UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte AVI J. ASHKENAZI, DAVID BOTSTEIN, KELLY H. DODGE, AUDREY GODDARD, AUSTIN L. GURNEY, KYUNG JIN KIM, DAVID A. LAWRENCE, ROBERT PITTI, MARGARET A. ROY, DANIEL B. TUMAS, and WILLIAM I. WOOD

Appeal No. 2005-2208
Application No. 09/894,924

HEARD October 20, 2005

Before SCHEINER, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to antibodies that bind a protein called DcR3. The examiner has rejected the claims as anticipated or obvious. We have jurisdiction under 35 U.S.C. § 134. Because we conclude that prior art under 35 U.S.C. § 102(e) need not disclose a utility in order to anticipate, we affirm.

Background

The tumor necrosis factor (TNF) family of cytokines includes TNF-α, TNF-β, and Fas ligand, among others. Specification, page 1. "Two distinct TNF receptors of approximately 55-kDa (TNFR1) and 75-kDa (TNFR2) have been identified." Page 2.

The specification discloses "nucleotide sequences encoding polypeptides referred to in the present application as DcR3. . . . Using BLAST and FastA sequence alignment computer programs, Applicants found that a full-length native sequence DcR3 (shown in Figure 1 and SEQ ID NO:1) has about 28% amino acid sequence identity with human TNFR2. Accordingly, it is presently believed that DcR3. . . likely is a newly identified member of the TNFR family and may possess activities or properties typical of the TNFR protein family." Page 11.

"It is presently believed that DcR3 may be a soluble decoy receptor that is capable of binding Fas ligand and/or inhibiting Fas ligand activity, including inhibiting apoptosis induction by Fas ligand. . . . [T]he DcR3 gene is amplified in a considerable number of primary lung and colon cancers, suggesting that certain cancers may escape immune-cytotoxic attack by expressing a decoy receptor such as DcR3 that blocks Fas ligand-induced apoptosis. . . . Antibodies to DcR3 can be used to sensitize DcR3-producing cancers to immune-cytotoxic attack and to enhance proliferation of tumor-reactive lymphocytes." Id.

Discussion

1. Claim construction

Claims 14, 67, 69-72, 74-77, and 79-85 are pending and stand rejected. The claims subject to each rejection stand or fall together. See the Appeal Brief, page 3. Claims 14, 81, and 85 are representative and read as follows:

> 14. An isolated antibody which binds to a DcR3 polypeptide, wherein said DcR3 polypeptide (a) comprises amino acids 1 to 300 of Fig. 1 (SEQ ID NO:1) or (b) comprises amino acids 1 to X, wherein X is any one of amino acids 215 to 300 of Fig. 1 (SEQ ID NO:1).

81. An isolated monoclonal antibody which binds to a DcR3 polypeptide consisting of amino acids 1 to 300 of Fig. 1 (SEQ ID NO:1) or consisting of amino acids 1 to 215 of Fig. 1 (SEQ ID NO:1).

85. The antibody of claim 80[1] wherein said antibody is linked to a detectable moiety selected from the group consisting of one or more radioisotopes, fluorescent compounds, chemiluminescent compounds, and enzymes.

Thus, claim 14 is directed to an isolated antibody that binds to DcR3 (the polypeptide having the amino acid sequence shown in SEQ ID NO:1). Claim 85 is directed to a labeled antibody that binds to DcR3.

2. Anticipation

The examiner rejected claims 14, 67, 69-72, 74-77, and 79-84 under 35 U.S.C. § 102(e), as anticipated by Emery[2] with evidence provided by Ladner.[3] The examiner reasoned that Emery discloses a polypeptide (designated TR4) that has an amino acid sequence identical to this application's SEQ ID NO:1, as well as antibodies that bind to TR4. See the Examiner's Answer, page 3 (citing Emery's SEQ ID NO:2 and columns 10-11). The examiner cited Ladner as evidence that the methods disclosed in Emery were routine in the art. See id.

