Client Alert

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Is obviousness becoming the new anticipation? How the Federal Circuit is redrawing the line between anticipation and obviousness in favor of anticipation.

There was a time when inherent anticipation of a claim directed to a therapeutic method resulted when the prior art actually carried out the steps of that method to achieve a particular result, but simply did not appreciate an additional result (the one now claimed) achieved by that method. Now, it suffices if the prior art merely proposes the steps of the method, without knowledge of whether those method steps will achieve any result, much less the result claimed in the therapeutic method.

There was a time when anticipation of a narrow range in view of a prior art broader range required either an example within the narrow range or some disclosure demonstrating a "pattern of preferences" for the narrow range. Now, the bar has been raised so that the mere overlap is sufficient.

There was a time when anticipation of a combination of components required disclosure of all those components "arranged as in the claim," without the need for picking and choosing disparate components from multiple lists. Now, the bar has been raised so that anticipation arises even with picking and choosing among tens or hundreds of thousands of possible combinations.

This recent metamorphosis of obviousness rejections to anticipation rejections is not a question of mere academic interest. As those who practice know, there is a whole arsenal of tools available for overcoming an obviousness rejection, including showing that a reference teaches away from an invention or showing that the invention gives rise to one of the so-called secondary considerations such as unexpected results, commercial success, failure of others and long-felt need. None of these tools is available for an applicant or patentee to overcome an anticipatory reference. Indeed, in the cases discussed below, the court has already used its expansive application of anticipation to shut the door on a patentee's reliance on a prior art's teaching away.

We will now examine the specific cases demonstrating the court's newfound approach.

(1) Federal Circuit expands doctrine of anticipation to cover situations where the prior art merely proposes a claimed pharmaceutical method without knowing if it will even work

In *In re Montgomery* (Fed. Cir. 2012), the court reviewed the patentability of a claim reciting "[a] method for the treatment or prevention of stroke or its recurrence," comprising "***administering to a patient diagnosed as in need of such treatment or prevention***, an inhibitor of the renin angiotensin system," such as ramipril.

Montgomery appealed the affirmance by Patent Office Board of Appeals and Interferences ("the Board") of the Primary Examiner's rejection of the claims as being anticipated by several references, all of which, according to the Board, "describe the administration of ramipril to subjects at risk of stroke," although none actually showed effectiveness. The question as framed by the court was whether a showing of effectiveness was necessary for inherent anticipation of Montgomery's method.

(1) The prior art

The only reference ultimately relied upon by the Federal Circuit described the design of a larger trial of ramipril to prevent myocardial infarction, stroke or cardiovascular death for a group of patients at high risk for cardiovascular events such as myocardial infarction and stroke. Although the study ultimately found that patients receiving ramipril had a statistically significant reduction in the risk of stroke, these results were irrelevant to an anticipation analysis because they were not published until after Montgomery's priority date. The only actual administration of ramipril reported in the reference used a dose of ramipril below the therapeutic dose as part of an initial patient "randomization" carried out before the actual trial.

(2) The proceedings on appeal

The Board rejected Montgomery's argument that none of the references demonstrated that ramipril actually treats or prevents stroke, noting that ramipril inherently treats or prevents stroke, and "[i]t matters not that those of ordinary skill heretofore may not have recognized these inherent characteristics."

Finding that "there is no question here that treating stroke-prone patients with ramipril does in fact inevitably treat or prevent stroke," the Federal Circuit affirmed the Board's rejection based on inherent anticipation. Referring to its decision in *Bristol-Myers Squibb*[1], the court noted that "[w]e have repeatedly held that '[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent.' … As we stated in *Cruciferous Sprout*, 301 F.3d at 1350, '[i]t matters not that those of ordinary skill heretofore may not have recognized the[] inherent characteristics of the [prior art].' "[2] The court also cited *King v. Eon Labs*[3] where a claim directed to increasing the bioavailability of a drug by taking it with food was found to be inherently anticipated by a prior art taking the same drug with food to reduce stomach distress.

