



The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

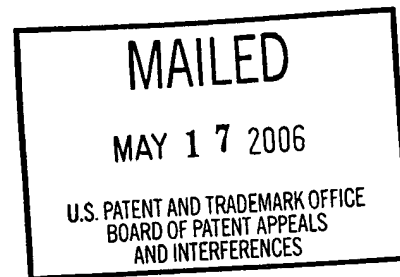
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte RICHARD H. TULLIS

Appeal No. 2006-0210
Application No. 08/078,768

HEARD April 27, 2006



Before SCHEINER, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to an antisense-based method of therapy. The examiner has rejected all of the claims as nonenabled, and has rejected one claim for obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 134. We reverse the nonenablement rejection, but affirm the double patenting rejection and enter a new rejection extending it to most of the claims.

Background

According to Appellant, this application is a continuation of application 07/633,452 (abandoned), which was a continuation of application 07/355,140 (issued as U.S. Patent 5,023,243). See the amendment received June 16, 1993, page 2. The

'140 application in turn claimed priority under 35 U.S.C. § 120 to an application filed on October 23, 1981. See the amendment received January 9, 1992, page 1. Thus, the effective filing date of the present application is apparently October 23, 1981.

The specification discloses what are now referred to as antisense methods of regulating protein synthesis. See, e.g., page 3:

a stabilized oligonucleotide, preferably in a phosphotriester form, is provided having a base sequence substantially complementary to a portion of messenger ribonucleic acid coding for a biological component of an organism. Due to the complementary nature of the oligonucleotide and the messenger ribonucleic acid, the two components can readily hybridize under appropriate conditions to control synthesis of the organism's biological component.

Hybridization of the oligonucleotide and the cellular messenger RNA (mRNA) "causes blocking of the translation of the mRNA into protein." Page 5. "[T]he oligonucleotide can be designed specifically for the mRNA coding for just one protein, and should not cross-react with mRNA for other proteins." Page 9.

Discussion

1. Claim construction

Claims 64-76 and 78-83 are pending and on appeal. Claims 64, 71, and 78 are representative and read as follows:

64. A method of selectively inhibiting the expression of a target protein in a cell producing messenger ribonucleic acids encoding the target protein and other proteins without inhibiting the expression of the other proteins, said method comprising the steps of:

- (a) synthesizing an oligonucleotide having a base sequence substantially complementary to a subsequence of a messenger ribonucleic acid said subsequence coding for the target protein,
- (b) introducing the oligonucleotide into the cell; and,
- (c) hybridizing the oligonucleotide to the subsequence of the messenger ribonucleic acid to inhibit the expression of the target protein.

71. The method of claim 64 wherein the oligonucleotide is stabilized to inhibit degradation by nucleases.

78. A method of selectively inhibiting the expression of a target protein in a cell producing messenger ribonucleic acid encoding the target protein, said method comprising the steps of:

selecting a base sequence substantially complementary to said messenger ribonucleic acid of said cell coding for the target protein,
providing a synthetic oligonucleotide that is stabilized against in vivo degradative enzymes, said synthetic oligonucleotide having said selected base sequence, and

introducing said synthetic oligonucleotide into the cell whereby said synthetic stabilized oligonucleotide hybridizes to the subsequence of the messenger ribonucleic acid.

Thus, claim 64 is directed to a method of inhibiting expression of a specific protein in a cell using “an oligonucleotide having a base sequence substantially complementary to a subsequence of a messenger ribonucleic acid said subsequence coding for the target protein.” In the context of the claims, “having” is equivalent to “comprising”: claim 65 depends on claim 64 and adds the limitation that “the entire sequence of the oligonucleotide is complementary to the subsequence of a messenger ribonucleic acid coding for the target protein.” Since a dependent claim must further limit the claim from which it depends, 35 U.S.C. § 112, fourth paragraph, claim 64 apparently includes oligonucleotides in which only part of the sequence is complementary to the target mRNA. Thus, “having” must be interpreted as open claim language.

Claim 64 also only requires that the oligonucleotide be complementary to part of the protein-coding subsequence of the target mRNA, not the entire protein-coding region. This interpretation is made apparent by claim 67, which depends on claim 64 and limits the length of the oligonucleotide to “about 23 bases.”

Claim 71 depends on claim 64 and adds the limitation that the oligonucleotide is stabilized against degradation by nucleases.

