United States Court of Appeals for the Federal Circuit

02-1187

(Interference No. 104,415)

RANDOLPH J. NOELLE,

Appellant,

v.

SETH LEDERMAN, LEONARD CHESS, and MICHAEL J. YELLIN,

Appellees.

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

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DECIDED: January 20, 2004

Before CLEVENGER, BRYSON, and GAJARSA, Circuit Judges.

GAJARSA, Circuit Judge.

This is an appeal from an interference proceeding involving the claims of United States Patent Application Serial No. 08/742,480 (the "'480 application") and United States Patent No. 5,474,771 (the "'771 patent"). Randolph J. Noelle ("Noelle") is the inventor named on the '480 application. Seth Lederman, Leonard Chess, and Michael J. Yellin (collectively "Lederman") are the inventors named on the '771 patent. Noelle appeals the decision of the United States Patent and Trademark Office, Board of Patent Appeals and Interferences ("Board"), finding no interference-in-fact between the '480 application and the '771 patent and rejecting claims 51, 52, 53, 56, 59, and 60 of the '480 application pursuant to 35 U.S.C. § 102(b) (2000). Noelle v. Lederman, Interference No. 104,415 (Bd. Pat. App. & Int. Oct. 19, 2001). Because the decision of the Board is supported by substantial evidence and is not contrary to law, we affirm.

BACKGROUND

A. Antibodies

This case relates to antibodies and their role in the immune response system. A vertebrate's immune system serves to identify and destroy foreign invading organisms and neutralize the toxic molecules they produce. Antibodies, which are proteins also referred to as immunoglobulins ("Ig"), serve to designate foreign particles, broadly referred to as antigens, for destruction by other components of the immune system such as lymphocytes.[1] Lymphocytes, otherwise known as white blood cells, produce antibodies and destroy antigens. T-cells and B-cells are the two types of lymphocytes needed for antibody production. One specific type of T-cell is the helper T-cell. Helper T-cells recognize antigens and then induce B-cells to produce antibodies through a series of events. First the helper T-cell is activated after it recognizes an antigen. Once activated, the helper T-cell activates the B-cell by a combination of binding with the B-cell and secreting signaling molecules. Once the B-cell is activated, it differentiates,[2] proliferates, and produces antibodies specific to a particular antigen. The antibodies then circulate in the bloodstream and permeate other bodily fluids, where they bind to the antigen, thereby flagging it for destruction.

The present interference involves competing claims to an antibody ("CD40CR antibody") that represses the cell-to-cell signaling interaction between helper T-cells and B-cells. CD40CR antigen[3] is found on activated, but not resting, helper T-cells. CD40CR antigen acts as a "key" to unlock a protein ("CD40") located on the surface of resting B-cells. Once CD40CR antigen and CD40 bind, the B-cell begins down the pathway to differentiation, proliferation, and antibody production. The CD40CR antibody binds to the CD40CR antigen located on the T-cell surface, thereby inhibiting its ability to bind to the CD40 receptor located on the resting B-cell. B-cells cannot then become activated, thereby preventing the B-cell from producing antibodies. CD40CR antibodies are useful for treating a hyperactive immune system that causes allergic reactions and autoimmune diseases.

B. The Interference

Noelle's '480 application was filed November 1, 1996. The '480 application is a continuation of application Serial No. 08/338,975 ("the '975 application"), filed November 14, 1994, which is in turn a continuation of application Serial No. 07/835,799 ("the '799 application"), filed on February 14, 1992. The claims of Noelle's '480 application are directed to the genus, murine ("mouse"), chimeric

("hybrid"), humanized, and human forms of the CD40CR monoclonal antibody. Noelle also claims the hybridomal[4] cell lines that produce the CD40CR antibody.

