

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte SUSAN LOVE,
JULIAN NIKOLCHEV, and
DAVID HUNG

Appeal No. 2006-2415
Application No. 09/410,336

ON BRIEF

Before ADAMS, MILLS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to methods of identifying the location of breast cancer cells within breast ducts. The examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 134. Because the cited references support a prima facie case of obviousness, which Appellants have not rebutted, we affirm.

Background

“Breast cancer proceeds through discrete premalignant and malignant cellular stages: normal ductal epithelium, atypical ductal hyperplasia, ductal carcinoma in situ and finally invasive ductal carcinoma. The first three stages are confined within the

ductal system . . . and therefore if diagnosed and treated, offer the greatest probability of cure.” Specification, page 7.

The specification discloses that “[a]ll of these stages can be characterized by unique cellular markers and epitopes, each of which can be targeted by specific molecules coupled to identifying agents to define the precise location of the lesions within the ductal system.” Id. Thus, “the invention provides a method of identifying atypical or cancerous cells lining or proximal to the ductal networks using an identifying agent, for example, monoclonal antibodies.” Id. at page 10.

The identifying agent may itself have a detectable moiety, or it may “be coupled to identifying compounds such as radio-opaque, radioactive or similarly detectable substances. . . . The identification, localization, and delineation of the extent of the intraductal lesion(s) greatly enhance the ability of physicians to localize and direct appropriate therapies to the lesion(s).” Id. at pages 10-11.

Thus, for example, the invention “provides a method of locating a lesion that can be detected by magnetic resonance imaging (MRI) or other such means that does not require the breast tissue to be opened, including also, e.g., positron emission tomography (PET). A targeting molecule labeled with and/or conjugated to an MRI-detectable molecule . . . or opaque molecule, etc. or a radioactive compound . . . can provide additional or separate guidance to a surgeon before cutting tissue, or to aid in an MRI-assisted excisional biopsy.” Id. at page 8.

Discussion

1. Claims

Claims 33-39 are pending and are on appeal. Appellants have not argued the claims separately. Therefore, the claims subject to each rejection stand or fall together. 37 CFR § 41.37(c)(1)(vii). Claims 33 and 34 are representative and read as follows:

33. A method of identifying the location of breast cancer cells within a breast duct or breast ductal network, said method comprising:
providing a compound comprising a targeting agent coupled to an identifying agent;
delivering said compound into at least one breast duct and allowing said delivered compound to specifically bind to at least one breast cancer cell within at least one duct or ductal network;
washing said breast duct or ductal network with a solution to remove non-specifically bound compound; and
detecting the presence of said identifying agent within said breast duct or ductal network;
wherein the presence of said identifying agent identifies the location of breast cancer cells within said a breast duct or breast ductal network.

34. A method as in claim 33, wherein delivering comprises non-percutaneous cannulation or catheterization of the breast duct.

Thus, claim 33 is directed to a process of locating breast cancer cells within a breast duct by delivering a compound comprising a targeting agent coupled to an identifying agent to the breast duct and allowing the compound to bind to cancer cells within the duct. The targeting agent can be an antibody. Specification, page 9. The identifying agent can be gadolinium. Id. at page 11.

The breast duct is then washed with a solution to remove non-specifically bound compound. The specifically bound identifying agent remains within the duct and provides the location of the cancer cells within the duct.

Claim 34 requires the coupled compound used for detecting the cells to be delivered by non-percutaneous cannulation or catheterization of the breast duct.

2. Obviousness of claims 33 and 36-39

The examiner has rejected claims 33 and 36-39 under 35 U.S.C. § 103 as obvious in view of Yoshimoto,¹ Schmitt-Willich,² and Canto.³ The examiner cites Yoshimoto as teaching “a method for diagnosing a primary lesion of breast cancer cells and assessing its spread within the breast by magnetic resonance galactography comprising injecting gadolinium-DTPA directly into a discharging breast duct and performing magnetic resonance imaging (MRI) of the breast.” Answer, pages 5-6.

The examiner acknowledges that “Yoshimoto et al. does not teach delivering a compound comprising an identifying agent coupled to a targeting agent.” Id. at page 6. The examiner relies on Schmitt-Willich to meet the limitation requiring delivery of the coupled compound to a breast duct.