Claim 78 is similar to claim 64 but requires that the oligonucleotide be “stabilized against in vivo degradative enzymes.”

2. Enablement

The examiner rejected claims 64-76 and 78-83 under 35 U.S.C. § 112, first paragraph, on the basis that “the specification, while being enabling for claims limited to the preparation of stabilized forms of oligodeoxyribonucleotides that are phosphotriesters, does not reasonably provide enablement for all stabilized forms of oligodeoxyribonucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.” Examiner’s Answer, page 5. The examiner provided no further elaboration of his reasoning supporting the rejection, nor did he cite to a previous Office action containing a more complete statement of the rejection.

Appellant argues that the specification indicates a preference for phosphotriester-modified oligonucleotides, but that very preference shows that other forms of stabilized oligonucleotides were contemplated. See the Appeal Brief, page 8: “Given the language of the specification including ‘such as,’ ‘preferred,’ and variations thereof, one of ordinary skill in the art readily understands that other forms of stabilized oligonucleotides were contemplated and equally useful in the methods of the invention.”

Appellant also argues that “other forms of stabilized oligonucleotides were known in the art at the time of filing,” i.e., October 1981. Appeal Brief, page 9. As evidence

supporting his position, Appellant cites several declarations submitted under 37 CFR § 1.132 and references published in or before 1981. See id.

Appellant concludes that “[o]ne having ordinary skill in the art need only have substituted for the phosphotriester oligonucleotides of Appellant’s examples other known forms of stabilized oligonucleotides to determine their efficacy in the invention. This would not have required undue experimentation on the part of an artisan of ordinary skill.” Id., page 10.

“When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. If the PTO meets this burden, the burden then shifts to the applicant to provide suitable proofs indicating that the specification is indeed enabling.” In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

In this case, even if we assume for the sake of argument that the examiner made out a prima facie case of nonenablement, we conclude that Appellant has provided sufficient evidence to overcome it. Appellant has provided Rule 132 declarations by Jerry L. Ruth, Dennis E. Schwartz, and Stanley T. Crooke. Each of these declarants states that a number of stabilized nucleic acid analogues were known in the art. See the Schwartz declaration, pages 2-3; the Ruth declaration, pages 2-3; and the Crooke

declaration, pages 3-5. Each of the declarants cites references from the scientific literature in support of his assertion.

Appellant has also cited several scientific papers, published before October 23, 1981, that disclose oligonucleotides that were modified in ways that made them resistant to enzymatic degradation. See the Appeal Brief, page 9, second paragraph.

We agree with Appellant that the evidence of record shows that those skilled in the art would have been aware of several forms of oligonucleotides that were stabilized against degradation by enzymes. We also agree with Appellant that, since the examiner has indicated that the claims are enabled for use of phosphotriester-stabilized oligonucleotides, the only additional experimentation that would apparently be required to practice the claimed method with other types of stabilized oligonucleotides would be to substitute the other forms of oligonucleotides for phosphotriester-containing oligonucleotides and evaluate the results.

The examiner argues that the specification does not mention specific stabilized forms of oligonucleotides other than the phosphotriester forms, and that, while "the state of the prior art provides for the availability of stabilized oligonucleotides . . . [w]hat is in question is whether the use of any stabilized oligodeoxyribonucleotides, other than phosphotriesters . . . is enabled by the instant application." Examiner's Answer, page 12. See also page 7 ("[I]t is the application that is to be enabling, not further searching and extrapolation by those of skill in the art").

As we understand it, the examiner's concern is that the specification itself does not list other forms of stabilized oligonucleotides that were available in the art in October 1981 or specify which of the available forms would be likely to be functional in antisense

applications. This degree of guidance, however, is not required to meet the enablement requirement of 35 U.S.C. § 112. See In re Chilowsky, 229 F.2d 457, 460, 108 USPQ 321, 324 (CCPA 1956) (“[T]he applicant ‘may begin at the point where his invention begins, and describe what he has made that is new and what it replaces of the old. That which is common and well known is as if it were written out in the patent and delineated in the drawings.’”); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1987) (“[A] patent need not teach, and preferably omits, what is well known in the art.”); In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) (“That some experimentation may be required is not fatal; the issue is whether the amount of experimentation required is ‘undue.’”) (emphasis in original).