Appellants do not dispute that "the polypeptide sequence of DcR3 is the same as the TR4 polypeptide sequence." Appeal Brief, page 4. Nor do Appellants appear to argue that undue experimentation would have been required to make antibodies that bind to DcR3/TR4 based on Emery's disclosure.

[1] The claims originally submitted as 80-84 were re-numbered under 37 CFR § 1.126 as claims 81-85. Thus, what was submitted as claim 80 became claim 81; claim 85 actually depends on claim 81.
[2] Emery et al., U.S. Patent 5,885,800, issued March 23, 1999 (application filed Feb. 4, 1997).
[3] Ladner et al., U.S. Patent 4,946,778, issued August 7, 1990.

Instead, Appellants argue that, Emery must comply with § 101 and the how-to-use provision of § 112, ¶ 1, in order to properly anticipate, because it qualifies as prior art under 35 U.S.C. § 102(e), not § 102(a) or (b). Appellants reason that "the proper standard is that articulated by the Court of Customs and Patent Appeals in In re Wertheim and Mishkin, 209 USPQ 554 (CCPA 1981); namely, that a U.S. patent can anticipate under 35 U.S.C. § 102(e) as of a particular date only to the extent that there is a sufficient disclosure under 35 U.S.C. § 112, first paragraph, for the subject matter at issue (i.e., the subject matter of the claims being rejected as being anticipated under §102(e) by the patent)." Appeal Brief, page 7.

Appellants argue that Emery does not disclose DcR3/TR4-binding antibodies sufficiently to meet the utility requirement of § 101 and the how-to-use provision of § 112, ¶ 1.[4] See id., pages 4-7. Therefore, Appellants conclude, Emery's disclosure should not be found to anticipate the present claims.

We do not agree with Appellants' reading of In re Wertheim, 646 F.2d 527, 209 USPQ 554 (CCPA 1981). That case involved claims rejected as anticipated by a U.S. patent ("Pfluger IV") that claimed priority as follows: "Pfluger IV was designated a continuation of Pfluger III, which was designated a continuation-in-part (CIP) of Pfluger II, which was designated a CIP of Pfluger I." Id. at 529, 209 USPQ at 557. The board affirmed a "§§102(e)/103" rejection "on the basis of teachings which the board found in Pfluger I, read as though it were a proper prior art reference, taken with further suggestions from . . . the secondary references." Id. at 531, 209 USPQ at 559. That is, the board accorded the Pfluger IV reference a § 102(e) date based on the Pfluger I

[4] We conclude, as discussed below, that § 102(e) references do not need to disclose a utility for a product in order to anticipate claims to that product. Therefore, we need not and do not reach the issue of

parent application, with respect to disclosure that had "carried over" from Pfluger I to Pfluger IV, and concluded that that disclosure, when combined with a second reference, would have made the claimed method obvious.

The Wertheim court noted the Supreme Court's approval of so-called "§§ 102(e)/103 rejections"; i.e., using prior art that qualifies under § 102(e), combined with another reference, as the basis for a § 103 rejection. See id. at 533, 209 USPQ at 560 (citing Hazeltine Research Inc. v. Brenner, 382 U.S. 252, 147 USPQ 429 (1965)). The court noted, however, that a

> different situation arises where, unlike in Milburn[5] or Hazeltine, the reference patent issues not after only one application, but after a series of applications. In other words, after permitting the use of a patent reference in both §102(e) and §§102(e)/103 rejections as of the reference filing date, the next question confronting the courts was what filing date was to be accorded a reference patent which issues after a series of applications. How far back can one extend the effective date of a reference patent as "prior art" in such a case?

Id. at 533, 209 USPQ at 561.