Read in a vacuum, the court's rationale seems rather straightforward: (1) the prior art proposes administering ramipril to patients prone to cardiovascular disorders such as high blood pressure and stroke; (2) when ramipril is in fact administered to such patients, it will treat or prevent stroke; (3) our inherency case law makes clear that it matters not whether one of ordinary skill in the art would have appreciated this effect at the time of the invention, so long as that effect is indeed the necessary result of the process.

The problem here is that the court's premise, that administration of ramipril is a "newly discovered result of a ***known*** process directed to the same purpose," appears to represent a newly minted judicial expansion of what is meant by "known." In particular, is a process "known" if it is merely proposed and if one does not even know if it will work at all, much less for the purposes recited in the claim? In this regard, earlier inherency cases cited by the court are inapposite because in those cases, the processes were specifically known to work and the patentee merely recognized an additional inherent benefit of those processes.

For example, in *Cruciferous,* the claim recited "[a] method of preparing a food product rich in glucosinolates, comprising germinated cruciferous seeds … and harvesting sprouts prior to the 2-leaf stage, to form a food product comprising a plurality of sprouts." However, it was undisputed that such sprouts were already being grown, harvested and consumed in the prior art for nutritional purposes and it

[1] *Bristol-Myers Squibb Co. v. Ben Venue Labs, Inc.*, 246 F.3d 1368, 1376, 58 U.S.P.Q.2d 1508, 1514 (Fed. Cir. 2001).

[2] *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1350, 64 U.S.P.Q.2d 1202, 1207 (Fed. Cir. 2002).

[3] *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 95 U.S.P.Q.2d 1833 (Fed. Cir. 2010).

did not matter whether the grower/harvester/consumer knew that it was a food product rich in glucosinolates that was being grown/harvested/consumed.

Likewise, in *King,* the claim recited "[a] method of increasing the bioavailability of metaxalone to a patient receiving metaxalone therapy" by administering "a therapeutically effective amount of metaxalone in a pharmaceutical composition with food." Again, it was undisputed that patients were already taking metaxalone with food, albeit to reduce stomach upset, and it did not matter whether such patients appreciated that they were enhancing the bioavailability of the drug while they did so.

So in both cases, in the course of achieving one effect with a process known to be effective, another unappreciated effect was inevitably also achieved. This is classic inherency. Here, however, there did not already exist in the prior art a process known to achieve a first effect that was later discovered to achieve a second effect previously unappreciated. Rather, the prior art was assessing whether administering ramipril to a patient ***might work*** for any of three identified effects, one of which was susceptibility to stroke.

So in the final analysis, the distinction lost on the majority is the difference between appreciating an additional benefit to a process already known to work for a particular purpose, as in both *Cruciferous* and *King*, versus knowing whether a process will work at all for any purpose as in *Montgomery*.

The majority sought to justify its holding based on two other premises.

First, the majority referred to its decision in *Schering* where "we held that a prior art patent that disclosed administering loratadine to a patient inherently anticipated a patent for a metabolite of loratadine because the inherent result of administering loratadine to a patient is the formation of the metabolite." However, as in *Cruciferous* and *King*, the prior art process in *Schering* was already known to be effective, unlike here.

The court's final justification was based on a purported admission by Montgomery's counsel that the prior reference would in its own right have been sufficient to support a patent. This is particularly interesting for a couple of reasons. First, as the dissent pointed out, the prior art reference ended up having to alter its study before it would be accepted for publication. Second, Judge Dyk, who wrote the *Montgomery* decision, authored the *In re '318 litigation* decision, in which he specifically held that an invention directed to a method of treating Alzheimer's was not enabled because it was based on an unproved hypothesis, even though that hypothesis proved to be correct::

> Thus, at the end of the day, the specification, even read in the light of the knowledge of those skilled in the art, does no more than state a hypothesis and propose testing to determine the accuracy of that hypothesis. That is not sufficient. *See Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1325 (Fed. Cir. 2005) ("If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to 'inventions' consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the 'inventor' would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention rather than merely proposing an unproved hypothesis.").

It is difficult here not to conclude that there is a double standard at play, since speculation that proved to be correct did not entitle an inventor to a patent in *'318* yet similar speculation in a prior art article was enough to constitute an inherent anticipation.

Judge Lourie summed it up well in his dissent:

> The majority further states that even if HOPE merely proposed administering ramipril for treatment or prevention of stroke (without actually doing so), it would still anticipate. … The majority's view is flawed. A description of a process, even if not carried out, is an anticipation of that process. But a mere description of a process that, *if* it had been carried out, *might* yield a particular *undisclosed* result is not an inherent anticipation of that result. Stated somewhat differently, inherency requires description of action that inevitably produces a result, not merely description of action that might have been carried out, but was not, and might have yielded a particular result, but did not. The HOPE reference is only a description of what has not been carried out; whether or not, if carried out, it would inherently accomplish the claimed result is not before us, for HOPE is only a plan.

(2) Federal Circuit expands doctrine of anticipation to cover a range within a range absent a showing of criticality

In *ClearValue, Inc. v. Pearl River Polymers, Inc.* (Fed. Cir. 2012), the court reviewed the validity of a claim, reciting "[a] process for clarification of water of raw alkalinity ***less than or equal to 50 ppm*** by chemical treatment" comprising adding and blending with the water both a particular high molecular weight aluminum chlorohydrate ("ACH") polymer and a particular high molecular weight quaternized ammonium polymer (DADMAC) "in an amount sufficient to form a flocculated suspension in the water and to remove turbidity from the water." The district court found that ClearValue's patent was both valid and infringed.

On appeal, the Federal Circuit reviewed whether ClearValue's claims were anticipated over prior art generally teaching treatment of water with an alkalinity of 150 ppm or less and providing a specific example showing the same combination of DADMAC and ACH to clarify water, but with an alkalinity of between 60 and 70 ppm. ClearValue argued that the prior art's teaching of clarifying water with alkalinity of 150 ppm or less is too broad to anticipate the 50 ppm or less limitation of its claim.

The question thus addressed by the court was whether a prior art disclosure of a genus of less than 150 ppm anticipated a claim setting forth a species of less than 50 ppm. ClearValue cited *Atofina v. Great Lakes Chemical Corp.*, 441 F.3d 991, 78 USPQ2d 1417 (Fed. Cir. 2006), for the proposition that a broader genus does not anticipate a narrower species. The court in *Atofina* found that a temperature range of 100–500° C in the prior art did not anticipate a claimed range of 330–450° C in a method of synthesizing difluoromethane ("Here, the prior art, JP 51-82250, discloses a temperature range of 100 to 500° C which is broader than and fully encompasses the specific temperature range claimed in the '514 patent of 330° to 450° C. Given the considerable difference between the claimed range and the range in the prior art, no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate this limitation of the claim.").

Interestingly, although the *Atofina* decision cited the lack of "sufficient specificity" as its rationale, the panel in *ClearValue* went in a completely different direction, relying on the fact that Atofina's patent states that "only a narrow temperature range enables" the process "to operate as claimed," and that problems occur when operating the reaction either below 330° C or above 400° C. The court thus concluded that "[i]n *Atofina*, the evidence showed that one of ordinary skill would have expected the synthesis process to operate differently outside the claimed temperature range, which the patentee described as 'critical' to enable the process to operate effectively." By contrast, "ClearValue has not argued that the 50 ppm limitation in claim 1 is 'critical,' or that the claimed method works differently at different points within the prior art range of 150 ppm or less. Nor does ClearValue argue that the Hassick reference fails to teach one of ordinary skill in the art how to use the claimed invention, i.e., that Hassick is not enabled to the extent required to practice claim 1 of the '690 patent."

There are several very disturbing aspects to the court's holding.

First, the most applicable precedent, *Atofina*, said nothing in its holding about the claimed range being critical to enable the invention to operate as claimed but rather simply relied on the fact that the prior art range was so much broader than the claimed range. Accordingly, why would ClearValue have made such an argument?

Second, to the extent the new coin of the realm for avoiding anticipation of a narrower species in view of a broader prior art genus is intrinsic evidence of criticality of the narrower range, then ClearValue seems to meet that test as well as Atofina did. In particular, the patent at issue in *ClearValue* indeed did disclose a critical difference between its claimed range of under 50 versus the prior art range of under 150:

> It is well known that significantly greater chemical dosages are needed for clarification of water with low alkalinity than for clarification of water with high alkalinity. (… Water having a high alkalinity can be defined as water with alkalinity of greater than 60 ppm.) …. [W]ater having a low alkalinity and a low turbidity is very difficult to clean.

