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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JOSEPH KOST, AHARON AZAGURI, and
YANA YUDILEVICH

Appeal 2020-001299
Application 14/198,701
Technology Center 3700

Before PHILLIP J. KAUFFMAN, ANNETTE R. REIMERS, and
TARA L. HUTCHINGS, *Administrative Patent Judges*.

REIMERS, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the Examiner’s decision to reject claims 1, 3–14, and 16–22. Claims 2, 15, and 23 have been canceled. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

¹ We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as B.G. Negev Technologies and Applications, Ltd. Appeal Brief (“Appeal Br.”) 3, filed June 20, 2019.

CLAIMED SUBJECT MATTER

The claimed subject matter relates to “methods of treating a subject afflicted with cancer, neoplasms or metastatic cancer using ultrasound.”

Specification dated May 30, 2014 (“Spec.”)² 1:10–12.

Claim 1, the sole independent claim on appeal, recites:

1. A method of treating a subject suffering from a disease or a disorder associated with hyperproliferating cells, said method comprising non-invasively administering to said subject ultrasound in a dose effective to selectively prevent the growth of said hyperproliferating cells or to eliminate said hyperproliferating cells in said subject, while substantially not affecting the cell viability of normal cells of said subject, resulting in a cell viability of less than 40% of said hyperproliferating cells and a cell viability of more than 60% of said normal cells,

wherein said ultrasound is administered at a transducer frequency ranging from 20 kHz – 200 kHz and a transducer intensity of between 4 W/cm² and 100 W/cm², wherein said intensity is pre-determined such that said intensity is lower than a cavitation threshold intensity for the selected frequency.

THE REJECTION

Claims 1, 3–14, and 16–22 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.³

² Although the May 30, 2014 Specification is not the original specification filed in the application, it appears identical in content with the original specification. The May 30, 2014 Specification appears to differ from the original specification only in that the May 30 Specification is printed in darker type and without line numbers erroneously inserted into the text. “Submission of Substitute Specification” dated May 30, 2014.

³ Rejections of claims 1, 3–14, and 16–22 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, and under 35 U.S.C. § 112, second paragraph, as indefinite, have been

ANALYSIS

The Examiner concludes that the Specification fails to enable the full scope of independent claim 1. Non-Final Act. 3; Ans. 4.⁴ “Although not explicitly stated in [35 U.S.C. §112, first paragraph], to be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’” *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993) (citing *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991)). Procedurally, the Patent and Trademark Office (“PTO”):

bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by the claim is not adequately enabled by the description of the invention provided in the specification [T]his 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.

Wright at 1561–62 (citing *In re Marzocchi*, 439 F.2d 220, 223–224 (CCPA 1971)); *see also* MANUAL OF PATENT EXAMINING PROCEDURE (“MPEP”) § 2164.04 (9th edition, rev. June 2020).⁵ Appellant contends that the Examiner has not articulated a reasonable and persuasive explanation as to why the scope of independent claim 1 is not adequately enabled by the Specification. *See generally* Appeal Br. 12–17; Reply Br. 3–9.⁶

withdrawn by the Examiner in the Answer. Examiner’s Answer (“Ans.”) 3, dated Oct. 3, 2019.

⁴ Non-Final Office Action (“Non-Final Act.”), dated Mar. 26, 2019.

⁵ All references to the MPEP will be to the most recent edition and revision, unless otherwise noted.

⁶ Reply Brief (“Reply Br.”), filed Dec. 2, 2019.

An examiner must weigh eight factors identified by our reviewing court in order to determine whether the Specification adequately enables a claim. These factors include the breadth of the claim, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples, and the quantity of experimentation necessary. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988); *see also* MPEP § 2164.01(a). The Examiner need not make explicit findings as to each of the eight factors. Nevertheless, the Examiner must reach a conclusion as to whether the Specification enables the claim based on a consideration of the evidence of record as a whole, viewed through the prism of these factors. MPEP § 2164.01(a).

As noted earlier,

there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility.

Vaeck, 947 at 496. In making this determination, the Examiner must consider not only the breadth of the claim at issue, but also the relative skill of those in the art, as well as the predictability or unpredictability of the art. *See id.* (affirming an enablement rejection of claim to a chimeric gene, at least in part, because the art was unpredictable and the class of bacteria by which the gene might be expressed was not yet thoroughly researched); *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1536–37 (Fed. Cir. 1987) (reversing an enablement rejection of a claim directed to a method of

fabricating a laser structure where the particular process alleged not to have been enabled, namely, brazing, was a predictable, well understood, mechanical process).

In this case, the Examiner has made findings concerning at least three of the *Wands* factors as those factors apply to independent claim 1, namely, the breadth of the claim, the amount of direction or guidance presented, and the presence or absence of working examples. In particular, the Examiner finds the amount of direction or guidance presented by the Specification inadequate compared with the breadth of claim 1. Non-Final Act. 3 (“[T]he [S]pecification does not disclose detail that [would have] enable[d] one of ordinary skill in the art to produce the claim[ed] result for the wide range of parameters in the claim.”); Ans. 4. Furthermore, the Examiner finds that all the working examples described in the Specification were performed using ultrasound radiation having a frequency of 20 kHz; and that, in addition, the examples discussed on pages 24–27 of the Specification, and summarized in Figures 2–3 of the subject application, used ultrasound radiation having intensities of either 4.15 W/cm², 4.38 W/cm², or 5.09 W/cm². Non-Final Act. 3; Ans. 5. As the Examiner correctly finds, these examples are restricted to the lower portions of the ranges of 20 kHz–200 kHz and 4 W/cm²–100 W/cm² recited in claim 1. Non-Final Act. 3; Ans. 6.

However, the Examiner’s findings relating to the state of the prior art, the relative skill of those in the art, and the predictability or unpredictability of the art, are less persuasive. The Examiner finds, for example, that because claim 1 was not rejected as unpatentable under 35 U.S.C. § 103, there is no prior art. Ans. 5. As Appellant correctly points out, obviousness under 35 U.S.C. § 103 and enablement under 35 U.S.C. § 112, first

paragraph, are separate inquiries. Reply Br. 2. Because they are separate inquiries, the absence of a rejection under 35 U.S.C. § 103 does not imply that there is no prior art or otherwise evidence the relative skill of those in the art. Furthermore, the Examiner finds that the art is unpredictable based on the alleged non-linearity of the experimental results summarized in Figures 2–3 of the Specification. This finding is not persuasive, because non-linearity alone, especially in a sample consisting of just three-to-six working examples, is not probative of a high degree of unpredictability.

Here, the Examiner concludes that the Specification fails to enable claim 1 based on findings regarding the breadth of the claims, the amount of direction or guidance presented, and the presence or absence of working examples, without adequately articulating persuasive findings as to the state of the prior art, the relative skill of those in the art, or the predictability or unpredictability of the art. Because the Examiner has not provided us with reliable findings as to the state of the prior art, the relative skill of those in the art, or the predictability or unpredictability of the art, we are not persuaded that an unreasonable amount of experimentation would have been required to make and use the subject matter of claim 1. In other words, the Examiner has not articulated a reasonable and persuasive explanation as to why the scope of independent claim 1 is not adequately enabled by the Specification.

Accordingly, for the foregoing reasons, we do not sustain the Examiner's rejection of claims 1, 3–14, and 16–22 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 3-14, 16-22	112, first paragraph	Enablement		1, 3-14, 16-22

REVERSED