The examiner points out that Schmitt-Willich discloses detectable gadolinium-containing polymer complexes that are more stable than gadolinium-DTPA “and provide marked contrast enhancement of peripheral tumor tissue by nuclear magnetic imaging for a prolonged period, bringing a marked diagnostic gain; see entire document (e.g., column 8, lines 19-26 and lines 44-52).” Id. at page 7. The examiner also points out that Schmitt-Willich “teaches the gadolinium-containing polymer complexes can be covalently attached to a biomolecule or a macromolecule” such as a monoclonal

¹ Yoshimoto et al., “Magnetic resonance galactography for a patient with nipple discharge,” Breast Cancer Research and Treatment, Vol. 42, pp. 87-90 (1997).

² Schmitt-Willich et al., U.S. Patent 5,681,543, issued October 28, 1997.

³ Canto et al., “Methylene blue selectively stains intestinal metaplasia in Barrett’s esophagus,” Gastrointestinal Endoscopy, Vol. 44, No. 1, pp. 1-7 (1996).

antibody specific for human breast tumors, thereby allowing visualization of the tumors.

Id.

The examiner also acknowledges that “Yoshimoto et al. does not teach washing the breast duct into which the compound is injected to remove non-specifically bound compound.” Id. at page 6. However, the examiner points out that “Canto et al. teaches an endoscopic procedure comprising an in vivo washing step before identifying the location of tumor tissue within a patient's body.” Id. at page 8. The examiner notes that Canto identifies the location of tumor tissue in a patient by “contacting the tissue and surrounding area with an identifying agent, allowing the identifying agent to bind to the cells of the tissue, washing off the excess of an identifying agent, and localizing the tumor tissue so identified.” Id.

As stated in In re Oetiker, 977 F.2d 1443, 1445-1446, 24 USPQ2d 1443, 1444-1445 (Fed. Cir. 1992):

[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.

...
[T]he conclusion of obviousness vel non is based on the preponderance of evidence and argument in the record.

We agree that a preponderance of the evidence supports the examiner's position that the cited teachings would have rendered the process recited in claim 33 prima facie obvious. Specifically, it would have been obvious to substitute Schmitt-Willich's gadolinium-polymer complex for the gadolinium-DTPA used in Yoshimoto's breast duct evaluation, because Schmitt-Willich teaches that the gadolinium-polymer complex is more stable than gadolinium-DTPA, as well as having other advantages. Schmitt-

Willich, column 8, lines 19-27 and 44-52. One of ordinary skill using Yoshimoto's ductal injection methods for locating breast tumors would also have considered it obvious to attach Schmitt-Willich's gadolinium-polymer complex to an antibody specific for breast tumors, since Schmitt-Willich teaches that gadolinium-polymer complexes attached to monoclonal antibodies specific for human breast tumors can be used "for visualization of tumors." Id. at column 13, lines 25-52.

We also agree that a person of ordinary skill, following the suggestion in Schmitt-Willich of using the antibody-polymer-gadolinium complex to visualize breast cancer tumors, would have considered it obvious to wash away unbound detecting agent before performing the detecting step. As argued by the examiner, "the presence of such non-specifically bound reagents will preclude or obscure detection of the location of the specifically-bound reagent. If the diagnostic procedure is an endoscopic procedure, which is performed in vivo, the[n] necessarily the step of washing must be performed in vivo." Answer, page 19.

Canto supports the examiner's position. Canto identifies the location of a specific undesirable esophageal cell type in patients by applying a dye which binds specifically to those cells, and then washing away the excess dye. Canto, page 2. By washing away the non-specifically bound excess dye, Canto was able to determine the location of the undesirable cells. Id. ("Positive staining was defined as blue-stained endoscopically normal esophageal mucosa that persisted despite vigorous water irrigation.") (Emphasis added.)

Thus, in our view, one skilled in the art would have recognized that removing non-specifically bound detecting agent by washing the breast duct would have made it

easier to visualize specifically bound detecting compound, such as the antibody-polymer-gadolinium complex taught by Schmitt-Willich. One of ordinary skill detecting cancer cells in a breast duct with the antibody-polymer-gadolinium complex suggested by Schmitt-Willich would therefore have considered it obvious to include a washing step.

Appellants argue that the cited references, “either alone or in combination, do not teach or suggest all the claim limitations of claims 33 and 36-39.” Appeal Brief, page 4. The examiner responds that “one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references.” Answer, page 13, citing In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981), and In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Appellants urge that the examiner’s argument “is incorrect because . . . the Examiner must satisfy all three criteria to establish a prima facie case of obviousness including the criteria that all of the limitations of the claims must be taught or suggested by the prior art.” Appeal Brief, page 4, citing In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

We do not agree with Appellants that the cited references, when viewed in combination, fail to suggest all limitations in claim 33. As argued by the examiner (Answer, pages 13-14), in assessing obviousness “[the reference] must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole.” Merck, 800 F.2d at 1097, 231 USPQ at 380.

In our view, Appellants analyze each reference in isolation, rather than in the combination presented in the appealed rejection, as Merck requires. For example, Appellants urge that because gadolinium-DTPA is a non-specific imaging agent “[o]ne of ordinary skill in the art simply cannot look to Yoshimoto et al. to learn a method of

detecting the specific location of breast cancer cells within a breast duct or ductal network.” Appeal Brief, page 5; see also Reply Brief (filed August 12, 2005), pages 1-5.

However, Appellants’ argument ignores the fact that Schmitt-Willich discloses (column 13, lines 24-52) that breast cancer tumors can be visualized by attaching monoclonal antibodies specific for breast cancers to detectable gadolinium-polymer complexes. Thus, viewing Yoshimoto and Schmitt-Willich together, one of ordinary skill would have recognized that using Yoshimoto’s methods to deliver the antibody-polymer-gadolinium complex taught by Schmitt-Willich to the breast duct network would allow the antibodies to bind to the cancer cells within the ducts, thereby allowing the practitioner to visualize the location of tumors within the ducts.

Appellants argue that Yoshimoto teaches away from the claimed method because Yoshimoto states that their method did not show the exact location of diseased tissue within the breast. Appeal Brief, paragraph bridging pages 4 and 5.

We disagree. In our view, rather than teaching away, the asserted lack of specificity in Yoshimoto’s method, combined with the ability of the detectable antibody-polymer-gadolinium complex of Schmitt-Willich to specifically pick out tumor cells within the breast duct, would have suggested that Schmitt-Willich’s complexes would have been advantageous in the diagnostic methods taught by Yoshimoto.

Appellants argue that Schmitt-Willich does not teach or suggest that the complexing agents, disclosed as being useful in magnetic resonance imaging, can be used “to identify the specific location of lesions within breast ducts.” Appeal Brief, page 6. Appellants urge that “[i]n fact, throughout the entire [Schmitt-Willich] document, there is but a single mention of breast cancer and that is in relation to the use of

antibodies specific for a number of tumors including tumors of the gastrointestinal tract, breast, liver, bladder, gonads and of melanoma.” Id.; see also Reply Brief (filed August 12, 2005), pages 4-5 (“To suggest that [Schmitt-Willich] is enabling for conjugates of gadolinium-containing polymer complexes with monoclonal antibodies specific for tumor associated antigens of the breast is fallacious.”).

We do not agree with Appellants that Schmitt-Willich fails to suggest the delivery of a targeting agent to identify the specific location of a lesion within a breast duct. While we note that only a single section of the reference discusses breast cancer, “[a]ll the disclosures in a reference must be evaluated, including nonpreferred embodiments, and a reference is not limited to the disclosure of specific working examples.” In re Mills, 470 F.2d 649, 651, 176 USPQ 196, 198 (CCPA 1972) (citations omitted).

The section of Schmitt-Willich discussing linking detectable complexing agents to targeting agents such as antibodies clearly states that “[t]he complexing ligands (as well as the complexes) . . . can . . . be attached on biomolecules or macromolecules, of which it is known that they concentrate in the organ or organ part to be examined.” Schmitt-Willich, column 13, lines 25-28.

Regarding the biomolecules to be coupled to the detectable moiety, Schmitt-Willich states that “[e]specially to be stressed are conjugates with . . . antibodies, such as, for example, monoclonal, for tumor-associated antigens.” Id. at column 13, lines 34-37. Schmitt-Willich goes on to state that “for example for visualization of tumors, monoclonal antibodies or their fragments Fab and F(ab’)₂ are suitable, which, for example, are specific for human tumors of the . . . breast.” Id. at column 13, lines 48-57 (citations omitted, emphases added).

We note that Schmitt-Willich does not provide a working example of locating a tumor within a breast duct. However, Schmitt-Willich does provide a working example of preparing an antibody-polymer-gadolinium complex. Column 61, lines 41-67. Schmitt-Willich also provides a working example where the detectable antibody complex renders a subcutaneous colon carcinoma in a mouse “clearly visible by the concentration of the contrast medium[,]” as well as distinguishing that tumor from one derived from a different cell line. Column 62, lines 1-14.

In our view, one of ordinary skill in the art viewing these teachings from Schmitt-Willich would have concluded that cancer cells within breast ducts would have been visualized by administering a breast cancer-specific antibody-polymer-gadolinium complex as taught by Schmitt-Willich, to the breast ducts in the manner disclosed by Yoshimoto.

Moreover, Appellants have not provided any evidence undermining Schmitt-Willich’s presumptively enabled disclosure. They therefore have not carried their burden of establishing that the cited disclosures are not enabling. See In re Kumar, 418 F.3d 1361, 1368, 76 USPQ2d 1048, 1052-1053 (Fed. Cir. 2005) (Appellants bear the burden of establishing that prior art is not enabled).

Appellants next argue that “the washing step described in Canto et al. can not be used to improve the specificity of the test by reducing the generation of non-specific, undesired signals because methylene blue does not stain specifically.” Appeal Brief, page 7; see also, Reply Brief (filed August 12, 2005), pages 5-6.

We do not agree with Appellants’ reading of Canto. The Canto article is entitled “Methylene blue selectively stains intestinal metaplasia in Barrett’s esophagus.” Canto,

page 1 (emphasis added). Canto's abstract states that "[t]he overall accuracy of methylene blue staining for detecting specialized columnar epithelium was 95%." Id. Canto summarizes its results by stating that "[i]n conclusion, methylene blue selectively stains SCE [(specialized columnar epithelium)] in Barrett's esophagus, including cells with dysplasia." Id. at page 6 (emphasis added).

Thus, we agree with the examiner that Canto's step of washing cells specifically stained with methylene blue would have reasonably suggested washing breast ducts so as to remove non-specifically bound detecting agent.

We agree with Appellants that Canto does not suggest that methylene blue would selectively stain breast cancer cells. Appeal Brief, page 7; Reply Brief, page 6. However, the examiner has not made that assertion. Rather, the examiner argues that "Canto et al. teaches an endoscopic procedure comprising an in vivo washing step to remove the excess of an identifying agent before identifying the location of tumor tissue within a patient's body." Answer, page 20. The examiner urges that "it would have been understood . . . that such steps improve the specificity of the test by reducing background noise, or the generation of non-specific, undesired signals." Id. at page 21.

We agree that one of ordinary skill using antibody-based detecting agents such as Schmitt-Willich's to determine the location of cancer cells within breast ducts would have recognized that washing away non-specifically bound detecting agent before performing the detecting step, in the manner taught by Canto, would have improved the diagnostic procedure. In our view, the combination of references cited by the examiner suggests all of the limitations in claim 33.

Appellants argue that “[t]here is no clear, particular suggestion or motivation in the prior art to combine the teachings in the applied references in the proposed manner to arrive at the specific method of identifying the location of breast cancer cells within a breast duct” using the steps recited in the claims. Appeal Brief, page 11; see also Reply Brief, page 7. Appellants argue that the lack of a specific motivation to combine the cited prior art results in an inappropriate “obvious to try” rejection, and that “the general teachings of administering non-specific contrast agents and dyes to patients are not sufficient to make Applicants’ invention obvious.” Appeal Brief, pages 12-13.

We do not agree that the cited references lack the specificity required to motivate one skilled in the art to practice the claimed invention. “[T]he ‘motivation-suggestion-teaching’ test asks not merely what the references disclose, but whether a person of ordinary skill in the art, possessed with the understandings and knowledge reflected in the prior art, and motivated by the general problem facing the inventor, would have been led to make the combination recited in the claims.” In re Kahn, 441 F. 3d 977, 988, 78 USPQ2d 1329, 1337 (Fed. Cir. 2006).

In our view, one skilled in the art would have recognized that, because they were capable of locating breast cancer cells, Schmitt-Willich’s breast cancer-specific antibody-polymer-gadolinium complexes would have been useful in Yoshimoto’s methods of detecting breast cancer tumors within breast ducts. In addition to conferring higher specificity through antibody binding, Schmitt-Willich provides motivation for using antibody-polymer-gadolinium complexes in Yoshimoto’s methods by disclosing (column 8, lines 19-27) that “the polymer complexes according to the invention . . . are more stable than Gd-DTPA,” i.e., the gadolinium-DTPA complex taught by Yoshimoto.

We agree with the examiner that, combined with Canto's suggestion of washing away non-specifically bound detecting agent to remove undesired background signals, Yoshimoto and Schmitt-Willich would have suggested practicing the claimed subject matter.

Appellants further argue that the examiner has failed to establish the prima facie obviousness of claim 33 because Yoshimoto, Schmitt-Willich and Canto "alone or in combination, fail to provide the necessary expectation of success." Appeal Brief, page 13. Appellants assert that Yoshimoto, Schmitt-Willich and Canto "all describe the use of non-specific contrast agents or dyes for use in human diagnostics or therapeutics. There would be no expectation that the administration of such non-specific contrast agents and dyes would successfully bind to specific cancer cells in a breast duct or ductal network." Id.

However, as discussed supra, Schmitt-Willich discloses that "for visualization of tumors" detectable polymer-gadolinium complexes can be attached to "monoclonal antibodies or their fragments Fab and F(ab')₂ . . . , which, for example, are specific for human tumors of the . . . breast." Column 13, lines 25-57. Schmitt-Willich also provides a working example where an intravenously injected antibody-polymer-gadolinium complex allowed visualization of a subcutaneous tumor in a mouse. Column 62, lines 1-14.

Based on these disclosures, we agree with the examiner that one skilled in the art would have reasonably expected that breast cancer cells would have been detected by applying the detectable breast cancer-specific antibody-polymer-gadolinium complexes taught by Schmitt-Willich to the breast duct cancer diagnostic methods of

Yoshimoto. One skilled in the art would also have reasonably expected that removing unbound detecting agent by washing in the manner described by Canto would have removed undesired background signals, thereby increasing the specificity of the assay.

Therefore, a preponderance of the evidence supports the examiner's position that Yoshimoto, Schmitt-Willich and Canto would have rendered claim 33 prima facie obvious. Claims 36-39 fall with claim 33.

3. Obviousness of claims 34 and 35

The examiner has also rejected claims 34 and 35 as obvious in view of Yoshimoto, Schmitt-Willich, and Canto as applied to claims 33 and 36-39, and in further view of Barsky.⁴ Answer, page 9. Acknowledging that Yoshimoto, Schmitt-Willich and Canto do not teach the steps recited in claims 34 and 35,⁵ the examiner asserts that Barsky "teaches delivering a desired diagnostic material through one or more orifices at the surface of the breast and into the lumens of the associated breast ducts by cannulation or catheterization without piercing or perforating the skin; see entire document (e.g., column 6, lines 54-55)." Id. at page 10.

The examiner asserts that Barsky would have rendered obvious claim 34's step of delivering the coupled diagnostic compound by non-percutaneous cannulation or catheterization of the breast duct because Barsky teaches that the claimed method is "a means by which a desired diagnostic material can be instilled through one or more

⁴ Barsky et al., U.S. Patent 6,168,779 B1, issued January 2, 2001 (application filed September 16, 1997).

⁵ In the rejection of claims 34 and 35, the examiner incorrectly refers to Schmitt-Willich as "US Patent 6,168,779 B1." Answer, page 10, first and second full paragraphs. It is clear from the context, however, that the examiner intended to refer to Schmitt-Willich. The examiner's discussion on page 10 of the Answer also refers to U.S. Patent 4,628,027. However, the examiner has pointed out that citing that patent "was inadvertent error, as the prior art reference has not been considered, or relied upon in determining the obviousness of the claimed invention." Answer, page 3.

orifices at the surface of the breast and into the lumens of the associated breast ducts.”

Id. at pages 11-12.

As motivation for delivering diagnostic agents such as Schmitt-Willich’s to breast ducts in the manner described by Barsky, the examiner cited the ability “to identify the location of lesions in one or more breast ducts or breast ductal networks by magnetic resonance imaging for the purposes of excising the lesions and surrounding tissue by conservative surgery and otherwise clinically intervening in the course of the disease as soon as possible and as deemed appropriate following the localization of any precancerous lesions.” Id.

The examiner noted that Barsky would have provided additional motivation for practicing the washing step. The examiner stated that “because [Barsky] teaches aspirated saline washings of the ductal lumen may be collected for further diagnostic use, one ordinarily skilled in the art at the time the invention was made would have been motivated to wash the lumen both to remove non-specifically bound targeting agent before image acquisition and to collect cells for additional diagnostic use.” Id.

Appellants reiterate their argument that the cited references “either alone or in combination, do not teach or suggest all the claim limitations.” Appeal Brief, page 15; Reply Brief, page 8. Appellants urge that Barsky “simply does not teach or suggest the use of a complexing agent[] to identify the location of cancerous breast cells within a breast duct or breast ducts. Also, [Barsky] does not teach or suggest a method of delivering a coupled compound to more than one breast duct or ductal network.”

However, as noted supra, a reference “must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole.” In re Merck & Co.,

800 F.2d at 1097, 231 USPQ at 380.

As pointed out by the examiner (Answer, page 11), Barsky discloses that its methods reliably identify and access all of the ductal networks (column 2, lines 39-42), and are useful for introducing contrast media in imaging methods described in other prior art (column 2, lines 8-20). As also pointed out by the examiner (Answer, page 10), Barsky discloses that once a breast duct is accessed for endoscopic examination by non-percutaneous cannulation, “[d]esired diagnostic . . . material may then be instilled into the duct.” Column 6, lines 54-55.

Thus, contrary to Appellants’ argument (Appeal Brief, page 17; Reply Brief, page 8), one need not look to references other than Barsky for a teaching of introducing diagnostic media into breast ducts. Moreover, Barsky’s disclosure of the desirability of their methods in delivering diagnostic agents to breast ducts must be viewed in combination with Yoshimoto’s disclosure of delivering detectable media to breast ducts to locate cancerous lesions, and with Schmitt-Willich’s disclosure of detectable breast cancer-specific antibody-polymer conjugates.

We agree with the examiner that, by viewing these disclosures together, one of ordinary skill would have been motivated by Yoshimoto to use Schmitt-Willich’s cancer-specific antibodies to detect cancer cells within breast ducts, and would have been further motivated by the diagnostic advantages of non-percutaneous cannulation disclosed by Barsky to have used that method in delivering the detectable diagnostic agents to more than one breast duct. The cited combination of references therefore suggests all claim limitations.

We also do not agree with Appellants' argument (Appeal Brief, pages 18-21) that the cited references fail to provide a sufficiently specific teaching, suggestion or motivation to practice the claimed invention. One of ordinary skill viewing the cited references would have recognized that the claimed combination of steps would have been desirable in a method of detecting cancer cells within the breast ductal network.

Thus, one of ordinary skill detecting cancerous lesions according to Yoshimoto would have recognized from Schmitt-Willich the advantage of a more stable detectable agent, as well as the diagnostic advantage of using an antibody specific for breast cancer tumors. The skilled artisan also would have recognized that washing away non-specifically bound detecting agent from the breast ductal network would result in less background signal, thereby increasing assay specificity, much like the washing step in Canto. Lastly, Barsky would have informed the skilled artisan of the advantages of non-percutaneous cannulation. In our view, by looking only to the prior art cited by the examiner, one of ordinary skill would have had incentive to practice the claimed process.

Appellants' additional arguments with respect to this rejection have been adequately addressed above.

Therefore, we conclude that a preponderance of the evidence supports the examiner's position that Yoshimoto, Schmitt-Willich, Canto and Barsky would have rendered claim 34 prima facie obvious. Claim 35 falls with claim 34.

Summary

We affirm the rejections of claims 33-39 under 35 U.S.C. § 103.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Donald E. Adams)	
Administrative Patent Judge)	
)	
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)	BOARD OF PATENT
Demetra J. Mills)	
Administrative Patent Judge)	APPEALS AND
)	
)	INTERFERENCES
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