

Keywords: anticipation; jury instructions

General: For a claim to be anticipated, each claim element must be disclosed, either expressly or inherently, in a single prior art reference, and the claimed arrangement or combination of those elements must also be disclosed, either expressly or inherently, in that same prior art reference.

Therasense Inc. v. Becton, Dickinson and Co.
93 U.S.P.Q.2d 1481 (Fed. Cir. 2010)
Decided January 25, 2010

I. Facts

Abbott's U.S. patent number 5,628,890 is directed to electrochemical sensors for measuring glucose levels in blood. A droplet of blood is placed on a disposable test strip that has two electrodes: a "working electrode" and a "counter electrode." The working electrode is coated with an enzyme and a mediator. The enzyme serves as a catalyst to facilitate a chemical reaction in which glucose molecules in the blood sample lose some of their electrons, and the mediator then transfers those electrons to the working electrode. As the electrons flow through the working electrode, an electrical current is detected. The magnitude of the electrical current can then be correlated to the concentration of glucose molecules in the blood. To complete this circuit, the blood must be in contact with both electrodes at the same time. A problem occurs, however, if the blood only partially covers the working electrode. For example, if too little blood is supplied, or if the test strip is not held in a horizontal position, the blood may not fully cover the working electrode. This will result in the production of fewer free electrons between the two electrodes, and the sensor will report an erroneously low glucose level.

The '890 patent addresses this "short fill" problem by placing the counter electrode on a downstream side of the working electrode, where the blood necessarily makes contact with the working electrode before it makes contact with the counter electrode. This arrangement helps to ensure that a circuit is not completed, and that no measurement is taken, until the working electrode is fully covered with blood. Independent claim 11 of the '890 patent is exemplary:

11. An electrode strip for use in an electrochemical sensor for measuring a compound in a sample, comprising:
an elongated electrode support defining a sample transfer path for directional flow of the sample from an application point along said electrode support;
a reference or counter electrode in said sample transfer path; and
a covering layer defining an enclosed space over the sample transfer path, the reference or counter electrode and said working electrode, said covering layer having an aperture for receiving sample into said enclosed space;
said aperture spaced away from and upstream of said electrodes in said sample transfer path and said reference or counter electrode spaced downstream of said working electrode in said sample transfer path.

Claim 12 depends from claim 11 and adds a requirement that the counter electrode is spaced downstream of "any portion" of the working electrode.

Abbott accused BD/Nova of infringing claims 11 and 12 of the '890 patent. BD/Nova denied infringement and asserted that claims 11 and 12 are invalid under §§ 102, 103, and 112 ¶ 1. More specifically, under §§ 102 and 103, BD/Nova asserted that claims 11 and 12 are anticipated or rendered obvious in light of both U.S. patent number 5,120,420 ("Nankai") and U.S. patent number 5,582,697 ("Ikeda").

The jury, using a special verdict form, found that BD/Nova infringed claims 11 and 12 under the doctrine of equivalents. However, the jury also found that claims 11 and 12 were invalid. More specifically, the jury checked “Yes” in response to the question, “Have defendants proven by clear and convincing evidence that Claims 11 and 12 of the ‘890 patent are invalid by reason of anticipation or obviousness?” In accordance with this verdict, the district court entered judgment in favor of BD/Nova. The district court denied Abbott’s post-trial motions for JMOL and for new trial. Abbott appealed the judgment that claims 11 and 12 are invalid and BD/Nova filed a cross-appeal with regard to the jury’s finding that BD/Nova infringed claims 11 and 12.

II. Issues

- A. Was the jury instruction regarding the law of anticipation erroneous?
- B. Was the jury instruction “Have defendants proven by clear and convincing evidence that Claims 11 and 12 of the ‘890 patent are invalid by reason of anticipation or obviousness?” erroneous?

III. Discussion

A. Yes. Abbott contended that this verdict is a general verdict encompassing separate legal theories of anticipation and obviousness, and that the verdict must be reversed, or a new trial granted, if any legal theory is legally flawed or is unsupported by substantial evidence. In particular, Abbott contended that the district court’s jury instruction on the law of anticipation was erroneous, and that the jury could not have found the claims obvious under either of BD/Nova’s two obviousness contentions. The district court instructed the jury on the law of anticipation as follows:

For anticipation, it is not enough that all of the elements could have been found among two or more references. If, at the time of the patent application, a single prior-art reference already described all of the elements of the claimed invention and would have informed those skilled in the art that those elements *could have been arranged* as in the claimed invention, then the prior-art reference is deemed to “anticipate” the claimed invention and thereby render it unpatentable and thus invalid. It would not be enough, however, that all of the elements were in random passages in the reference. By the same token, *for anticipation to apply, it is not necessary that the prior-art reference expressly lay out the elements in the exact way laid out in the claim.* Rather, for anticipation, it is sufficient if the single reference would have informed those skilled in the art that all of the claimed elements *could have been arranged* as in the claimed invention.

