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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JOHN D. BLIZZARD and ROBERT L. MCKELLAR [1]

Appeal 2019-005127
Application 15/872,516
Technology Center 1600

Before JEFFREY N. FREDMAN, DEBORAH KATZ, and JOHN G. NEW, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the inventors, John D. Blizzard and Robert L. McKellar, as the real parties-in-interest. App. Br. 1.

SUMMARY

Appellant files this appeal under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of claim 11 as lacking enablement under 35 U.S.C. § 112(a).

Claim 11 also stands rejected as unpatentable under the nonstatutory doctrine of obviousness-type double patenting over claim 1 of U.S. Patent No. 9,902,744 B2 ("the '744 patent")

We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

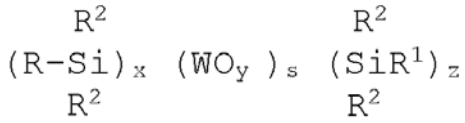
NATURE OF THE CLAIMED INVENTION

Appellant's invention is directed to a method of treating bacteria, viruses, algae, mildew, or mold with a silanol-containing antimicrobial compound. Spec. 1, ll. 13–19.

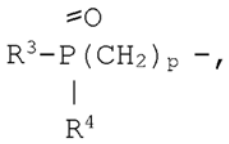
REPRESENTATIVE CLAIM

Claim 11 is the sole claim on appeal and recites:

> 11. A method of reducing the number of bacteria, viruses, algae, mildew or mold, said method comprising:
>
> i. providing bacteria, a virus, algae, mildew, or mold to be reduced in numbers;
>
> ii. treating said bacteria, virus, algae, mildew or mold using a composition of matter having the average general formula:

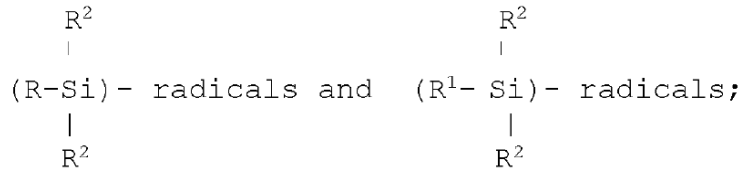


wherein the average molar ratio of x:y:z is 0.25–3:4:0.25–3, with the proviso that there is present at least one RSi- unit and at least one R′Si unit and W is independently selected from the group consisting essentially of Si, Ti, and Zr, and Al, wherein R is a cure functionality based on the chemistry selected from the group consisting of glycidoxy, amino, acrylamide, methacrylamide, acrylate, methacrylate, C_2– C_8 alkenyl, mercapto, ester, isocyanato, epoxycyclohexyl, carboxylic acid, and



wherein p has a value of from 1 to 6 and R^3 is selected from the group consisting of hydroxyl and alkoxy groups having 1 to 4 carbon atoms;

R^2 is independently selected from the group consisting of hydroxyl groups,

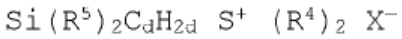


s has a value of about 1 to 5;

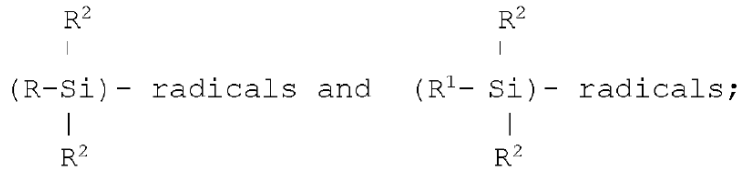
y has a value of 4;

R^1 is selected from the group consisting of:

i. a sulfonium salt of the formula

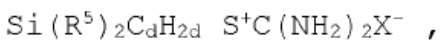


in which R^4 is independently an alkyl group or aralkyl group wherein there is a total of less than 60 carbon atoms in the molecule, R^5 is independently selected from the group consisting of hydroxyl groups,