The examiner also cites several post-filing references that review problems that have been encountered in trying to move antisense-based therapies from the laboratory to the clinic. We agree with Appellant that these references are not related to the issue of enablement in this case. First, clinical efficacy is not required to enable the claims on appeal. See CFMT, Inc. v. Yieldup Int’l Corp., 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003) (“Enablement does not require an inventor to meet lofty standards for success in the commercial marketplace.”); In re Brana, 51 F.3d 1560, 1569, 34 USPQ2d 1436, 1442 (Fed. Cir. 1995) (“Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development.”).

In addition, the examiner has indicated that the claims are enabled to the extent that they are carried out with phosphotriester-modified oligonucleotides. If those skilled

in the art could practice the claimed method using phosphotriester-modified oligonucleotides, then apparently the experimentation involved in practicing antisense methods in general is not a bar to enablement. Therefore, the references cited by the examiner do not seem to be applicable to the enablement issue on appeal.

3. Obviousness-type double patenting

The examiner rejected claim 71 based on the doctrine of obviousness-type double patenting, on the ground that the claimed method is not patentably distinct from the method of claim 1 of U.S. Patent 5,023,243. See the Examiner's Answer, page 4: "Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of U.S. Patent 5,023,243 is a specific embodiment of the generic method of claim 71 in the instant application."

Obviousness-type double patenting entails a two-step analysis. First, the allegedly conflicting claims are construed and, second, the difference(s) between the claims are considered to determine whether the claims are patentably distinct. See Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 968, 58 USPQ2d 1869, 1878 (Fed. Cir. 2001). "A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim." Id.

"A patentable distinction does not lie where a later claim is anticipated by an earlier one. That is, a later patent claim that fails to provide novel invention over an earlier claim is not patentably distinct from the earlier claim." Id. at 970, 58 USPQ2d at 1880. "[A] later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim." Id. at 971, 58 USPQ2d at 1880.

In this case, we agree with the examiner that claim 1 of the '243 patent is a species that is encompassed by the genus of claim 71 of the instant application. That is, the claims are directed to the same method and differ only in that the method claimed in the '243 patent is carried out using an oligodeoxyribonucleotide stabilized by "being in the form of a phosphotriester," while instant claim 71 is carried out using an oligonucleotide that is "stabilized to inhibit degradation by nucleases" in any manner.¹ The instant specification makes clear that phosphotriester modification is one method by which oligonucleotides can be made stable to degradation. See page 5, lines 24-26 ("The oligonucleotide . . . can be transformed to a more stable form, such as a phosphotriester form, to inhibit degradation.").

Appellant argues that claim 1 of the '243 patent is not a specific embodiment of instant claim 71: "The oligonucleotide of present claim 71 has a sequence substantially complementary to the coding portion of the target mRNA, whereas the sequence of the oligodeoxyribonucleotide of claim 1 of the '243 patent is substantially complementary to any region of the mRNA coding for the targeted protein. Because the portion of the target protein [sic, mRNA] to which the oligonucleotide of claim 1 of the '243 patent is not limited to the coding region of the mRNA, that claim is not a specific embodiment of, and thus does not render obvious, claim 71 of the present application." Appeal Brief, pages 18-19.

¹ Appellant does not do not assert any patentable distinction based on the recitation of an "oligonucleotide" in instant claim 71 and an "oligodeoxyribonucleotide" in the '243 patent's claim 1. The instant specification makes clear that "oligonucleotides" encompass oligodeoxyribonucleotides (i.e., DNA; see the specification, page 5, line 24).

Admittedly, the language of the '243 patent's claim 1 could be interpreted in the manner urged by Appellant. However, the examiner has cited the prosecution history of the application that issued as the '243 patent as evidence that the language of that patent's claim 1 was intended to limit the claimed method to one carried out using an oligonucleotide that was complementary to a protein-coding portion of the target mRNA. See the Examiner's Answer, page 4. Most significantly, the examiner cites the amendment that was received on April 4, 1986, which introduced the claim (claim 68) that issued as claim 1 in the patent. In the remarks accompanying that amendment, Appellant distinguished the prior art on the ground that

neither alone nor in combination do the cited references disclose or suggest the introduction of oligonucleotides complementary to specific portions of the coding region of an organism's mRNA so as to inhibit synthesis of the particular targeted proteins. Moreover, in the claims, as now amended, these restrictions are explicit.

Page 12 (emphasis added).

Claims should be interpreted in light of their prosecution history. See Renishaw plc v. Marposs Societa per Azioni, 158 F.3d 1243, 1249 n.3, 48 USPQ2d 1117, 1121 n.3 (Fed. Cir. 1998) ("Likewise, any interpretation that is provided or disavowed in the prosecution history also shapes the claim scope."). The prosecution history of the '243 patent confirms our interpretation that the oligonucleotide recited in claim 1 is one that is complementary to part of the protein-coding region of the target mRNA.

We agree with the examiner that the method of claim 1 of the '243 patent is a specific embodiment that falls within the scope of claim 71 on appeal. In the absence of a terminal disclaimer, therefore, issuance of claim 71 is barred by the doctrine of obviousness-type double patenting.

New Grounds of Rejection

Under the provisions of 37 CFR § 41.50(b), we enter the following new grounds of rejection:

- Claims 64-68, 70, 72-76, 78, and 79 are rejected under the doctrine of obviousness-type double patenting over claims 1-4 of U.S. Patent 5,023,243; and
- Claim 69 is rejected under the doctrine of obviousness-type double patenting over claim 8 of U.S. Patent 5,023,243 and Summerton.²

1. The rejected claims

Claims 64 and 78 are reproduced above. Claims 65-70, 72-76, and 79 read as follows:

65. The method of claim 64 wherein the entire sequence of the oligonucleotide is complementary to the subsequence of a messenger ribonucleic acid coding for the target protein.

66. The method of claim 64 wherein the oligonucleotide is at least 14 bases in length.

67. The method of claim 64 wherein the oligonucleotide is about 23 bases in length.

68. The method of claim 64 wherein the oligonucleotide is between 14 and 23 bases in length.

69. The method of claim 64 wherein the messenger ribonucleic acid is viral.

70. The method of claim 64 wherein the messenger ribonucleic acid encodes a hormone.

72. The method of claim 64 wherein the oligonucleotide is an oligodeoxynucleotide.

² Summerton, "Intracellular inactivation of specific nucleotide sequences: A general approach to the treatment of viral diseases and virally-mediated cancers," Journal of Theoretical Biology, Vol. 78, pp. 77-99 (1979). Summerton was cited in the Examiner's Answer (page 3).

73. A method of selectively inhibiting the expression of a target protein in a cell producing messenger ribonucleic acids encoding the target protein and other proteins without inhibiting the expression of the other proteins, said method comprising the steps of:

selecting a synthetic oligonucleotide that has enhanced resistance against nuclease enzymes and has a base sequence substantially complementary to a subsequence of a messenger ribonucleic acid of said cell, said subsequence coding for the target protein,

introducing said synthetic oligonucleotide into the cell, and
hybridizing said synthetic oligonucleotide to the subsequence of the messenger ribonucleic acid to inhibit the expression of the target protein.

74. The method of claim 73 wherein said synthetic oligonucleotide is between 14 and about 23 bases in length.

75. A method of selectively inhibiting the expression of a target protein in a cell producing messenger ribonucleic acids encoding the target protein and other proteins without inhibiting the expression of the other proteins, said method comprising the steps of:

selecting a synthetic oligonucleotide that has enhanced resistance against nuclease enzymes and has a base sequence substantially complementary to a subsequence of a messenger ribonucleic acid of said cell, said subsequence coding for the target protein, and

introducing said synthetic oligonucleotide into the cell to hybridize said synthetic oligonucleotide to the subsequence of the messenger ribonucleic acid.

76. The method of claim 75 wherein said synthetic oligonucleotide is between 14 and about 23 bases in length.

79. The method of claim 78 wherein said synthetic oligonucleotide is between 14 and about 23 bases in length.

2. The claims of U.S. Patent 5,023,243

Claims 1-4 and 8 of the '243 patent read as follows:

1. A method of selectively inhibiting in vivo synthesis of one or more specific targeted proteins without substantially inhibiting the synthesis of non-targeted proteins, comprising the steps of:

synthesizing an [o]ligodeoxyribonucleotide having a nucleotide sequence substantially complementary to at least a portion of the base sequence of messenger ribonucleic acid coding for said targeted protein,

at least a portion of said oligodeoxyribonucleotide being in the form of a phosphotriester to limit degradation in vivo;

introducing said stable oligodeoxyribonucleotide into a cell; and hybridizing said stable oligodeoxyribonucleotide with said base sequence of said messenger ribonucleic [sic] acid coding for said targeted protein, whereby translation of said base sequence is substantially blocked and synthesis of said targeted protein is inhibited.

2. The method of claim 1, wherein said oligodeoxyribonucleotide comprises at least 14 nucleotides.

3. The method of claim 1, wherein said oligodeoxyribonucleotide comprises about 23 nucleotides.

4. The method of claim 1, wherein said targeted protein is follicle stimulating hormone, which has an alpha and a beta chain.

8. A method of controlling the infection of a host organism by a foreign organism through the selective inhibition of the synthesis of a protein vital to the foreign organism's viability, comprising the steps of:

determining the base sequence of the foreign organism's nucleic acid, said base sequence coding for at least a portion of said protein vital to the foreign organism's vitality;

synthesizing an oligodeoxyribonucleotide the order of nucleotides being substantially complementary to a portion of the foreign organism's messenger ribonucleic acid coding for said protein vital to said foreign organism's viability,

at least a portion of said oligodeoxyribonucleotide being in the form of a phosphotriester to inhibit degradation in vivo;

introducing said oligodeoxyribonucleotide into the cells of said host organism; and

hybridizing said oligodeoxyribonucleotide with said portion of the foreign organism's messenger ribonucleic acid so as to substantially block translation of said foreign organism's messenger ribonucleic acid coding for said protein, thereby inhibiting synthesis of said protein vital to the viability of the foreign organism.

3. Double patenting: claims 64-68, 70, 72-76, 78, and 79

We have already concluded that claim 1 of the '243 patent is a specific embodiment of method defined by the present application's claim 71. Claim 71 depends on claim 64. Therefore, the '243 patent's claim 1 is also a "species" encompassed by instant claim 64.

Claim 65 depends on claim 64 and adds the limitation that the entire sequence of the oligonucleotide is complementary to a protein-coding part of the target mRNA. As we have interpreted the claim language, claim 1 of the '243 patent requires the use of an oligonucleotide having a sequence complementary to part of the protein-encoding sequence of the target mRNA. The claim does not require that the oligonucleotide have any sequences other than the sequence complementary to the protein-encoding sequence of the target mRNA. Therefore, those skilled in the art would have found it obvious to use an oligonucleotide having a sequence that is entirely complementary to part of the protein-encoding sequence of the target mRNA, and instant claim 65 is not patentably distinct from the '243 patent's claim 1.

Claim 66 depends on claim 64 and adds the limitation that "the oligonucleotide is at least 14 bases in length." Claim 2 of the '243 patent depends on claim 1 and adds the limitation that "said oligodeoxyribonucleotide comprises at least 14 nucleotides." In this context, "bases" and "nucleotides" are synonymous; the '243 patent's claim 2 is a specific embodiment encompassed by instant claim 66. For the same reason, the '243 patent's claim 3 is a specific embodiment of instant claim 67.

Claim 68 depends on claim 64 and adds the limitation that "the oligonucleotide is between 14 and 23 bases in length." As discussed above, claims 2 and 3 of the '243 patent recite oligodeoxyribonucleotides that are at least 14 and about 23 nucleotides long, respectively. These patent claims would have suggested the limitation of instant claim 68 to those of ordinary skill in the art. Claim 68 is therefore not patentably distinct from claims 2 and 3 of the '243 patent.

Claim 70 depends on claim 64 and adds the limitation that the target mRNA “encodes a hormone.” Claim 4 of the ‘243 patent depends on claim 1 and adds the limitation that the “targeted protein is follicle stimulating hormone.” The targeted protein in claim 1 is the protein encoded by the mRNA to which the synthesized oligodeoxyribonucleotide hybridizes. Thus, claim 4 of the ‘243 patent is a specific embodiment of the method defined by instant claim 70.

Claim 72 depends on claim 64 and adds the limitation that the oligonucleotide is an oligodeoxynucleotide. This limitation is met by the ‘243 patent’s claim 1.

