2019 PAT. APP. LEXIS 9312

Patent Trial and Appeal Board

October 10, 2019, Decided

Appeal 2019-000284 ; Application 11/165,200 ; Technology Center 1600

USPTO Bd of Patent Appeals & Interferences; Patent Trial & Appeal Bd Decs.

Reporter
2019 PAT. APP. LEXIS 9312 *

Ex parte TOHRU KOUDA, CHIKA MORISHIMA, KENTARO INAGAWA, and SHINOBU SEKI

Notice:

[*1] ROUTINE OPINION. Pursuant to the Patent Trial and Appeal Board Standard Operating Procedure 2, the opinion below has been designated a routine opinion.

Core Terms

sleep, wave, slow, insomnia, patient, glycine, shorten, stress, duration, latency, comprise, disorder, teach, composite, encompass, species, deep

Panel: Before ERIC B. GRIMES, ULRIKE W. JENKS, and MICHAEL A. VALEK, Administrative Patent Judges.

Opinion By: ULRIKE W. JENKS

Opinion

JENKS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to *35 U.S.C.* § 134(a), Appellant [1] appeals from the Examiner's decision to reject claims as obvious. We have jurisdiction under *35 U.S.C.* § 6(b).

We REVERSE.

STATEMENT OF THE CASE

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[1] We use the word Appellant to refer to "applicant" as defined in *37 C.F.R. § 1.42(a)*. Appellant identifies the real party in interest as Ajinomoto Co., Inc. Appeal Br. 2. We have considered, and herein refer to, the Specification of June 24, 2005 ("Spec."); Non-Final Office Action of Nov. 15, 2017 ("Non-Final Act."); Appeal Brief of May 16, 2018 ("Appeal Br."); Examiner's Answer of July 25, 2018 ("Ans."); Reply Brief of Sept. 25, 2018 ("Reply Br."); and prior Board Decision Appeal 2013-007339 of Mar. 23, 2016 ("Dec.").

According to the Specification, "present-day life tends to be sympathetic dominant due to mental stress and the like." Spec. 11:24-25. The ingestion of glycine right before bedtime is helpful in order "to induce shift to slow wave sleep (deep sleep), [which] improves the quality of sleep **[*2]** during sleep hours, appropriately controls visceral activity during sleep and encourages natural sleep by allowing dominant action on [the] parasympathetic [nervous system] that acts opposite to sympathetic dominant [nervous system]." *Id.* at 12:1-12:4.

CLAIMED SUBJECT MATTER

Claims 12, 24-26, 28-34, and 36-40 are on appeal, and can be found in the Claims Appendix of the Appeal Brief. Claim 12 and 24 are representative of the claims on appeal, and read as follows:

> Claim 12: A method of shortening slow wave sleep latency, comprising administering a composition comprising glycine to a human subject in need of such shortening, wherein the composition comprises 5 g or less of amino acids other than glycine.
>
> Claim 24: A method of extending the duration of slow wave sleep in early stage sleep, comprising administering a composition comprising glycine to a human subject in need of such extension, wherein the composition comprises 5 g or less of amino acids other than glycine.

Appeal Br. 25 (Claims Appendix).

Appellant seeks review of the following rejections made by Examiner:

1. Claims 12, 24, 25, 28-31, 33, and 36-39 under *35 U.S.C.* § 103(a) as unpatentable over Komissarova **[*3]** [2] and Kryger. [3]

2. Claims 26 and 34 under *35 U.S.C.* § 103(a) as unpatentable over Komissarova, Kryger, and Blum. [4]

3. Claims 32 and 40 under *35 U.S.C.* § 103(a) as unpatentable over Komissarova, Kryger, and Choi. [5]

OPINION

Since all three rejections rely upon the teaching of Komissarova and Kryger regarding the administration of glycine for the purpose of "shortening slow wave sleep latency" or "extending the duration of slow wave sleep in early stage sleep," the same issue is dispositive for all of these rejections. Thus, we will consider the rejections together.