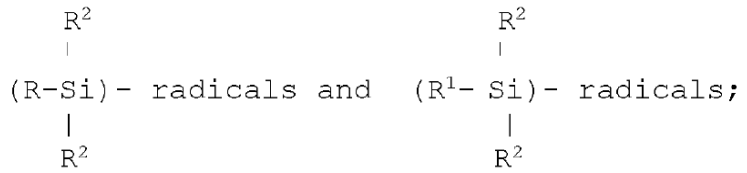


d is an integer of 1 or greater and X^- is a water soluble monovalent anion;

ii. an isothiuronium salt of the formula

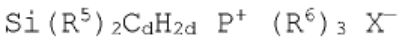


R^5 is independently selected from the group consisting of hydroxyl groups,



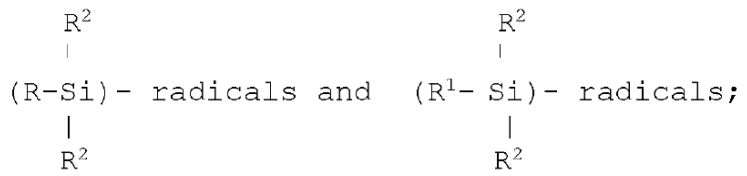
d is an integer of 1 or greater and X^- is a water soluble monovalent anion;

iii. a phosphonium salt of the formula



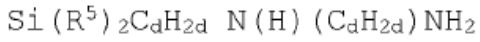
in which R^6 is independently selected from an alkyl group or aralkyl group wherein there is a total of less than 60

carbon atoms in the molecule, R^5 is independently selected from the group consisting of hydroxyl groups,

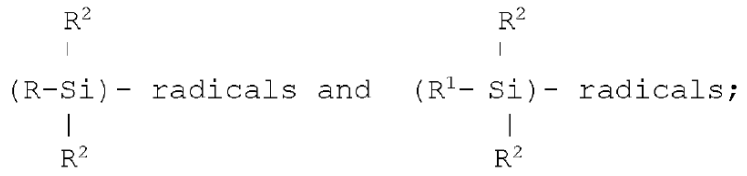


d is an integer of 1 or greater and X^- is a water soluble monovalent anion and;

iv. an amine of the formula



wherein R^5 is independently selected from the group consisting of hydroxyl groups,



in which d is an integer of 1 or greater, wherein (WO_y) is derived from $W(OR^7)_4$ wherein (OR^7) is independently selected from the group consisting of

i. $-OCH_3$,
ii. $-OCH_2CH_3$,
iii. $-OCH(CH_3)_2$,
iv. $-O(CH_2)_3(CH_3)_2$,
v. $-OCH_2CH(CH_3)_2$,
vi. –O(2-ethylhexyl),
vii. acetoxy, and,
viii. oximo.

Claims App’x.

ISSUES AND ANALYSIS

We agree with, and expressly adopt, the Examiner's findings, reasoning, and conclusion that the claim is not enabled by the Specification. We decline to adopt the Examiner's findings and conclusion with respect to the obviousness-type double patenting rejection. We address below the arguments raised by Appellant.

A. 35 U.S.C. § 112(a), lack of enablement

Issue

Appellant argues that it is the Examiner's burden to show that the claimed compounds do not kill a variety of bacteria, viruses, algae, mildew, and mold, and in the absence of evidence to the contrary, Appellant is entitled to the full scope of the claim. App. Br. 2.

Analysis

The Examiner determines "the specification, while being enabling for treating *E. coli* bacteria and by reducing the number of bacteria, does not reasonably provide enablement for treating and reducing any or all bacteria, viruses, algae, mildew and mold as generically embraced in the claim language." Final Act. 2–3. In making the determination, the Examiner addressed the factors set forth in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). *Id.* at 3.

The Examiner begins with reviewing the nature of the invention, the state of the prior art, and the predictability of the art. *See* Final Act. 3–13.

