Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc. et al Doc. 179 Att. 28

Exhibit 21

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United States District Court
For the Northern District of California

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,

Plaintiff,

v.

VISIBLE GENETICS, INC.,

Defendant.
_____/

and related counterclaims
_____/

No. C 01-03671 CRB

CLAIM CONSTRUCTION ORDER

This patent infringement action involves three method patents, the '268, '128, and '086, owned by plaintiff The Board Of Trustees Of The Leland Stanford Junior University ("Stanford"). The patents-in-suit claim a method for identifying when an HIV-infected patient has developed resistance to his current drug regimen and is therefore likely to suffer immunological decline. Although there were several terms in dispute in the joint claim construction statement, now, after claim construction briefing, there are essentially three disputes. In this Order the Court will address only those issues disputed by the parties in their claim construction briefs.

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LEGAL STANDARD FOR CONSTRUCTION OF A PATENT CLAIM

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Patent infringement analysis involves two steps: the proper construction of the asserted claim and a determination as to whether the accused method or product infringes the asserted claim as properly construed. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). The interpretation of patent claims is a matter of law determined exclusively by the court. See id. at 979.

"In interpreting an asserted claim, the court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). In examining the intrinsic evidence, the court should first review the words of the claims themselves to define the scope of the invention. See id. While "words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer" and alter the meaning of any words "as long as the special definition is clearly stated in the patent specification or file history." Id.

After examining the patent's claims, the court should then also review the patent specification "to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." Id. The specification is a written description of the invention which is designed to be clear and complete enough so that a person of ordinary skill in the art could make and use the invention. "The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Id. The Federal Circuit teaches that "the specification is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term." Id. Drawings included in the patent application have the same effect on the interpretation of claim language as other portions of the specifications. See Autogiro Co. of America v. United States, 384 F.2d 391, 398 (Ct. Cl. 1967).

The third type of intrinsic evidence that the Court may consider is the prosecution history of the patent, if it is in evidence. See Vitronics, 90 F.3d at 1582. The prosecution history contains the entire record of the prosecution of the patent claim before the patent office, including any representations about the scope of the claim or the meaning of certain terms made by the applicant.

Ordinarily, the intrinsic evidence alone will resolve any ambiguity in a disputed term. "In those cases where the public record unambiguously describes the scope of the patented invention, reliance on any

extrinsic evidence is improper." Id. at 1583. By relying first on the patent claims, specification, and prosecution history, a court can protect a patentee's rights while at the same time enabling the public to rely on the public record of the patentee's claim. "In other words, competitors are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention and, thus, design around the claimed invention." Id. (citing Markman, 52 F.3d at 978-79).

Extrinsic evidence, which is evidence external to the patent and prosecution history such as expert and inventor testimony, dictionary definitions, and learned treatises, may be admitted in the court's discretion "for background and education on the technology implicated by the presented claim and construction issues." Key Pharm. v. Hercon Labs. Corp., 161 F.3d 709 (Fed. Cir. 1998).

THE DISPUTED CLAIMS

The claimed method is to use genotyping to determine if the patient has developed certain mutations in the HIV genetic code in order to predict future immunoloigc decline. The '268 claims, in relevant part:

> 1. A method of evaluating the effectiveness of **antiretroviral therapy** of an HIV-infected patient comprising:
>
> (i) collecting a plasma sample from an HIV-infected patient who is being treated with **an antiretroviral agent**; and
>
> (ii) determining whether the plasma sample comprises nucleic acid encoding HIV reverse transcriptase having a mutation at codon 215
>
> in which the presence of the mutation **correlates positively with future immunologic decline** of the patient within a six to twelve month period.

(Disputed terms emphasized).

The '128 similarly claims, again in relevant part:

> 1. A method of evaluating the effectiveness of antiretroviral therapy of an HIV-infected patient comprising:
>
> (i) collecting a plasma sample from an HIV-infected patient who is being treated with an antiretroviral agent; and
>
> (ii) determining whether the plasma sample comprises nucleic acid encoding HIV reverse transcriptase having a mutation at codon 74, or codons 215 and 74
>
> in which the presence of the mutations **correlates positively with future immunologic decline** of the patient within a six to twelve month period.

The '086 claims, in relevant part:

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1. A method of evaluating the effectiveness of **antiretroviral therapy** of an HIV-infected patient comprising:

(i) collecting a plasma sample from an HIV-infected patient; and

(ii) determining whether the plasma sample comprises nucleic acid encoding IIIV reverse transcriptase having a mutation at codons 215 or 74, or codons 215 and 74, in which the presence of the mutations **correlates positively with an accelerated immunologic decline** of said patient compared to patients who do not have the mutations.

