IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF WISCONSIN

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THIRD WAVE TECHNOLOGIES, INC.,

Plaintiff,

v.

ERAGEN BIOSCIENCES, INC.,
JAMES R. PRUDENT and
DAVID J. MARSHALL,

Defendants.

OPINION AND ORDER

02-C-507-C

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Two patents owned by plaintiff Third Wave Technologies, Inc. disclose a method of detecting the presence of certain nucleic acids by "cleaving," or separating, oligonucleotides from a target nucleic acid and analyzing the remaining fragments. In this civil suit, plaintiff contends that the method of cleaving nucleic acids employed by defendant EraGen Biosciences, Inc. in its GeneCode products infringes on plaintiff's patents. In addition, plaintiff has asserted claims for breach of contract, unjust enrichment, constructive trust and conversion against defendants James Prudent and David Marshall, who are former employees of plaintiff now working for defendant EraGen. Finally, plaintiff contends that defendant EraGen has intentionally interfered with plaintiff's contractual relationship with defendants

Prudent and Marshall. (Because plaintiff's claims against defendants Prudent and Marshall are not at issue for the purposes of this opinion, from this point on, I will refer to defendant EraGen as simply "defendant.")

A claim construction hearing regarding plaintiff's two patents was held on February 28, 2003. The issue before the court is the proper construction of several terms used in United States Patent No. 6,090,543 (the '543 patent) and United States Patent No. 6,348,314 (the '314 patent). I construe claim 16 of the '543 patent and claim 14 of the '314 patent as permitting reagents to be provided before or during the mixing step. I construe the term "complementary" in claim 16 of the '543 patent and claim 14 of the '314 patent as referring to "bases that are related by the base pairing rules" that are not limited to bases that hydrogen bond in a standard "Watson-Crick" fashion. Finally, I construe the term "non-target cleavage products" as meaning products of a cleavage reaction that are derived from the 5' portion of the first oligonucleotide.

OPINION

The parties dispute the meaning of claim 16 of the the '543 patent and claim 14 of the '314 patent. (The parties also refer to claim 17 of the'543 patent, which is dependent from claim 16. However, because there are no disputed terms in claim 17, I have not included that claim in the discussion.) Construing the meaning of the claims begins with the

language of the claims and ends there if the claim language is clear, since it is the language of the claims that defines their scope. York Products, Inc. v. Central Tractor Farm & Family Center, 99 F.3d 1568, 1572 (Fed. Cir. 1996). Claim 16 discloses:

> 16. A method of detecting the presence of a target nucleic acid molecule by detecting non-target cleavage products comprising:
>
> a) providing:
>
> i) a cleavage means,
>
> ii) a source of target nucleic acid, said target nucleic acid having a first region, a second region and a third region, wherein said first region is downstream from said second region and wherein said second region is contiguous to and downstream from said third region;
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> iii) first and second oligonucleotides having 3' and 5' portions, wherein said 3' portion of said first oligonulceotide contains a sequence complementary to third region of said target nucleic acid and wherein said 5' portion of first oligonucleotide and said 3' portion of said second nucleotide each contain sequence fully complementary to said second region of said target nucleic acid, and wherein said 5' portion of said second oligonucleotide contains sequence complementary to said first region of said target nucleic acid;
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> b) mixing, in any order, said cleavage means, said target nucleic acid, said first oligonucleotide and said second oligonuncleotide to create a reaction mixture under reaction conditions such that at least 3' portion of said first nucleotide is annealed to said target nucleic acid and wherein at least said 5' portion of said second oligonucleotide is annealed to said target nucleic acid so as to create a cleavage structure and wherein cleavage of said cleavage structure occurs to generate non-target cleavage products, each non-target cleavage product having a 3'-hydroxyl group; and
>
> c) detecting said non-target cleavage products.

Claim 14 of the '314 patent is similar to claim 16 of the '543 patent. Claim 14 discloses:

> 14. A method of detecting the presence of a target nucleic acid molecule by detecting non-target cleavage products comprising:
>
> a) providing:
>
> i) a thermostable 5'-nuclease;
>
> ii) a source of target nucleic acid, said target nucleic acid comprising a first region and a second region, said second region downstream of and contiguous to said first region;
>
> iii) a first oligonucleotide, wherein at least a portion of said first oligonucleotide is completely complementary to said first portion of said first portion of said first target nucleic acid;
>
> iv) a second oligonucleotide comprising a 3' portion and a 5' portion, wherein said 5' portion is completely complementary to said second portion of said target nucleic acid
>
> b) mixing said cleavage agent, said target nucleic acid, said first oligonucleotide and said second oligonuncleotide to create a reaction mixture under reaction conditions such that at least said portion of said first nucleotide is annealed to said first region of said target nucleic acid and wherein at least said 5' portion of said second oligonucleotide is annealed to said second region of said target nucleic acid so as to create a cleavage structure, and wherein cleavage of said cleavage structure occurs to generate non-target cleavage product; and
>
> c) detecting the cleavage of said cleavage structure.

For the purposes of this action, there appears to be no dispute that the terms used in claim 16 of the '543 patent have the same meaning as they do in the context of claim 14 of

the‘ 314 patent.

A. Providing/Mixing

The parties dispute whether the patents require that the ingredients listed in step (a) must be "provided" *before* the "mixing" step or whether ingredients (the parties refer to them as "reagents") may be "provided" *during* the mixing step. (The reagents are the cleavage means, a source of target nucleic acid, a first oligonucleotide and a second oligonucleotide.) The dispute is not quite so straightforward as it might appear, that is, whether the ingredients must be lined up on the counter before beginning the mixing step. Rather, defendant argues that before the oligonucleotides are mixed together, they must be in the state identified in the providing step, that is, they must be complementary to the target nucleic acid in the manner described in that step. According to plaintiff, so long as the reagents are "provided" at some point before the completion of the process, they do not need to be in the state identified in the providing step when they are mixed together initially.

The parties agree that plaintiff's patents allow reagents to be added in any order. For example, the "second oligonucleotide" may be "provided" before the "first oligonucleotide" or vice-versa. They agree also that the "mixing" step may begin before all the reagents are added to the mix. Each reagent does not have to be added at the same time. The precise dispute is whether each reagent must be in the same form as is described in the providing

step when it is added to the mix, that is, whether it must be "provided" before it is added to the mix or whether it can be "provided" while it is being mixed.

Although claim 14 of the '314 patent and claim 16 of the '543 patent label the "providing" step as "a)," the "mixing" step as "b)" and the "detecting" step as "c)," the claim language contains no express requirement that the providing, mixing and detecting occur in any particular order. The parties agree that when a claim does not recite an order for the steps of a disclosed method, the court should first "look to the claim language to determine if, as a matter of logic or grammar, they must be performed in the order written." Altiris, Inc. v. Symantec Corp., 318 F.3d 1363, 1369 (Fed. Cir. 2003). If not, the court looks to the rest of the specification to determine whether it requires a narrow construction. Id.

In this case, it must be conceded that, as a matter of logic, not all the steps are interchangeable. For example, the "detecting" step cannot come before the "providing" or "mixing" steps because the "non-target cleavage products" cannot be detected until after the reagents have been provided and mixed. See Mantech Environmental Corp. v. Hudson Environmental Services, Inc., 152 F.3d 1368, 1375-76 (Fed. Cir. 1998) (concluding that steps in claim must be performed in sequential order because no step could be performed until previous step was completed). Logic also demonstrates that *something* must be "provided" before the mixing step begins; otherwise there would be no ingredients to mix. However, this does not resolve the dispute over *what form* the ingredients must be in when

they are first mixed together. Defendant argues that they must be in the form identified in the providing step, relying on the claims' use of the word "said" (as in "before mentioned"). Both claim 14 of the '314 patent and claim 16 of the '543 patent state that the method involves the mixing of "*said* cleavage means, *said* target nucleic acid, *said* first oligonucleotide and *said* second nucleotide." (Emphasis added.) Defendant maintains that the "said" refers back to the ingredients identified in the providing step. For instance, part (iii) of the "providing" step of claim 16 refers to "first and second oligonucleotides having 3' and 5' portions" that are "complementary" to the "target nucleic acid." Thus, defendant argues, before the oligonucleotides are mixed, they must have the degree of "complementarity" described in the providing step.

I agree with defendant that the "mixing" step refers to the reagents as they are described in the "providing" step. The claims are unambiguous: a target nucleic acid and a first and second oligonucleotide with the requisite degree of complementarity must be provided and mixed. As defendant points out, one cannot mix what has not yet been provided. But this conclusion does not resolve the dispute. Defendant's argument is more than just that each reagent must be provided and then mixed; it is that reagents must be "provided," that is, they must be fully formed, when they are *added* to the mix.

At the claim construction hearing, defendant made a comparison to a recipe that calls for caramel. Just as the cook could not substitute the *ingredients* of caramel for caramel,

defendant argued, plaintiff's patents do not permit substituting the ingredients necessary to make a complementary oligonucleotide for the complementary oligonucleotide itself. Although cooking analogies can be useful, this one fails to take into account an important difference between making turtle cookies and detecting nucleic acids. Mixing the ingredients of caramel together with other ingredients will never make caramel, but a complementary oligonucleotide *can* be generated during the mixing step, even if it was not added to the mix fully formed.

Furthermore, there is no language in the claims requiring any of the ingredients to be fully formed when they are added to the mix. The mixing step states only that complementary oligonucleotides must be mixed. It does not state that complementary oligonucleotides must be present when mixing *begins*. So long as reagents described in the "providing" step are "provided" before mixing is *completed*, the claims' requirements have been satisfied.

What appears to be at the heart of the dispute regarding the providing and mixing steps is whether the oligonucleotides can be generated by polymerase chain reaction, or PCR. (Under the PCR method, complementary oligonucleotides would be synthesized during the mixing step rather than before.) Defendant has pointed to nothing in the patents' specifications or their prosecution histories that would limit the way the reagents are "provided" in the manner defendant proposes. See Rexnord Corp. v. Laitram Corp., 274

F.3d 1336, 1343 (Fed. Cir. 2001) (patent's specification may be consulted to "determine whether the patentee has disclaimed subject matter or has otherwise limited the scope of the claims"); id. ("[S]tatements made during the prosecution of a patent may affect the scope of the invention.") The specifications of both patents state that the oligonucleotides "may be generated in any manner." Pat. '543, col. 18, line 65; Pat.'314, col. 16, line 16.

It is true that plaintiff's patents distinguish the inventions from polymerase chain reaction. However, the patents do not differentiate between methods of creating oligonucleotides inside or outside the mix, before or during the mixing step. The distinction plaintiff makes in the patents between PCR and its inventions is in the method of *detecting* sequences, *not* in the method of providing the ingredients necessary to perform the detection. See Pat. '543, cols. 1-5; Pat.'314, cols. 1-5 (describing PCR as one method "to detect and characterize specific nucleic acid sequences and sequence variations"); see also Pat.'543, col. 26, lines 16-19; Pat. '314, col. 23, lines 11-14 ("This method relies upon the amplification of the detection molecule rather than upon amplification of the target sequence itself as do existing methods of detecting specific target sequences.")

Accordingly, I construe claim 16 of the '543 patent and claim 14 of the '314 patent as permitting the reagents to be provided before or during the mixing step.

B. Complementary

As noted above, claim 16 of the '543 patent and claim 14 of the the '314 patent require the first and second oligonucleotides to be "complementary" to the target nucleic acid. In addition, specific portions of the oligonucleotides must be "fully" or "completely" complementary to certain regions of the target nucleic acid. The parties dispute the meaning of "complementary." (They agree that "fully" and "completely" mean the same thing, that is, that *every* base in a nucleotide sequence is "complementary.") Plaintiff proposes the reading that the term "complementary" "refers to bases that are related by the base pairing rules." Defendant contends that "complementary" refers to bases related by the base pairing rules and that the term "base pairing rules" refers to bases that bond in a standard "Watson-Crick" fashion to a specific base complement, A to T and G to C.

The claims do not provide a definition for "complementary" and do not limit its meaning to a particular type of complementarity. However, the definitions sections in the specifications of both patents provide: "As used herein, the terms 'complementary' or 'complementarity' are used in reference to polynucleotides (i.e., a sequence of nucleotides such as an oligonucleotide or a target nucleic acid) related by the base pairing rules. For example, for [sic] the sequence 'A-G-T,' is complementary to the sequence 'T-C-A.'" Pat. '543, col. 17, lines 33-38; Pat. '314, col. 14, lines 51-54. The parties agree that this definition controls the meaning of "complementary" in both patents. See Rexnord, 274 F.3d

at 1232 ("[P]atent law permits the patentee to choose to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term that could differ in scope from that which would be afforded by its ordinary meaning."); Cultor Corp. v. A.E. Staley Manufacturing Co., 224 F.3d 1328, 1331 (Fed. Cir. 2000) (relying on definition in specification to limit scope of claim).

The definition provided in the specification does not resolve the dispute. It refers only to "the base pairing rules"; it does not identify what those rules are. Although the example given follows the Watson-Crick base pairing rules, there is no express statement limiting the patent to the Watson-Crick rules. If anything, providing an example suggests that the example is only one way nucleotides can be complementary and that there are other ways of achieving complementarity, even if they are less preferable. Even if all the examples provided in the patents used the Watson-Crick base pairing rules, that fact alone would not require a narrow interpretation of "complementary." See Specialty Composites v. Cabot Corp., 845 F.2d 981, 986-87 (Fed. Cir. 1988) (patent that used term "plasticizer" covered both "internal plasticizers" and "external plasticizers" even though the patent provided examples of "external plasticizers" only).

Defendant places great emphasis on use of the phrase "*the* base pairing rules." Defendant does not argue that those skilled in the art would understand the term "the base pairing rules" as *always* meaning the Watson-Crick rules. Rather, defendant's argument goes

something like this: "Because plaintiff's patents refer to *the* base pairing rules and the only base pairing rules explicitly referred to in the patents are the Watson-Crick rules, *the* base pairing rules *must* be the Watson-Crick rules." The problem with this logic is that plaintiff's patents never limit the invention explicitly to the Watson-Crick base pairing rules. Just because the base pairing rules in plaintiff's claims *encompass* the Watson-Crick base pairing rules does not necessarily mean that they are *limited* to those rules. See Northern Telecom Ltd. v. Samsung Electronics Co., Ltd., 215 F.3d 1281, 1290 (Fed. Cir. 2000) ("This court has repeatedly and clearly held that it will not read unstated limitations into claim language.") If the applicants meant to limit *the* base pairing rules to the Watson-Crick rules, they could have stated this in the patents. They did not.

Defendant points to Example 33 in the specification as supporting its interpretation of "complementary." Example 33 is titled, "The [U]se of Universal Bases in the Detection of Mismatches by Invader™-Directed Cleavage." It begins:

> The term "degenerate base" refers to a base on a nucleotide that does not hydrogen bond in a standard "Watson-Crick" fashion to a specific base complement, i.e., A to T and G to C. For example, the inosine base can be made to pair via one or two hydrogen bonds to all the natural bases (the "wobble" effect) and thus is called degenerate.

Defendant argues that "[t]his passage makes clear that bases 'related by the base pairing rules' are those bases that 'hydrogen bond in a standard 'Watson-Crick' fashion.'" Dft.'s Br., dkt # 41, at 13. I disagree. Although the example refers to Watson-Crick base pairing, there

is no language in the passage limiting the invention to use of those base pairing rules. Rather, the passage is *contrasting* base pairing using degenerate bases with Watson-Crick base pairing. The specification of the '543 patent makes express allowance for the use of the degenerate base inosine. See Pat. '543, col. 20, lines 19-22 ("Certain bases not commonly found in natural nucleic acids may be included in the nucleic acids of the present invention and include, for example, inosine and 7-deazaguanine.") In short, Example 33 does not help defendant. Referring to a concept and identifying it as a limitation are not the same thing.

Next, defendant argues that plaintiff "repeatedly sought to rely on the standard definition of 'complementarity' during prosecution to distinguish over extensive prior art that describes cleavage-based methods of nucleic acid detection." Dft.'s Br., dkt. #41, at 14. However, the only example cited by defendant is a statement by the applicants for the '543 patent that "this complementarity is an important feature of the presently claimed invention." See Aff. of Gabrielle Bina, dkt. #42, Ex. 6, at 13 (Amendment and Response to Sept. 19, 1997 Office Action). Looking at this statement in context shows that "this complementarity" refers to the *degree* of complementarity and not to a specific type of base pairing rules. The two sentences following the one cited by defendant state:

> As shown in Figure 29 and described in the specification . . . the presently claimed invention teaches that the probe (i.e. the first oligonucleotide of Claim 16) is complementary to both regions X and Z. As described below, none of the prior art cited by the Examiner teach a first nucleotide with contiguous regions of complementarity to these regions of the target nucleic acid.

Id. The applicants emphasize the "contiguous regions of complementarity"; they make no reference to the Watson-Crick base pairing rules.

Finally, defendant contends that if "the base pairing rules" do not refer to the Watson-Crick rules, then a third party reading plaintiff's patents will be "at a total loss regarding the 'rules' by which it can assess [their] scope." Dft.'s Br., dkt. #42, at 14. Plaintiff responds that one skilled in the art would know how to determine whether bases are related by the base pairing rules. This dispute may assume significance in the future but it does not need to be resolved at this time. The only issue to be decided is whether claim 16 in the '543 patent and claim 14 in the '314 patent limit the meaning of "complementary" to "bases that hydrogen bond in a standard 'Watson-Crick' fashion." Because there is no support for this limitation in the claims, the specifications or the prosecution history, I conclude that the meaning of "complementary" is not so limited.

C. Non-target Cleavage Products

During the mixing step of claim 16 of the '543 patent, two oligonucleotides are annealed, or paired, with a target nucleic acid, creating a "cleavage structure." The subsequent pulling apart of the cleavage structure causes it to break apart into fragments. Some of these fragments are "non-target cleavage products," each of which must have a 3'-hyrodoxyl group. These products are then detected to determine the existence of a particular

target nucleic acid. Detection occurs by adding nucleotides to the 3'-hydroxyl group. Pat. '548, col. 9, lines 60-65. (Claim 14 of the '314 patent uses a different method of detection that is not at issue.)

Defendant argues that a "non-target cleavage product" should be defined as including *each fragment* generated from the first oligonucleotide as a result of the cleavage reaction. Plaintiff argues that a "non-target cleavage product" includes only those fragments "derived from the 5' portion of the first nucleotide." Plt.'s Br., dkt. # 35, at 26. (Each oligonucleotide has a 3' portion and a 5' portion.)

Again, the claim does not specify what the applicants mean by "non-target cleavage products." However, in the definitions section of the specification, they defined "non-target cleavage product" as follows: "[A] product of a cleavage reaction which is not derived from the target nucleic acid. As discussed above, in the methods of the present invention, cleavage of the cleavage structure occurs within the probe [first] oligonucleotide. The fragments of the probe [first] oligonucleotide generated by this target nucleic acid-dependent cleavage are 'non-target cleavage products.'" Pat. '543, col. 21, lines 38-40, 42-44. Although this definition limits "non-target cleavage products" to fragments of the first oligonucleotide, it is broad enough to include *all* fragments from the first oligonucleotide generated by the cleavage reaction, and not just those derived from the 5' portion. In isolation, this definition appears to support defendant's interpretation of the claim.

However, plaintiff contends that the meaning of "non-target cleavage products" in claim 16 must be determined in light of claim 19, which is dependent on claim 16. Claim 19 provides: "The method of claim 16, wherein at least said first oligonucleotide contains a dideoxynucleotide at the 3' terminus." A dideoxynucleotide is simply a nucleotide that lacks a 3'-hydroxyl group. Because it has no 3'-hydroxyl group, it cannot be extended. Thus, the method of claim 19 is the same as claim 16, *except* the first oligonucleotide will have a hydroxyl group on the 5' portion of the oligonucleotide only. When the cleavage reaction occurs, there will be one fragment from the 3' portion of the first oligonucleotide that will not have a hydroxyl group and cannot be extended.

Both parties recognize that claim 19 and claim 16 can be reconciled only if "non-target cleavage products" are limited to fragments derived from the 5' portion of the first oligonucleotide. As plaintiff explains, if *all* fragments from the first nucleotide are "non-target cleavage products" then, according to claim 16, *all* the fragment must also have a 3'-hydroxyl group. But this cannot be true under the method of claim 19 because, as noted above, one fragment from the first nucleotide *will not have a 3'-hydroxyl group*. However, the only fragment that will lack a hydroxyl group is the one that comes from the 3' portion of the oligonucleotide. If the term "non-target cleavage products" is limited to include *only* fragments from the 5' portion of the first oligonucleotide, then each "non-target cleavage product" generated by the method in claim 19 will satisfy the requirements of claim 16,

because each "non-target cleavage product" will still have a 3'-hydroxyl group. (Claims 9 and 25 depend from other claims employing "non-target cleavage products," each of which must have "a 3'-hydroxyl group,"; both employ a first oligonucleotide containing a dideoxynucleotide at the 3' terminus.)

The problem is further complicated by numerous references in the specification, including in a discussion of a preferred embodiment, to instances in which the invention employs a first oligonucleotide with a dideoxynucleotide at the 3' terminus. One portion of the specification provides:

> In another preferred embodiment, one or more of the first and the second oligonucleotides contain a dideoxynucleotide at the 3' terminus. When dideoxynucleotide-containing oligonucleotides are employed, the detection of non-target cleavage products preferably comprises: a) incubating said non-target cleavage products with a template-independent polymerase and at least one labelled nucleoside triphosphate under conditions such that at least one labelled nucleotide is added to the 3'-hydroxyl group of said non-target cleavage products to generate labelled non-target cleavage products; and b) detecting the presence of said labelled non-target cleavage products.

Pat. '543, col. 9, lines 55-66. This passage supports an interpretation of "non-target cleavage products" that excludes fragments derived from the 3' portion of the first oligonucleotide. In the preferred embodiment, "at least one labelled nucleotide is added to the 3'-hydroxyl group of said non-target cleavage products." This is so even though one of the fragments of the first oligonucleotide may contain a dideoxynucleotide at the 3' terminus. As discussed above, a dideoxynucleotide lacks a hydroxyl group and thus more nucleotides cannot be

added to it. Therefore, under this preferred embodiment, "non-target cleavage products" *must* be limited to fragments from the 5' portion of the oligonucleotide. Otherwise, a nucleotide could not be added to each of the "said non-target cleavage products." See also id. at col. 7, lines 33-35 ("Further, one or more of the first, second, third and the fourth oligonucleotides may contain a dideoxynucleotide at the 3' terminus."); id. at col. 8, lines 38-40 ("In another preferred embodiment, one or more of the first, second and third oligonucleotides contain dideoxynucleotide at the 3' terminus.); id. at col. 52, lines 44-65 (referring to Figure 67, in which a first nucleotide contains "a blocked or non-extendable 3' end" and a "5' end label"; after cleavage of the first oligonucleotide, it is extended).

Plaintiff is correct that courts are to interpret dependent and independent claims of a patent in a consistent manner when it is reasonable to do so. Rambus, Inc. v. Infineon Technologies Ag, 318 F.3d 1081, 1093 (Fed. Cir. 2003) (interpretations of independent claims that render terms in dependent claim meaningless are disfavored); Inverness Medical Switzerland GmbH v. Princeton Biomeditech Corp., 309 F.3d 1365, 1371 (Fed. Cir. 2002) ("A claim term used in multiple claims should be construed consistently.") However, in the case plaintiff cites, Laitram Corp. v. NEC Corp., 62 F.3d 1388, 1392 (Fed. Cir. 1995), the court used the language of the dependent claim to *confirm* an interpretation suggested by the independent claim and the patent's specification. That is not the situation in this case. The specification in the '543 patent suggests different interpretations of "non-target cleavage

products," one broad and one narrow.

At the same time, in light of the different meanings of the term suggested by the specification, I do not believe it is fair to say, as defendant argues, that the term "non-target cleavage products" is susceptible to only one meaning and therefore claim 19 should be invalidated. See Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357 (Fed. Cir. 1999) ("[W]here, as here, claims are susceptible to only one reasonable interpretation and that interpretation results in a nonsensical construction of the claim as a whole, the claim must be invalidated."). The Supreme Court has held that determining the meaning of a term requires "a necessarily sophisticated analysis of the whole document" because "a term can be defined only in a way that comports with the instrument as a whole." Markman v. Westview Instruments, Inc., 517 U.S. 370, 389 (1996). The substantial number of references in the specification to oligonucleotides that do not have a 3'-hydroxyl group and the number of dependent claims that contemplate the use of dideoxynucleotides suggest a narrow definition of "non-target cleavage products," limited to fragments derived from the 5' portion of the first oligonucleotide. See Newell Co., Inc. v. Kenney Manufacturing Co., 606 F. Supp. 1282, 1292 (D.R.I. 1985), aff'd, 864 F.2d 757 (Fed. Cir. 1988) (although by itself term "securement means" could be interpreted broadly, specification and drawings contemplate a specific type of securement, supporting a narrower interpretation).

A narrow interpretation is also consistent with the function of the invention, which

is to detect fragments by adding nucleotides to them. See Pat. '548, col. 9, lines 60-65. Fragments with a dideoxynucleotide at the 3' terminus cannot be extended in this manner. Thus, it makes little sense to include those fragments in the definition of "non-target cleavage products" when the purpose of step (c) of claim 16 is to "detec[t] said non-target cleavage products." "[A] claim interpretation that aligns with the purpose of the invention is likely to be correct." Hockerson-Halberstadt, Inc. v. Avia Group International, Inc., 222 F.3d 951, 956 (Fed. Cir. 2000) (citing Renishaw PLC v. Marposs Societa'Per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

Finally, I note that adopting the interpretation suggested by defendant would invalidate not only claim 19, but would exclude a preferred embodiment. Such an interpretation "is rarely, if ever correct." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583 (Fed. Cir. 1995). Viewing the patent as a whole, I conclude that the term "non-target cleavage products" means products of a cleavage reaction that are derived from the 5' portion of the first oligonucleotide.

ORDER

IT IS ORDERED that the claims of plaintiff Third Wave Technologies, Inc.'s U.S. Patent Nos. 6,090,543 and 6,348,314 are construed as follows:

1. In claim 16 of the '543 patent and claim 14 of the '314 patent, reagents may be

provided before or during the mixing step.

2. In claim 16 of the '543 patent and claim 14 of the '314 patent the term "complementary" refers to "bases that are related by the base pairing rules" that are not limited to bases that hydrogen bond in a standard "Watson-Crick" fashion." The base pairing rules are not limited to bases that hydrogen bond in a standard "Watson-Crick" fashion.

3. In claim 16 of the '543 patent the term "non-target cleavage products" means products of a cleavage reaction that are derived from the 5' portion of the first oligonucleotide.

Entered this 18th day of March, 2003.

BY THE COURT:

BARBARA B. CRABB
District Judge