With respect to the nature of the invention, the Examiner finds "[t]he instant compounds are disclosed to have inhibiting activity with varying degree in panel of three laboratory strains of bacteria … and it is recited that the instant compounds are therefore useful in treating and preventing all bacterial infections for which applicants provide no competent evidence." *Id.* at 5.

With respect to the state of the art, the Examiner finds that "one of skill in the art is unable to fully predict possible results from the method of uses of the compounds of formula (I) due to the unpredictability of the role of the instantly claimed compounds." Final Act. 11–12. The references cited by the Examiner indicate that identifying antimicrobial compounds requires extensive experimentation, as "susceptibility to antimicrobials is no longer predictable." *Id.* at 11. For example, Theuretzbacher discloses that "[n]early dry antibacterial and antifungal R&D pipelines will fall short of addressing currently untreatable infections caused by [multi-drug resistant] bacteria and fungi." Theuretzbacher, U. and Mouton, J. W., *Update on antibacterial and antifungal drugs — can we master the resistance crisis?* 11 CURRENT OPINION IN PHARMACOLOGY 429, 432 (2011) ("Theuretzbacher").[2]

With respect to the predictability of the art, the Examiner finds that "[p]harmacological activity in general is a very unpredictable area." Final Act. 12. The Examiner finds that Appellant has "not provided any

[2] Theuretzbacher was introduced into the record by the Examiner in the Non-Final Rejection dated February 21, 2018.

competent evidence or disclosed tests that are highly predictive for the use of the instant compounds." *Id.* at 12–13.

The Examiner finds the instant claim embraces "treating any or all bacteria, viruses, algae, mildew and mold with a huge genus [of the compound] of formula I." *Id.* The Examiner finds the "Specification has no working examples to show treating any or all bacteria, viruses, algae, mildew and mold." *Id.* Although the Specification discloses two antimicrobial tests performed against *E. coli* disclosed, the Examiner finds the Specification does not show that "the genus of [the] compound of formula of claim 11 is equally effective against all bacteria, viruses, algae, mildew and mold … as generically embraced in the instant claim[]." *Id.* at 18.

The Examiner concludes with the quantity of experimentation needed to support the broad use of the claimed compounds. Final Act. 13. The Examiner finds "[d]ue to the unpredictability in the pharmaceutical art, … each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* … screening to determine which compounds exhibit the desired pharmacological activity and which method of use would benefit from this activity." *Id.* The Examiner determines that it would be "an undue burden to one skilled in the art since there is inadequate guidance given to the skilled artisan." *Id.* Accordingly, the Examiner concludes that undue experimentation would be required to perform Appellant's invention, and consequently, the Specification does not enable the full scope of the claim. *See id.* at 15–16.

Appellant argues that the claimed method is "quite easy and straightforward" once the compounds have been identified. App. Br. 2.

Appellant contends that the method is reduced to the simple steps of 1. providing any one of bacteria, virus, algae, mildew or mold, and 2. treating with the claimed compositions. *Id.* Appellant argues that the Examiner's citations are limited to methods of therapeutic treatment as opposed to the "new and novel" compounds of the claim. Finally, Appellant contends:

> the compounds as known to the Appellants do indeed kill a variety of bacteria, viruses, algae, mildew and mold, and unless the examiner can show by some publication or other prior art that such is not the case, then the Appellant is entitled to the scope set forth in the instant claim.

Id.

We are not persuaded. "[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). In *Wright*, our reviewing court explained:

> 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.

999 F.2d at 1561–62.

Appellant does not dispute the Examiner's findings that the claim has a very broad scope, i.e., treating any bacteria, virus, algae, mildew or mold.[3] *See* App. Br. *supra.* Appellant argues that the Examiner's findings regarding the state of the art are limited to "therapeutic treatments." *See id.* at 2. However, Appellant does not provide evidence contradicting the Examiner's findings regarding the unpredictability of antimicrobial compounds, given the state of the art of increasing anti-bacterial and anti-fungal resistance. Moreover, the broad scope of the claim encompasses any application of the claimed compounds, including both therapeutic treatment and non-therapeutic treatments. Neither claim 11 nor Appellant's Specification provide any guidance with respect to the specific environment for applying the compounds, nor any limitation on the effective amount or concentration of the compounds depending on the mode of application. Contrary to Appellant's arguments, we find the Examiner has set forth a reasonable explanation that the scope of protection provided by that claim is not adequately enabled by the Specification. Therefore, the burden shifts to Appellant to provide "suitable proofs" that the Specification is enabling. *See* 999 F.2d at 1561–62.

