United States Court of Appeals for the Federal Circuit

04-1075
(Serial No. 08/822,509)

IN RE JAMES F. CRISH and RICHARD L. ECKERT

Peter G. Carroll, Medlen & Carroll, LLP, of San Francisco, California, argued for appellants. With him on the brief was Thomas W. Brown.

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Appealed from: United States Patent and Trademark Office
Board of Patent Appeals and Interferences

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(Serial No. 08/822,509)

In re JAMES F. CRISH and RICHARD L. ECKERT

DECIDED: December 21, 2004

Before MAYER, Chief Judge, LOURIE and DYK, Circuit Judges.

LOURIE, Circuit Judge.

James F. Crish and Robert L. Eckert (collectively, "Crish") appeal from the decision of the United States Patent and Trademark Office ("PTO") Board of Patent Appeals and Interferences affirming the rejection of claims 53-55 of United States patent application 08/822,509 as unpatentable on the ground of anticipation under 35 U.S.C. § 102(b). Ex Parte Crish, Appeal No. 2002-0533 (Bd. Pat. Apps. & Interfs. July 16, 2003). We affirm.

BACKGROUND

The claimed invention relates to purified DNA molecules having promoter activity for the human involucrin gene (hINV). The outermost layers of the skin and other stratifying squamous epithelia are composed of dead cells densely packed with a fibrous protein called keratin. Involucrin is a protein that interacts with keratin and other intracellular proteins to form a cross-linked envelope within the dead cells to strengthen the plasma membrane of the cells.

As the name indicates, the involucrin gene contains the DNA sequence that codes for involucrin. Crish's application discloses that Crish has isolated and

sequenced the promoter sequence of hINV from plasmid pSP64λI-3 H6B using standard molecular biology techniques.[1] Crish determined that the hINV promoter sequence was approximately 2.5 kb (kilobases) in size. Crish's application also identified and numbered each nucleotide in the hINV promoter sequence and designated it as SEQ ID NO:1.

Claims 53-55 on appeal are all independent and read as follows:

> 53. A purified oligonucleotide comprising at least a portion of the nucleotide sequence of SEQ ID NO:1, wherein said portion consists of the nucleotide sequence from 521 to 2473 of SEQ ID NO:1, and wherein said portion of the nucleotide sequence of SEQ ID NO:1 has promoter activity.
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> 54. A purified oligonucleotide comprising at least a portion of the nucleotide sequence of SEQ ID NO:1, wherein said portion consists of the nucleotide sequence from 1141 to 2473 of SEQ ID NO:1, and wherein said portion of the nucleotide sequence of SEQ ID NO:1 has promoter activity.
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> 55. A purified oligonucleotide comprising at least a portion of the nucleotide sequence of SEQ ID NO:1, wherein said portion consists of the nucleotide sequence from 1488 to 2473 of SEQ ID NO:1, and wherein said portion of the nucleotide sequence of SEQ ID NO:1 has promoter activity.

During prosecution, the examiner rejected claims 53-55 under 35 U.S.C. § 102(b) as being anticipated by a Crish publication[2] and a Welter publication.[3] The Crish

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[1] Inasmuch as the language of molecular biology has been known for many years and described in several decisions of this court, familiarity with such subject matter is presumed and we will not go into detail except as necessary to understand this appeal.

[2] Crish et al., Tissue-Specific and Differentiation-Appropriate Expression of the Human Involucrin Gene in Transgenic Mice: An Abnormal Epidermal Phenotype, 53 Differentiation 191-200 (1993).

[3] Welter et al., Fos-related Antigen (*Fra*-1), *jun*B, and *jun*D Activate Human Involucrin Promoter Transcription by Binding to Proximal and Distal AP1 Sites to Mediate Phorbol Ester Effects on Promoter Activity, 270 J. Biol. Chem. 12614-22 (1995).

publication lists James Crish, coinventor on the '509 application, as a coauthor. The Crish publication analyzed the phenotype (physical appearance) of mice pups that had hINV (including the promoter region) microinjected into them at the embryonic stage. The microinjected hINV was isolated from the same plasmid pSP64λI-3 H6B referenced in Crish's patent application. The Crish publication also disclosed the complete structure of hINV (the promoter region of hINV used in the Crish publication, however, was not sequenced), including the approximate size (2.5 kb) of the promoter region, and referenced an earlier publication[4] disclosing how the plasmid pSP64λI-3 H6B was obtained.

