UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/013,139	01/25/2011	Bailin Li	PHI 3707+ (35290-041)	8178

26691 7590 08/23/2016

POTTER ANDERSON & CORROON LLP
ATTN: JANET E. REED, PH.D.
P.O. BOX 951
WILMINGTON, DE 19899-0951

EXAMINER	
KOVALENKO, MYKOLA V	

ART UNIT	PAPER NUMBER
1662	

MAIL DATE	DELIVERY MODE
08/23/2016	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BAILIN LI and KEVIN A. FENGLER

Appeal 2014-007516
Application 13/013,139[1]
Technology Center 1600

Before FRANCISCO C. PRATS, MELANIE L. McCOLLUM, and RYAN H. FLAX, *Administrative Patent Judges*.

FLAX, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134(a) involving claims directed to an isolated labeled polynucleotide that discriminates between soybean plants tolerant to or susceptible to herbicides. Claims 1, 2, 5, 6, and 28–33 are on appeal as rejected under 35 U.S.C. §§ 101 and 112, first paragraph. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

---

[1] The Real Party in Interest is E. I. du Pont de Nemours and Company. App. Br. 3.

STATEMENT OF THE CASE

The Specification discloses two variants of a full length cDNA of a soybean gene (i.e., Glyma19g1940.1), the differences between which determine whether a soybean plant is tolerant of herbicides or susceptible to herbicides. Spec. 1–2. The cDNA of the soybean tolerant of herbicides is identified in the Specification as SEQ ID NO: 124 and the cDNA of the soybean susceptible thereto is identified as SEQ ID NO: 125. Spec. 9. These two sequences are set forth at Figure 5B, which also identifies the nucleotide differences, or SNPs, between them which account for the difference in herbicide tolerance/susceptibility phenotype. *See, e.g.*, Spec. 138–39 (Table 23) and Figure 5B.

The Specification describes using nucleotide sequence primers and/or probes, for example, to identify and distinguish between these two genetic sequences and, therefore, the respective phenotypes. *See, e.g.*, Spec. 8–9, 29–30, 137–39 (Example 10), and Figure 2. The Specification describes labeling such primers or probes, e.g., radioactively or fluorescently, so as to be able to detect the polynucleotide and hybridized duplex thereby. *See, e.g.*, Spec. 19, 29–30, 32–37. Finally, the Specification describes using the genetic detection capability to identify soybean plants with the desired tolerance or susceptibility phenotypes and perpetuating such traits via segregation and introgression. Spec. 14.

The appealed claims can be found in the Claims Appendix of the Appeal Brief. Claims 1, 28, and 31 are independent claims. Claim 1 is representative reads as follows:

> 1. An isolated labeled polynucleotide, wherein the polynucleotide discriminates between a soybean that displays

> tolerance and a soybean that displays susceptibility to one or more herbicides, and wherein the polynucleotide detects at least one SNP within a genomic sequence set forth in SEQ ID NO: 124 or SEQ ID NO: 125.

App. Br. 20 (Claims App'x).

The following rejections are on appeal:[2]

Claims 1, 2, 5, and 6 stand rejected under 35 U.S.C. § 101. Final Action 3.

Claims 1, 2, 5, 6, and 28–33 stand rejected under 35 U.S.C. § 112, first paragraph, as failing under the written description requirement. Final Action 6.

Claims 1, 2, 5, 6, and 28–33 stand rejected under 35 U.S.C. § 112, first paragraph, as not enabled. Final Action 10.

DISCUSSION

The rejection of claims 1, 2, 5, and 6 under 35 U.S.C. § 101.

The Examiner determined that the claims read on a product of nature because "[t]he claimed labeled isolated polynucleotide [], would read on polynucleotides naturally occurring in [a] soybean genome," and "[o]ne skilled in the art would have recognized that radioactive isotopes, such as for example C14, occur naturally and get incorporated in biological molecules, such as polynucleotides, without the hand of man." Ans. 2–3. The Examiner's determination is premised on an incorrect interpretation of the claims.

---

[2] Rejections under 35 U.S.C. § 112, second paragraph, and § 103(a) were withdrawn by the Examiner in the Advisory Action dated Oct. 16, 2013.

