United States District Court,
N.D. California.

GENETIC TECHNOLOGIES LTD,
Plaintiff.
v.
APPLERA CORPORATION,
Defendant.

No. C 03-1316 PJH

Sept. 15, 2004.

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Matthew D. Powers, Vernon M. Winters, Weil Gotshal & Manges, Redwood Shores, CA, Jennifer H. Wu, John Davis Garretson, Esq., Nicholas Philip Groombridge, Esq., Adrian Suehee Shin, Weil, Gotshal & Manages LLP, New York, NY, for Defendant.

CLAIM CONSTRUCTION ORDER

PHYLLIS J. HAMILTON**, District Judge.**

A claim construction hearing to construe the disputed terms of U.S. Patent Nos. 5,621,179 ("'179 patent") and 5,851,762 ("'762 patent") pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996), was held on September 1, 2004 before this court. Plaintiff appeared through its counsel Felicia Boyd and Natalie Hanlon-Leh, and defendant appeared through its counsel Nicholas Groombridge and John Garretson. Having read the parties' papers and carefully considered their arguments and the relevant legal authority, the court hereby rules as follows.

BACKGROUND

Plaintiff Genetic Technologies Ltd. ("GTG") is the assignee for the '179 and ' 762 patents, both of which cover methods of analyzing non-coding portions of DNA.

Each organism's unique genetic information is stored in its DNA. Genes are located along a DNA strand, and control that organism's traits, such as eye color or hair color. An allele is defined as the different types of traits that are possible with a certain type of gene, so if the gene controls eye color, for instance, the alleles could be blue, brown, or green. A haplotype, in comparison, is a tendency for certain alleles to be inherited together, such as blond hair and blue eyes, or red hair and green eyes.

DNA consists of two strands of proteins connected by protein base pairs in a double helix form. These strands are to be read in a certain direction, with the beginning of the DNA strand designated as the 3' end and the end of the strand designated as the 5' end. Groups of proteins in the DNA strand, or genes, can be transcribed and translated by the cell into instructions to create other proteins, which yield certain traits. DNA is stored in the nucleus of the cell, in compacted forms known as chromosomes.

Genes themselves contain various subregions. Only the region known as the exon contains actual instructions on protein coding. Other portions of the gene are copied in the beginning of the transcription process, but are ultimately deleted before translation of the gene into protein coding instructions begin. These "non-coding" portions include sections known as "introns," "untranslated regions" ("UTRs"), and "intergenic regions." UTRs are further designated as either 3' UTRs or 5', to indicate the direction of the DNA strand. Scientific discovery is ongoing with respect to the non-coding portions and it is possible that new regions will be designated and named later.

Previously, these non-coding DNA regions were considered of no scientific interest in molecular biology. However, the discovery at issue in these two patents is that the non-coding regions in fact contain information that correlates with certain genetic traits. So, for instance, the gene that causes cystic fibrosis might be correlated with a certain specific protein string in the deleted regions, so it would be possible to determine whether a person carried that gene by analyzing whether a certain protein string could be found in the non-coding regions of their DNA. FN1

FN1. None of the examples provided in this order are to be taken as scientific fact, and those examples provided by the court may even be wrong.

The patents thus cover methods of discovering whether or not a certain protein string exists in a DNA strand, either to detect an allele or group of alleles, or to locate where on a chromosome an allele or group of alleles can be found. To do so, the scientist first makes copies of the DNA strand in question, in a process known as "amplification." After the DNA strand is amplified, various different methods for analyzing the strands can be used to find certain information. The '179 patent covers a method of analysis by which strands are compared with other known strands to determine whether the strand at issue contains a certain allele. The '762 patent, in comparison, covers a method of analysis where the strands are analyzed to determine where on the chromosome the gene controlling the trait in question can be found, also through comparison between the strand in question and DNA from the general population.

DISCUSSION

A. Legal Standards

In construing claims, the court must begin with an examination of the claim language itself. "The terms used in the claims bear a 'heavy presumption' that they mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art." Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202 (Fed.Cir.2002) (citations omitted), *cert. denied,* 538 U.S. 1058, 123 S.Ct. 2230, 155 L.Ed.2d 1108 (2003). *See also* Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248 (Fed.Cir.1998) ("The claims define the scope of the right to exclude; the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim."). In determining ordinary meaning, the court is explicitly permitted to rely on reference materials such as dictionaries,

treatises, or encyclopedias in general use on the date of the patent's issuance. Texas Digital, 308 F.3d at 1202-03 (citations omitted).

The words in the claim must then be interpreted "in light of the intrinsic evidence of record, including the written description, the drawings, and the prosecution history, if in evidence." Teleflex, Inc. v. Ficosa North Am. Corp., 299 F.3d 1313, 1324-25 (Fed.Cir.2002) (citations omitted). "Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996).

A patentee is presumed to have intended the ordinary meaning of a claim term in the absence of an express intent to the contrary. York Products, Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1572 (Fed.Cir.1996). Furthermore, "unless compelled otherwise, a court will give a claim term the full range of its ordinary meaning as understood by persons skilled in the relevant art." Texas Digital, 308 F.3d at 1202 (citations omitted).

Intent to limit the scope of a claim, despite apparently-broad language, can be shown in four ways. First, if the patentee "acted as his own lexicographer," and clearly set forth a definition of the disputed term in either the specification or the prosecution history, the court will defer to that definition. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed.Cir.2002) (citations omitted). Second, the court will alter the ordinary meaning of a term "if the intrinsic evidence shows that the patentee distinguished that term from prior art on the basis of a particular embodiment, expressly disclaimed subject matter, or described a particular embodiment as important to the invention." Id. at 1367. Third, a claim term will not take its ordinary meaning "if the term chosen by the patentee so deprives the claim of clarity as to require resort to the other intrinsic evidence for a definite meaning." *Id*. Finally, a term in a step- or means-plus-function claim is limited by statute to the structure or step described in the embodiment. 35 U.S.C. s. 112 para. 6.

Limitations from the specification, such as from the preferred embodiment, cannot be read into the claims absent an express intention to do so. Teleflex, 299 F.3d at 1326 ("The claims must be read in view of the specification, but limitations from the specification are not to be read into the claims.") (citations omitted); CCS Fitness, 288 F.3d at 1366 ("a patentee need not describe in the specification every conceivable and possible future embodiment of his invention."); Altiris v. Symantec Corp., 318 F.3d 1363, 1372 (Fed.Cir.2003) ("resort to the rest of the specification to define a claim term is only appropriate in limited circumstances"). To protect against this, the court should not consult the intrinsic evidence until after reviewing the claims in light of the ordinary meaning of the words themselves. Texas Digital, 308 F.3d at 1204-05 (to act otherwise "invites a violation of our precedent counseling against importing limitations into the claims") (citations omitted).

Only if an analysis of the intrinsic evidence fails to resolve any ambiguity in the claim language may the court then rely on extrinsic evidence, such as expert declarations. Vitronics, 90 F.3d at 1583 ("In those cases where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper").

B. '179 Patent

Five terms are at issue in the '179 patent.

1. "Non-Coding Region Sequence"

GTG proposes the definition "*any untranslated DNA sequences, such as sequences between exons, the 5' and 3' untranslated regions, and sequences between genetic loci*." Applera proposes "*all non-exon sequences, including sequences between exons, the 5' and 3' untranslated regions, and sequences between genetic loci*." The parties agree that the definitions' examples of untranslated DNA sequences are accurate, but dispute whether the term "untranslated DNA sequences" or "non-exon sequences" better describes the regions at issue.

In the prosecution of the '179 patent, the applicant conceded that the term "non-coding region sequence" should be substituted for the term "intron" throughout the claims, because the applicant was using the term "intron" in a broader sense than its then-accepted definition at the time. GTG Exh. E at 58227 (Sept. 23, 1992 Preliminary Amendment). Thus, the specification states:

As used herein, the term "intron" refers to untranslated DNA sequences between exons, together with 5' and 3' untranslated regions associated with a genetic locus. In addition, the term is used to refer to the spacing sequences between genetic loci (intergenic spacing sequences) which are not associated with a coding region and are colloquially referred to as "junk." While the art traditionally uses the term "intron" to refer only to untranslated sequences between exons, this expanded definition was necessitated by the lack of any art recognized term which encompasses all non-exon sequences.

'179 patent col. 5:40-50.

GTG argues that its definition is more accurate than Applera's, because at the time the patent issued, the 5' and 3' UTRs were considered exons, *see, e.g.*, GTG Exhs. U, V (biology texts defining 5' and 3' sections as exons), and it would thus be inconsistent to define the term "non-exon sequences" as including an exon sequence. FN2 Texas Digital, 308 F.3d at 1202-03 (dictionaries in use at the time of the patent's issuance may be relied upon in construing a claim). The court agrees with GTG. The term is thus construed as: **any untranslated DNA sequences, such as sequences between exons, the 5' and 3' untranslated regions, and sequences between genetic loci.**

FN2. The analogy provided at the hearing was that it would be inconsistent to proffer a definition such as "non-shoe objects, including trucks, cars, and stilettos," since stilettos are a type of shoe and it would be inconsistent to define a shoe as a "non-shoe object."

2. "Spans [a Non-Coding Region Sequence]"

The parties agree that the term "spans" can be construed as "*amplifies*." However, Applera argues that the term "spans a non-coding region sequence" must be further limited to encompass the further requirement that the sequence in question include introns as non-conserved DNA sequences. GTG argues that no limitation is necessary.

A conserved sequence is one which does not vary significantly between individuals. Thus, if a conserved sequence is included in the non-coding region of the DNA to be analyzed, that section will not show any significant differences between the strand in question and the other strands used in comparison. Thus, non-conserved sections must also be included in the DNA region analyzed in order to find the necessary variations between the strand under analysis and the comparator strands to perform the method described in the patent.

Applera argues that because the specification defines a "non-coding" region as synonymous with the term "intron," and because the specification defines the term "intronspanning primer" as spanning non-conserved regions, the term "spans" must require that non-conserved sequences be included in a non-coding region sequence. However, nothing in the claims or prosecution history implies that the description in the specification for "intronspanning primer" should be imported into the claim interpretation for the term "spans," and thus to do so would be improper. *See* Texas Digital, 308 F.3d at 1204-05; Teleflex, 299 F.3d at 1326. The term "spans" is thus construed as: **amplifies,** with no further limitation that the region spanned must include a non-conserved intron section.

3. "In Genetic Linkage"

GTG proposes that the term "in genetic linkage" be construed as "*a tendency of DNA sequences on the same chromosome to be linked together,*" and Applera proposes "*DNA sequences that are on the same chromosome and are inherited together*." Both parties agree that the dictionary definition of the term "genetic linkage" requires only a tendency for traits to be inherited together. However, Applera claims that prosecution history estoppel limits the breadth of the claims.

Prosecution history estoppel only occurs when a patentee clearly and unmistakably disavows the breadth of a claim. *See, e.g.,* Omega Eng'g Inc. v. Raytek Corp., 334 F.3d 1314, 1326 (Fed.Cir.2003). While the statement that "DNA sequences which are in genetic linkage are regions of genomic DNA that are inherited together" in the prosecution history could potentially be read as stating that 100% certainty of linkage is necessary, *see* Applera Exh. L at 5, that reading does not demonstrate the necessary "clear and unmistakable surrender" of subject matter for that reading of the prosecution history to apply. Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352, 1359 (Fed.Cir.2003), *cert. denied,* 540 U.S. 1213, 124 S.Ct. 1426, 158 L.Ed.2d 141 (2004).

Furthermore, the next sentence of that section of the prosecution history reaffirms that "[s]ince the meaning of the term 'genetic linkage' is well known in the art and is used in the specification and claims in a manner consistent with that definition, the meaning of the claims is clear." Applera Exh. L. at 5. On this record, Applera cannot show "clear and unmistakable" intent to require 100% certainty of linkage beyond the dictionary definition of the term.

The court thus adopts GTG's definition, and construes the term "in genetic linkage" as: **a tendency of DNA sequences on the same chromosome to be linked together.**

4. "Characteristic of Said Allele"

GTG originally proposed the definition "capable of distinguishing at least one allele from at least one other allele. More than one amplified DNA sequence may be used for loci where alleles differ by single nucleotide substitutions that are not unique to the allele or when information regarding remote alleles (haplotypes) is desired." At the claim construction hearing, GTG modified its definition to simply "*capable of distinguishing at least one allele from at least one other allele*." Applera proposes "*a trait, quality, or property that is unique*." Following the hearing, GTG submitted a subsequent modification to its definition to: "*a trait, quality, or a group of them distinguishing an individual, group, or type*."

GTG is correct that the prosecution history does not limit the claims to a construction where a one-to-one correspondence has been demonstrated between the DNA sequences and the allele in question, nor does it

imply "uniqueness," as Applera argues. When read in context, it is clear that the one-to-one correlation described in both the prosecution history and the specification is merely provided as an example and is not intended to limit the scope of the claims. *Id.;* Applera Exh. N at 19; '179 patent col. 7:24-28. However, Applera is correct that nothing in the claims or prosecution history requires that the term "characteristic" be given a construction other than its standard definition of "a trait, quality, or property or a group of them, distinguishing an individual, group, or type," as set forth in the prosecution history. Applera Exh. L at 5. GTG appears to have acknowledged this in their post-hearing proposed construction.