Examiner finds that Komissarova teaches pharmaceutical preparations containing glycine that have anti-stress or stress protective and nootropic effects, as well as exhibiting sedative qualities. Non-Final Act. 7 (citing Komissarova 2:38-45, 6:25-29, 12:54-59, 13:1-45); Ans. 4-5. Examiner acknowledges that Komissarova "does not explicitly **[*4]** teach the administration of the glycine containing composition to human subjects in the claimed amounts." Non-Final Act. 7; Ans. 4. Examiner looks to Kryger for teaching "that stress is probably the most frequent cause of a transient or short term insomnia, with the stress arising from positive or negative life events or cognitive expectancies." Non-Final Act. 8; Ans. 4. Based on these combined teachings, Examiner concludes that it would have been obvious to administer glycine to patients experiencing stress related transient insomnia because glycine is taught to reduce stress. Non-Final Act. 8; Ans. 4.

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[2] Komissarova et al., US 5,643,954, issued July 1, 1997 ("Komissarova").

[3] *Principles and Practice of Sleep Medicine*, 3rd ed., editors Meir H. Kryger, Thomas Roth, and William C. Dement, 627-28 (2000) ("Kryger").

[4] Blum et al., *Synergy of Ethanol and Putative Neurotransmitters: Glycine and Serine*, SCIENCE 176:2935-94 (1972) ("Blum").

[5] Choi et al., US 6,416,795 B1, issued July 9, 2002 ("Choi").

Examiner finds that the claims define a patient population to whom the claimed glycine treatment is administered, namely patients that are in need of shortened slow wave sleep latency or extended duration of slow wave sleep. Non-Final Act. 6. According to Examiner, "[t]he difference in the basis of the definitions does not patentably distinguish the claimed patient populations from those suffering from insomnia." Non-Final Act. 6; Ans. 9. Specifically, Examiner finds that "[t]he patient population encompassed by the claims is broader than indicated by applicants and can even be broader **[*5]** than subjects suffering from insomnia." Non-Final Act. 6; *see also* Ans. 10 ("the patient population of the claimed method is quite broad and substantially overlaps with the patient population to whom glycine would be administered").

Appellant contends that "a skilled artisan at the time of present invention: (i) would not have understood all insomnia patients to be in need of improved [slow wave sleep (SWS)], and (ii) would not have reasonably expected that an insomnia treatment would be effective in improving SWS." Appeal. Br. 9 (citing Bannai Declaration, [6] AASM, [7] Kotorii, [8] and Pagel [9]). Specifically, Appellant contends that "[a] skilled artisan would have understood that insomnia is a broader concept than SWS." Appeal Br. 11 (citing Bannai Decl. P 22).

This is the second time rejected claims based on this application have come before us for review. In our prior decision, in Appeal 2013-007339 **[*6]** (entered March 23, 2016), we affirmed obviousness rejections over Komissarova either alone or in conjunction with Blum. *See* Dec. 1-12. As explained in that decision, "Examiner has identified a group of patients (a species), those suffering from stress, that are administered glycine." Dec. 6 (citing *Aventis Pharma Deutschland GmbH v. Lupin, Ltd., 499 F.3d 1293, 1300 (Fed. Cir. 2007)* (disclosure of a species in the prior art renders a later claim to a genus encompassing that species unpatentable)). Since that decision, the claims have been amended to recite a different patient population. The present claims no longer recite a broad genus, but instead recite a narrower species. Specifically, the presently claimed patient population is directed to those requiring either "shortening slow wave sleep latency" or "extending the duration of slow wave sleep in early stage sleep."

The contention lies with the interpretation of the relevant patient population. The Specification discloses that "[t]he concept represented by what is called a 'sleep disorder' and 'insomnia' is also included in the concept of the aforementioned 'deep sleep disorder.'" Spec. 11:1-3, *see also* 9:23-10:25. The Specification broadly defines "deep sleep disorder" to include conditions such as insufficient **[*7]** sleep hours due to mental and/or physical stress, and to also encompass "shallow sleep, difficult shift to slow wave sleep indicating profound sleep after sleep onset" among others. *Id.* at 9:23-11:3, *see also* 24:2-4 ("the time from the lights-out to slow wave sleep considered to represent deep sleep was shortened and extension of the slow wave sleep in the early stage of sleep onset was confirmed"). In other words, "deep sleep disorder" and "insomnia" represent a genus of patients encompassing different etiologies that manifest in the disruption of sleep. *Id.* at 9:23-11:3. Disruption in achieving slow wave sleep or maintaining slow wave sleep are two species out of a broader genus of conditions leading to insomnia. *Id.* at 9:23-11:3, 24:2-4.