Lederman's '771 issued patent has an effective filing date of November 15, 1991. Lederman's '771 patent describes and claims the human form of CD40CR monoclonal antibody (the "5c8 antibody"). The 5c8 antibody binds to "the 5c8 antigen located on the surface of activated T cells and thereby inhibits T cell activation of B cells." Also, Lederman claims a hybridomal cell line created to produce monoclonal antibody 5c8.

On September 3, 1999, an interference was declared by the United States Patent and Trademark Office ("USPTO") between the issued claims of Lederman's '771 patent and Noelle's '480 application. Noelle was designated the junior party and Lederman was designated the senior party based on their effective filing dates. The USPTO established only one count in the interference. The count reads as follows:

> The monoclonal antibody of claim 1 of 5,474,771 or the monoclonal antibody of claim 42 or claim 51 of 08/742,480.

Claim 1 of Lederman's '771 patent reads as follows:

> A monoclonal antibody, which specifically binds and forms a complex with the 5c8 antigen located on the surface of activated T cells and thereby inhibits T cell activation of B cells, the 5c8 antigen being an antigen to which monoclonal antibody 5c8 (ATCC Accession No. HB 10916) specifically binds.

Claim 42 of Noelle's '480 application reads as follows:

> A monoclonal antibody or fragment thereof which specifically binds to an antigen expressed on activated T cells, wherein said antigen is specifically bound by the monoclonal antibody secreted by hybridoma MR1 which hybridoma has been deposited and accorded ATCC Accession No. HB 11048.

Claim 51 of Noelle's '480 application reads as follows:

> A monoclonal antibody or fragment thereof which specifically binds CD40CR.

Claim 52 of Noelle's '480 application reads as follows:

> The monoclonal antibody or fragment of Claim 51, wherein said CD40CR is expressed by activated human T cells.

For sake of the simplicity, Claim 1 of Lederman's '771 patent and Claim 52 of Noelle's '480 application will be referred to as claims to the "human" form of CD40CR antibody. Claims 42 and 51 of Noelle's '480 application will be referred to as claims to the "mouse" and "genus" forms of CD40CR antibody, respectively.

On June 28, 2001 the Board held a hearing to dispose of the parties' preliminary motions. Lederman moved to have Noelle's claims rejected and sought to redefine the count. Likewise, Noelle also sought to have the count redefined. The Board denied Lederman's motions for judgment against Noelle's mouse claims for lack of written description, lack of enablement, and indefiniteness. See 35 U.S.C. § 112 (2000). The Board found that Lederman had failed to demonstrate that the mouse claims in Noelle's '480 application failed to comply with 35 U.S.C. § 112, paragraphs (1) and (2), as of November 1, 1996, the date Noelle filed his '480 application. The Board, however, determined that the human and genus claims in Noelle's '480 application failed to comply with the written description requirement pursuant to 35 U.S.C. § 112, paragraph (1), as of February 14, 1992, the date Noelle filed the previous '799 application. The Board made a detailed analysis of this court's precedent pertaining to the doctrine of written description, focusing on the holding from Regents of the University of California v. Eli Lilly & Co. that an "adequate written description of a DNA sequence claim requires a precise definition, such as structure, formula, chemical name, or physical properties." 119 F.3d 1559, 1566 (Fed. Cir. 1997). The Board analogized the DNA claims from Regents to the antibodies in Noelle's application. Accordingly, the Board held that Noelle's claims regarding the genus and human claims from the '480 application lacked written description support in the specification of Noelle's earlier '799 application because Noelle failed to describe any structural features of the human or genus antibodies or antigens. In other words, the Board found that the claims covering the genus and human antibodies constituted new matter because they lacked adequate written description in Noelle's earlier '799 application. The Board did not reject the claims, but rather denied them the benefit of the earlier filing date of Noelle '799.