The Welter publication, which also lists James Crish as a coauthor, identified five protein-binding sites on the promoter region of hINV. The publication also confirmed that protein binding on two of those sites was necessary for the cell to begin transcribing the DNA coding region. The hINV that was used for this study was from plasmid pSP64λI-3 H/Hc. Although plasmids pSP64λI-3 H6B and pSP64λI-3 H/Hc are not identical, the PTO contends that the promoter regions of hINV contained in both plasmids are identical.

In reply to the examiner's rejection, Crish argued, inter alia, that even if the Crish and Welter publications used the same plasmid as Crish's application, other workers have sequenced plasmid pSP64λI-3 H6B and have obtained promoter sequences different from SEQ ID NO:1. Crish relies primarily on a Lopez-Bayghen[5] publication that

[4] Robert L. Eckert and Howard Green, Structure and Evolution of the Human Involucrin Gene, 46 Cell 583-89 (1986) ("Eckert publication").

[5] Lopez-Baygen et al., Transcription Analysis of the 5'-Noncoding Region of the Human Involucrin Gene, 271 J. Biol. Chem. 512-20 (1996).

sequenced the hINV promoter sequence using the plasmid pSP64λI-3 H6B. In a declaration submitted to the PTO, Crish noted that Lopez-Bayghen sequenced a promoter region having 74 nucleotides different from SEQ ID NO:1 and that the Lopez-Bayghen promoter region was 17 nucleotides longer than SEQ ID NO:1. Accordingly, Crish asserted that the same starting plasmid does not necessarily possess the same DNA sequence. Crish also argued that a person of ordinary skill in the art would not have recognized SEQ ID NO:1 in view of differing promoter sequences obtained by other workers. Finally, Crish contended that claims 53-55 used the transition phrase "consists" and were, therefore, limited to only the recited numbered nucleotide sequences of SEQ ID NO:1. Because neither the Crish nor the Welter publication specifically disclosed the nucleotide sequence of SEQ ID NO:1, according to Crish, those publications could not be anticipatory.

The Board affirmed the examiner's final rejection. The Board first rejected Crish's argument that the claims were limited to only the portions of SEQ ID NO:1 specified in the claims and not the entire sequence. The Board held that the transition language "comprising" allowed the claims to cover the entire involucrin gene plus the other portions of the plasmid, as long as the gene contained the specific portions of SEQ ID NO:1 recited by the claim. The Board also agreed with the examiner's 35 U.S.C. § 102(b) rejection based on the Crish and Welter publications. Crish's application disclosed that SEQ ID NO:1 was obtained by sequencing the same plasmid disclosed in the cited prior art references. Although the plasmids used in the prior art were not sequenced, the Board found that the plasmids used in the prior art would have necessarily possessed the same DNA sequence as Crish's claimed oligonucleotides.

Although Lopez-Bayghen obtained a promoter sequence different from what Crish claims, the Board found that Crish failed to demonstrate that the plasmids used in the Crish and Welter publications had a nucleotide sequence different from that in the plasmid used in his application. Moreover, Crish did not provide any evidence demonstrating that the DNA sequence differences found in Lopez-Bayghen's promoter sequence were not the result of mere experimental error.

Crish now appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

A determination that a claim is anticipated under 35 U.S.C. § 102(b) involves two analytical steps.[6] First, the Board must interpret the claim language, where necessary. Because the PTO is entitled to give claims their broadest reasonable interpretation, our review of the Board's claim construction is limited to determining whether it was reasonable. In re Morris, 127 F.3d 1048, 1055 (Fed. Cir. 1997). Secondly, the Board must compare the construed claim to a prior art reference and make factual findings that "each and every limitation is found either expressly or inherently in [that] single prior art reference." Celeritas Techs. Ltd. v. Rockwell Int'l Corp., 150 F.3d 1354, 1360 (Fed. Cir. 1998). We review those factual findings for substantial evidence. In re Gartside, 203 F.3d 1305, 1315 (Fed. Cir. 2000) (holding that factual determinations underlying an obviousness rejection under 35 U.S.C. § 103 are reviewed for substantial evidence). Substantial evidence is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion, id. at 1312 (quoting Consol. Edison Co. v. NLRB, 305

[6] Crish does not dispute that the Crish (1993) and Welter (1995) publications qualify as prior art under 35 U.S.C. § 102(b). Both references were published more than one year prior to the '509 application's filing date of March 27, 1997.

U.S. 197, 229-30 (1938)), and "the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence," id. (quoting Consolo v. Fed. Mar. Comm'n, 383 U.S. 607, 620 (1966)). We agree with the PTO that the claimed nucleotides were anticipated by the Crish publication.