Examiner finds that "[t]he definition of slow wave sleep or delta sleep [is] related to the physiological characteristics of various stages of sleep. Being in need of shortened slow wave sleep latency or extended duration of SWS defines the patient population to whom the claimed treatment (glycine) is administered." Non-Final Act. 6; Ans. 9 (short wave sleep is known to be the "most restorative stage of sleep"). Because "[i]nsomnia is defined as insufficient **[*8]** sleep or not feeling rested or a complaint of the inability to either initiate or maintain sleep. . . .

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[6] Declaration under *37 C.F.R. § 1.132* by Makoto Bannai signed Dec. 22, 2016 ("Bannai Decl.").

[7] *The international classification of sleep disorders*, AMERICAN ACADEMY OF SLEEP MEDICINE (2001) ("AASM").

[8] Kotorii, *Effect of psychoactive drugs on sleep in insomnia*, JAPANESE J. CLIN. PSYCHOPHARM. 14:401-10 (2011) ("Kotorii").

[9] Pagel and Parnes, *Medications for the Treatment of Sleep Disorders: An Overview*, PRIMARY CARE COMPANION J. CLIN. PSYCHIATRY 3:118-25 (2001) ("Pagel").

Therefore patients suffering from insomnia fall within the scope of the patient population of the instant claims." Ans. 9.

On this record, we find that Appellant has the better position. We agree with Appellant that insomnia is a broad concept encompassing all complaints about sleep. Appeal Br. 10 (citing Bannai Decl. P 20). We understand that sleep has many stages. However, not all sleep disruptions leading to insomnia affect the same stage of sleep. *See* Bannai Decl. PP 20-24 (citing AASM, Kotorii, and Pagel). Appellant explains that patients presenting with insomnia do not necessarily need improved slow wave sleep, as evidenced by successfully treating insomnia with sleep aids that either do not have an effect on slow wave sleep or may even disrupt slow wave sleep. Reply Br. 2 [10] (citing Bannai Decl. PP 1-4, 19, 23); Appeal Br. 11. Here, Appellant has presented a sufficient evidentiary basis from which to conclude that not all insomnia has the same underlying etiology, therefore, treatment with **[*9]** glycine would not necessarily have the same effect on all insomnia patients. Reply Br. 13; Bannai Decl. P 23; *see generally* AASM. In other words, administering glycine to treat a patient with stress-induced insomnia, as taught by the cited prior art, will not necessarily shorten slow wave sleep latency or extend the duration of slow wave sleep, because the underlying etiology of the patient's insomnia may not be associated with slow wave sleep. Nor is there evidence of record connecting stress-induced insomnia to slow wave sleep such that it would be obvious that glycine could also be used to shorten slow wave sleep latency or extend the duration of slow wave sleep, as claimed.

CONCLUSION

We conclude that the preponderance of the evidence of record does not support the Examiner's conclusion that the combination of Komissarova and Kryger discloses a method having all limitations of independent claims 12 and 24 and dependent claims thereto. We thus reverse the rejections under *35 U.S.C.* § 103(a) that rely on the teachings of Komissarova and Kryger.

DECISION SUMMARY

Claims	**35 U.S.C. §**	**Basis**	**Affirmed**	**Reversed**
Rejected				
12, 24, 25, 28-31, 33, 36-39	103	Komissarova, Kryger		12, 24, 25, 28-31, 33, 36-39 **[*10]**
26, 34	103	Komissarova, Kryger, Blum		26, 34
32, 40	103	Komissarova, Kryger, Choi		32, 40
Overall Outcome				12, 24-26, 28-34, 36-40

REVERSED

USPTO Bd of Patent Appeals & Interferences; Patent Trial & Appeal Bd Decs.

End of Document

[10] Appellant's Reply Brief is not paginated; we refer here to the second of nine pages.