DISCUSSION

A. Antiretroviral therapy and an antiretroviral agent

The first issue is whether "antiretroviral therapy" as used in the phrase "evaluating the effectiveness of antiretroviral therapy," is limited to monotherapy, that is, treatment with just one drug, such as AZT. A related issue is whether "an antiretroviral agent," as used in the phrase "HIV-infected patient who is being treated with an antiretroviral agent," is also limited to a patient being treated with just one drug, and in particular, with either AZT or ddI, and no other drug. Defendant Visible Genetics asks the Court to so limit the claims because today HIV-infected patients are treated with a "drug cocktail," that is, a combination of drugs. Visible Genetic's reading of the word monotherapy into the claims, however, is not supported by the intrinsic evidence.

First, the plain language of the claims is not in any way limited to monotherapy. See Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186 (Fed. Cir. 1998) ("The appropriate starting point . . . is always with the language of the asserted claim itself."). The plain meaning of "antiretroviral therapy" is therapy, that is, treatment, using something that fights, or has an effect against, retroviruses, such as HIV. See Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed. Cir. 1999) (stating that there is a "heavy presumption in favor of the ordinary meaning of claim language").

Similarly, defining the invention as comprising of "collecting a plasma sample from an HIV-infected patient who is being treated with an antiretroviral agent" means that the patient is being treated with at least one antiretroviral agent; it does not limit the claim to a patient who is being treated with only one antiretroviral agent. This reading is consistent with the general rule that "the indefinite articles 'a' or 'an,' when used in a patent claim, mean 'one or more' in claims containing open-ended transitional phrases such as 'comprising' . . . . Under this conventional rule, the claim limitation 'a,' without more, requires at least one." Crystal Semiconductor Corp. v. TriTech Microelectronics Intern., Inc., 246 F.3d 1336, 1347 (Fed.

Cir. 2001).

Second, the specification supports the plain reading of the claims as not being limited to monotherapy with AZT or ddI. The specification describes patients who are being treated with a combination of drugs. See, e.g., '268, col. 13, l. 11-21 ("27 patients were evaluated before and 1 mo after initiation of AZT, ddI, or combination therapy.") (emphasis added). Visible Genetics argues that these examples are taken from tests related to an invention which was actually never claimed in the patents; in other words, that the descriptions cited are irrelevant to the invention finally patented. That may be true, but it does not change the fact that at the time of the patent application, the inventors, those of ordinary skill in the art, and those reading the patent specification, were aware of drug combination therapy. That fact is further intrinsic evidence that "antiretroviral therapy" means what it says and not something more limited, such as monotherapy with AZT or ddI.

Notwithstanding the unambiguous language of the claims, Visible Genetics argues that the claims should be limited to monotherapy with AZT or ddI because all of the examples in the specification (other than the portions of the specification that involve the other, ultimately non-patented invention) involve patients receiving monotherapy with one or the other drug. Visible Genetic's construction, however, violates the well-established rule that "limitations from the specification are not to be read into the claims." Comark Communications, 156 F.3d at 1186. "While ... claims are to be interpreted in light of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims." Id. (citations and internal quotations omitted). The Court recognizes "that there is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification." Id. Here, however, the line is not so fine. The language of the claim is unambiguous and supported by the specification and the prior art. See Comark, 156 F.3d at 1186 ("In this case, the term 'video delay circuit' has a clear and well-defined meaning. This term is not so amorphous that one of skill in the art can only reconcile the claim language with the inventor's disclosure by recourse to the specification.").

Finally, Visible Genetics argues that given that all of the tests used at the time of the invention with respect to the relationship between mutations at codon 215 and 74 and immunologic decline were performed on patients receiving monotherapy, one "could not assume that patients being treated with two

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or more antiretroviral agents would develop the same mutations that proved resistant to drugs administered separately." Visible Genetics offers no proof, however, that no such correlation exists, that is, that identifying mutations at codon 215 and/or 74 is only helpful with patients receiving monotherapy.

Since the claims are not limited to monotherapy, it also follows that they are not limited to patients receiving monotherapy of AZT or ddI. Again, the claims are unambiguous: "antiretroviral therapy" and "antiretroviral agent." There is no suggestion of an intent to limit the claims to a particular antiretroviral agent, namely, AZT or ddI.