I. Claim Construction

At the outset, Crish challenges the Board's decision affirming the PTO's construction of the pending claims as expanding the scope of the claims to allow nucleotides in addition to the specified portions of SEQ ID NO:1. Crish alleges that in affirming the PTO's construction, the Board ignored the claims' second transition term, "consists." Crish argues that during prosecution, the term "consists" was added to limit the claimed oligonucleotide to a specific DNA sequence in the promoter region, as opposed to the entire SEQ ID NO:1. The parties do not otherwise dispute the construction of any terms of the pending claims.

We affirm the PTO's claim construction. During prosecution, as indicated above, the PTO gives claims their broadest reasonable meaning in light of the specification. Morris, 127 F.3d at 1053-54. Moreover, it is well-established that "'[c]omprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501 (Fed. Cir. 1997). Following these principles, the Board's construction that does not limit the pending claims to the recited portions of SEQ ID NO:1 is surely reasonable. Each pending claim contains the open-ended transition term "comprising." Moreover, the language requiring "at least a

portion" of SEQ ID NO:1 implies that the pending claims contemplate additional nucleotides. Crish's principal argument here that the claims also contain the closed-ended transition term "consists," and that that term narrows the entire claim, is unpersuasive. The reasonable interpretation of the claims containing both of the terms "comprising" and "consists" is that the term "consists" limits the "said portion" language to the subsequently recited numbered nucleotides, but the earlier term "comprising" means that the claim can include that portion plus other nucleotides.[7] Read in context, the claims thus do not preclude a DNA sequence having additional nucleotides.

II. Anticipation

Next, Crish contests the Board's decision affirming the PTO's rejection on the ground that the Crish and Welter publications anticipate the pending claims under 35 U.S.C. § 102(b). First, Crish argues that the Crish and Welter publications cannot anticipate his claims because the prior art does not provide any information regarding nucleotide sequences. According to Crish, the fact that Crish's application references a prior art plasmid is irrelevant; the pending claims cover a specified novel DNA sequence, not the starting materials. Secondly, Crish asserts that even if the Crish and Welter publications are relevant, a person of ordinary skill in the art starting with the plasmid disclosed in the Crish and Welter publications would not necessarily obtain SEQ ID NO:1. Crish explains that different DNA sequencing techniques, for example,

[7] Crish has not argued that the portions of the plasmid not consisting of the involucrin gene are not nucleotides, nor has he argued that the preamble term "purified" has any operative meaning in this appeal.

using different restriction enzymes,[8] may result in workers obtaining different DNA sequences. Specifically, Crish relies upon the Lopez-Bayghen publication where workers purportedly used the same plasmid disclosed in Crish's application, but obtained a DNA sequence different from SEQ ID NO:1. Finally, Crish argues that there is no evidence that the plasmid disclosed in the Crish publication is the same plasmid used to obtain SEQ ID NO:1. Crish raises the possibility that the plasmid referenced in Crish's application may have become contaminated or mutated, thus having a DNA sequence different from the plasmid disclosed in the Crish publication.

We reject Crish's argument that the claims are not anticipated because the Crish publication did not sequence the promoter region of hINV.[9] While the PTO's position that the discovery of new properties of a known material does not make claims reciting those properties novel is correct, and we agree with the PTO as to its conclusion, we differ with its characterization of the nucleotide sequence of the gene as a property of that gene. The sequence is the identity of the structure of the gene, not merely one of its properties. The gene may have functional, biological properties, and it may have physical properties, but its structure is its identity, not merely one of its properties.

A long line of cases confirms that one cannot establish novelty by claiming a known material by its properties. E.g., In re Spada, 911 F.2d 705, 708 (Fed. Cir. 1990)

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[8] A gene is not sequenced as a single, long DNA segment. Rather, the gene is "chopped up" by various restriction enzymes that cleave the DNA segment at specific nucleotide locations. The "chopped-up" segments are then sequenced. Based on knowledge of the restriction enzymes' cleavage sites, the sequence of the entire DNA segment of the gene can be derived.

[9] Although the Board found Crish's application to be anticipated by both the Crish and Welter publications, we need only consider the Crish publication for purposes of this appeal.

("The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from prior art, can not impart patentability to claims to the known composition."); Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 782 (Fed. Cir. 1985) (composition claim reciting a newly discovered property of an old alloy did not satisfy section 102 because the alloy itself was not new); In re Pearson, 494 F.2d 1399, 1403 (CCPA 1974) (intended use of an old composition does not render composition claim patentable); In re Benner, 174 F.2d 938, 942 (CCPA 1949) ("no provision has been made in the patent statutes for granting a patent upon an old product based solely upon discovery of a new use for such product").

As explained by this court in Titanium Metals, "[t]he patent law imposes certain fundamental conditions for patentability, paramount among them being the condition that the claims, be new." Id. at 780. The fundamental inquiry in Titanium Metals was thus whether the claimed alloy was new. The same inquiry is pertinent here. The promoter region of hINV was not new. As explained above, hINV was known and used years before.[10] Moreover, the promoter region of hINV was specifically identified by size and location in the Crish and Eckert publications. The only arguable contribution to the art that Crish's application makes is the identification of the nucleotide sequence of the promoter region of hINV. However, just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel.

Moreover, Crish's characterization that the pending claims cover a novel DNA sequence having promoter activity, whereas the references disclose only the starting

[10] Plasmid pSP64λI-3 H6B was first disclosed by the Eckert publication in 1986. See supra footnote 4.

material plasmid, is unsound. The starting material plasmid necessarily contains the gene of interest, including the promoter region, and once we have affirmed the PTO's construction of the claims as "comprising" more than the recited numbered nucleotides, the claims necessarily encompass the gene incorporated in the starting material plasmid. Accordingly, Crish's pending claims encompassing the gene plus other nucleotides are anticipated by the starting material plasmid, which consists of the gene plus other nucleotides.

Citing Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043 (Fed. Cir. 1995), Crish also argues that the Crish publication is not anticipatory because a person of ordinary skill in the art using the plasmid disclosed in the Crish publication would not necessarily obtain SEQ ID NO:1. According to Crish, Glaxo instructs that a reference is not anticipatory when the use of the same starting materials can yield two similar, yet different compositions, and the Lopez-Bayghen publication demonstrated that even using the same plasmid pSP64λI-3 H6B, a person of ordinary skill in the art would not obtain SEQ ID NO:1.

Crish misapprehends Glaxo, which is distinguishable from the facts of this appeal. Glaxo addressed whether a prior art process for manufacturing a chemical compound, ranitidine hydrochloride, could inherently anticipate claims directed to a particular polymorph of ranitidine hydrochloride, Form 2 ranitidine hydrochloride, which was at times produced in the process. Id. at 1045-46. We held that the claims were not inherently anticipated because the prior art process did not always yield Form 2. Id. at 1047-48. In two out of thirteen experiments, the prior art process was shown to yield Form 1 instead of Form 2. Id. In the instant appeal, in contrast, the prior art reference is not a method that may or may not yield a particular DNA sequence of the promoter region of hINV. The prior art reference actually discloses a material that contains the promoter region of hINV.

Furthermore, it is irrelevant whether other workers, such as Lopez-Bayghen, used the same plasmid as Crish and obtained a different sequence for the promoter region of hINV. Crish is claiming what Crish earlier disclosed, and we presume that

Crish correctly sequenced the promoter region of the hINV gene from plasmid pSP64λI-3 H6B, as he has described in his application on appeal. Crish cannot rely upon the inability of another worker to correctly sequence the promoter region of the hINV gene from plasmid pSP64λI-3 H6B when he has sequenced it accurately himself. His own work, as recited in his application, is better evidence than Lopez-Bayghen's work.

Finally, we address Crish's argument that the Board improperly assumed that the plasmid referenced in Crish's application is the same plasmid used in the Crish publication. We have previously explained that when the prior art evidence reasonably allows the PTO to conclude that a claimed feature is present in the prior art, the evidence "compels such a conclusion if the applicant produces no evidence or argument to rebut it." Spada, 911 F.2d at 708 n.3. Here, the Board reasonably concluded that the plasmids used in Crish's application and the Crish publication were the same. Several facts support the reasonableness of the Board's assumption. First, Crish is both an inventor on the subject application and an author of the prior art publication. Secondly, both the application and the publication refer to the promoter region as approximately 2.5 kb in size. Third, both the application and the publication refer to the same source for plasmid pSP64λI-3 H6B, a publication by Eckert et al. See supra note 9. These facts constitute substantial evidence supporting the Board's decision. Other than the less probative Lopez-Bayghen publication, Crish has provided no evidence that the plasmids used in Crish's application and the Crish publication were different.

We have considered Crish's remaining arguments and find them not persuasive.

CONCLUSION

The Board correctly affirmed the examiner's rejection of claims 53-55 of the '509 application on the ground of anticipation under 35 U.S.C. § 102(b). Accordingly, the Board's decision is

AFFIRMED.