

NOTE: This disposition is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

**IN RE: MANUEL MARQUEZ, SAMANTHA M.
MARQUEZ,**
Appellants

2017-2038

Appeal from the United States Patent and Trademark
Office, Patent Trial and Appeal Board in No. 12/726,158.

Decided: July 2, 2018

MATTHEW JAMES DOWD, Dowd Scheffel PLLC, Wash-
ington, DC, argued for appellants. Also represented by
LOUIS VENTRE, JR., Law Firm of Louis Ventre, Jr., Oak-
ton, VA.

AMY J. NELSON, Office of the Solicitor, United States
Patent and Trademark Office, Alexandria, VA, argued for
appellee Andrei Iancu. Also represented by NATHAN K.
KELLEY, MARY L. KELLY, THOMAS W. KRAUSE.

Before O'MALLEY, WALLACH, and HUGHES, *Circuit Judges*.
HUGHES, *Circuit Judge*.

Manuel and Samantha Marquez appeal the decision of the Patent Trial and Appeal Board affirming the rejection of U.S. Patent Application No. 12/726,158. The Board did not err in concluding that the application fails to enable claims 1–5, 7–8, 13, and 31–36. We therefore affirm.

I

Manuel and Samantha Marquez (collectively, Marquez) filed the '158 application, entitled “An Artificial Micro-Gland,” in March 2010. The application relates to artificial glands and various methods of creating them. The claimed artificial gland is an independent unit that comprises a membrane shell surrounding a “bio-reactor” that acts as a container or reservoir for products produced by the membrane. J.A. 82. For most of the claims on appeal, the membrane shell is composed of living cells. *See* J.A. 146–56. The application describes dozens of cells that can be used to form the outer membrane such as stem cells, skin cells, white cells, neurons, and kidney cells. In preferred embodiments, the bio-reactor enclosed by the membrane is a gas, liquid, or gel capable of containing whatever the membrane cells produce.

Claims 33 and 34 uniquely cover artificial glands with membrane shells made up of cellular components rather than cells. *See* J.A. 159–60. The application identifies a wide range of cellular components that can be formed into such membranes including enzymes, viruses, mitochondria, and chlorophyll.

According to the specification, the claimed artificial gland “holds the potential to play a vital role in tissue engineering, stem cell engineering, synthetic biology, and in the design of multicellular vehicles for food and pharmaceutical applications.” J.A. 85. The invention allegedly achieves these goals by providing a means to spatially arrange cells and subcellular units “through the use of external fields, microfluidic channels, and solvent-phase

partitioning.” *Id.* In addition, the invention allegedly provides a new means for “manipulating controlled releases or absorptions supporting biological activity.” J.A. 86.

In the Final Office Action, the examiner rejected all pending claims of the ’158 application on a number of grounds. The examiner rejected claims 1–4, 7, and 33–36 under 35 U.S.C. § 101 as being directed to patent-ineligible subject matter; rejected claims 1–5, 7–8, and 13 under 35 U.S.C. § 112 for lack of written description; rejected claims 1–5, 7–8, 13, and 31–36 under § 112 for lack of enablement; and rejected claims 1–2, 4–5, 7, and 33–36 as anticipated under 35 U.S.C. § 102(b), or, in the alternative, as obvious under 35 U.S.C. § 103(a).¹

Marquez appealed to the Board, which affirmed in part and reversed in part the examiner’s rejections. Ultimately, the Board affirmed the rejection of each claim on at least one ground. The Board affirmed the rejection of claims 1–4, 7, and 35 for claiming patent-ineligible subject matter; affirmed the rejection of claims 1–5, 7–8, and 13 for lack of written description; affirmed the rejection of claims 1–5, 7–8, 13, and 31–36 for lack of enablement; and affirmed the rejection of claims 1–2, 4, 7, and 35 as anticipated or obvious. In affirming the examiner’s rejection of all claims on appeal for lack of enablement, the Board noted that Marquez waived its challenge to the examiner’s enablement rejection of claims 1–5, 7–8, 13, 31–32, and 35–36.

¹ The America Invents Act (AIA), Pub. L. No. 112-29, effective September 16, 2012, amended §§ 102, 103, and 112 for claims with effective filing dates falling on or after March 13, 2013. Because Marquez’s application was filed before March 13, 2013, we refer to the pre-AIA versions of these provisions.

Marquez appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

II

We begin with the Board's rejection of claims 1–5, 7–8, 13, and 31–36 for lack of enablement. For a patent to issue, the application must describe the invention and “the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the” claimed invention. 35 U.S.C. § 112, ¶ 1 (2012). A claim lacks enablement if, at the effective filing date, a person of ordinary skill in the art could not practice the invention without “undue experimentation.” *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013). Whether undue experimentation is required is “a conclusion reached by weighing many factual considerations.” *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010) (quoting *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)).

We review the Board's ultimate enablement determination de novo and any underlying factual determinations for substantial evidence. *See Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1288 (Fed. Cir. 2012).