Claims 73, 75, and 78 are independent claims that recite basically the same manipulative steps as claim 64 but include the limitation that the oligonucleotide “has enhanced resistance against nuclease enzymes” (claims 73 and 75) or “is stabilized against in vivo degradative enzymes” (claim 78). The ‘243 patent’s claim 1 states that the oligodeoxyribonucleotide is “in the form of a phosphotriester to limit degradation in vivo.” Since, as discussed above, phosphotriester modification is one method of “enhanc[ing] resistance against nuclease enzymes” or “stabiliz[ing] against in vivo degradative enzymes,” the ‘243 patent’s claim 1 is a specific embodiment of instant claims 73, 75, and 78.

Claims 74, 76, and 79 depend on claims 73, 75, and 78, respectively, and each adds the limitation that the “oligonucleotide is between 14 and about 23 bases in length.” As discussed above in reference to claim 68, this limitation is suggested by the ‘243 patent’s claims 2 and 3. Thus, claims 74, 76, and 79 are not patentably distinct from claims 2 and 3 of the ‘243 patent.

3. Double patenting: claim 69

Instant claim 69 is not patentably distinct from the '243 patent's claim 8. As with the claims discussed above, claim 69 is generic to the '243 patent's claim 8 in the sense that claim 8 requires use of a phosphotriester-stabilized oligodeoxyribonucleotide, while claim 69 is open to the use of any oligonucleotide.

However, unlike the other claims discussed, '243 claim 8 is also generic in a sense to instant claim 69. Claim 8 of the '243 patent is directed to a "method of controlling the infection of a host organism by a foreign organism," and recites an oligonucleotide complementary to mRNA from the "foreign organism," while instant claim 69 recites an oligonucleotide complementary to a "viral" mRNA.

Nonetheless, we conclude that instant claim 8 would have been obvious to those skilled in the art in view of '243 claim 8 and Summerton. Summerton teaches a method of treating viral disease by administering a nucleic acid complementary to the viral genome and modified so that it would cross-link with the viral genome. See the abstract ("[A]ntiviral complexes . . . would consist of a specially designed bifunctional crosslinking agent bound to a single-stranded segment of virus-specific nucleic acid (the carrier). Pairing this complex with its complementary target sequence would generate covalent interstrand crosslinks[,] . . . inactivating the target sequence.").

Since '243 claim 8 is directed to a method of treating infections by foreign organisms generally and Summerton teaches that viral infections can be treated with virus-specific nucleic acids, a person of ordinary skill in the art would have found it obvious to apply the method of claim 8 using a virus-specific oligonucleotide.

Therefore, '243 claim 8 is not patentably distinct from instant claim 69.

Other Issue

We have not applied the new grounds of rejection to claims 80-83. These claims require the steps of "selecting a plurality of base sequences that are complementary to [the target] messenger ribonucleic acid, providing a synthetic oligonucleotide corresponding to each of said base sequences, [and] selecting a preferred one of said synthetic oligonucleotides for inhibition of the expression of said target protein in a cell."

None of the claims of the '243 patent include the steps of providing a plurality of oligonucleotides and selecting a preferred one for use. Nor have we found such steps suggested by the prior art references in the record. However, we have not thoroughly reviewed the prior art of record. The examiner may be aware of prior art that suggests the limitations of claims 80-83 that do not appear in the '243 patent's claims.

On return of this application, if the examiner believes that claims 80-83 would have been obvious variants of any of the claims in the '243 patent, he should enter an appropriate rejection for obviousness-type double patenting.

Summary

We reverse the rejection for nonenablement and affirm the rejection of claim 71 for obviousness-type double patenting. We also enter new rejections of claims 64-70, 72-76, 78, and 79 for obviousness-type double patenting.

Time Period for Response

Regarding the affirmed rejection(s), 37 CFR § 41.52(a)(1) provides "[a]ppellant may file a single request for rehearing within two months from the date of the original decision of the Board."

In addition to affirming the examiner's rejection(s) of one or more claims, this decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .

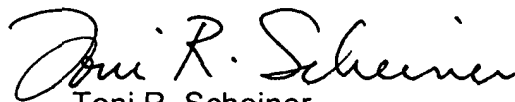
(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

Should the appellant elect to prosecute further before the examiner pursuant to 37 CFR § 41.50(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

No time period for taking any subsequent action in connection with this appeal
may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART, 37 CFR § 41.50(b)



Toni R. Scheiner
Administrative Patent Judge



Eric Grimes
Administrative Patent Judge



Lofa M. Green
Administrative Patent Judge

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