Next, the Board addressed the implication of finding a lack of written description for the genus and human claims in Noelle's '480 application. The Board determined that the claims to the human and

genus forms of CD40CR antibody in Noelle's '480 application were anticipated by either Lederman '771, which claims priority to U.S. Application 07/792,728, filed November 15, 1991, or Armitage 5,961,974 (the "'974 patent"), which claims priority to U.S. applications 07/783,707 and 07/805,723 filed October 25, 1991, and December 5, 1991, respectively. Noelle had not attempted to distinguish his human and genus claims from the prior art and had conceded that Lederman '771 and Armitage '974 would anticipate those claims if the '480 application were not afforded the earlier filing date of Noelle's '799 application. Thus, the Board found the genus and human claims of Noelle's '480 application to be anticipated under 35 U.S.C. § 102(b) by the two forms of prior art and, as a result, rejected the claims to the human and genus forms of CD40CR antibodies and their respective cell lines pursuant to 37 C.F.R. § 1.641.

On October 19, 2001, the Board ruled on the motions remaining from the previous hearing. The Board had determined in its previous hearing that the deferred motions were essentially requests to decide whether an interference-in-fact existed between the two parties' claims. Lederman then withdrew his pending motions and filed a new motion requesting that the Board find no interference-in-fact.

The Board concluded from the evidence submitted that there was no interference-in-fact. The Board reasoned that a person of ordinary skill in the art lacked a reasonable expectation of success of obtaining the other party's claimed invention given the state of the art at the time. The Board noted three different methods disclosed in Noelle's '480 specification by which a person of ordinary skill in the art could have isolated the human form of the CD40CR antibody given the mouse version of the CD40CR antibody. Dr. Edward A. Clark, Noelle's expert, declared that a person skilled in the art would have had a reasonable expectation of success in isolating human CD40CR antibody by utilizing the methods disclosed in Noelle's specification.

First, Clark testified that human CD40CR antibody could be isolated by immunizing a host with human CD40CR antigen expressing cells or cell lines and selecting the antibody to the CD40CR antigen by functional or competition binding with CD40-Ig.[5] Next, Clark suggested methods of making and

isolating antibodies using affinity purified human CD40CR antigen. Last, Dr. Clark declared that one skilled in the art could use the mouse CD40CR antibody or CD40-Ig to clone CD40CR antigen DNA using a method known as expression cloning.

The Board found that one skilled in the art would not have had a reasonable expectation of success of isolating human CD40CR antibodies given the mouse form of CD40CR antigen. At the outset, the Board reasoned that any reference to Noelle's own specification as prior art was improper because the specifications underlying the respective claims cannot be considered "prior art" and an interference-in-fact analysis requires the comparison between the parties' claims, not their specifications. In re Vaeck, 947 F.2d 488, 493 (Fed. Cir. 1991). Nevertheless, the Board refuted the three methods disclosed in Noelle's specification and endorsed by Clark. First, the Board found that the immunization technique found in the prior art would be ineffective because, at the relevant time, one skilled in the art would not have had a reasonable expectation of success of identifying the activated T-cells that produced the required CD40CR antigen or of isolating the antigen itself. Second, the Board found that it would have been "extremely difficult" for a person of ordinary skill in the art to isolate successfully CD40-Ig, which, as Noelle asserted, could then be used to obtain the claimed CD40CR antibodies. Third, the Board cited statements made during the prosecution of Armitage application 07/969,703 for the proposition that a skilled artisan could not have used expression cloning to isolate CD40CR antibody with a reasonable likelihood of success.

Thus, the Board determined that a person of ordinary skill in the art would not have been reasonably likely to isolate human CD40CR antibody given Noelle's claimed invention of mouse CD40CR antibody. As a result, the Board found no interference-in-fact between Noelle's remaining murine CD40CR antibody claim and Lederman's claim to the human form of CD40CR antibody. Noelle timely appealed to this court and we have jurisdiction under 28 U.S.C. § 1295(a)(4)(A) (2000).

