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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JOACHIM STRUCK, CHRISTIAN NICKEL, ROLAND BINGISSER, SVEN GIERSDORF, and OLIVER HARTMANN[1]

Appeal 2017-000269
Application 12/583,350
Technology Center 1600

Before DONALD E. ADAMS, JOHN G. NEW, and JOHN E. SCHNEIDER, *Administrative Patent Judges.*

NEW, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1]Appellants state the real party-in-interest is B.R.A.H.M.S. GmbH. App. Br. 1.

SUMMARY

Appellants file this appeal under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of claims 14–17 and 20–32 as unpatentable under 35 U.S.C. § 103(a) as being obvious over Struck et al. (WO 2009/019230 A2, February 12, 2009) ("Struck").

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

We AFFIRM.

NATURE OF THE CLAIMED INVENTION

Appellants' invention is directed to assays and *in vitro* methods for the *in vitro* diagnosis, prognosis and risk stratification of a patient having a primary, non-infectious disease, in which the level of procalcitonin ("PCT") in a sample of a body fluid of the patient is indicative for the risk of the patient to contract a further disease or medical condition. Abstract.

REPRESENTATIVE CLAIM

Claim 14 is representative of the claims on appeal and recites:

> 14. A method for diagnosing a bacterial infection in a patient who does not have a primary disease, and who presented to the emergency department with one or more non-specific complaints, by detection and quantification of a marker of bacterial infection, wherein
>
> > said complaints are selected from the group consisting of "not feeling well," "feeling weak," "feeling exhausted," "being tired or sleepy," "feeling dizzy," having a lack of appetite, being unable to cope with usual daily activities, and the patient being unable to recall why they were sent to the emergency department, with the proviso that the patient did not present to the emergency department with any complaints specific to infection,

comprising the steps of:

(i) detecting and quantifying the level of a Procalcitonin (PCT), or a fragment thereof having at least 12 amino acids (collectively, PCT analyte) in a bodily fluid sample from said patient, wherein the detection and quantitation comprises a PCT detection assay with a functional assay sensitivity of below 0.06 ng/mL, comprising contacting said PCT analyte with a capture molecule that specifically binds to the PCT analyte to form a detectable PCT analyte:capture molecule complex, and detecting the complex;

(ii) comparing the thus-detected level of PCT analyte in said sample to a predetermined threshold level of between 0.02 ng/mL and 0.25 ng/mL; and

(iii) diagnosing whether said patient has a bacterial infection or not by comparing said determined PCT level with said predetermined threshold level;

wherein the patient is diagnosed with a bacterial infection if the PCT analyte level is higher than the predetermined threshold level, and whereby the diagnosis is used to determine whether to prescribe antibiotic treatment for the patient diagnosed with a bacterial infection.

App. Br. 8.

ISSUES AND ANALYSIS

We herein agree with, and adopt, the Examiner's findings and conclusion that the appealed claims are obvious over the cited prior art references. We address the arguments raised by Appellants on appeal below.

Issue 1

Appellants argue the Examiner erred in finding that Struck teaches or suggests the limitation of claim 14 reciting: "A method for diagnosing a bacterial infection in a patient who does not have a primary disease, and who presented to the emergency department with one or more non-specific complaints." App. Br. 3.

Analysis

The Examiner finds the procalcitonin ("PCT") testing method of Struck is the same as claimed, but that Appellants' claims have additional limitations concerning the patient cohort subjected to testing. Final Act. 4. Specifically, the Examiner finds Appellants' claim 14 defines this cohort as patients who do not have a primary disease and are presenting to the emergency department with one or more nonspecific complaints listed in the claims. *Id.* However, the Examiner finds that the patient cohort defined by Struck are patients with a primary, noninfectious disease with an asymptomatic second disease. *Id.*

The Examiner therefore finds that, because the diagnosis of the infection is wholly disconnected from the symptoms of the primary disease, as shown by Struck; it is evident that the presence of a primary disease is not required for practicing the claimed invention. Final Act. 4. Furthermore, the Examiner finds, Struck points to evidence, in the prior art, that PCT can be used to diagnose non-septic infections, such as pneumonia, bacterial meningitis and malaria. *Id.* (citing Struck 1–2). The Examiner therefore concludes that it would have been obvious to one of ordinary skill in the art

that the method of Struck would apply no differently to a patient without a primary non-infectious disease. *Id.*

