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Proper Anticipation Rejections: Reminders from Recent Case Law

Virtual Instructor Led Training (VILT)

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Training Approach

- Several recent cases from the Court of Appeals for the Federal Circuit will be used to review important points about anticipation rejections.
- The cases do not announce any new legal tests for anticipation, so the concepts discussed will be familiar to examiners.
- The cases have been chosen because they address issues regarding anticipation rejections that have been identified in recent quality reviews.

Training Objectives

This training is intended to reinforce the ideas that:

- anticipation requires an express or inherent disclosure of every claim limitation,
- in order to anticipate, a reference must provide every element of the claimed invention arranged as in the claimed invention,
- anticipation requires a sufficiently precise and detailed description of the invention in a single reference,
- a reference must make an unambiguous disclosure of the claimed subject matter in order to anticipate, and
- it is improper to read unclaimed elements into a claim when conducting an anticipation analysis.

Eli Lilly v. LA Biomed:

History of the Case

- U.S. patent 8,133,903, entitled “Methods of Use of Inhibitors of Phosphodiesterases and Modulators of Nitric Oxide, Reactive Oxygen Species, and Metalloproteinases in the Treatment of Peyronie’s Disease, Arteriosclerosis and Other Fibrotic Diseases,” issued on March 13, 2012 and was assigned to Los Angeles Biomedical Research Institute (LA Biomed).
- Lilly challenged the validity of the ‘903 patent on the grounds of anticipation by the Whitaker reference in an inter partes review (IPR) proceeding at the Patent Trial and Appeal Board (PTAB).
- **The PTAB held that the claims were not anticipated by Whitaker.**
- Lilly appealed the PTAB’s decision to the Court of Appeals for the Federal Circuit (Federal Circuit or court).
- **The Federal Circuit affirmed the PTAB’s decision.** *Eli Lilly & Co. v. Los Angeles Biomed. Res. Inst.*, 849 F.3d 1073 (Fed. Cir. 2017).

Eli Lilly v. LA Biomed: Simplified Claim 1

1. A method comprising:

a) administering a [drug] according to a continuous long-term regimen to an individual with at least one [fibrotic disorder]; and

b) arresting or regressing the at least one [fibrotic disorder],

wherein the [drug] is administered at a dosage up to 1.5 mg/kg/day **for not less than 45 days.**

PTAB's Finding of No Anticipation by Whitaker Reference

1. A method comprising:
a) administering a [drug] according to a continuous long-term regimen to an individual with at least one [fibrotic disorder]; and
b) arresting or regressing the at least one [fibrotic disorder], wherein the [drug] is administered at a dosage up to 1.5 mg/kg/day **for not less than 45 days.**

- PTAB agreed with Lilly that Whitaker taught administering a drug of claim 1, at a dosage within the scope of the claim, in order to treat a disorder within the scope of the claim.
- Lilly argued that Whitaker's teaching of "chronic" or "daily" dosing, and an example of patients taking the drug "greater than 70% of the time" over a course of 8 or 12 weeks, inherently met the limitation of "for not less than 45 days."
- PTAB determined that "for not less than 45 days" was not inherently met, especially because Whitaker had taught that administration for as little as three days could be effective.

Lilly, 849 F.3d at 1074.

***Eli Lilly v. LA Biomed*: Court Affirms PTAB's Finding of No Anticipation by Whitaker**

- The court stressed that anticipation requires **an express or inherent disclosure of every claim limitation**.
- The court acknowledged that Whitaker may have *suggested* long-term daily treatment, but stated that a suggestion “is not enough” to establish inherent anticipation.
- PTAB’s holding of no anticipation was affirmed because Whitaker did not “disclose the claimed treatment regimen with sufficient clarity to satisfy the **demanding standard for anticipation**.”

Lilly, 849 F.3d at 1074-76 (internal citations omitted).

Wasica v. Continental Auto:

History of the Case

- U.S. patent 5,602,524, entitled “Device for Monitoring the Air-Pressure in Pneumatic Tires Fitted on Vehicle Wheels,” issued on February 11, 1997. Wasica became the patent owner.
- In separate IPR proceedings before the PTAB, both Continental and Schrader challenged the validity of the '524 patent on several grounds, including that claim 6 was anticipated by the Oselin reference.
- In both proceedings, **the PTAB held that claim 6 was not anticipated by Oselin.**
- The two IPR proceedings were consolidated on appeal to the Federal Circuit.
- **The Federal Circuit affirmed the PTAB’s decision** that claim 6 was not anticipated by the Oselin reference. *Wasica Finance GmbH v. Continental Automotive Sys., Inc.*, 853 F.3d 1272 (Fed. Cir. 2017).

Wasica v. Continental Auto: **Simplified Dependent Claim 6**

6. A monitoring device [for monitoring the air pressure in the air chamber of pneumatic tires fitted on vehicle wheels] . . . wherein transmission of the signals from the transmitter to the receiver is carried out with electromagnetic waves of **constant frequency** acting as carrier waves.

Wasica v. Continental Auto: PTAB's Finding of No Anticipation by Oselin Reference

6. A monitoring device . . . wherein transmission of the signals from the transmitter to the receiver is carried out with electromagnetic waves of **constant frequency** acting as carrier waves.

- The Oselin reference concerned vehicular systems for monitoring tire pressure. PTAB agreed with the challengers that Oselin taught all limitations other than “electromagnetic waves of **constant frequency** acting as carrier waves.”
- The challengers pointed to Oselin’s teaching that the transmission of signals could use “any modulating scheme,” and argued that the “constant frequency” limitation was met because a well-known scheme existed (phase key shifting) that utilized constant frequency electromagnetic waves as carrier waves.
- PTAB was not convinced that such a general teaching by Oselin could be the basis for a finding of anticipation, because Oselin had not taught any specific constant frequency transmission method.

IPR 2014-00295; *Wasica*, 853 F.3d at 1285.

Wasica v. Continental Auto: Court Affirms PTAB's Finding of No Anticipation by Oselin

6. A monitoring device . . . wherein transmission of the signals from the transmitter to the receiver is carried out with electromagnetic waves of **constant frequency** acting as carrier waves.

Schrader's argument: The "constant frequency" limitation is met because Oselin teaches transmitting signals at "a" frequency.

- The court reiterated that anticipation requires a **sufficiently precise and detailed description** of the invention in a single reference, and that **an ambiguous disclosure does not anticipate**.
- Although Oselin's transmitters were tuned to a "common" working frequency, that did not necessarily suggest that the frequency of each transmitted signal was constant because the "common" working frequency could mean an average frequency.
- Because Oselin was ambiguous as to the meaning of "a" frequency, it did not anticipate.

Wasica, 853 F.3d at 1284 (internal citations omitted).

Wasica v. Continental Auto: Court Affirms PTAB's Finding of No Anticipation by Oselin

6. A monitoring device . . . wherein transmission of the signals from the transmitter to the receiver is carried out with electromagnetic waves of **constant frequency** acting as carrier waves.

Continental's argument: Oselin anticipates because it teaches that "any modulation scheme" may be used, and that includes constant-frequency carrier waves.

- The court reiterated that a prior art genus may anticipate a claimed species only when the genus is so small that one of ordinary skill in the art would "**at once envisage** each member."
- Before the court, Continental had failed to establish the size of the "any modulating scheme" genus, and had not named any of its species.
- Because Continental had not shown that PHOSITA would have at once envisaged each member of the "any modulation scheme" genus, the court affirmed PTAB's decision that claim 6 was not anticipated.

Wasica, 853 F.3d at 1285-86 (internal citations omitted).

Respironics v. Zoll:

History of the Case

- U.S. patent 6,681,003, entitled “Data Collection and System Management for Patient-Worn Medical Devices,” issued on January 20, 2004. Zoll became the patent owner.
- In an IPR proceeding before the PTAB, Respironics challenged the validity of the '003 patent on the ground that the claims were anticipated by the Owen reference.
- As to claim 2, **PTAB found** that Owen did not disclose every limitation as construed, and so concluded **that claim 2 was not anticipated** by Owen.
- The **Federal Circuit disagreed with PTAB** as to how PTAB applied its claim construction to claim 2, and remanded the case for further consideration. *Respironics, Inc. v. Zoll Med. Corp.*, 656 F. App'x 531 (Fed. Cir. 2016). The parties settled the case. IPR2013-00322, Order Terminating Proceedings, December 29, 2016.

Respironics v. Zoll:

Simplified Independent Claim 2

2. A method of monitoring patient medical information . . . comprising the steps of:

. . .

transmitting the patient medical information, device performance data and **patient compliance data** to a health care provider

Respironics v. Zoll: PTAB's Finding of Anticipation of Claim 2 by Owen Reference

2. A method of monitoring patient medical information . . . comprising the steps of: . . . transmitting the patient medical information, device performance data and **patient compliance data** to a health care provider . . .

- Using the broadest reasonable interpretation (BRI) standard, PTAB construed the term “patient compliance data” to mean “data indicating whether a patient has followed instructions for use.”
- PTAB concluded that the “patient compliance data” limitation required **storage of information about the instructions** that had been given to the patient.
- PTAB found that Owen did not disclose storage of this type of data. Thus the PTAB concluded that claim 2 was not anticipated by Owen.

Respironics, 656 F. App'x at 535.

Respironics v. Zoll: Court Disagrees with PTAB's Finding of Anticipation and Remand

2. A method of monitoring patient medical information . . . comprising the steps of: . . . transmitting the patient medical information, device performance data and **patient compliance data** to a health care provider . . .

- The court agreed with the argument by Respironics that PTAB had improperly concluded that the “patient compliance data” limitation of claim 2 required **storage of information about the instructions** that had been given to the patient.
- The court stated that the PTAB had impermissibly added a limitation that was not present in claim 2.
- Furthermore, the court pointed out that **even if an unclaimed element is necessary for operability of the claimed invention, that element may not be imported into the claim** if it is not otherwise present.

Respironics, 656 F. App'x at 535-36, citing *SiRF Tech., Inc. v. Int'l Trade Comm'n.*, 601 F.3d 1319, 1330 (Fed. Cir. 2010).

Microsoft v. Biscotti:

History of the Case

- U.S. patent 8,144,182, entitled “Real Time Video Communications System,” issued on March 27, 2012 and was assigned to Biscotti.
- In an IPR proceeding before the PTAB, Microsoft challenged the validity of the '182 patent on several grounds, including that claim 6 was anticipated by the Kenoyer reference.
- As to claim 6, PTAB found that Kenoyer did not disclose every limitation, and so concluded that claim 6 was not anticipated by Kenoyer.
- The Federal Circuit affirmed the PTAB’s decision that claim 6 was not anticipated by Kenoyer. *Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052 (Fed. Cir. 2017).

Microsoft v. Biscotti: Simplified Independent Claim 6

6. A video communication system, comprising:

a first video communication device, comprising . . .
a **storage medium** . . ., the storage medium
having encoded thereon a set of instructions . . .

Microsoft v. Biscotti:

Arguments at the PTAB

6. A video communication system, comprising: a first video communication device, comprising . . .
a storage medium
. . ., the storage medium **having encoded thereon a set of instructions** . . .

- Although the parties and the PTAB agreed that Kenoyer taught the “storage medium,” there was disagreement as to the encoded “set of instructions.”
- In arguing anticipation, Microsoft relied heavily on this sentence in Kenoyer: “Embodiments of a subset or all (and portions or all) **of the above** may be implemented by program instructions stored in a memory medium or carrier medium and executed by a processor” (emphasis added).
- Biscotti countered that the sentence only applies to the immediately preceding figure (Figure 22), and could not reasonably be interpreted as applying to every prior disclosure in the document because some components “could not have been implemented in a storage medium.”

Microsoft, 878 F.3d at 1062-63.

***Microsoft v. Biscotti*: PTAB's Finding of No Anticipation of Claim 6 by Kenoyer Reference**

6. A video communication system, comprising: a first video communication device, comprising . . .
a storage medium
. . ., the storage medium **having encoded thereon a set of instructions** . . .

- PTAB characterized Microsoft's argument as "referring to and tying together a number of disclosures in various portions throughout Kenoyer regarding functions that may be performed in various embodiments."
- According to PTAB, "Kenoyer's program-instructions sentence does not make sense as a disclosure blanketing all of the preceding 34 pages."
- PTAB concluded that claim 6 was not anticipated because the general teaching of Kenoyer that instructions could be encoded on a storage medium did not refer specifically to any of the previously disclosed embodiments. Kenoyer did not teach an embodiment that anticipated claim 6.

Microsoft, 878 F.3d at 1063.

Microsoft v. Biscotti: Court Affirms PTAB's Finding of No Anticipation of Claim 6

6. A video communication system, comprising: a first video communication device, comprising . . . **a storage medium** . . ., the storage medium **having encoded thereon a set of instructions** . . .

- The court agreed with the PTAB that
 - “a prior art **reference must provide every element** of the claimed invention **arranged as in the claim** in order to anticipate,” and that
 - “anticipation is not proven by ‘multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention.’ ”
- Because the PTAB correctly applied these standards, and because the PTAB’s finding was supported by substantial evidence, the court agreed that claim 6 was not anticipated by Kenoyer.

Microsoft, 878 F.3d at 1069, 1072-73 (internal citations omitted).

Lessons from the Cases

Anticipation requires an express or inherent disclosure of every claim limitation.

- Ensure that every limitation is met by an embodiment taught by the reference, without the need for picking and choosing.
- Inherency may be the basis for anticipation, but remember that the inherent feature must necessarily be present. It is not sufficient that the element may possibly be present.
- A suggestion of an element by a reference may be sufficient for an obviousness rejection, but is not enough to support an anticipation rejection.

Lessons from the Cases

Anticipation requires a sufficiently precise and detailed description of the invention in a single reference; therefore, a reference that is ambiguous as to the description of the invention does not anticipate.

- If a reference may be interpreted in more than one way, it may not be sufficiently precise to anticipate.
- Consider making an obviousness rejection instead, or perhaps both an anticipation rejection and an obviousness rejection. Remember that even when the shorthand 102/103 form paragraph is used, an explanation of both the anticipation rejection and the obviousness rejection must be provided.

Lessons from the Cases

It is improper to read unclaimed elements into a claim when conducting an anticipation analysis.

- During prosecution claims must always be given their broadest reasonable interpretation consistent with the specification.
- However, apart from the special case of 35 U.S.C. 112(f), features that are not specifically included in the claims may not be read into them.
- The prohibition against reading unclaimed features into the claim applies even when the claimed invention would not function in the absence of the missing limitation.

Lessons from the Cases

In order to anticipate, a reference must provide every element of the claimed invention arranged as in the claimed invention.

- Anticipation requires a sufficiently precise disclosure of subject matter within the scope of the claim being examined.
- If it is necessary to combine different parts of a reference in order to arrive at the claimed invention, the reference does not anticipate unless the combination would be “at once envisage[d]” by a person of ordinary skill in the art. See *In re Petering*, 301 F.2d 676, 681 (CCPA 1962). The reference may, however, be usable in an obviousness rejection.

Lessons from the Cases

In order to anticipate, a reference must provide every element of the claimed invention arranged as in the claimed invention. (continued)

- MPEP 2131.02(III) provides further guidance about when PHOSITA can “at once envisage” the members of a genus:

“[W]hether a generic disclosure necessarily anticipates everything within the genus . . . depends on the factual aspects of the specific disclosure and the particular products at issue.” *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1083, 89 USPQ2d 1370, 1375 (Fed. Cir. 2008). See also *Osram Sylvania Inc. v. American Induction Tech. Inc.*, 701 F.3d 698, 706, 105 USPQ2d 1368, 1374 (Fed. Cir. 2012) (“how one of ordinary skill in the art would understand the relative size of a genus or species in a particular technology is of critical importance”).

- Remember that a reference must be interpreted in a reasonable manner. For example, it may not be appropriate to apply a general statement made in a reference to all embodiments that the references discloses.

Training Summary

This training should have reinforced the following concepts:

- anticipation requires an express or inherent disclosure of every claim limitation,
- in order to anticipate, a reference must provide every element of the claimed invention arranged as in the claimed invention,
- anticipation requires a sufficiently precise and detailed description of the invention in a single reference,
- a reference must make an unambiguous disclosure of the claimed subject matter in order to anticipate, and
- it is improper to read unclaimed elements into a claim when conducting an anticipation analysis.

Question?

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