.48 The court also noted that the written description did not suggest that the specific food conditions were necessary for increasing bioavailability.49 Rather, the court held that, according to the first patent, the natural result of taking metaxalone with food is an increase in the bioavailability of the drug.50 The court emphasized that the only steps taught in King’s first patent as required to increase metaxalone’s bioavailability were (1) ingesting metaxalone (2) with food.51 The court dismissed testimony of King’s expert that disclosure of taking metaxalone with food would not inherently disclose increasing bioavailability, stating that the prior art need only meet the inherently disclosed limitation to the extent the patented method does.52 The Federal Circuit also held that the dependent claims reciting time frames for ingesting metaxalone and food were anticipated.53

With regard to the claims requiring an informing step, the Federal Circuit held that although the district court erred when focusing solely on the “informing” limitation in invalidating the claims under 35 U.S.C. §101, addition of the informing limitation “adds no novelty to the method, which is otherwise anticipated by the prior art.”54 Accordingly, these claims were found invalid under the alternative ground that the claims were anticipated by the prior art. In particular, the court noted that the informing limitation was not functionally related to the otherwise anticipated method.55

The Federal Circuit also applied inherent anticipation to a method of treatment in Pericone v. Medicis Pharmaceutical Corporation (432 F.3d 1368, 77 U.S.P.Q.2d 1321 (Fed. Cir. 2005). There, the technology related to methods of

45616 F.3d at 1272, 95 U.S.P.Q.2d at 1837.
46616 F.3d at 1273, 95 U.S.P.Q.2d at 1837.
47616 F.3d at 1274, 95 U.S.P.Q.2d at 1838–1839.
48616 F.3d at 1275, 95 U.S.P.Q.2d at 1839.
treating or preventing sun damage through topical application of ascorbic acid (vitamin C) in a fat-soluble form. The two patents at issue covered methods of treating or preventing sunburn and methods of treating skin damage or disorders. Specifically, the patents disclosed the topical application of ascorbyl fatty acid ester (e.g., ascorbyl palmitate, ascorbyl laurate, ascorbyl myristate, and ascorbyl stearate) with a dermatologically acceptable carrier.56

Dr. Perricone sued Medicis for infringement of two patents based on a line of skin depigmenters made by Medicis. Certain claims of Perricone’s second patent were found invalid by the district court for nonstatutory obviousness-type double patenting over Perricone’s first patent.57 The district court also found the independent claims, as well as certain dependent claims, of Perricone’s patents inherently anticipated by a prior art patent disclosing a cosmetic composition for topical applications.58 The prior art patent disclosed skin benefit ingredients, including ascorbyl palmitate.59 In addition, the prior art patent identified the disclosed compositions as suitable for topical application to the skin or hair.60

On appeal, the district court’s finding of invalidity for nonstatutory obviousness-type double patenting over Perricone’s first patent was affirmed.61 With regard to anticipation, Perricone argued that the prior art’s disclosed skin benefit ingredients included ascorbyl palmitate among many others, so the prior art did not anticipate the specific claimed use of ascorbyl palmitate.62 Further, Perricone argued that the prior art did not disclose any benefit directed to skin sunburn.63

The Federal Circuit held that the prior art did not merely disclose a genus of skin benefit ingredients without disclosing the particular claimed ingredient.64 In contrast, ascorbyl palmitate was specifically identified in a list of 14 skin benefit ingredients.65 Moreover, the court distinguished cases in which a broad genus was disclosed without reference to the specific potentially anticipating species.66 Accordingly, the Federal Circuit found claims to methods of treatment or prevention including applying to “exposed skin surfaces” or “affected skin/tissue areas” inherently anticipated.67

However, the Federal Circuit held that a claim to a method for treating skin sunburn including topically applying to the skin sunburn was not inherently anticipated.68 The court held that skin sunburn is not analogous to skin surfaces generally.69 Because the prior art was silent about any sunburn prevention or treatment benefits, not to mention the mechanisms underlying such uses, the court held that the prior art did not anticipate Perricone’s claim to a method for treating sunburn.70 Moreover, the court did not take the position that a particular prevention method necessarily anticipates a treatment method, as proposed in the dissent.71 The court stated that such a prior art prevention method may render subsequent treatment claims obvious; however, these were unrealized possibilities that did not alter the analysis in this case, where the prior art did not disclose topical application to skin sunburn.72

The Federal Circuit recently extended the inherent anticipation doctrine to a method of treatment based on a reference disclosing a plan for a clinical trial that had not yet been carried out by the effective filing date of the patent. In In re Montgomery (677 F.3d 1375, 102 U.S.P.Q.2d 1881) (Fed. Cir. 2012), the technology related to

56 432 F.3d at 1371, 77 U.S.P.Q.2d at 1322.
57 432 F.3d at 1372–1375, 77 U.S.P.Q.2d at 1323–1325.
58 432 F.3d at 1376, 77 U.S.P.Q.2d at 1326.
59 432 F.3d at 1376, 77 U.S.P.Q.2d at 1326.
60 432 F.3d at 1376, 77 U.S.P.Q.2d at 1326.
61 432 F.3d at 1372–1375, 77 U.S.P.Q.2d at 1323–1325.
62 432 F.3d at 1376, 77 U.S.P.Q.2d at 1326.
63 432 F.3d at 1376, 77 U.S.P.Q.2d at 1326.
64 432 F.3d at 1377, 77 U.S.P.Q.2d at 1326.
65 432 F.3d at 1376, 77 U.S.P.Q.2d at 1326. The court characterized this list as a “handful of different compositions.” 432 F.3d at 1377, 77 U.S.P.Q.2d at 1326.
66 432 F.3d at 1376–1377, 77 U.S.P.Q.2d at 1326.
67 432 F.3d at 1379–1380, 77 U.S.P.Q.2d at 1328–1329.
68 432 F.3d at 1378–1379, 77 U.S.P.Q.2d at 1328.
69 432 F.3d at 1379, 77 U.S.P.Q.2d at 1328.
70 432 F.3d at 1379, 77 U.S.P.Q.2d at 1328.
71 432 F.3d at 1379, 77 U.S.P.Q.2d at 1328.
72 432 F.3d at 1379, 77 U.S.P.Q.2d at 1328.
a method for treatment or prevention of strokes by administering an inhibitor of the renin–angiotensin system (RAS). The specification noted that RAS inhibitors had been administered to treat high blood pressure. In particular, the method involved administering the known RAS inhibitor ramipril.

The case arose from a decision of the Board of Patent Appeals and Interferences (BPAI) affirming the USPTO’s rejection of the claims. The USPTO rejected the claims as anticipated by four prior art references describing the administration of ramipril to subjects at risk of a stroke. On appeal, the patentee argued that none of the references demonstrated that ramipril actually treated or prevented strokes. The BPAI affirmed the USPTO’s rejections by each of the prior art references, determining that each reference taught administration of ramipril to stroke-prone patients, and that treating or preventing stroke was an inherent characteristic based on the use described in the prior art.

The Federal Circuit, in a 2–1 panel decision, affirmed the rejection of the claims based on one of the cited references. The cited reference disclosed a clinical trial of utilizing ramipril in the prevention of myocardial infarction, stroke, or cardiovascular death. The study, which ultimately concluded that administering ramipril to such patients provided a statistically significant reduction in the risk of stroke, was not published until after the effective filing date of the patent at issue. The Federal Circuit indicated that the contested elements of the claim included the administration of ramipril (1) to a patient diagnosed as in need of stroke treatment or prevention, (2) where such administration is for the treatment and prevention of stroke or its reoccurrence. The Federal Circuit determined that even if the recited claims required an efficacy requirement, the cited reference anticipated the claims despite the lack of testing results at the effective filing date as efficacy was inherent in carrying out the steps of the claims. The Federal Circuit therefore disregarded the patentee’s argument that inherent anticipation required the claimed method to have been actually performed. Thus, a prior art reference that discloses a claimed method can serve to inherently anticipate a claim even if the method was not carried out in the prior art reference.

PROSECUTION STRATEGIES FOR PREVENTING AND RESPONDING TO INHERENCY REJECTIONS

The USPTO must provide objective evidence and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the prior art. An additional reference or evidence can be used to show an inherent characteristic of the thing taught by the primary reference. This can still be an anticipation rejection. Once the USPTO has provided objective evidence and/or technical reasoning, the burden shifts to the applicant to argue that the inference of lack of novelty was not properly drawn or show that the prior art and the claimed invention are different (MPEP §2112(V); In re Spada (911 F.2d at 708, 15 U.S.P.Q.2d at 1657) (Fed. Cir. 1990)).

Based on the foregoing, a number of practical considerations for avoiding and responding to inherency rejections can be identified. For example, in King Pharmaceuticals, Inc. v. Eon Labs, Inc. (616 F.3d 1267, 95 U.S.P.Q.2d 1833) (Fed. Cir. 2010), specific administration conditions giving rise to increased bioavailability of metaxalone were disclosed in the patent at issue. Similarly, in the In re Omeprazole Patent Litigation, specific process conditions were disclosed in the patent giving rise to an in situ
separating layer in the gastric acid–inhibiting drug (Astra Aktiebolag v. Andrx Pharmaceuticals, Inc.). Although the patent holder tried to rely on these administration/process conditions, they were unsuccessful, because these conditions were not recited as limitations in the claims. Accordingly, addition of claim limitations or dependent claims setting forth specific reaction/process conditions giving rise to the claimed improvements, as well as frequency of use or extent of use limitations, may be useful in overcoming or preventing such inherency rejections.

In addition, for a claim covering a new use of a known compound, identification of the subject of the use by distinct properties can remove a claim from the scope of the prior art, as shown in Perricone v. Medicis Pharmaceutical Corporation. As illustrated in King Pharmaceuticals, Inc. v. Eon Labs, Inc., notification limitations should be avoided as the source of distinction over the prior art. Such limitations are given no weight where they are not functionally related to the otherwise anticipated method (i.e., where they do not transform the claimed method).

One technique for distinguishing claims directed to a compound or composition over prior art in order to overcome an inherency rejection is to recite specific purity limitations and claim as an isolated form. In Schering Corp. (339 F.3d at 1381, 67 U.S.P.Q.2d at 1670), the Federal Circuit explicitly stated that a patentee may obtain patent protection for an inherently anticipated compound through proper claiming. The court further suggested claiming the metabolite at issue in its pure and isolated form or as a pharmaceutical composition. In addition, the court suggested claiming a method of administering the metabolite or the corresponding pharmaceutical composition.

As set forth in Schering Corp., there are a series of cases relating to accidental, unintended, and unappreciated disclosures (see, e.g., Eibel Process Co. v. Minnesota & Ontario Paper Co. (261 U.S. 45, 43 S. Ct. 322) (1923) and Tilghman v. Proctor (102 U.S. 707) (1880) (Chisum 2011). These cases hold that results obtained under unusual conditions or accidental results that are not intended and not appreciated do not constitute anticipation. Similarly, occasional results are not inherent (Mehl/Biophile Int’l. Corp. v. Milgram (192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1305) (Fed. Cir. 1999); see also In re Rijckaert (9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957) (1993) (optimal conditions not disclosed explicitly or implicitly do not constitute an inherent disclosure)). Accordingly, aligning the facts of your case with these cases relating to accidental anticipation or occasional results may be useful in arguing against an inherency rejection.

As described above, the disclosure of a pattern of preferences in the prior art that directs one of ordinary skill in the art to the claimed invention may lead to an inherency rejection (Sanofi-Synthelabo v. Apotex, Inc. (470 F.3d at 1376, 81 U.S.P.Q.2d at 1102)). However, broad generic disclosures that do not specifically disclose the claimed species and that do not provide specific preferences for narrowing the genus do not properly form a basis for an inherency rejection. This argument is particularly relevant where the art is unpredictable and a pattern of preferences leading to a narrow class of compounds including the claimed compound is lacking.

Once the USPTO makes a prima facie case of inherency, providing evidence of structural differences, compositional differences, or process differences may be the response most likely to result in a successful outcome. The USPTO will likely cite In re Best (562 F.2d 1252, 1255, 195 U.S.P.Q. 430, 433) (C.C.P.A. 1977) for the proposition that where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the USPTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of the claimed product. Although such comparative evidence may, at times, be costly and time-consuming to prepare, it is most likely to lead to a successful result in response to an inherency rejection.
CONCLUSION

As shown in the above discussion, consideration of inherent anticipation issues is critical when attempting to obtain or address enforcement of a patent on pharmaceutical or biotech technologies. Focusing claims on truly novel aspects and keeping in mind the approach of the courts and the USPTO on inherency issues will aid any effort to ensure a claimed invention is protectable.

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