"[T]he person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification. . . . To begin with, the context in which a term is used in the asserted claim can be highly instructive." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313–14 (Fed. Cir. 2005); *see also id.* at 1316 ("The Patent and Trademark Office ('PTO') determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction 'in light of the specification as it would be interpreted by one of ordinary skill in the art.'") (quoting *In re Am. Acad. of Science Tech Center*, 367 F.3d 1359, 1364 (Fed. Cir. 2004); *cf. In re Royka*. 490 F.2d 981, 984 (CCPA 1974) (reversing a Board decision, in part, for ignoring the specification in determining the claims' broadest reasonable interpretation).

We agree with Appellants (*see* App. Br. 8–10) that the claim term "labeled polynucleotide" is properly interpreted to require *intentional* tagging of the polynucleotide *for detection*. The way this term is used throughout the Specification corresponds to such a meaning. *See, e.g.*, Spec. 19; 29–30, 32–37. A naturally occurring polynucleotide would not have such an intentionally applied tag. The Examiner, moreover, does not direct us to any clear or specific evidence showing that labeled polynucleotides have been either detected in nature, or isolated therefrom.

For the above reasons, we reverse the § 101 rejection of the claims.

The rejection of claims 1, 2, 5, 6, and 28–33 under 35 U.S.C. § 112, first paragraph, as failing under the written description requirement.

The Examiner conceded, "Appellant describes isolated nucleic acids of the full length SEQ ID NO: 124, SEQ ID NO: 125, as well as two additional species that fall within the claimed genus" and "Appellant describes eight [actually twelve] nucleic acid sequences of polynucleotide markers that can detect at least one SNP within variants of SEQ ID NO 124 and 125" at, e.g., Example 10. Ans. 4, 13.

However, the Examiner determined the full subject matter encompassed by the claims is not described by the Specification because the claims "do not limit the length of the polynucleotide nor do they require that the region recognized by it be located within the sequences of SEQ ID NO: 124 or SEQ ID NO: 125" and "[b]ecause SEQ ID NO's 124 and 125 are both 3920 nucleotides long, and because the claimed SNPs are distributed throughout the sequence of SEQ ID NO's 124 and 125, the potential genus of markers encompassed by the claims is [too] large." Ans. 11–12.

Appellants contend the Specification's disclosure, per Examiner's concessions *supra*, provides sufficient disclosure for a person of ordinary skill in the art to identify the invention and "design" the claimed polynucleotides. App. Br. 11; Reply Br. 9–10. Appellants argue the claim language "wherein the polynucleotide detects at least one SNP," invokes the very types of detection for which the Specification provides disclosure and guidance. Reply Br. 9. Essentially, Appellants' argument is that the Specification described detecting either SEQ ID NO: 124 or 125, which determines herbicide tolerance or susceptibility, and the 12 SNPs defining

the phenotype-expressing differences therebetween, which amounts to a disclosure of possession of the claimed invention. We find Appellants' arguments persuasive.

The Federal Circuit explains, "[f]or generic claims, we have set forth a number of factors for evaluating the adequacy of the disclosure, including 'the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.'" *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (quoting *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005). The court also advised that the "doctrine never created a heightened requirement to provide a nucleotide-by-nucleotide recitation of the entire genus of claimed genetic material; it has always expressly permitted the disclosure of structural features common to the members of the genus." *Id.* at 1352.

Here, Appellants have gone to substantial lengths to illustrate the genetic differences (structural features) between herbicide-tolerant and herbicide-susceptible soybean plants, which they identify as definitively represented in SEQ ID NO: 124 and SEQ ID NO: 125. Identifying genetic sequences was well known as of the application date and the Specification undisputedly describes several known ways of doing so, e.g., via labeled probes and primers. With the knowledge of the sought genetic sequences (or defining portions thereof) in hand, the skilled artisan can find them. So long as such a polynucleotide can distinguish between the aforementioned genetic sequences and also identify an SNP between them, it would be recognized

by a person of ordinary skill in the art as the claimed invention, regardless of how long or short the isolated polynucleotide.[3]

For the above reasons we find the preponderance of the evidence supports Appellants' contentions and, so, we reverse the rejection of the claims for lack of written description.

The rejection of claims 1, 2, 5, 6, and 28–33 under 35 U.S.C. § 112, first paragraph, as not enabled.

The Examiner determined the Specification,

> while being enabling for isolated nucleotide sequences of SEQ ID NO: 124 and 125; and polynucleotide markers recognizing at least one SNP within those sequences, does not reasonably provide enablement for polynucleotide markers capable of discriminating between a soybean that displays tolerance to one or more herbicides and a soybean that displays susceptibility to one or more herbicides; nor does specification reasonably provide enablement for the methods of selecting herbicide tolerant or susceptible plants, or introgressing herbicide resistance into a soybean plant. 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.

---

[3] Similarly, Example 4 of the Written Description Training Materials (Rev. 1, Mar. 25, 2008) (http://www.uspto.gov/web/menu/written.pdf) (pages 13-16) explains that, in the context of expressed sequence tags, open "comprising" language including unnamed nucleotides flanking a sequence recited a claim does not lack descriptive support because each member of the genus necessarily contains the named sequence, and because adding any desired sequence would be within the knowledge and skill in the art. Here, the skilled artisan would similarly understand the claimed subject.

See Ans. 6. The Examiner also determined "[t]he claims rest on an implicit teaching that a single SNP would be a sufficient indicator of herbicide tolerance or susceptibility." Ans. 8. Finally, the Examiner determined "the range of herbicides encompassed by the claims is not limited to PPO inhibitors. The claims encompass mesotrione and isoxazole herbicides (both HPPD inhibitors) or 'one or more' unspecified herbicide. Yet the working examples teach specific SNPs only for the PPO inhibitors." Ans. 8.

The Examiner bears the burden of establishing that practicing the full scope of the claimed subject matter would have required undue experimentation. *In re Wright*, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993) ("[T]he 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.").

The appealed claims do not require determining the herbicide tolerance or susceptibility of a plant based on identification of a single SNP and such an interpretation is not reasonable. The claims recite an isolated labeled polynucleotide that can discriminate between an herbicide-tolerant and herbicide-susceptible soybean plant and can also detect at least one SNP in SEQ ID NO: 124 or SEQ ID NO: 125. These are two separately recited, albeit related, properties of the polynucleotide. As long as an isolated labeled polynucleotide can do each, it falls within the scope of the claims.

The Examiner concedes the Specification is "enabling for isolated nucleotide sequences of SEQ ID NO: 124 and 125," which suffices as enabling the claims because these polynucleotides are disclosed as

designating a soybean plant as herbicide-tolerant or herbicide-susceptible. Knowing the controlling gene and its key variations, developing complementary probes or primers thereto (*see, e.g.*, Spec. 116 (discussing designing Taqman® probe markers to distinguish between tolerant versus susceptible alleles)) was undisputedly well within the purview of the skilled artisan, even without the extensive disclosure of the Specification. And, we note the Specification discloses a series of examples illustrating the inventors' stepwise fashion, logic, and rationale in working from identifying soybean plants with herbicide tolerance or susceptibility, to identifying the genes responsible for the phenotype, to identifying the variations (SNPs) in those genes responsible for the phenotype, to using this genetic information to propagate the phenotypes in subsequent generations. Spec. 90–145 (Examples 1–12).

Finally, the Examiner's criticism of the working examples as relating to a single type of herbicide is unconvincing. The discussion of the working examples begins by studying several types of herbicides (e.g., Example 1's mesotrione and isoxazole, which are HPPD-inhibitors, and Example 3's sulfentrazone, which is a PPO inhibitor), but eventually focuses on PPO inhibitors. The same research reported for the PPO-type herbicides could also be conducted for HPPD-type or other type herbicides and, moreover, Appellants explain (App. Br. 16–17) the data relating to PPO tolerance or susceptibility is also likely applicable to HPPD tolerance/susceptibility because of co-localization of relevant genetic markers.

In any event, "[i]t is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an

unpredictable art." *In re Angstadt*, 537 F.2d 498, 502–03 (CCPA 1976). Although the disclosure must provide enablement commensurate with the scope of the claims, "[t]he enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins Univ. v. Cellpro Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998) (quoting *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991)).

Because the preponderance of the evidence supports Appellants' contention that, given the scope of the claims, level of skill in the art, and guidance provided by the Specification, any experimentation required to practice the present claims would be routine, we reverse the enablement rejection of the claims.

SUMMARY

The rejection of claims 1, 2, 5, and 6 under 35 U.S.C. § 101 as directed to non-statutory subject matter is reversed.

The rejection of claims 1, 2, 5, 6, and 28–33 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement is reversed.

The rejection of claims 1, 2, 5, 6, and 28–33 under 35 U.S.C. § 112, first paragraph, as not enabled is reversed

REVERSED