DISCUSSION

Whether a specification complies with the written description requirement of 35 U.S.C. § 112, paragraph (1), is a question of fact, Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1562 (Fed. Cir. 1991),

and is, in appeals from the Board, reviewed under the substantial evidence standard. In re Gartside, 203 F.3d 1305, 1315 (Fed. Cir. 2000). To apply a substantial evidence standard, this court must "examin[e] the record as a whole, taking into account evidence that both justifies and detracts from an agency's decision." Id. at 1312. A reviewing court must ask "whether a reasonable fact finder could have arrived at the agency's decision." Id. "[T]he possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence." Id.

A. Entitlement to Priority

The written description requirement has been defined many times by this court, but perhaps most clearly in Vas-Cath. The court held as follows:

> 35 U.S.C. § 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed.

Vas-Cath, 935 F.2d at 1563-64 (emphasis in original). Thus, the test to determine if an application is to receive the benefit of an earlier filed application is whether a person of ordinary skill in the art would recognize that the applicant possessed what is claimed in the later filed application as of the filing date of the earlier filed application. An earlier application that describes later-claimed genetic material only by a statement of function or result may be insufficient to meet the written description requirement. See Regents, 119 F.3d at 1566. This court has held that a description of DNA "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. (quoting Fiers v. Revel, 984 F.2d 1164, 1170 (Fed. Cir. 1993)). Therefore, this court has held that statements in the specification describing the functional characteristics of a DNA molecule or methods of its isolation do not adequately describe a particular claimed DNA sequence. Instead "an adequate written description of DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1566-67 (quoting Fiers, 984 F.2d at 1171). It should be noted, however, that this court in Vas-Cath warned that each case involving the issue of written description, "must be decided on its own facts. Thus, the precedential value of cases in this area is extremely limited." Vas-Cath, 935 F.2d at 1562 (quoting In re Driscoll, 562 F.2d 1245, 1250 (C.C.P.A. 1977)).

Indeed, the court in Enzo Biochem v. Gen-Probe, Inc., 323 F.3d 956, 964 (Fed. Cir. 2002) ("Enzo Biochem II"), stated that "the written description requirement would be met for all of the claims [of the patent at issue] if the functional characteristic of [the claimed invention was] coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed."

Also, the court held that one might comply with the written description requirement by depositing the biological material with a public depository such as the American Type Culture Collection ("ATCC"). Id. at 970. The court proffered an example of an invention successfully described by its functional characteristics. The court stated:

> For example, the PTO would find compliance with 112, paragraph 1, for a claim to an isolated antibody capable of binding to antigen X, notwithstanding the functional definition of the antibody, in light of the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature.

Id. The court adopted the USPTO Guidelines as persuasive authority for the proposition that a claim directed to "any antibody which is capable of binding to antigen X" would have sufficient support in a written description that disclosed "fully characterized antigens." Synopsis of Application of Written Description Guidelines, at 60, available at http://www.uspto.gov/web/menu/written.pdf (last visited Jan. 16, 2003) (emphasis added).

Therefore, based on our past precedent, as long as an applicant has disclosed a "fully characterized antigen," either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen.

Noelle did not provide sufficient support for the claims to the human CD40CR antibody in his '480 application because Noelle failed to disclose the structural elements of human CD40CR antibody or antigen in his earlier '799 application. Noelle argues that because antibodies are defined by their binding affinity to antigens, not their physical structure, he sufficiently described human CD40CR antibody by stating that it binds to human CD40CR antigen. Noelle cites Enzo Biochem II for this proposition. This argument fails, however, because Noelle did not sufficiently describe the human CD40CR antigen at the time of the filing of the '799 patent application. In fact, Noelle only described the mouse antigen when he claimed the mouse, human, and genus forms of CD40CR antibodies by citing to the ATCC number of the hybridoma secreting the mouse CD40CR antibody. If Noelle had sufficiently described the human form of CD40CR antigen, he could have claimed its antibody by

simply stating its binding affinity for the "fully characterized" antigen. Noelle did not describe human CD40CR antigen. Therefore, Noelle attempted to define an unknown by its binding affinity to another unknown. As a result, Noelle's claims to human forms of CD40CR antibody found in his '480 application cannot gain the benefit of the earlier filing date of his '799 patent application.

Moreover, Noelle cannot claim the genus form of CD40CR antibody by simply describing mouse CD40CR antigen. Noelle cites Staehelin v. Secher, 24 U.S.P.Q.2d 1513, 1519 (Bd. Pat. App. & Int. Sept. 28, 1992), as support for his argument that he has rights to the genus form of CD40CR antibody. In Staehelin, Dr. Secher had developed a hybridoma that produced a monoclonal antibody targeted to an antigen unavailable in pure form. Id. The antigen was human leukocyte interferon. Id. In Secher's foreign application, he had reported the isolation of a hybridoma-secreting antibody to human leukocyte interferon. Id. In his subsequent U.S. application, Secher claimed the genus form of the antibody. Id. at 1520. The Board held, "Secher's disclosure . . . would have reasonably conveyed to a person possessing ordinary skill in the art that Secher possessed the genus later claimed by them in their U.S. application in the sense of 35 U.S.C. 112, first paragraph." Id. The Board held it is not necessary to describe the exact details for preparing every species within the genus in order to claim the genus. Id. (citing Utter v. Hiraga, 845 F.2d 993, 998 (Fed. Cir. 1988)). Thus, Noelle argues, the disclosure in his previous '799 application of the mouse form of CD40CR antibody was sufficient to support his later genus claims.

Noelle's reliance on Staehelin is misplaced. First, it is a decision from the Board of Patent Appeals and Interferences which may be persuasive but it is not binding precedent on this court. Second, the Board in Staehelin cited Utter to support the proposition that a patentee need not cite every species of an antibody in order to claim the genus of that antibody. In Utter, this court held that not every species of scroll compressor used in air conditioners must be described in order for a genus claim to meet the written description requirement. 845 F.2d at 994. Since the Board's decision in Staehelin, this court has subsequently held that a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated. See Enzo Biochem II, 323 F.3d

at 965; Regents, 119 F.3d at 1568. Therefore, to the extent the Board's decision in Staehelin conflicts with our decisions in Enzo Biochem II and Regents, it has been limited in applicability.

The Board was also correct in its determination that the human and genus claims were anticipated by Lederman '771 and Armitage '974. The Board's decision was supported by substantial evidence, and Noelle conceded that without the earlier filing date of his '799 application, his claims were indistinguishable from the prior art cited by the Board.

B. Interference-In-Fact

Interference proceedings are subjected to the requirements of 37 C.F.R. §§ 1.601 – 1.690 (2003), promulgated pursuant to 35 U.S.C. § 135(a). Eli Lilly v. Bd. of Regents of the Univ. of Wash., 334 F.3d 1264, 1267 (Fed. Cir. 2003). A patent interference is designed to "determine whether two patent applications (or a patent application and an issued patent) are drawn to the same 'patentable invention' and, if so, which of the competing parties was first to invent the duplicative subject matter." Id. (citing Conservolite, Inc. v. Widmayer, 21 F.3d 1098, 1100-01 (Fed. Cir. 1994)); see also 37 C.F.R § 1.601(j). [6] In order to determine whether the two parties claim the same patentable invention, the USPTO has promulgated a "two-way" test, which has been approved by this court. Eli Lilly, 334 F.3d at 1270. The two-way test reads as follows:

> **Invention "A" is the same patentable invention as an invention "B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A". Invention "A" is a separate patentable invention with respect to invention "B" when invention "A" is new (35 U.S.C. 102) and non-obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A".**

37 C.F.R. § 1.601(n). In order for an interference-in-fact to exist, invention A must anticipate or make obvious invention B, and invention B must anticipate or make obvious invention A, thereby meeting both prongs of the "two-way" test. Eli Lilly, 334 F.3d at 1268; accord Winter v. Fujita, 53 U.S.P.Q.2d 1234, 1243 (Bd. Pat. App. & Int. Nov. 16, 1999). The Board in the present case worded the two-way test in a different way as follows:

> Thus, for Lederman to succeed in its motion for no interference-in-fact, Lederman need only demonstrate that: (i) Lederman's claims are not anticipated or rendered obvious by

> Noelle's remaining "mouse" claims; or (ii) Noelle's remaining "mouse" claims are not anticipated or rendered obvious by Lederman's claims.

