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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ADNAN M. M. MJALLI, CHRIS WYSONG, JEROME BAUDRY, THOMAS SCOTT YOKUM, ROB ANDREWS, and WILLIAM K. BANNER[1]

Appeal 2014-002352
Application 12/901,133
Technology Center 1600

Before FRANCISCO C. PRATS, MELANIE L. McCOLLUM, and TAWEN CHANG, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an ensemble of compounds. The Examiner has rejected the claims as lacking subject matter eligibility, written description, and enablement. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

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[1] Appellants identify the real party in interest as TransTech Pharma, Inc. (Br. 3).

STATEMENT OF THE CASE

Claims 1–4 are pending and on appeal (Br. 5). The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(iv). Claim 1 is representative and reads as follows:

1. An ensemble of compounds useful for constructing a screening library, the ensemble comprising a plurality of compounds, wherein:

(a) each one of the plurality of compounds has a molecular weight of less than 1000 amu and has at least three pharmacophoric features;

(b) each one of the plurality of compounds corresponds to one or more pharmacophoric profiles, where a pharmacophoric profile is defined by a unique combination of at least three pharmacophoric features;

(c) at least two compounds of the plurality of compounds correspond to each pharmacophoric profile within a set of pharmacophoric profiles, where the set of pharmacophoric profiles includes a pharmacophoric profile for each possible unique combination of at least three pharmacophoric features; and

(d) for each pharmacophoric profile within the set of pharmacophoric profiles, the at least two compounds corresponding to each pharmacophoric profile do not have their at least three pharmacophoric features arranged in a spatially identical manner;

wherein each pharmacophoric feature is independently selected from the group consisting of a hydrophobe, a hydrogen bond acceptor, a hydrogen bond donor, a negatively charged group, and a positively charged group; and

wherein each one of the plurality of compounds is a chemical compound that exists in isolated form.

Claims 1–4 stand rejected under 35 U.S.C. § 101 "because the claimed invention is directed to non-statutory subject matter" and under 35 U.S.C. § 112, first paragraph, as failing to comply with both the written description and enablement requirements (Ans. 4).

STATUTORY SUBJECT MATTER

The Examiner finds:

> [T]he claims are directed to an "ensemble of compounds". With regard to the embodiment embracing a set of real-world molecules, the instant claims would necessarily encompass all naturally occurring molecules that meet the recited properties of a specified molecular weight cut-off and corresponding to one or more non-specific pharmacophoric profiles. As such, the claim would encompass naturally occurring articles that do not involve the hand of man. Although the instant claims have been amended to recite "wherein each one" exists in an isolated form, there is no alteration or modification made to any compound contained within an ensemble. As such, the scope of the instant claims remains open to an expansive scope of compounds that are selected only by proposed pharmacological properties and, therefore, embrace those naturally occurring compositions that meet said pharmacological properties.

(Ans. 5–6.)

Principles of Law

In *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, the Supreme Court discussed their prior holding in *Funk Brothers Seed Co. v. Kalo Inoculant Co.,* 333 U.S. 127 (1948). *Myriad*, 133 S. Ct. 2107, 2117 (2013). In particular, the Supreme Court stated:

> In *Funk Brothers* . . . , this Court considered a composition patent that claimed a mixture of naturally occurring strains of bacteria that helped leguminous plants take nitrogen from the air and fix it in the soil. The ability of the bacteria to fix nitrogen was well known, and farmers commonly "inoculated" their crops with them to improve soil nitrogen levels. But farmers could not use the same inoculant for all crops, both because plants use different bacteria and because certain bacteria inhibit each other. Upon learning that several nitrogen-fixing bacteria did not inhibit each other, however, the patent applicant combined them into a single

> inoculant and obtained a patent. The Court held that the composition was not patent eligible because the patent holder did not alter the bacteria in any way. . . . His patent claim thus fell squarely within the law of nature exception.

Id. (citations omitted).

In *Myriad*, the Supreme Court held: "Myriad found the location of the BRCA1 and BRCA2 genes, but that discovery, by itself, does not render the BRCA genes 'new ... composition[s] of matter,' § 101, that are patent eligible." *Id.* "Nor are Myriad's claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule." *Id.* at 2118.