Appellants argue Struck teaches that their "invention is based on the surprising finding that in samples of patients with a primary, non-infectious disease, slightly elevated PCT concentrations have been detected at a large frequency and are of diagnostic relevance." App. Br. 3 (quoting Struck 3). According to Appellants, Struck also teaches that the "presence of slightly elevated PCT levels may be indicative for the risk of a patient having a non-infectious primary disease to acquire a yet clinically unmanifested and/or yet asymptomatic further disease or medical condition" and that "patients with a primary disease not being an infection should be assayed for their PCT level to allow for the prognosis of the risk to acquire a further disease or medical condition and ultimately to allow for the adaption of therapy." *Id.* Appellants therefore argue that the method taught by Struck involves a completely different patient class than that of Appellants' claimed method; *viz.*, that taught by Struck is defined as patients who have a primary disease, whereas the patient class in Appellants' claimed method constitutes patients who do not have a primary disease and who present with one or more non-specific complaints selected from a specified group. *Id.* at 3–4.

Appellants also point out that Struck discusses a prior study involving treating patients with lower respiratory tract infections in which only patients with PCT concentrations greater than 0.25 ng/ml or 0.5 ng/ml were treated with antibiotics. App. Br. 4. Appellants note that, based on this study, Struck teaches:

:

> [I]t is unclear so far, whether the presence of a primary disease in addition to an infection should influence the interpretation of PCT concentrations below 0.25 ng/mL. A relevant primary disease might put an additional burden on the immune system, and biomarkers of infection, such as PCT, in such situation might be indicative of an infection in a different, i.e. lower, concentration range than in the absence of a relevant primary disease.

Id. (quoting Struck 2).

Therefore, Appellants argue, Struck teaches that a determination that the presence of primary disease can have an effect, such that a concentration range of PCT lower than the concentration range used for indicating an infection in the "absence of a relevant primary disease," can be itself indicative of an infection. App. Br. 4.

Appellants dispute the Examiner's finding that Struck teaches that "the diagnosis of the infection is wholly disconnected from the symptoms of the primary disease." App. Br. 4 (quoting Final Act. 40). Appellants assert that Struck does not make such a disclosure or suggestion, but rather suggests that the presence of the primary disease affects the level of PCT and thereby permits the use of a lower concentration of PCT to be indicative of an infection, i.e., a lower, concentration range than is used when a primary disease is absent. *Id.* Appellants argue Struck suggests only using lower concentrations when a primary disease is present, and not when a primary disease is absent. *Id.* Therefore, Appellants contend, the teachings of Struck would not have led one of ordinary skill in the art to Appellants' claimed invention. *Id.*

Appellants further argue the surprising finding of the present invention is that patients with no symptoms of an infection, but who have

non-specific complaints severe enough to cause them to present themselves to an emergency room, may, nevertheless, have an infection and may be diagnosed by measuring their PCT level and comparing it to a threshold value that is outside the range used in the prior art for making the decision to treat for an infection. App. Br. 5. According to Appellants, patients with bacterial infections normally have classical clinical symptoms and/or manifestations of an infection. *Id.* However, argue Appellants, they have discovered that the threshold levels that are indicative of an asymptomatic infection in this patient class are relatively low: PCT levels of less than 0.25 ng/mL are considered normal; however, according to the present invention, patients who do not have symptoms of an infection and have what have been considered relatively normal PCT values, may nevertheless be diagnosed as having a bacterial infection by determining their PCT levels and comparing to the threshold values discovered by Appellants. *Id.*

Appellants contend that a person of ordinary skill in the art would understand from the teachings of Struck that the described patient class (i.e., patients having a primary, non-infectious disease) were not being diagnosed, but were rather having their risk of acquiring a yet clinically unmanifested and/or yet asymptomatic further disease or medical condition assessed. App. Br. 15. Appellants assert that the teachings of Struck would therefore not suggest to, or motivate, a skilled worker to consider PCT as a diagnostic marker in a different patient class. *Id.*

The Examiner responds that, comparing the patient cohort taught by Struck to that of Appellants' claims, the claims define a patient cohort broader in scope than that of Struck. Ans. 3. The Examiner finds the nonspecific complaints recited in claim 14 as defining the patient population,

i.e., "not feeling well," "feeling weak," "feeling exhausted," "being tired or sleepy," "feeling dizzy," etc., are necessarily nonspecific by definition and, as such, may well be associated with the primary disease of the patient cohort defined by Struck. *Id.* at 3–4. The Examiner finds that, because the diagnosis of the patient cohort of the instant claims is inherently unknown, as they are presenting to the emergency room with non-specific complaints, the cohort recited in claim 14 must inevitably include patients who have an undiagnosed primary non-infectious disease who fall within the cohort defined by Struck. *Id.* at 4.