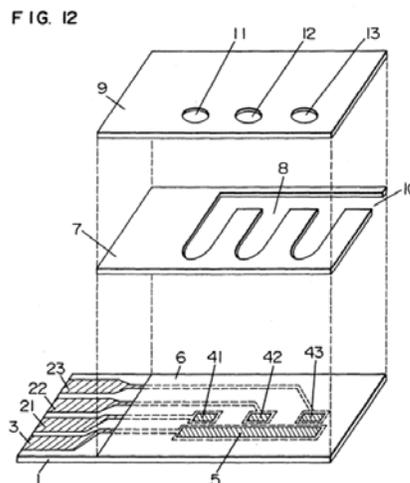
Over Abbott’s objection, the district court then instructed the jury on how it should apply the law of anticipation to the prior art Nankai reference:

For anticipation to apply, Nankai did not have to discuss the subject of shortfill. Rather, what matters is whether or not Nankai’s specification and figures would have informed those of ordinary skill in the art that the claimed combination *could have been arranged* as in the claimed invention in suit. If Nankai did not do so, then it did not anticipate. If Nankai did so, then it did anticipate. It would not matter that it was subsequently discovered that the arrangement in question was also useful in solving the shortfill problem. What is already in the public domain does not become patentable merely because a new use for a known approach is discovered.

The Federal Circuit held that the instruction was erroneous because it makes sufficient, for purposes of anticipation, prior art having individual claim elements that “could have been arranged” in a way that is not itself described in the anticipatory reference. Citing *Net MoneyIN, Inc. v. VeriSign, Inc.*, among other cases, the Federal Circuit held that for a claim to be anticipated, each claim element must be disclosed, either expressly or inherently, in a single prior art reference, and the claimed arrangement or combination of those elements must also be disclosed, either expressly or inherently, in that same prior art reference. Therefore, the district court’s instruction on the law of anticipation was legally erroneous.

B. No. The Federal Circuit noted that the only result that may have been prejudiced in this case was the jury’s affirmative response to the question, “Have defendants proven by clear and convincing evidence that Claims 11 and 12 of the ‘890 patent are invalid by reason of anticipation or obviousness?” The Federal Circuit noted that because anticipation and obviousness were presented together in the same jury question, it is impossible to know which of the two legal theories the jury relied on to invalidate the claims. However, an erroneous instruction on the law of anticipation could not have changed the result in this case if claims 11 and 12 would have been obvious as a matter of law, such that no reasonable jury could have returned a verdict that the claims are not obvious. The Federal Circuit held that claims 11 and 12 would have been obvious at least in view of the Nankai reference as a matter of law.

Figure 12 of Nankai shows a sensor in which fluid is introduced through introducing port 10 and is drawn along three channels 8 towards discharge ports 11, 12, 13. While following the paths of the three channels, the fluid encounters three separate working electrodes 41, 42, 43 and a counter electrode 5 that is shared by all three working electrodes. As shown below, counter electrode 5 is on a downstream side of working electrodes 41, 42, 43 relative to introducing port 10.



The disputed elements were “directional flow” and “said covering layer having an aperture for receiving sample.” As for “directional flow,” because it is difficult to know beforehand which of the three channels 8 the fluid will fill up first, Abbott contended that the fluid does not move in a “particular direction” as required by the district court’s construction of “directional flow.” In Abbott’s view, if the fluid fills the rightmost channel first, then the counter electrode will be upstream, not downstream, of working electrodes 41 and 42; alternatively, if the fluid fills the middle channel first, then the counter electrode will be upstream, not downstream, of working electrodes 41 and 43.

However, the claims require only that a *single* counter electrode be spaced downstream of a *single* working electrode: “said reference or counter electrode spaced downstream of said working electrode.” While the open-ended transitional phrase “comprising” allows for additional working electrodes to be present in the claimed invention, it is sufficient for purposes of the “downstream” limitation if the counter electrode is located downstream of only a *single* working electrode. Thus, regardless of which channel the fluid fills up first in Nankai, the fluid will necessarily encounter at least one working electrode before reaching the counter electrode. Therefore, Nankai discloses “directional flow.”

Abbott also argued that “said covering layer having an aperture for receiving sample” is absent from Nankai because the introducing port 10 of Figure 12 is located on a side of the sensor rather than in the cover 9. However, Figure 13 of Nankai shows an introducing port 10 and discharge ports 11, 12 located in the same cover 9. In addition, Nankai states that “in the examples, the same numbering is used for common elements.” Indeed, in their reply brief, Abbott conceded that moving an aperture to the cover is an “insubstantial” or “obvious” difference.

Abbott’s final argument against a verdict of obviousness is that the claimed invention solved the so-called “short fill” problem, a problem for which Abbott argued there was a long-felt but unsolved need, but one which Nankai does not solve. However, the Federal Circuit stated that Abbott’s objective evidence of non-obviousness fails because it is not “commensurate in scope with the claims which the evidence is offered to support.”

IV. Conclusion

Therefore, the Federal Circuit concluded that the asserted claims would have been obvious in view of Nankai as a matter of law. Because the jury could not have returned a different verdict, the district court’s erroneous instruction on the law of anticipation could not have changed the result.