B. Correlates positively with future immunologic decline

The parties' next dispute centers on whether "correlates positively with future immunologic decline" means that if the mutation at codon 215 or 74 develops the patient *will* suffer immunologic decline, no matter what is done, or *would* suffer immunologic decline if other steps are not taken, such as modifying the therapy. Visible Genetics asserts that the claims are limited to those patients who, once the mutation is detected, will more likely than not suffer immunologic decline regardless of whether their therapy is modified. In other words, Visible Genetics asks the Court to construe the claims so that they do not apply to the patient whose drug therapy is successfully modified stave off immunologic decline after identification of the mutation.

Once again Visible Genetics's interpretation is at odds with the intrinsic evidence. The claims are for a method of "evaluating the effectiveness of antiretroviral therapy." The evaluation is done by detecting the presence of mutations which correlate positively with "future" or "accelerated" immunologic decline. Its plain meaning is that one evaluates how effective the current therapy is by looking for the mutation. If the mutation is present, the patient is more likely than not (the correlation) going to suffer an immunologic decline if the course of treatment is not changed. Visible Genetics argues that because the claim does not include "if the treatment/therapy is not changed," it does not include such meaning. Such meaning, however, is implied. One is evaluating the effectiveness of the current therapy by determining whether if the patient stays on this course of treatment he will suffer immunologic decline in six to 12 months. How else can one evaluate the effectiveness of the treatment if it is not the effectiveness, or more precisely, future effectiveness, of the current treatment?

Visible Genetics's interpretation is also at odds with the specification. The summary of the

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invention states in describing one of the embodiments that

> [o]nce mutation at codon 215 has been detected in a patient undergoing antiretroviral therapy, an alteration in the therapeutic regimen must be considered. . . . It is therefore extremely important to strive ***to avoid deterioration of the immune system*** in these patients. Because the present invention enables the early prediction of immunological decline, it allows alteration of a patient's therapeutic regimen so as to avoid opportunistic infections, and therefore may be used to promote survival and improve the quality of life of HIV-infected patients.

'268, col. 2 l.56 to col. 3 l.6 (emphasis added). The inventors thus described their invention as a means to "avoid" immunologic decline, not just lessen the effects of what they believed was an inevitable impairment of the immune system.

C. The presence of mutations

The final issue is whether the claims are limited to a method which identifies mutations at codon 215 and/or 74 and no other mutations. Visible Genetics concedes that the plain language of the claims suggests the claims require "at least" a mutation at 215 and 74. The claims describe a method in which one step "comprises of" "determining whether the [HIV has] a mutation at [codons 215 and 74]." This language on its face does not limit the claims to methods which only determine mutations at those codons only and no others. See Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501 (Fed. Cir. 1997) ("'Comprising' 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.").

Visible Genetics nonetheless argues that Stanford is barred by prosecution estoppel from asserting that its claims cover methods that determine mutations at codons in addition to 215 and 74. The parent patent application was denied as anticipated by Richman and obvious in view of Japour and Mullis. In their new continuing application, the inventors emphasized that the prior art did not teach that the codon 215 mutation predicts future immunologic decline of the patient, which the proposed patent teaches. Visible Genetics contends that based on this statement, Stanford is estopped from contending that its claims cover methods that detect mutations at codon 215 as well as additional mutations.

Visible Genetics's interpretation of the prosecution history goes too far. A patent applicant only limits the reach of his claims in the course of prosecution if he either alters the claim language to escape an examiner's rejection or clearly disavows claim coverage. See York Prods., Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1575 (Fed. Cir. 1996) (citing Senmed, Inc. v. Richard-Allan Med. Indus.,

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Inc., 888 F.2d 815, 820 (Fed. Cir. 1989)). The inventors did not amend claim language to escape rejection. Nor did they clearly disavow claim coverage of methods that detect more than the mutation at codon 215 as correlating to immunologic decline. Instead, they merely explained why the Richmond reference did not anticipate their proposed claims.

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CONCLUSION

For the foregoing reasons, the Court rules as follows:

1. "Antiretroviral therapy" in the context of the claims means any therapy designed to have an effect against a retrovirus, such as HIV.

2. "an antiretroviral agent" in the context of the claims means being treated with at least one agent having an effect against a retrovirus, such as HIV.

3. "in which the presence of the mutation(s) correlates positively with future immunologic decline of the patient within a six to twelve month period" in the context of the claims means it is more likely than not that within six to 12 months from detection of the mutation(s) the patient would experience a reduction in their immune system function.

4. "comprising: . . . having a mutation at codon 215 [and/or 74]" means having at least a mutation at codon 215 and/or 74 and is not limited to methods that only look for mutations at the specified locations.

IT IS SO ORDERED.

Dated: August 23, 2002

/s/
CHARLES R. BREYER
UNITED STATES DISTRICT JUDGE

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