The court concluded that the "determinative question here is whether the invention claimed in the Pfluger patent [Pfluger IV] finds a supporting disclosure in compliance with §112, as required by §120, in the 1961 Pfluger I application so as to entitle that invention in the Pfluger patent, as 'prior art,' to the filing date of Pfluger I. Without such support, the invention, and its accompanying disclosure, cannot be regarded as prior art as of that filing date." Id. at 537, 209 USPQ at 564. The basis of this rule is "the rationale behind the Supreme Court decisions in Milburn and Hazeltine that 'but for' the delays in the Patent Office, the patent would have earlier issued and

---

whether Emery's disclosure satisfies § 101 and the how-to-use provision of § 112, ¶ 1, for the presently claimed antibodies.

[5] Alexander Milburn Co. v. Davis-Bournonville Co., 270 U.S. 390 (1926).

would have been prior art known to the public," id. at 536, 209 USPQ at 563: "if a patent could not have issued the day the application was filed, it is not entitled to be used against another as 'secret prior art,' the rationale of Milburn being inapplicable." Id. at 536, 209 USPQ at 564.

The Wertheim court held that

> [t]he dictum in Lund . . ., that
>
> > * * * the continuation-in-part application is entitled to the filing date of the parent application as to all subject matter carried over into it from the parent application * * * for purposes of * * * utilizing the patent disclosure as evidence to defeat another's right to a patent * * * (emphasis in original)
>
> is hereby modified to further include the requirement that the application, the filing date of which is needed to make a rejection, must disclose, pursuant to §§120/112, the invention claimed in the reference patent. . . . Without the presence of a patentable invention, no patent could issue 'but for the delays of' the PTO.

Id. at 539, 209 USPQ at 565-66 (citing In re Lund, 376 F.2d 982, 153 USPQ 625 (CCPA 1967)).

Thus, the Wertheim court held that a patent that is relied on under § 102(e) must disclose, sufficiently to comply with § 112, the invention claimed in that patent. In the present case, the Wertheim holding means that, if Emery meets the requirements of § 112 with respect to the polynucleotides, vectors, and host cells claimed therein, it is entitled to its filing date as prior art under § 102(e).

Appellants have presented no evidence to show that Emery's claims are not described and enabled by the Emery specification, in compliance with § 112. In fact, they purport not to raise this issue. See the Appeal Brief, page 7, n.2 ("Appellant, by this argument, does not present for consideration by the Board the question of whether

or not the subject matter actually claimed in the Emery et al., patent is supported within the meaning of § 112, first paragraph.").[6] Therefore, under the rule set out in Wertheim, Emery is available as prior art under § 102(e) as of its filing date.

Appellants also argue that a § 102(e) reference should not be held to anticipate unless it discloses a later-claimed product sufficiently to comply with all of the provisions of §§ 101 and 112, first paragraph. See the Appeal Brief, page 12: "Emery can only be entitled to a prior art effect for the currently claimed antibodies to DcR3 if it disclosed antibodies in a manner that would have permitted the grant of claims to such antibodies in that application."

Appellants acknowledge that no such requirement applies to prior art under, e.g., § 102(b) but they argue that a reference that is available only under § 102(e) should be held to a higher standard than a § 102(b) reference. See the Appeal Brief, page 11. Appellants argue that public policy considerations support this rule:

> Of particular importance to the present appeal is the decision of the Office to adjust its standards in 2000 regarding the requirements of 35 U.S.C. §101 and §112, first paragraph. . . .
>
> Critically, Emery et al. was examined and issued prior to the enactment of the aforementioned guidelines. . . . Under the Office's current examination standards, Emery et al., should not have issued as a patent, and cannot support – under §§ 101 and 112, first paragraph – the presently claimed invention. . . . Stated simply, Emery et al. should not be able to enjoy prior art effect under § 102(e) for subject matter that is unpatentable to Emery et al.

[6] At another point in the brief, Appellants assert that "[u]nder the Office's current examination standards, Emery et al., should not have issued as a patent." Id., page 13. Appellants, however, cite no evidence to support this assertion. "In patent prosecution, the examiner is entitled to reject application claims as anticipated by a prior art patent without conducting an inquiry into whether or not that patent is enabled. . . . The applicant, however, can then overcome that rejection by proving that the relevant disclosures of the prior art patent are not enabled." Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1355, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003). Emery is presumed to be enabling and Appellants have shown no evidence to the contrary. Therefore, Appellants have not adequately supported their assertion that Emery would not have issued under the Office's current examination policies.