The Examiner recognizes that Appellants also argue that Struck does not teach how to use the PCT level diagnostically to detect the presence of an infection. Ans. 4 (citing App. Br. 5–6). The Examiner finds Struck introduces the method they define with the following statement:

> [The s]ubject of the invention is the *in vitro* diagnosis, prognosis and risk stratification of a patient having a primary, noninfectious disease, whereby the level of Procalcitonin (PCT) in a sample of a body fluid of the patient is indicative for the risk of the patient to contract a further disease or medical condition.

Ans. 4 (quoting Struck 1). The Examiner finds the teachings of Struck expand significantly on the diagnostic aspect of the method, teaching: "An *in vitro* method for diagnosis of the presence of a bacterial infection in a patient, the method comprising: determining the level of procalcitonin…." *Id.* (quoting Struck claim 26; *see also* Struck 10, 13). The Examiner finds therefore finds that Struck teaches its method specifically as a method for diagnosing an infection. *Id.*

We are not persuaded by Appellants' arguments. The language of claim 14 reciting: "A method for diagnosing a bacterial infection in a

patient who does not have a primary disease…." Is part of the preamble of the claim, and we therefore must consider whether the language is limiting upon the claim.

Generally, a preamble limits the invention if it recites essential structure or steps, or if it is "necessary to give life, meaning, and vitality" to the claim. *See Catalina Marketing Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (citing *Pitney Bowes, Inc. v. Hewlett–Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999)). Moreover, a preamble may limit an invention when it is employed to distinguish a new use of a prior art apparatus or process. *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1375 (Fed. Cir. 2001). Conversely, a preamble is not limiting "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." *Catalina*, 289 F.3d at 808 (quoting *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997)).

In the appeal before us, the question presented is whether the preambular language reciting "A method for diagnosing a bacterial infection in a patient who does not have a primary disease" is so essential to the practice of Appellants' claims that it limits the claims. We conclude that it does not. Appellants' claim further recites:

> "[W]ho presented to the emergency department with one or more non-specific complaints, by detection and quantification of a marker of bacterial infection, wherein
>
> said complaints are selected from the group consisting of "not feeling well," "feeling weak," "feeling exhausted," "being tired or sleepy," "feeling dizzy," having a lack of appetite, being

> unable to cope with usual daily activities, and the patient being unable to recall why they were sent to the emergency department, with the proviso that the patient did not present to the emergency department with any complaints specific to infection

We agree with the Examiner that the claim thus requires patients explicitly presenting at an emergency department with only non-specific complaints and that this class of required patients could include both patients with a primary disease (e.g., arteriosclerosis, heart failure, acute coronary syndrome, coronary disease, myocardial infarction, cancer, diabetes, chronic gastrointestinal diseases, chronic renal diseases, hypertension, orthopaedic diseases including osteoporosis, and neurodegenerative diseases including Alzheimer's disease (*See* Spec. 8) as well as those without. We therefore conclude that the preambular language reciting "in a patient who does not have a primary disease" is not necessary to the invention, because the limitation expressly requiring patients presenting at an emergency department with one or more non-specific complaints is sufficient to practice the invention without necessarily relying on the language of the preamble.

As for Appellants' alleged "surprising finding" that that patients with no symptoms of an infection, but who have non-specific complaints severe enough to cause them to present themselves to an emergency room, may, nevertheless, have an infection and may be diagnosed by measuring their PCT level and comparing it to a threshold value, Appellants point to no evidence of record that such a finding is indeed "surprising." *See* App. Br. 5. Appellants point to no evidence of record in the prior art that suggests that it would be otherwise surprising that patients with nonspecific symptoms sufficient to warrant a trip to the emergency room might have a bacterial infection. *See In re Baxter Travenol Labs.*, 952 F.2d 388, 392

(Fed. Cir. 1991) ("[W]hen unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art"). As such, Appellants provide only attorney argument, to which we accord little probative value. *See In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997) (Attorney arguments and conclusory statements that are unsupported by factual evidence are entitled to little probative value).

Appellants do not argue that their claimed method is otherwise different from that taught by Struck. We therefore conclude that Appellants' argument that their claimed invention is not obvious over the teachings of Struck because the preamble to claim 14 recites "in a patient who does not have a primary disease" is not persuasive. We consequently affirm the Examiner's rejection of the claims.

DECISION

The Examiner's rejection of claims 14–17 and 20–32 as unpatentable under 35 U.S.C. § 103(a) is affirmed.

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). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED