

FEDERAL CIRCUIT REVIEW

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The law of anticipation denies patent protection over subject matter already known or disclosed to the public, and therefore not novel. The prior art is said to anticipate, and invalidate, a patent claim when a single reference exhibits or discloses all limitations of the claim in the same arrangement or combination as the claim.

This issue will explore recent decisions of the Federal Circuit concerning anticipation. First, we discuss two cases that clarify the rules for determining when broad disclosures of the prior art, such as a list of potential ingredients or a range of concentrations, anticipate narrower claims, such as for a particular combination of ingredients or concentration. Next, we turn to anticipation under Section 102(g)(2) of the Patent Act, which concerns prior making of the invention in the U.S. by a person other than the patentee. Finally, we discuss cases that provide further guidance on inherent anticipation, or anticipation by a reference that discloses each claim limitation only implicitly.

The law of anticipation will continue to change, particularly in light of legislative developments. Patent applications filed on or after March 16, 2013 will be subject to provisions of the America Invents Act governing novelty and other conditions for patentability. These provisions move the U.S. patent system away from a first-to-invent regime and, in doing so, alter the scope of prior art against which patentability will be determined. In particular, prior invention by another will not generally be grounds for denying patent protection. Nonetheless, the existing body of law on anticipation will apply with full force to patents that have issued or that issue from applications that are currently pending, and thus will continue to govern the vast majority of patent disputes in the near term.

ANTICIPATION OF A COMPOUND BY PRIOR DISCLOSURES OF ITS INGREDIENTS IN LISTS

In order for a prior art reference to anticipate a patent claim, it must disclose all of the limitations of the claim arranged or combined in the same way as in the claim. Thus, even where all of the limitations of a claim are separately disclosed by a single reference, the reference will not necessarily anticipate the invention. As illustrated by the case of *WM. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, whether a reference disclosing components of an invention anticipates a claimed combination of components turns on whether the combination would be immediately apparent to one of ordinary skill. 683 F.3d 1356 (Fed. Cir. 2012).

Wrigley's patent was directed to a chewing gum composition containing a combination of the coolants menthol and WS-23. Cadbury, the accused infringer and defendant in the court below, asserted that the patent was anticipated by a prior art patent reference directed to oral compositions including chewing gum, toothpaste, and other products. In listing possible ingredients for such products, the reference disclosed WS-23 as one of three particularly preferred cooling agents, and menthol as one of 23 flavoring agents. The reference also disclosed that a cooling agent, or combination of cooling agents, was a preferred, nonessential component of an oral composition. Agreeing with the defendant that the reference disclosed chewing gum containing menthol and WS-23, and thus anticipated certain patent claims, the district court granted summary judgment of invalidity. *Id.* at 1359–61.

A divided panel of the Federal Circuit affirmed. According to the Federal Circuit, “[t]he question for purposes of anticipation is . . . whether the number of categories and components in [the prior art reference] was so large that the combination of WS-23 and menthol would not be immediately apparent to one of ordinary skill in the art.” *Id.* at 1361. The Federal Circuit found that one of ordinary skill would view the reference as envisioning the use of WS-23 and menthol in a single product. Notably, the reference specifically disclosed menthol as a flavoring agent, and WS-23 as a cooling agent, and both in amounts falling within claimed ranges. This distinguished the circumstances from those in *Impax Labs., Inc. v. Aventis Pharm.*, in which the court found no anticipation based on art that would have required one of ordinary skill to pick components from lists and then experiment with component amounts in order to arrive at the invention. *Id.* at 1361–62 (citing 545 F.3d 1312 (Fed. Cir. 2008)). Although the reference identified menthol as a flavoring agent rather than a cooling agent, the Federal Circuit reasoned that the use of menthol as a cooling agent in chewing gum was well known in the art, and even the patent-in-suit conflated cooling and flavoring characteristics. *Id.* at 1362. The panel opinion was authored by Judge Bryson and joined by District Judge Fogel, sitting by designation.

Judge Newman authored an opinion concurring in part but dissenting from the panel's holding concerning anticipation. According to Judge Newman, the prior art reference did not show the specific combination of WS-23 and menthol, nor did it "present so short and selective a list of these ingredients as to warrant an inference that their combination was already known." *Id.* at 1371. Judge Newman assigned error to the district court's finding that a mere listing of ingredients was sufficient to anticipate the combination so long as it was enabled. Rather, "[i]t is the scope, specificity, and content of the lists that controls whether the disclosure is so specific as to be deemed a disclosure of specific combinations." *Id.* at 1372. In Judge Newman's view, since the reference included lists of at least nine categories of ingredients, with over a million possible combinations, its disclosures were insufficiently specific to anticipate the claimed menthol-WS-23 composition. *Id.*

Cases Referenced

WM. Wrigley Jr. Co. v. Cadbury Adams USA LLC, 683 F.3d 1356 (Fed. Cir. 2012)

Impax Labs., Inc. v. Aventis Pharm., 545 F.3d 1312 (Fed. Cir. 2008)

ANTICIPATION OF A NARROW RANGE BY DISCLOSURES OF A BROAD RANGE

While the disclosure of a genus is not considered a disclosure of every species within that genus, the disclosure of a broad numerical range may anticipate a narrower range, as explained in *ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340 (Fed. Cir. 2012). ClearValue obtained a patent directed to "[a] process for clarification of water of raw alkalinity less than or equal to 50 ppm by chemical treatment" *Id.* at 1342 (emphasis added). A prior art reference disclosed clarifying water with an alkalinity of 150 ppm or less. However, according to the patentee's expert, the reference also taught that the specific polymer blend claimed by the patent did not work very well. *Id.* at 1344. The jury found no anticipation, and the district court concluded that the jury verdict was supported by substantial evidence. *Id.*

On appeal, the patentee argued that the prior art reference's disclosure of 150 ppm or less did not anticipate the claimed limitation of 50 ppm or less, citing the Federal Circuit's decision in *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991 (Fed. Cir. 2006). In *Atofina*, the Federal Circuit held that prior art that disclosed synthesizing difluoromethane at temperatures between 100 and 500 degrees did not anticipate a claim for synthesizing the compound at between 330 and 400 degrees. The *Atofina* court relied on disclosures by the applicant in the patent and during prosecution that significant problems occurred when the reaction was attempted at below 330 degrees or above 400 degrees, and that the narrow range of 330 to 400 degrees was critical to enabling the claimed process. See *ClearValue* at 1344–45.

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A panel of the Federal Circuit disagreed that *Atofina* controlled the outcome in the instant case, distinguishing it on its facts. Unlike in *Atofina*, there was no evidence that the narrow range claimed by the patent was “critical,” or that the claimed process worked any differently at different points within the range disclosed in the prior art reference. The reference also provided examples at various alkalinities within the broader range of 0 to 150 ppm, supporting the notion that it enabled carrying out the process throughout the stated range. Finding no considerable difference between the claimed and disclosed ranges, the Federal Circuit reversed the district court’s denial of judgment as a matter of law of invalidity for anticipation. *Id.* at 1346.

The Federal Circuit also held that the district court erred in giving weight to testimony that the prior art reference taught away from the invention, at least with regard to anticipation. *Id.* at 1344. Disclosures that teach away from an invention may be relevant for determining whether the invention would have been obvious to one of ordinary skill, but are inapplicable to an anticipation analysis. To anticipate, the reference need only disclose the invention and enable one of ordinary skill to practice an embodiment without undue experimentation. *Id.*

Cases Referenced

ClearValue, Inc. v. Pearl River Polymers, Inc., 668 F.3d 1340 (Fed. Cir. 2012)

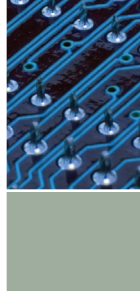
Atofina v. Great Lakes Chem. Corp., 441 F.3d 991 (Fed. Cir. 2006)

PRIOR MAKING OF THE INVENTION BY ANOTHER

Section 102(g)(2) of the Patent Act provides that a person shall not be entitled to a patent if “the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it.” Because the prior invention need not actually be published or disclosed generally to the public, Section 102(g)(2) provides grounds for invalidating patents based on what is sometimes referred to as “secret” prior art. Two recent cases address the “invention was made” and “in this country” requirements of this Section, respectively.

Prior invention does not require an appreciation for patented features

In *Teva Pharm. Indus. Ltd. v. AstraZeneca Pharm. LP*, the Federal Circuit confirmed that prior invention by another does not mean that the prior inventor necessarily appreciated the patentability of the invention, or understood precisely how it works. Rather, it is enough that the prior inventor conceived of the invention and exercised reasonable diligence in reducing it to practice. 661 F.3d 1378, 1383 (Fed. Cir. 2011).



Teva's patent was directed to a stabilized drug compound—specifically, a statin formulation stabilized exclusively by an amido-group containing polymeric compound (AGCP) or amino-group containing polymeric compound. The accused infringer and defendant in the court below, AstraZeneca, asserted that the patent was invalid on the basis of its own prior manufacture of a batch of a stabilized statin formulation months before the patentee's asserted date of invention. The defendant appreciated at the time of its supposed prior invention that the resulting compound was stable, but was not aware that the specific stabilizing effect was a result of the ingredient crosopvidone, an AGCP compound. The district court granted the defendant's motion for summary judgment of invalidity, concluding that an appreciation by the defendant that the AGCP compound was the sole stabilizing compound was not necessary to establish invention. *Id.*

On appeal, the patentee argued that the district court implicitly applied an overbroad construction of the claims so that they covered stable formulations containing AGCP compounds whether or not the AGCP compound acted as the sole stabilizer. The patentee also argued that the district court erred by not finding that the defendant concealed its invention. *Id.* at 1382. The patentee conceded for purposes of its appeal that the defendant's early formulation would infringe the patent. *See id.* at 1385.

Finding no factual dispute and deciding the issue purely as a matter of law, the Federal Circuit held that the defendant did not have to understand that the AGCP compound crosopvidone stabilized the formulation in order to prove its prior invention. *Id.* at 1382. Prior invention could be established by showing that it reduced the invention to practice first, or was the first to conceive of the invention and exercised reasonable diligence in reducing the invention to practice. *Id.* at 1384. Importantly, "[a]n inventor need not understand precisely why his invention works in order to achieve an actual reduction to practice." *Id.* (quoting *Parker v. Frilette*, 462 F.2d 544, 547 (C.C.P.A. 1972)). The Federal Circuit observed in the case law a consistent rule that:

To establish prior invention, the party asserting it must prove that it appreciated what it had made. The prior inventor does not need to know everything about how or why its invention worked. Nor must it conceive of its invention using the same words as the patentee would later use to claim it.

Id.

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Addressing the argument that the district court had essentially read the limitation “stabilizing effective amount” out of the claim when defining the invention, the Federal Circuit noted that that “[the patentee] effectively asks this court to fault [the defendant] for not first conceiving of its drug in the same words in which [the patentee] later chose to claim it.” But “[t]he invention is not the language of the [claim] but the subject matter thereby defined.” *Id.* at 1385 (quoting *Dow Chem. Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 1341 (Fed. Cir. 2001), in turn quoting *Silvestri v. Grant*, 496 F.2d 593, 599 (C.C.P.A. 1974)). There was no dispute that the defendant was aware that its formulation was stable, and that the formulation contained an amount of the AGCP compound crosprovidone falling within the range of the “stabilizing effective amount” that the patentee later claimed. Furthermore, the defendant could not be faulted for allegedly suppressing or concealing the stabilizing properties of the AGCP compound crosprovidone when the law did not require the defendant even to appreciate this property. *Id.* at 1385.

Non-written disclosure of the invention to persons in the U.S. may constitute making the invention in this country

Section 102(g)(2) refers specifically to inventions “*made in this country* by another inventor” (emphasis added). Previous iterations of Section 102(g) applied both to priority contests, or interferences, as well as to conditions for patentability generally. At least in the interference context, the Federal Circuit has held that an inventor of a foreign invention may rely on the date that the invention was disclosed in the United States as a conception date for priority purposes. See *Scott v. Koyama*, 281 F.3d 1243, 1247 (Fed. Cir. 2001). The recent case of *Amkor Tech., Inc. v. Int’l Trade Comm.* extends the law to unwritten disclosures in the United States of a foreign invention. No. 2010-1550, 2012 U.S. App. LEXIS 17789 (Fed. Cir. Aug. 22, 2012).

Amkor, the patentee, initiated a Commission investigation with allegations that the respondents, Carsem Semiconductor and related companies, violated Section 337 of the Tariff Act through the importation of encapsulated integrated circuits. *Id.* at *2. Section 337 prohibits unfair practices in import trade, including the importation into the U.S. of products that infringe a valid and enforceable U.S. patent. The patentee alleged that the respondents’ encapsulated integrated circuits infringed three patents. *Id.* at *3. The respondents countered that the patents were invalid, and presented evidence that the invention was conceived by a third party in a foreign country and disclosed, verbally, to colleagues in the U.S. in the same year as the patentee’s supposed invention. *Id.* at *7–9, 17. The alleged date of the third-party prior conception and disclosure was April or May, whereas the patentee allegedly conceived of the invention during May through August or December of the same year. Analyzing these overlapping date ranges, an administrative law judge concluded that the respondents failed to prove prior conception by another by clear and convincing

evidence. The Commission reversed the administrative law judge, determining that the earliest date the patentee was entitled to was in December, on the last day of the asserted range. On remand, the administrative law judge found the verbal disclosure to be an anticipating prior making of the invention and held the pertinent claims invalid under Section 102(g)(2). *Id.* at *8–10.

On appeal, the patentee argued that the third party's disclosures of its foreign-made invention were insufficient to establish prior invention in the U.S. under Section 102(g)(2), and that the Commission erred in determining that the patentee was entitled to a priority date no earlier than December. The patentee did not dispute that disclosure of a foreign-made invention in the U.S. constitutes making the invention in the U.S., but asserted that Section 102(g)(2) required a full, written disclosure of the invention. *Id.* at *13. However, agreeing with both the respondents and the Commission, the Federal Circuit held that there is no per se requirement that the domestic disclosure be in writing, so long as the disclosure is sufficient to establish conception. *Id.* at *15–17. The disclosure must be "specific enough to encompass the complete and operative invention," but could take any form, including an oral communication, the contents of which are later proven through testimony. *Id.* at *16–17 (quotation to *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986) omitted).

Notwithstanding the sufficiency of the disclosure, however, the Federal Circuit found that the Commission erred in determining the priority date for Amkor's patent. The Commission had relied on *Oka v. Youssefieh*, a case holding that a junior party to an interference who established conception only within a range of dates was deemed to have conceived of the invention at the very end of that range. 849 F.2d 581, 584 (Fed. Cir. 1998). The patentee argued that this rule applied to any party bearing the burden of persuasion, but not to patent owners in a validity dispute. *Scott* at *20. The Federal Circuit agreed, noting that respondents, as the party charging invalidity, bore the burden of persuasion. Turning to the evidence, the Federal Circuit determined that the respondents had established third-party invention only as early as May, on the last day of their asserted range. This overlapped with the range of dates asserted by the patentee as its priority date, proving only that the patentee might not have been the first inventor. A mere possibility of prior invention by another did not satisfy the respondents' burden of proving invalidity by clear and convincing evidence. *Id.* at *20–21. Finding that the Commission committed legal error as to the applicable dates, the Federal Circuit reversed the Commission's finding of invalidity.

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Effect of the America Invents Act

Among the changes imposed by the America Invents Act is the elimination of Section 102(g)(2) and the availability of “secret” prior art. Accordingly, while *Teva* and *Amkor* reflect today’s law, they do not reflect the law that will apply to patents that issue from applications filed on or after March 16, 2013.

Cases Referenced

Amkor Tech., Inc. v. Int’l Trade Comm., No. 2010-1550, 2012 U.S. App. LEXIS 17789

(Fed. Cir. Aug. 22, 2012)

Teva Pharm. Indus. Ltd. v. AstraZeneca Pharm. LP, 661 F.3d 1378 (Fed. Cir. 2011)

Scott v. Koyama, 281 F.3d 1243 (Fed. Cir. 2001)

Dow Chem. Co. v. Astro-Valcour, Inc., 267 F.3d 1334 (Fed. Cir. 2001)

Oka v. Youssefyeh, 849 F.2d 581 (Fed. Cir. 1998)

Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367 (Fed. Cir. 1986)

Silvestri v. Grant, 496 F.2d 593 (C.C.P.A. 1974)

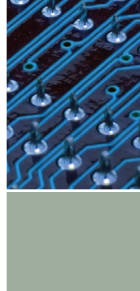
Parker v. Friette, 462 F.2d 544 (C.C.P.A. 1972)

INHERENT ANTICIPATION

Although an anticipatory reference must disclose each and every limitation of the claim, this disclosure need not be explicit. Rather, a reference may anticipate inherently if all of the limitations are “necessarily present, or inherent” in the reference, even if not expressly recognized or stated. *Verizon Servs. Corp. v. Cox Fibernet Va., Inc.*, 602 F.3d 1325, 1337 (Fed. Cir. 2010). As seen in the recent cases of *In re Montgomery*, 677 F.3d 1375 (Fed. Cir. 2012) and *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629 (Fed. Cir. 2011), reasonable judicial minds may differ on whether limitations are disclosed inherently by a reference.

Efficacy limitation inherent in disclosure of a clinical test protocol

Montgomery filed a patent application that included claims directed to “a method for the treatment or prevention of stroke or its recurrence” through administration of rennin-angiotensin system (RAS) inhibitors “to a patient diagnosed as in need of such treatment or prevention.” The examiner rejected the claims as anticipated by prior art that described a study protocol for administration of ramipril, an RAS inhibitor, to subjects at risk for stroke. *Montgomery*, 677 F.3d at 1376–77. The patent applicant appealed the examiner’s rejection to the Board of Patent Appeals and Interferences, arguing that none of the cited references demonstrated that administration of the RAS inhibitor actually treated or prevented stroke. The Board dismissed this argument, noting that such efficacy was inherent, and affirmed the examiner’s rejection. *Id.* at 1379.



In an opinion authored by Judge Dyk and joined by Judge Prost, a divided panel of the Federal Circuit affirmed. The Federal Circuit expressed skepticism “that a proper interpretation of the claims would include an efficacy requirement,” but concluded that even if it did, this requirement was inherently satisfied by carrying out the steps of the treatment. *Id.* at 1380–81. According to the court, there was no dispute that at least one of the cited references disclosed administration of an RAS inhibitor to subjects at risk for stroke, and that such administration inevitably treats or prevents stroke. *Id.* at 1381. “Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent,” whether or not one of ordinary skill would have recognized these inherent characteristics of the prior art. *Id.* (quoting *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001)). While the prior art described a study procedure rather than the actual administration of the RAS inhibitor, the court viewed these disclosures as enabling administration, and thus sufficient to anticipate. *Id.* at 1382. In reaching its holding, the panel was no doubt influenced by similarities it saw between the description in the patent application, which also did not disclose results of actual testing, and the descriptions in the prior art study, which the applicant conceded would have been sufficient for the authors to obtain the patent claims at issue. “It is well established that a patent may be secured, and typically is secured, before the conclusion of clinical trials,” the court noted. The court declined to apply a more stringent standard for disclosures of the alleged anticipatory art than those of the patent applicant. *Id.* at 1382–83.

Dissenting Judge Lourie argued that the panel had adopted an overbroad concept of inherency. *Id.* at 1383. In Judge Lourie’s view, “inevitability” was the “keystone of the inherency doctrine,” and the efficacy of RAS inhibitor treatment was not inevitable from the disclosures of a proposal for further experimentation. *Id.* at 1384. Quoting the court’s decision in *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367 (Fed. Cir. 2005), Judge Lourie noted that “[a]n invitation to investigate is not an inherent disclosure,” especially in unpredictable arts. *Id.* In Judge Lourie’s view, inherency followed from carrying out the activity that produces what it is claimed, not from the mere description of the activity.

Claimed functionality not inherent in disclosures of a structure that might perform the same function

The panel in *Bettcher Indus, Inc. v. Bunzl USA, Inc.*, similarly split over whether certain limitations, this time expressed as functionality of structural features, were inherent in the prior art. 661 F.3d 629 (Fed. Cir. 2011). The patent-in-suit was directed to a rotary knife used for meat packing and other food processing. The knife included a ring-shaped blade having a groove, or race, along its outer edge. The claims referred to the upper and lower faces of the race as “bearing surfaces” or “bearing faces.” The race fit over a protrusion, or bearing structure, on the knife handle that

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supported the blade during use. *Id.* at 633–34. The accused infringer, who was the defendant in the district court, asserted that the patent was invalid in view of the patentee’s own prior art blades. These blades also included a groove, which had upper and lower beveled surfaces, or chamfers. The defendant argued that these surfaces were “bearing surfaces,” but there was contradictory evidence before the district court regarding whether these surfaces could serve a bearing function. *Id.* at 639. On appeal, the defendant argued that the chamfers were inherently bearing surfaces due to their physical configuration. In an opinion authored by Judge Lynn and joined by Judge Bryson, the Federal Circuit panel held that the defendant had not established more than a mere possibility that the chamfers could perform the function of a bearing surface, and the jury was free to disregard this evidence. *Id.* at 639–40. The court rejected the defendant’s “attempts to characterize one structure (chamfers) as a completely different structure (a bearing race) based on a hypothetical configuration of surrounding structures nowhere disclosed in the prior art (expressly or inherently)” *Id.* at 640. Judge Reyna dissented, arguing that the patentee’s decision to claim the surfaces in terms of their functionality, rather than their physical structure alone, did not alter the fact that the structures themselves were known and disclosed in the prior art. *Id.* at 653–54.

Cases Referenced

In re Montgomery, 677 F.3d 1375 (Fed. Cir. 2012)

Bettcher Indus., Inc. v. Bunzl USA, Inc., 661 F.3d 629 (Fed. Cir. 2011)

Verizon Servs. Corp. v. Cox Fibernet Va., Inc., 602 F.3d 1325 (Fed. Cir. 2010)

Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354 (Fed. Cir. 2005)

Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368 (Fed. Cir. 2001)

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