Analysis

Appellants argue "that the Examiner erred by failing to give weight to two key features of the claimed invention: (1) that claim 1 recites an 'ensemble...useful for constructing a screening library'; and (2) that each chemical compound in the claimed ensemble 'exists in isolated form.'" (Br. 9.) We are not persuaded.

With regard to the recitation in claim 1 that "each one of the plurality of compounds is a chemical compound that exists in isolated form," we note that the Supreme Court did not find this argument persuasive, even where the isolation "severs chemical bonds." *Myriad*, 133 S. Ct. at 2118. Here, Appellants have not shown that any structural change to the compounds is required by the isolation.

With regard to the recitation in claim 1 of an "ensemble of compounds useful for constructing a screening library," we conclude that Appellants have not adequately explained how this language distinguishes the present

case from *Funk Brothers*, which the Supreme Court stated "fell squarely within the law of nature exception." *Id.* at 2117.

Conclusion

Supreme Court precedent supports the Examiner's position that representative claim 1 is directed to non-statutory subject matter. We therefore affirm the rejection under 35 U.S.C. § 101.

WRITTEN DESCRIPTION

The Examiner finds that the claims contain "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention" (Ans. 6).

Principles of Law

A "disclosure that names one species encompassed within a genus will adequately describe a claim directed to that genus only if the disclosure 'indicates that the patentee has invented species sufficient to constitute the gen[us].'" *In re Curtis*, 354 F.3d 1347, 1358 (Fed. Cir. 2004) (citing *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 967 (Fed. Cir. 2002)).

Analysis

Appellants argue that "it is clear from the specification that the inventors were in possession of an ensemble of synthesized (i.e., 'real world') chemical compounds as of the filing date of the application" (Br. 10). Thus, Appellants argue that "the specification provides proper written description support for the claimed invention" (*id.*). However, Appellants' argument does not address the Examiner's concern that they

have "not demonstrated support for the full scope of the claimed invention" (Ans. 10).

Conclusion

The evidence supports the Examiner's conclusion that representative claim 1 lacks written descriptive support. We therefore affirm the written description rejection.

ENABLEMENT

The Examiner finds that the claims contain "subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention" (Ans. 7).

Principles of Law

"[T]o 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).

> The enablement requirement ensures that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims. The scope of the claims must be less than or equal to the scope of the enablement. The scope of enablement, in turn, is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation.

National Recovery Techs. Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195–96 (Fed Cir. 1999).

Some experimentation, even a considerable amount, is not "undue" if, e.g., it is merely routine, or if the specification provides a reasonable amount

of guidance as to the direction in which the experimentation should proceed. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

> Factors to be considered in determining whether a disclosure would require undue experimentation . . . include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id.

Analysis

Appellants argue "that the specification provides ample description of how the ordinarily skilled artisan would synthesize compounds contained in the ensemble" (Br. 11). In addition, Appellants argue "that the Examiner has made no reference at all to the various *Wands* factors, and has engaged in no effort to conduct fact-finding on any relevant *Wands* factors" (*id.*). We are not persuaded.

First, we conclude that the record reflects that the Examiner has considered at least some of the *Wands* factors (Ans. 7–8). In this situation, we do not agree that the failure to specifically refer to them as the *Wands* factors is dispositive.

In addition, we note that the "examiner does not disagree with the appellant[s] in that there are routine and art recognized techniques for synthesizing and manufacturing some of the compounds encompassed under the instant claims" (*id.* at 11). Appellants do not adequately explain why the Examiner erred in finding:

> [T]he claims are open to, and therefore encompass, any and all compounds that fit a pharmacological profile derived by a

> computer modeling technique; however artisans are left to their own devices as far as figuring out how to synthesis the compounds themselves. As such, an artisan would turn to art recognized techniques of compound synthesis. However, the claims embrace all in silico generated, hypothetical compositions selected by pharmacological properties alone, which may or may not be physically realizable, even by reliance on routine synthesis techniques known in the art. As such, an artisan would have to rely on trial and error experimentation in order to make all compounds that may be selected in accordance with a pharmacological profile.

(*Id.* at 11–12.)

Conclusion

The evidence supports the Examiner's conclusion that representative claim 1 is not enabled. We therefore affirm the enablement rejection.

TIME PERIOD FOR RESPONSE

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

AFFIRMED