Accordingly, as between GTG and Applera, GTG's final proposal is the most accurate. The court thus adopts GTG's construction of the term "characteristic of said allele" as: **a trait, quality or property, or a group of them, distinguishing an individual, group, or type.**

5. "To Determine"

GTG proposes the construction "*to conclude or ascertain,*" while Applera proposes "to *fix conclusively or authoritatively*." The main dispute is whether the analysis of the DNA strand must be absolutely correct to fall within the scope of the claims.

Nothing in the dictionary definition of the term "to determine" implies that the determination must be 100% accurate, and nothing in the claims, specification, or prosecution history indicates any intent to limit the patent in that fashion. The term "to determine" is construed as: **to conclude or ascertain.**

B. '762 Patent

Ten terms are at issue in the '762 patent, though several terms were previously construed in the context of the '179 patent.

1. "To Identify"

The main dispute over this term concerns whether the preamble of the patent should be read as a limitation on the claim. GTG argues that the preamble does not limit the claim, and the claim need not be construed. Applera argues that the preamble should be construed, and proposes the construction "*establishing the identity of*." FN3

FN3. The verb "identify" appears in a number of places throughout both the preamble to claim 1 and the claims themselves, but the parties appear to focus solely on the use of the specific term "to identify" at col. 37:43-44.

Claims are only limited by the preamble if the preamble "recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim." Catalina Marketing Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed.Cir.2002) (citation omitted). In contrast, if the patent claims define "a structurally complete invention in the claim body," and the preamble is used "only to state a purpose or intended use of the invention," the preamble cannot be used to limit the claims, "unless there is clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art." Intertool, Ltd. v. Texar Corp., 369 F.3d 1289, 1295 (Fed.Cir.2004), *citing* Catalina, 289 F.3d at 808.

Here, the preamble merely sets forth the purpose of claim 1 of the '762 patent, which is to outline a method

for identifying markers and using the markers to find chromosomal regions. The claims themselves do not rely on the statement of purpose in any way, and do not rely on that definition of "identify" in setting forth the method at issue. Furthermore, there is no indication in the prosecution history that the applicant relied in any way on the use of the term "identify" in the preamble to distinguish the invention from the prior art. There is thus no reason to find the preamble limiting on the claims in this patent, and the court declines to construe the term. FN4

FN4. The term "identify" will thus be given its ordinary meaning when reading the claim, which in practice will result in a reading consistent with Applera's proposed dictionary definition of the term.

2. "Non-Coding Sequence"

Both parties agree that this term should be construed identically to "non-coding region sequence" in the '179 patent. "Non-coding sequence" is construed as: **any untranslated DNA sequences, such as sequences between exons, the 5' and 3' untranslated regions, and sequences between genetic loci.**

3. "To Determine"

The parties proffer the same constructions and repeat their previous arguments concerning this term as it appeared in the '179 patent. The court construes "to determine" identically to its construction in the '179 patent, as: **to conclude or ascertain.**

4. "Haplotypic Pattern"

GTG proposes the construction "*data, from an analytical method, that is characteristic of a particular haplotype*." Applera proposes "*a pattern of DNA fragments that have been separated according to mobility and visualized, and which is uniquely indicative of the presence of a particular haplotype,*" based on its reading of the prosecution history.

While it is true that in the prosecution history of the '762 patent, the patent examiner found the previously-proposed claims overbroad and unsupported by the specification, Applera Exh. U at 4, those findings were in relation to claims that did not contain the term "haplotypic pattern" but merely stated generally that a locus would be "identified." *See, e.g.,* Applera Exh. S at 68. Those claims were then cancelled and newer, more specific claims describing the type of identification to be made, involving "haplotypic patterns," were substituted in their place on January 2, 1997. GTG Exh. N (also located at Applera Exh. W). Based on this file history, it is clear that GTG has not disclaimed coverage for haplotypic patterns that are not visualized, and that the claim covers any identification made through the comparison of haplotypic patterns in any way.

Furthermore, nothing in the specification or prosecution history implies that the identification made must be "uniquely indicative" of a particular haplotype, so that element of Applera's proposed construction is incorrect as well.

The court thus adopts GTG's construction, and construes the term "haplotypic pattern" as: **data, from an analytical method, that is characteristic of a particular haplotype,** without requiring that the data identify a haplotype to 100% accuracy or further specifying the analytical methods to be used.

5. "Selected Technique"

GTG proposes the construction "*any analytical method chosen to detect haplotypic patterns,*" while Applera proposes "*a method that produces patterns of DNA fragments that have been separated according to mobility and visualized, meaning RFLP analysis, primer defined length polymorphism and allele- and haplotype-specific amplification analysis*."

The court adopts GTG's proposed construction. As previously discussed in the context of the term "haplotypic patterns," the prosecution history does not support Applera's interpretation of the claim as limiting the patent to two specific analytic methods. The term "selected technique" is construed as: **any analytical method chosen to detect haplotypic patterns.**

6. "Marker for a Haplotype"

GTG proposes the construction "*indicator for a haplotype,*" and Applera proposes "*a haplotypic pattern which uniquely identifies a haplotype*."

The court adopts GTG's proposed construction. For the reasons stated previously, the patent and the prosecution history do not require that the haplotypic pattern "uniquely" identify the haplotype in question. The term "marker for a haplotype" is construed as: **indicator for a haplotype.**

7. "To Identify the Haplotype"

GTG proposes the construction "*to establish as being a particular haplotype,*" and Applera proposes "*to establish the identity of a unique haplotype*."

The court adopts GTG's proposed construction. As previously stated, nothing in the patent or prosecution history indicates that the haplotypes must be uniquely identified. The term "to identify the haplotype" is construed as: **to establish as being a particular haplotype.**

8. "Subseries of Adjacent Selected Chromosomal Regions"

GTG proposes the construction "*a successive subset of chosen chromosomal regions,*" and Applera proposes "*a subseries of selected chromosomal regions within the same locus or, for intron DNA sequences not associated with a genetic locus, immediately preceding or following the locus*."

The construction of this claim is a close call, but GTG's arguments are slightly more persuasive than Applera's. The claim language here is admittedly ambiguous as to whether the subseries covers chromosomal regions that are adjacent to one another within a selected series of regions (GTG's proposal), or chromosomal regions that are adjacent to one another on the DNA strand before they are selected (Applera's proposal). In this circumstance, the court may properly rely on the specification to clarify the language. *See, e .g.*, CCS Fitness,, 288 F.3d at 1367.

The specification describes a method by which individual haplotypic regions on the DNA strand, separated by anywhere from .01 to 2 million DNA base pairs, are selected and analyzed. *See* '762 patent col. 13:7-21 (after one region is analyzed, the next haplotypic region appearing on the DNA strand is analyzed to create a map of "contiguous overlapping haplotypic regions."). In contrast, there is no description in the specification supporting Applera's interpretation of the claim that a continuous section of DNA is first selected, and then a second continuous subsection is then selected from within the first selected section.

While Applera proposes a plausible reading of what appears to be a rather poorly-drafted claim, when looking at the claim language in the context of the specification, the court is persuaded that GTG's position better describes the intended steps of the method described. Teleflex, 299 F.3d at 1324-25 (citations omitted). However, the court finds that GTG's construction is not entirely clear either. The court thus construes the disputed term as follows: **a group of chromosomal regions identified by the following process: Chromosomal regions on a DNA strand are selected. The regions need not be adjacent to each other on the DNA strand. The selected regions are then arranged in the order in which they appear on the DNA strand. Regions that are next to one another in this reconfiguration are then selected to comprise a group.**

The court acknowledges that this construction, while simplistic, may be imprecise. Accordingly, the court offers the parties the opportunity to stipulate to an alternate construction that embodies the court's basic finding that the chromosomal regions in question need not be adjacent to one another on the actual DNA strand. Any stipulation shall be submitted no later than one week after the filing of this order. If the parties are unable to reach an agreement, the court's construction will be the final construction of this claim.

9. "Indication"

GTG proposes this term be construed as "*suggestion or sign of,*" while Applera proposes "*positive identification of said central selected chromosomal region as being associated with the trait*."

The court adopts GTG's position. As previously discussed, the patent and prosecution history do not require "positive identification" of the region in question. "Indication" is thus construed as: **suggestion or sign of.**

10. "Analyzing Said Plurality of Amplified DNA Sequences"

GTG proposes the construction "*observing any variation in the DNA sequence using any technique,*" and Applera proposes "*applying the selected technique to said plurality of amplified DNA sequences*."

The court adopts GTG's position. There is no indication in the claim language that limits the type of analysis that may be performed. Applera's proposed construction improperly imports limitations from the specifications into the claims. Texas Digital, 308 F.3d at 1204-05; Teleflex, 299 F.3d at 1326. The term is thus construed as: **observing any variation in the DNA sequence using any technique.**

The parties are ordered to submit a joint case management status report pursuant to Patent Standing Order para. 13 within 21 days of the filing of this order. The court will review the report and contact the parties if a further case management conference is needed. This order fully adjudicates the matter listed at no. 65 on the clerk's docket for this case.

IT IS SO ORDERED.

N.D.Cal.,2004.
Genetic Technologies Ltd. v. Applera Corp.