A

The Board did not err in rejecting claims 33 and 34 for lack of enablement. These claims recite artificial glands with membranes made up of cellular components. The Board determined that the '158 application does not provide guidance for how to form cellular components into a membrane capable of surrounding a bio-reactor. The application's only working examples of artificial glands use cells rather than cellular components. The Board further determined that, as of the filing date, the prior art

did not teach the creation of membranes from cellular components.²

Marquez argues that the specification discloses general methods of creating artificial glands out of whole cells that can be applied to creating membranes from cellular components. These methods make use of “basic factors” like “minimization of interfacial energy” and “electrostatic interaction” to form cells or cellular components into membranes. J.A. 31. The Board pointed out, however, that, although these same basic factors may influence whether cellular components adhere together to form a membrane, whole cells and cellular components may be affected differently by the manipulation of those forces. The Board’s position is not, as Marquez claims, that “positively-charged particles and negatively-charged particles would sometimes be attracted to each other, and sometimes not,” Appellant’s Reply Br. 25. Rather, the Board observed that manipulating electrostatic forces to form membranes out of cellular components as diverse as enzymes, viruses, and chlorophyll likely requires adjusting the known methods used to form membranes out of whole cells. The Board further noted that neither the ’158 application nor the prior art teach what sort of adjustments would be necessary.

The Board’s observations about differences between the formation of cell-based membranes and the formation of cellular component-based membranes are supported by substantial evidence. On that basis, the Board did not err

² On appeal, Marquez references a slideshow purporting to depict the claimed artificial gland with a membrane constructed from particles smaller than cells. Appellant’s Reply Br. 28 (reproducing J.A. 216). This slideshow post-dates the ’158 application’s filing date and there is no indication that it was ever presented to the Board. Accordingly, we do not consider this evidence.

in concluding that creating the artificial glands covered by claims 33 and 34 would require undue experimentation.³

B

We also agree with the Board that Marquez waived their challenge to the examiner's rejection of claims 1–5, 7–8, 13, 31–32, and 35–36 for lack of enablement.

In appeals from the Board, “we have before us a comprehensive record that contains the arguments and evidence presented by the parties’ and our review of the Board’s decision is confined to the ‘four corners’ of that record.” *In re Watts*, 354 F.3d 1362, 1367 (Fed. Cir. 2004) (quoting *In re Gartside*, 203 F.3d 1305, 1314 (Fed. Cir. 2000)). While the court retains case-by-case discretion over whether to apply waiver, we have routinely held that a party waives an argument when its failure to present the argument to the Board deprives the court of “the benefit of the [Board’s] informed judgment.” *In re NuVasive, Inc.*, 842 F.3d 1376, 1380 (Fed. Cir. 2016) (quoting *Watts*, 354 F.3d at 1367–68).

Here, Marquez failed to present the Board with any challenges to the examiner’s enablement rejection of claims 1–5, 7–8, 13, 31–32, and 35–36. These claims all relate to artificial glands with membranes composed of whole cells. Unlike for claims 33 and 34, the examiner’s rejection of these claims for lack of enablement was not based on the application’s failure to enable the creation of such artificial glands. Instead, the examiner determined that the application did not enable any laboratory or in

³ Because we affirm the Board’s determination that the ’158 application failed to enable the creation of the artificial glands covered by claims 33 and 34, we do not decide whether the Board erred in separately determining that the application failed to enable any use of those artificial glands.

vitro uses of these artificial glands. While the application mentions tissue engineering and controlled-release drug delivery as potential uses, neither the application nor the prior art disclose how the claimed gland could be used to accomplish those feats. Accordingly, in the examiner's view, undue experimentation would be required to use the claimed artificial glands.

In their appeal brief to the Board, Marquez did not address this part of the examiner's rejection. Marquez's brief devoted four pages to the examiner's enablement rejections in a section entitled "Claims 31 and 32 – Ground for rejection: Lack of Enablement." J.A. 730. While the section header refers to claims 31 and 32, the section's analysis discusses the formation of artificial gland membranes using cellular components, which makes clear that the argument concerned the examiner's rejection of claims 33 and 34.⁴ This section of Marquez's brief responds to the examiner's argument that the '158 application does not enable any uses of artificial glands made of cellular components. But Marquez only argued that the artificial glands made of cellular components could be used in the same research activities as the artificial glands made of whole cells. They never responded to the examiner's argument that the application failed to enable any uses of artificial glands made of whole cells.

Marquez now argues that they implicitly challenged the examiner's enablement rejections by (1) stating at the start of their brief that "all rejections are in error"; (2) challenging the examiner's construction of the term "gland" in the section of their brief discussing § 101 eligibility; and (3) citing, in the section of their brief discussing anticipation and obviousness, an expert decla-

⁴ The Board noted this error in its final decision and treated these arguments as directed to the rejections of claims 33 and 34 as well.

ration that asserts without explanation that the claimed invention is useful. But a broad assertion of error and arguments in response to other rejections did not indicate to the Board that Marquez intended to challenge the examiner's enablement rejections of claims 1–5, 7–8, 13, 31–32, and 35–36. On these facts, we conclude that Marquez waived any challenge to the rejection of these claims for lack of enablement.

III

For the foregoing reasons, we affirm the Board's rejection of claims 1–5, 7–8, 13, and 31–36 for lack of enablement. We have considered Marquez's remaining arguments but find them unpersuasive. Because we affirm the Board's rejection of every claim on appeal for lack of enablement, we need not address Marquez's challenges to the Board's other grounds for rejection.

AFFIRMED

COSTS

No costs.