> . . . [I]n the present case, the Office, by applying its current standards to the present claims, will refuse to grant Appellant patent claims concerning antibodies, despite the fact that Emery et al[.] was not granted such claims. Thus no party will be granted patent rights in the presently claimed subject matter.

Id., pages 12-14. Appellants conclude that "[t]he only viable resolution of this dilemma is for the Office to construe the law governing § 102(e) so as to require a patent – when it is cited as prior art under § 102(e) – to support the subject matter defined by the rejected claims in a manner that complies with the requirements of § 112, first paragraph (including, inter alia, the requirements of § 101)." Id., page 14.

We disagree. Our starting point is that "it is beyond argument that no utility need be disclosed for a reference to be anticipatory of a claim to an old compound." In re Schoenwald, 964 F.2d 1122, 1124, 22 USPQ2d 1671, 1673 (Fed. Cir. 1992). As Appellants have pointed out, Schoenwald concerned a reference that qualified as prior art under § 102(b), not § 102(e) as here.

The issue, then, is whether we should apply a different standard to § 102(e) references. Appellants argue that we should because, otherwise, a patent disclosure can be found to be insufficient to support patent claims but at the same time sufficient to block future patent claims to the same product. Thus, the argument goes, no one can patent that product and it will not be commercially developed.

That outcome, however, is not unique to references that are prior art under § 102(e): it is the inevitable result of the rule that a disclosure need not teach how to use a product in order to anticipate later claims to that product. Consider Schoenwald, for example. In that case, a publication disclosed a certain compound without disclosing a use for it; the authors of the publication apparently did not file a patent application claiming the compound. See 964 F.2d at 1122-23, 22 USPQ2d at 1672.

Schoenwald later filed a patent application claiming the same compound. The court held that "the compound claimed by Schoenwald is not new," id. at 1123, 22 USPQ2d at 1673, and therefore was unpatentable to him. Thus, the result in Schoenwald was that the original disclosure would not have supported a patent (because it did not teach a use) but defeated Schoenwald's attempt to patent the same product, so no one was able to patent the product.

Having different standards for patent-anticipating and patent-supporting disclosures will inevitably result in some products being disclosed in such a way that they become unpatentable to anyone. Whether that result is good or bad can be debated, but the case law is clear and we are bound to follow it.

We see no compelling reason to treat a disclosure that qualifies as prior art under § 102(e) differently than one that qualifies under § 102(b). Appellants argue that a § 102(e) reference should be treated differently because the public is not actually in possession of the disclosure at the time the patent is filed:

> [I]f, more than one year before an application's filing date, a publication discloses enough information . . . to enable one skilled in the art to make or use an invention, the public is deemed to be "in possession of" that invention and the invention cannot be novel under § 102(b). . . .
>
> Section 102(e), on the other hand, gives patents prior art status as of their filing date rather than the date . . . the information actually comes into the "possession" of the public. So-called "secret prior art" under § 102(e) is not actually known to the public until the date the patent issues or until the application publishes under § 122. A fundamental difference between § 102(e) and § 102(b) prior art, then, is that the public cannot be "in possession of" § 102(e) art of which it is not aware.

Appeal Brief, page 11.

It is true that a § 102(e) reference is not actually available to the public as of its filing date. However, the disclosure of a § 102(e) reference is treated as if it was

available immediately to the public. That is the rationale of Alexander Milburn Co. v. Davis-Bournonville Co., 270 U.S. 390, 400-401 (1926):

> [I]f Whitford [the later applicant] had not applied for his patent until after the issue to Clifford [the earlier applicant], the disclosure by the latter would have had the same effect as the publication of the same words in a periodical. . . . The invention is made public property as much in the one case as in the other. But if this be true, as we think that it is, it seems to us that a sound distinction cannot be taken between that case and a patent applied for before but not granted until after a second patent is sought. The delays of the patent office ought not to cut down the effect of what has been done. . . . Clifford had done all that he could do to make his description public. He had taken steps that would make it public as soon as the Patent Office did its work.

(Emphasis added.)

That is, the earlier-filed application would have issued as a patent on the day it was filed, except that examining the application required time. Since the applicant had done all he could to make the disclosure public, it was treated as if it were publicly available as of its filing date, even though it was not actually available to the public until it issued as a patent.

The rule announced in Alexander Milburn was later codified as 35 U.S.C. § 102(e). The rationale of Alexander Milburn, and therefore of § 102(e), does not support Appellants' argument that § 102(e) references should be held to a higher disclosure standard than § 102(b) references: a § 102(e) reference is simply treated as if it was available to the public as of its filing date, because the filing date of the § 102(e) reference would be an actual disclosure date, were it not for the delay caused by examining the application. Therefore, regardless of whether a reference qualifies as prior art under § 102(e) or § 102(b), the same disclosure standards should apply.

In summary, neither the cases nor the policy-based rationale relied on by Appellants justify a heightened disclosure requirement for § 102(e) references. Emery is available as prior art and we affirm the examiner's rejection under 35 U.S.C. § 102(e).

3. Obviousness

The examiner rejected claim 85 under 35 U.S.C. § 103 on the basis that labelled antibodies that bind DcR3 would have been obvious in view of Emery and Ladner. Claim 85 is directed to an antibody that binds DcR3/TR4 and that is labelled with a radioisotope, fluorescent compound, chemiluminescent compound, or enzyme.

Emery discloses antibodies that bind DcR3/TR4 and the usefulness of such antibodies in ELISA (enzyme-linked immunosorbent assay) tests. See the Examiner's Answer, page 4 (citing Emery, column 13, lines 13-39). The examiner cited Ladner for its teaching of "detectably labeled antibodies, including labeling with agents such as chemiluminescent labels (e.g., col. 31, lines 59-63)" and concluded that "[i]t would have been obvious to one of skill in the art at the time the invention was made to detectably label an antibody that bound TR4 [a.k.a. DcR3] using the teachings of [Ladner] because Emery et al. teach the usefulness of such labeled antibodies in detection assays." Examiner's Answer, page 4. Emery teaches that such assays are useful in diagnosing various disorders. See column 10, lines 13-32.

We agree with the examiner's reasoning and conclusion.

Appellants argue that "the disclosure of Emery et al. is insufficient to anticipate the presently claimed antibodies. The [Ladner] patent does not provide any further teachings to cure the deficiencies of Emery et al. . . . Because the primary reference of Emery et al. is insufficient for the reasons set forth above, the present rejection is improper and should be withdrawn." Appeal Brief, pages 14-15.

We have considered Appellants' arguments with regard to Emery's status as prior art and have found them unpersuasive. Emery is available as prior art, the combination of Emery and Ladner would have made claim 85 prima facie obvious, and Appellants have not rebutted the prima facie case. The rejection of claim 85 under 35 U.S.C. § 103 is affirmed.

Summary

Neither precedent nor policy justifies a heightened disclosure requirement for references that qualify as prior art under 35 U.S.C. § 102(e). Emery discloses the product of claim 14 and Emery and Ladner combined would have made the product of claim 85 obvious. The examiner's rejections are affirmed.

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

AFFIRMED

Toni R. Scheiner	)
Administrative Patent Judge	)
	)
	)
	) BOARD OF PATENT
Eric Grimes	)
Administrative Patent Judge	) APPEALS AND
	)
	) INTERFERENCES
	)
Lora M. Green	)
Administrative Patent Judge	)

EG/dym

Genentech Inc
1 DNA Way
South San Franisco, CA 94080-4990