(Emphasis in original).

Noelle's argument that the Board improperly required a two-way patentability test, or, as the Board phrased it, a "one-way distinctiveness" test, is without merit in light of this court's recent ruling in Eli Lilly upholding the Director's two-way test as consistent with the language of the regulation. 334 F.3d at 1268. Therefore, the Board applied the proper "two-way test." First, it determined that "one skilled in the art lacked a reasonable expectation of success of obtaining Lederman's claimed 'human' subject matter when provided with Noelle's 'mouse' subject matter and using the screening techniques cited by Noelle." Although the Board did not have to conduct the second prong of the test to find no interference-in-fact, it did so anyway by finding that "one skilled in the art would have lacked a reasonable expectation of success of obtaining Noelle's 'mouse' subject matter when provided with Lederman's claimed 'human' subject matter and using the same screening methods." Therefore, the Board utilized the correct test to find no interference-in-fact.

Noelle's argument that the Board erred in its application of the obviousness question in the interference-in-fact analysis by ignoring the specification in Noelle's '480 application is also without merit. Both Lederman and Noelle concede that the anticipation portion of the interference-in-fact analysis is not an issue in light of the agreed variance between claims to mouse versus human forms of CD40CR antibodies. Thus, only the obviousness analysis pursuant to 35 U.S.C. § 103 is left to be determined. Obviousness is determined as follows:

> a proper analysis under § 103 requires, inter alia, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.

In re Vaeck, 947 F.2d at 493. Both the suggestion and the reasonable expectation of success "must be founded in the prior art, not in the applicant's disclosure." Id.; see also In re Dow Chem. Co., 837 F.2d 469, 473 (Fed. Cir. 1988).

The parties agree that a skilled artisan would have been motivated to obtain the human CD40CR antibody if the mouse CD40CR antibody were available. The two parties disagree, however, as to whether the prior art would provide a reasonable likelihood of success in so doing. Therefore, the issue before us is whether substantial evidence supports the Board's determination that one of ordinary skill in the art would not have had a reasonable expectation of success of isolating the other party's invention given the disclosures found in the claims. A reasonable likelihood of success does not necessarily mean an absolute predictability, but rather a reasonable expectation of success. Yamanouchi Pharm. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1343 (Fed. Cir. 2000).

Noelle argues that the methods disclosed in his '799 patent application would have provided a reasonable likelihood of success for a person of ordinary skill in the art to isolate human CD40CR antibodies using mouse CD40CR antibodies. Specifically, Noelle argues it would have been obvious to a skilled artisan to use the CD40-Ig fusion protein disclosed in the '799 application as a screen to locate, within a hybridomal library, monoclonal antibodies that specifically bind to human CD40CR antigen. Noelle further argues the Board improperly ignored this method of antibody isolation merely because it was disclosed in Noelle's written description as opposed to Noelle's claims.

The Board correctly found no interference-in-fact between Noelle's claims and Lederman's claims. First, the Board was correct in not considering Noelle's methods of isolation of human CD40CR antigen using CD40-Ig found in his '799 specification because the methods were neither part of the parties' inventions nor "prior art." USPTO rules establish that an interference-in-fact exists when both parties claim the "same patentable invention." 37 C.F.R. § 1.601(n). A patentee's invention is only found in a patentee's claims, unless the patentee uses sufficient means-plus-function language to invoke 35 U.S.C. § 112, paragraph (6). Thus, if the Board is to compare two inventions, the Board must only compare the parties' claims. Noelle does not claim a method of isolating CD40CR antigens, CD40-Ig, or the receptor CD40 itself. Obviously, if certain terms in Noelle's or Lederman's claims were ambiguous, we could resort to the specification or other sources to define those terms; however, it is unnecessary here as none of the terms in the claims are ambiguous. Therefore, Noelle cannot rely on a method of isolating human CD40CR antigen using CD40-Ig in order to prove obviousness between his

invention and Lederman's invention because the method is not claimed.