So in fact, there was a criticality set forth in ClearValue's specification relating to carrying out the process with water having an alkalinity under 50, and the prior art fell squarely in the definition of those systems having alkalinity higher than 60, which were expected to be treatable by the process. Perhaps it was ClearValue's purported failure to argue this criticality that distinguishes this case, though this would be rather harsh given that this is a doctrine created by this panel on the fly.

Finally, in addition to establishing a new test for anticipation of a range within a range that goes well beyond what was established by precedent such as *Atofina*, this case also now conflates well-entrenched differences between obviousness and anticipation. In particular, when a claim is obvious over the prior art, it is well established that one can rely on a teaching away or secondary considerations such as unexpected results. On the other hand, when a claim is anticipated, a teaching away or an unexpected result is legally irrelevant. By this holding, the court creates a new hybrid animal, where one looks to factors relevant to obviousness, such as criticality of a claimed range, to determine whether a claim is anticipated.

So in essence, this court now wants you to rebut anticipation by providing it with evidence, such as criticality, which it heretofore held was irrelevant to anticipation!

What should the court have done here? If the court had been true to precedent, the case would have held (1) that there is no anticipation citing *Atofina* and (2) the difference in range is prima facie obvious, but rebuttable by showing for example that one of ordinary skill in the art would not have expected to be able to treat water with an alkalinity below 50 ppm.

(3) Federal Circuit expands doctrine of anticipation to cover selection of multiple components from multiple listings

In *WM Wrigley Company v. Cadbury Adams* (Fed. Cir. 2012), the court reviewed the validity of Wrigley's claim directed to a gum including as flavor components menthol and a N-2,3-trimethyl-2-isopropylbutanamide, which goes by the trade name "WS-23." The district court concluded that the gum was anticipated by Shahidi, U.S. Patent No. 5,688,491. On appeal, Wrigley argued (1) that while Shahidi discloses all the claim limitations, it does not disclose them in the combination recited and (2) that Shahidi would not have enabled a person of ordinary skill in the art to derive the claimed combination without undue experimentation.

The Shahidi reference broadly disclosed oral compositions including toothpastes, mouth rinses, liquid dentifrices, lozenges and gums containing copper bisglycinate. The compositions include both essential and nonessential components.

Essential components:

- Xylitol
- Copper bisglycinate
- Pharmaceutically acceptable carriers including mouthwashes, toothpastes, tooth powders, prophylaxis pastes, lozenges, chewing gums

Optional Components

- Water
- A cooling agent or combination of cooling agents including all of those described in five different patents, and three preferred compounds identified as WS-3, WS-23 and TK-10
- A water-soluble fluoride compound
- A humectant
- An abrasive polishing material
- A surfactant, including anionic, cationic, zwitterionic and nonionic surfactants
- Thickening agents if a toothpaste
- Antimicrobial agents
- Buffering agents
- Non-cationic water insoluble agents
- A flavoring agent, including as "the most suitable" 23 different agents, one of which is menthol
- Coloring agents
- Sweeteners
- Ethyl alcohol

On review, the court acknowledged, as argued by Wrigley, that "[f]or a prior art reference to anticipate a claim, it must disclose all of the limitations of the claim 'arranged or combined in the same way as in the claim.' " citing *Net MoneyIN, Inc. v. VeriSign, Inc.*[4] Nonetheless, the court concluded that "[t]his is not a case in which the prior art discloses a genus and the claim at issue recites a species of that genus" and where the issue of anticipation therefore "turns on whether the genus was of such a defined and limited

[4] 545 F.3d 1359, 1370 (Fed. Cir. 2008).

class that one of ordinary skill in the art could 'at once envisage' each member of the genus,'" citing *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*[5] Rather, in this case "Shahidi envisions using WS-23 and menthol in a single product. While Shahidi discloses a number of different combinations of cooling and flavoring elements, one of them is the combination of menthol, which Shahidi identifies as one of the 'most suitable' flavoring agents, with WS-23, which Shahidi identifies along with WS-3 as among a group of three 'particularly preferred cooling agents.' Based on the disclosure of the combination of those components, we agree with the district court that Shahidi anticipates [the claim]."

The court noted that "the number of categories and components in Shahidi" was not "so large that the combination of W-23 and menthol would not be immediately apparent to one of ordinary skill in the art." The court found in particular that "Shahidi specifically discloses the use of both WS-23 and menthol in chewing gum." Relying on the fact that the patent under review had as its objective the obtaining of a cooling flavor composition that will contribute a long-lasting cooling sensation, the court noted that "the Shahidi reference clearly identifies the combination of WS-23 … and menthol."

There are two somewhat questionable aspects to the court's logic. First, the court appears to have relied on the fact that the Wrigley patent was seeking a cooling flavor agent as the basis for selecting such agent in the prior art Shahidi reference ("Given the objective of the [Wrigley] patent, to obtain 'a cooling flavor composition that will contribute a long-lasting cooling sensation' and a chewing gum with a 'clean, high-quality flavor … with a good cooling effect,' the Shahidi reference clearly identifies the combination of WS-23 … and menthol"). In other words, the court impermissibly relied on Wrigley's own specification to support selection of a cooling agent and a flavoring agent. Second, though the court was technically correct when it noted that the prior art characterized menthol as one of the "most suitable" for use in the invention, the court conveniently omitted from its discussion that all the other listed flavoring agents (more than 20 others) were similarly characterized as being "the most suitable."

The fact that the selection of single components from multiple lists is now being viewed by some judges on the Federal Circuit as anticipatory represents a significant lowering of the bar and calls into question the validity of many issued patents. It has indeed been the case that a very long list of compounds, even on the order of tens of thousands of them, could anticipate a claim directed to a single compound (*See In re Gleave*[6]). It has also been the case that a compound could be rejected as anticipated where the prior art describes a broad class of substituents on a compound but in addition discloses a much more limited class such that "one skilled in the art would … at once envisage each member of this limited class." *In re Petering*[7]. Finally, it has been the case that the composition recited in a method can be rejected as anticipated when the active component is specifically set forth in a list, even though it is only one of 14 components in that list (*See Perricone*[8]). However, selecting specific combinations of components, where each component itself has to be selected from a separate list of optional components, has generally not been viewed as anticipatory (*See Akzo N.V. v. U.S. International Trade Commission*.[9] (No anticipation where the prior art "would have required [patentee] randomly to pick and choose among a number of different polyamides, a plurality of solvents, and a range of inherent viscosities."))

Thus, in *Wrigley*, one had to choose to use (a) a gum (1/6); (b) one of the optional components (1/2); (c) the particular combination of cooling agent and flavoring agent (1/14)(1/14);, (d) WS-23 as the cooling

[5] 471 F.3d 1369, 1376 (Fed. Cir. 2006).

[6] *In re Gleave*, 560 F.3d 1331, 90 U.S.P.Q.2d 1235 (Fed. Cir. 2009).

[7] *In re Petering*, 301 F.2d 676, 681, 133 U.S.P.Q. 275, 280 (C.C.P.A. 1962).

[8] *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 77 U.S.P.Q.2d 1321 (Fed. Cir. 2005).

[9] 808 F.2d 1471, 1 USPQ2d 1241 (Fed. Cir. 1986).

agent (1/3); and (e) menthol and the flavoring agent (1/23), for a total likelihood of 1 out of 162,288 possible combinations. This, according to the Federal Circuit, was "immediately apparent."

Conclusion

Whether your viewpoint tends to lean pro-patent or anti-patent, the above cases are disturbing to the extent that they thwart settled case law and expectations of practitioners. It is of little surprise that there were vigorous dissents in two of the three cases. Each case is troubling in its own way. *Montgomery* concludes that a therapeutic method is the inherent or necessary result of a prior art method that is merely proposed and may or may not work. This is new law. *ClearValue* concludes that a smaller range within a larger range is anticipated even without an example or a pattern of preferences directing one of ordinary skill in the art to that narrower range. This is new law. *Wrigley* holds that selection of optional components from multiple lists is an "immediately apparent" anticipation even where there is less than a 1 in 100,000 chance of selecting such components. This is new law.

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