We find that Appellant has not provided sufficient evidence that the Specification is enabling. Appellant's Specification provides two working examples of reducing the number of *E. coli* bacteria by treating with two specific compositions encompassed by the claim. Spec. 9. These two tests

[3] We note the extreme breadth of the microbes encompassed by the claim, none of which, other than *E. coli*, is described in the Specification. *See* Spec. *supra*.

alone cannot support enablement for a wide range of bacteria alone, much less the additionally claimed viruses, algae, mildew, or mold. Moreover, Appellant has not provided any other evidence that the mode of action of the compound of claim 11 applies to the broad range of microbes recited, or that the biochemical assay recited in the Specification is broadly applicable to microbes other than *E. coli*. *See* Ans. 20. "Attorneys' argument is no substitute for evidence." *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1581 (Fed. Cir. 1989).

Appellant argues "[a] patent application is not a research paper and therefore, does not require extended standards or kill data on every species as claimed." App. Br. 2. We agree. However, our reviewing court explained:

> Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997) (internal citations omitted). As discussed above, the Specification does not provide reasonable detail to enable members of the public to understand and carry out the full scope of claim 11. Accordingly, we affirm the Examiner's rejection that claim 11 is unpatentable under 35 U.S.C. § 112(a) for lack of enablement.

B. Nonstatutory Obviousness-Type Double Patenting

Issue

Appellant argues "[t]he cited patent claims novel compounds and the instant application claims a method of use of those compositions." App. Br. 3.

Analysis

The Examiner finds the claim 11 is not patentably distinct from claim 1 of the '744 patent "because the method of us[ing] the compound embraced in the instant claim 11 is obvious over the composition claims of the same compound." Final Act. 27. The Examiner determines one skilled in the art "would look beyond the issued claims into the specification for utility and claim construction purposes and would arrive at the instant method of use for treating *E. coli* infection." *Id.*

Obviousness-type double patenting requires comparing the claims of the '744 patent to claim 11 of the instant application. "Because nonstatutory double patenting compares earlier and later claims, an earlier patent's disclosure is not available to show nonstatutory double patenting." *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1385 (Fed. Cir. 2003). In *Geneva*, our reviewing court found that the claims of the earlier patent did not adequately disclose the patentable bounds of the invention, and therefore, the court examined the patent specification to ascertain any overlap in claim scope. *See id.* In contrast, claim 1 of the '744 patent adequately discloses the patentable bounds of the invention. *See* '744 patent, cols. 7–9, ll. 40–11. Namely, claim 1 of the '744 patent recites the identical compounds of claim 11 of the instant application. Even if we

review the '744 patent's specification to determine the utility of the compounds of claim 1, we find that the mere disclosure of reducing *E. coli* using two compounds within the genus would not enable reducing the wide range of microbes recited by claim 11, as discussed at length above. Nor would the disclosure of reducing *E. coli* make obvious the treatment of any bacteria, virus, algae, mold, or mildew. Because claim 1 of the '744 patent neither anticipates nor makes obvious claim 11 of the instant application, we reverse the Examiner's rejection under obviousness-type double patenting.

CONCLUSION

The rejection of claim 11 as unpatentable under 35 U.S.C. § 112(a), is affirmed.

The rejection of claim 11 as unpatentable under the doctrine of nonstatutory obviousness-type double patenting is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1).

AFFIRMED

Claim Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
11	112(a)	Enablement	11	
11		Nonstatutory Double-Patenting		11
Overall Outcome			11	