Second, the Board's determination was supported by substantial evidence because a person of ordinary skill in the art, given the state of prior art at the time of the '799 filing, would not have had a reasonable likelihood of success in isolating human CD40CR antibodies from the mouse CD40CR antigen and its antibody. Noelle argues that one skilled in the art would have had a reasonable likelihood of success in manufacturing a set of hybridomas that secrete monoclonal antibodies to activated human helper T-cell surface antigens. Noelle, as outlined previously, cited three different screening methods disclosed in his specification that would isolate the desired hybridomas and their antibodies. The first two of Noelle's proposed screening methods require the use of CD40-Ig. As the expert testimony of Dr. Aruffo, the named inventor in the patent claiming CD40-Ig, indicated to the Board, it would have been unpredictable and unreasonable to expect a skilled artisan to produce CD40-Ig given the state of the art at the time.

Finally, Noelle's expert witness, Dr. Clark, addressed the third and final proposed screening method. Dr. Clark declared that, given the mouse form of CD40CR antibody or CD40-Ig and the utilization of expression cloning methods available at the time, a person of ordinary skill in the art would have had a reasonable expectation of success in isolating the human form of CD40CR antigen. Armitage, however, during the prosecution of his '703 application, stated that the use of expression cloning could not have reasonably led to successful isolation of human CD40CR antigen.

After examining the record as a whole, we conclude there was substantial evidence to support the Board's decision. The Board's decision was reasonable in that, given the state of the art in the early 1990s as described by the expert witnesses, a person of ordinary skill in the art would not have had a reasonable likelihood of success in isolating human CD40CR antigen given mouse CD40CR antigen.

CONCLUSION

For the foregoing reasons, the decision of the Board rejecting claims 51, 52, 53, 56, 59, and 60 of Noelle's U.S. Application No. 08/742,480 is affirmed. The decision of the Board granting Lederman's preliminary motion of no interference-in-fact is also affirmed.

AFFIRMED

No costs.

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[1] For additional background on the function of antibodies, as well as methods of isolating antibodies, see In re Wands, 858 F.2d 731, 733-34 (Fed. Cir. 1988) and Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1368-69 (Fed. Cir. 1986).

[2] Cell differentiation is the process of modifying a cell's structure and function in order for it to become more specialized and specific to the invading antigen.

[3] CD40CR antigen is also referred to as "CD40 counter receptor," "CD40 ligand," "CD40L," and simply "CD40CR." Lederman uses the term "5c8 antigen" or "T-B cell-activating molecule" ("T-BAM") to designate the 30-kilodalton human form of CD40CR antigen. Noelle uses the term "gp39" (glycoprotein 39 kD) to describe the 39-kilodalton mouse form of CD40CR antigen.

[4] A hybridoma is a man-made tissue culture consisting of cancerous B-cells fused to B-cells producing the antibody of choice. A hybridoma produces unlimited amounts of a desired "monoclonal" antibody. See Hybritech, 802 F.2d at 1368-69 (explaining the method for creating and using hybridomas).

[5] CD40-Ig is a fusion protein wherein a portion of the CD40 receptor is fused to an immunoglobulin (Ig). CD40-Ig is therefore not expressed on the surface of a B-cell but rather is essentially a soluble, free-floating molecule.

[6] 37 C.F.R. §1.601 (j) reads as follows:

> An interference-in-fact exists when at least one claim of a party that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention.