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Paper 9
Entered: August 31, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

CHUGAI SEIYAKU KABUSHIKI KAISA and
HOFFMANN LA ROCHE INC.,
Patent Owners.

IPR2022-00579
Patent 10,874,677 B2

Before ERICA A. FRANKLIN, JOHN G. NEW, and TINA E. HULSE, *Administrative Patent Judges.*

FRANKLIN, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Celltrion, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–8 of U.S. Patent No. 10,874,677 B2 (Ex. 1001, "the '677 patent"). Paper 2 ("Pet."). Chugai Seiyaku Kabushiki Kaisha, Genentech, Inc., and Hoffmann-La Roche Inc. ("Patent Owners") waived the filing of a Preliminary Response to the Petition. Paper 8.

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless there is a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314(a). Upon considering the argument and evidence presented in the Petition, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing the unpatentability of at least one claim challenged in the Petition. Accordingly, we institute an *inter partes* review of claims 1–8 the '677 patent.

A. Real Parties-in-Interest

Petitioner identifies itself, along with Celltrion Healthcare Co. Ltd. and Celltrion Healthcare U.S.A., Inc., as the real parties-in-interest. Pet. 24. Patent Owners identify themselves as the real parties-in-interest, noting that Chugai Seiyaku Kabushiki Kaisha and Hoffmann-La Roche Inc. is also called Chugai Pharmaceutical Co., Ltd. Paper 4, 1. Additionally, Patent Owners identify Genentech, Inc., as a real party-in-interest. *Id.*

B. Related Matters

The parties state that claims of the '677 patent were challenged in *Fresenius Kabi USA, LLC et al. v. Chugai Seiyaku Kabushiki Kaisha et al.*, IPR2021-01336, Paper 27 (PTAB February 23, 2022) (institution decision). Pet. 24; Paper 4, 1. Petitioner notes that it is also seeking *inter partes* review

of U.S. Patent No. 8,580,264 B2 ("the '264 patent"). Pet. 24; *see* IPR2022-00578, Paper 2. The '677 patent claims priority to the application that issued as the '264 patent. *See* Ex. 1001, code (62). Patent Owners identify a number of patent applications and issued patents that relate to U.S. Patent Application No. 16/254,105, which issued as the '677 patent. Paper 4, 1–2. Patent Owners also note that the '264 patent is the subject of IPR2022-00578. *Id.* at 2.

C. The '677 Patent

In one aspect, the '677 patent relates to methods for treating interleukin-6 (IL-6) related diseases, such as rheumatoid arthritis (also referred to as "RA"), with subcutaneously administered antibody that binds interleukin-6 receptor (anti-IL-6R antibody). Ex. 1006, 1:29–35. The '677 patent also relates to "devices useful for subcutaneous administration of an anti-IL-6R antibody." *Id.* at 1:39–40, 4:65–5:3.

IL-6 is a "proinflammatory, multifunctional cytokine produced by a variety of cell types," and "exerts its effects through a ligand-specific receptor (IL-6R) present both in soluble and membrane-expressed forms." *Id.* at 2:1–2, 16–18. It has been known in the art that "[e]levated IL-6 levels have been reported in the serum and synovial fluid of RA patients, indicative of production of IL-6 by the synovium." *Id.* at 2:19–21. It is also known in the art that "IL-6 levels correlate with disease activity in RA . . . and clinical efficacy is accompanied by a reduction in serum IL-6 levels." *Id.* at 2:23–25.

Tocilizumab (also referred to as "TCZ") is a recombinant humanized monoclonal antibody of the immunoglobulin IgG1 subclass which binds to human IL-6R. *Id.* at 2:27–29. Tocilizumab has been approved for use in treating a number of diseases, including rheumatoid arthritis and juvenile

idiopathic arthritis. *See id.* at 2:34–43. In one aspect, the '677 patent relates to identification of a fixed dose of anti-IL-6R antibody such as tocilizumab. *Id.* at 1:35–36.

D. Illustrative Claim

Petitioner challenges claims 1–8 of the '677 patent. Independent claim 1, set forth below, is illustrative of the challenged claims.

> 1. An article of manufacture comprising a subcutaneous administration device, which contains and delivers to a patient a 162 mg fixed dose of tocilizumab.

Ex. 1001, 63:45–47.

E. Asserted Grounds of Unpatentability

Petitioner asserts that the challenged claims are unpatentable based on the following two grounds:

Claims Challenged	35 U.S.C. §[1]	Reference(s)
1, 5	102	NCT '653[2]
1–8	103(a)	NCT '653, Morichika[3], and Kivitz[4]

[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284 (2011), amended 35 U.S.C. §§ 102 and 103, effective March 16, 2013. Because the application from which the '677 patent issued has an effective filing date prior to March 16, 2013, the pre-AIA version of §§ 102 and 103 applies.

[2] ClinicalTrials.gov, *A Study of Subcutaneously Administered Tocilizumab in Patients with Rheumatoid Arthritis*, NCT00965653, available at https://clinicaltrials.gov/ct2/show/NCT00965653 (first posted August 21, 2009) (last update posted Nov. 2, 2016) (Ex. 1004, "NCT '653").

[3] Morichika et al., WO 2009/084659 A1, published July 9, 2009 (certified English translation) (Ex. 1110, "Morichika").

[4] Kivitz et al., *HUMIRA® Pen: a novel autoinjection device for sub-cutaneous injection of the fully human monoclonal antibody adalimumab*, EXPERT REV. MED. DEVICES 4(2):109–16 (2007) (Ex. 1050, "Kivitz").

Petitioner also relies upon the Declarations of Dhaval K. Shah, Ph.D. (Ex. 1032); Maarten Boers M.D., Ph.D. (Ex. 1034), and Paul A. Dalby, Ph.D. (Ex. 1036).

II. ANALYSIS

A. Person of Ordinary Skill in the Art

The level of skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1323 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

Petitioner asserts that a person of ordinary skill in the art at the time of the invention (also referred to as a "POSA") "would in fact have been a team of individuals possessing the different skill sets typically employed on such a project." Pet. 18. Petitioner asserts that the "team would have included individuals skilled in the relevant area(s) of clinical medicine (e.g., rheumatologists), pharmacokineticists, formulators and project leads" working together as needed. *Id.* (citing Ex. 1034 ¶ 48; Ex. 1032 ¶ 27; Ex. 1036 ¶¶ 25–26). At this stage in the proceeding, Patent Owners do not dispute Petitioner's definition of the person of ordinary skill in the art.

We have considered Petitioner's proposed definition of a POSA, along with the testimony of its experts. We find it unconventional, however, to define the "person" having ordinary skill in the art as a "team" of individuals. Instead, we find the experts' alternative position more appropriate, i.e., that a POSA defined in another manner "would have had access to individuals skilled in clinical medicine, pharmacokinetics and formulation," as noted by Drs. Boers, Shah, and Dalby. *See* Ex. 1034 ¶ 49; Ex. 1032 ¶ 27; Ex. 1036 ¶ 27.

In the related case, IPR2021-01336, involving the same challenged claims and two of the same prior art references as here, the Board made a preliminary determination that the POSA would have been "an individual with an M.D. specializing in the treatment of autoimmune disorders and having several years of experience treating patients with such disorders, including rheumatoid arthritis, or having several years of experience researching treatments for autoimmune disorders, including rheumatoid arthritis." IPR2021-01336, Paper 27, 6. Based on our consideration of the current record, we find that the same preliminary determination is warranted here, with the further clarification that: (a) the POSA may also be an individual with a Ph.D. in a relevant field having several years of experience researching treatments for autoimmune disorders, including rheumatoid arthritis;" and (b) that the M.D. and/or Ph.D. "would have had access to individuals skilled in clinical medicine, pharmacokinetics and formulation."

Accordingly, for purposes of this Decision, we determine that a POSA would have been an individual with an M.D. specializing in the treatment of autoimmune disorders and having several years of experience treating patients with such disorders, including rheumatoid arthritis; or an individual with an M.D. and/or Ph.D. having several years of experience researching treatments for autoimmune disorders, including rheumatoid arthritis, wherein the M.D. and/or Ph.D. would have had access to individuals skilled in clinical medicine, pharmacokinetics and formulation. If the parties dispute this preliminary determination, they are encouraged to address it during the trial proceeding.

B. Claim Construction

The Board applies the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). 37 C.F.R. § 100(b) (2019). Under that standard, claim terms "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17).

Petitioner proposes constructions for three claim terms. *See* Pet. 27–28. In the following discussion, we address those proposed constructions.

1. "fixed dose"

Petitioner addresses the term "fixed dose" by asserting that the term is defined in the Specification as "a dosage of a drug, such as an anti-IL-6R antibody which is administered without regard to the patient's weight or body surface area (BSE), i.e., it is not administered as either a mg/kg or mg/m^2 dose." Pet. 27 (quoting Ex. 1001, 15:15–18). Because the term "fixed dose" is defined by the Specification and is not disputed by the parties, we determine, based on the current record, that the term requires no further construction.

2. "delivers to a patient"

Petitioner addresses the term "delivers to a patient" by asserting that the term is "merely a statement of intended use" of the claimed article of manufacture. Pet. 27. Petitioner argues that "delivers to a patient" is "not a patentable limitation as it fails to add any additional structural limitations beyond that of the subcutaneous administration device and the fixed dose of antibody." *Id.* at 27–28 (citing *In re Schreiber,* 128 F.3d 1473, 1477 (Fed. Cir. 1997)).

Based on the current record, we agree with Petitioner that the claim phrase "delivers to a patient" does not limit the claims. The claims are directed to a device and not to a method of treatment. The claim recitation that the device "delivers to a patient" the recited fixed dosage of tocilizumab is merely an intended use of the subcutaneous administration device, as defined by the Specification. *See* Ex. 1001, 20:7–11.

3. "subcutaneous administration device"

Petitioner addresses the term "subcutaneous administration device" by asserting that the term is defined in the Specification as "a device, such as syringe, injection device, infusion pump, injector pen, needleless device, patch delivery system, etc., which is adapted or designed to administer a drug or pharmaceutical formulation by the subcutaneous route." Pet. 28 (quoting Ex. 1001, 20:7–11). Because the term "subcutaneous administration device" is defined by the Specification and is not disputed by the parties, we determine, based on the current record, that the term requires no further construction.

C. Anticipation by NCT '653

Petitioner asserts that claims 1 and 5 are anticipated by NCT '653. Pet. 28–36.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Schering Corp. v. Geneva Pharms*, 339 F.3d 1373, 1379 (Fed. Cir. 2003) (quoting *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987)).

1. NCT '653

NCT '653 is a clinical trial study, entitled "A Study of Subcutaneously Administered Tocilizumab in Patients with Rheumatoid Arthritis." Ex. 1004, 1. The summary states, "This open-label randomized [2 arm] study will investigate the pharmacokinetics, pharmacodynamics, efficacy and safety of subcutaneously administered tocilizumab in patients with rheumatoid arthritis who have shown an inadequate response to methotrexate." *Id.* at 6. The summary explains further that "[p]atients will be randomized to receive tocilizumab 162 mg sc [subcutaneously] either weekly or every other week, in combination with methotrexate, for 12 weeks." *Id.*

2. Discussion

Petitioner identifies the disclosures in NCT '653 that Petitioner asserts disclose each limitation of claims 1 and 5. Pet. 28–36. Specifically, Petitioner relies on the NCT '653 protocol, which involves administering to a patient 162 mg of tocilizumab subcutaneously. *Id.* According to Petitioner, a POSA would have understood that NCT '653 discloses a device for administering the subcutaneous dose, as one must necessarily use a "subcutaneous administration device" to administer tocilizumab

subcutaneously. *Id.* at 30–31 (citing *In re Baxter Travenol Labs*, 952 F.2d 388, 390 (Fed. Cir. 1991)). Additionally, Petitioner asserts that the Specification describes tocilizumab as an anti-IL-6 receptor antibody and contends that it inherently comprises the recited light chain and heavy chain amino acid sequences of SEQ ID. Nos. 1 and 2, respectively, as further required for claim 5. *Id.* at 32–34.

Petitioner asserts also that NCT '653 would have enabled a POSA to make a subcutaneous administration device according to the claims, "by following the instructions and copying the recipe for the A8/A26formulation of tocilizumab disclosed . . . in *Morichika*." *Id.* at 34–35.

On the current record, Patent Owners do not dispute Petitioner's assertion that NCT '653 is prior art and enables the claimed article of manufacture. *See* Pet. 12, 28; Paper 8.

Based on the foregoing and the information presented at this stage of the proceeding, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing in showing that each and every limitation in claims 1 and 5 is disclosed expressly or inherently by NCT '653. In particular, we find persuasive, at this stage in the proceeding, Petitioner's argument and evidence that a POSA would have understood that the dosing regimen disclosed in NCT '653 necessarily involved using a subcutaneous administration device to administer the subcutaneous 162 mg fixed dose of tocilizumab.

Accordingly, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing claims 1 and 5 are anticipated by NCT '653.

D. Obviousness over NCT '653, Morichika, and Kivitz

Petitioner asserts that claims 1–8 would have been obvious over the combined teachings of NCT '653, Morichika, and Kivitz. Pet. 36–48.

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). "An obviousness determination requires finding both 'that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.'" *CRFD Research, Inc. v. Matal*, 876 F.3d 1330, 1340 (Fed. Cir. 2017) (quoting *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–1368 (Fed. Cir. 2016)).

Notwithstanding what the teachings of the prior art would have suggested to one with ordinary skill in the art at the time of the patent's invention, the totality of the evidence submitted, including objective evidence of nonobviousness, may lead to a conclusion that the challenged claims would not have been obvious to one with ordinary skill in the art. *In re Piasecki*, 745 F.2d 1468, 1471–72 (Fed. Cir. 1984); *see also Graham*, 383 U.S. at 17–18; *Leapfrog Enters., Inc. v. Fisher–Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007).[5]

[5] At this stage of the proceeding, Patent Owners do not assert evidence of objective indicia supporting nonobviousness of the challenged claim. *See* Paper 8.

We incorporate our description and discussion of NCT '653 in Section II.C. here.

1. Morichika

Morichika describes antibody-containing formulations for subcutaneous administration. Ex. 1110 Abstract. Morichika explains that most known antibody formulations are used for intravenous injection, but there is "growing demand" for antibody-containing formulations that can be self-injected subcutaneously. *Id.* ¶ 2. Morichika further explains that antibody-containing formulations for subcutaneous injection require increasing the concentration of the antibody in the injection solution because the antibody administered per dose is large, while the injection solution is generally limited for this dosage form. *See id.* ¶ 3.

Morichika discloses antibody-containing liquid formulations "especially suited for subcutaneous injection." *Id.* ¶ 53. The liquid formulations may contain 150–200 mg/mL antibody, 100–300 mM arginine and 10–50 mM methionine (stabilizers), 10–20 mM histidine (buffer), and 0.005–3% surfactants, such as polysorbates 20, 80 and poloxamer 188. *See id.* ¶¶ 15, 35, 40–41. In particular, Morichika describes a "highly concentrated antibody-containing preparation . . . that does not require reconstitution by lyophilization and does not require redissolution." *Id.* ¶ 10. The preparation "can be stably stored in solution for a long period of time and can be manufactured without a lyophilization step in the manufacturing process, thus addition of a sugar or the like as a cryoprotectant agent is not necessary." *Id.*

Morichika exemplifies an antibody sample formulation containing an anti-IL-6R antibody referred to as "MRA." *See id.* ¶¶ 29, 61. Morichika discloses examples A8 and A26, including 180 Mg/mL MRA (anti-IL6-R

antibody), 100 mM arginine, 30 mM methionine, 0.5 Mg/mL polysorbate 80, and 20 mM histidine, with a pH of 6.0. *Id.* ¶¶ 64, 82. Morichika discloses stability data for examples A8 and A26, that "suggests that the combination of arginine and methionine has a synergistic effect" on inhibiting a dimer impurity. *See id.* ¶¶ 68–70, 83–84.

2. Kivitz

Kivitz discusses the Humira® adalimumab pen, which is described as "a novel, integrated, disposable autoinjection delivery system for the subcutaneous injection of adalimumab." Ex. 1050, 109 (Abstract). Kivitz explains that "[s]elf-administered injectables offer several advantages over intravenous injections (i.e., portability, convenience and flexible scheduling)." *Id.* Kivitz further explains that "patients with chronic, debilitating diseases may need a self-administered medication available in an easy-to-use and convenient delivery device that minimizes pain and facilitates adherence to therapy." *Id.* Kivitz states that, "[b]ased on the positive response from patients to the adalimumab pen, it is quite possible that biological therapies delivered by autoinjector pens may rapidly become the preferred treatment in RA and related diseases." *Id.* at 114.

3. Discussion

Petitioner asserts that independent claims 1 and 5 are obvious over NCT '653 for the same reasons they have asserted that those claims are anticipated by the reference, i.e., because it discloses subcutaneous administration of a fixed dose of 162 mg of tocilizumab and inherently discloses a subcutaneous administration device, as required by the claims. Pet. 36. Petitioner acknowledges that NCT '653 "does not expressly describe a particular kind of 'subcutaneous delivery device'" to administer tocilizumab subcutaneously. *Id.* at 36–37.

Petitioner contends, however, that Kivitz and Morichika disclose subcutaneous delivery devices that meet the general limitation for the device in claims 1 and 5, as well as the specific subcutaneous administration devices recited in the dependent claims. *See id.* For example, Petitioner asserts that Kivitz teaches subcutaneous delivery devices, including pre-filled syringes (claims 3, 7) and autoinjectors (claims 4, 8), for delivering fixed doses of known antibody drugs. *Id.* at 37 (citing Ex. 1034 ¶ 213; Ex. 1050, 111). Additionally, Petitioner asserts that Morichika teaches tocilizumab (i.e., MRA) formulations especially suitable for fixed dose subcutaneous administration delivered via auto-injector or pre-filled syringe. *Id.* at 37 (citing Ex. 1034 ¶¶ 212, 214; Ex. 1110 ¶ 53).

According to Petitioner, it would have been obvious for a POSA to provide the 162 mg fixed dose regiment of NCT '653 in a convenient known format, which included the pre-filled syringes and autoinjectors disclosed by Kivitz, and as exemplified in Morichika. *See id.* at 38–41. Petitioner asserts that subcutaneously administering tocilizumab via pre-filled syringes and autoinjectors would have provided numerous advantages over the known IV regimen. *See id.* at 38–39. First, Petitioner argues that self-administering tocilizumab via subcutaneous administration devices is more convenient and costs less than IV dosing at a clinic. *See id.* (citing Ex. 1050, 110, 114; Ex. 1049, 265; Ex. 1034 ¶¶ 62–65, 115, 216). Second, Petitioner argues that fixed subcutaneous dosing has therapeutic benefits over intravenous dosing, by preventing dosing errors and providing smaller and more frequent doses. *See id.* at 38 (citing Ex. 1034 ¶¶ 64, 216). Third, Petitioner argues that Patent Owners announced the development of subcutaneous dosage forms of tocilizumab well in advance of the filing date of the '677 patent. *See id.* at 40 (citing Ex. 1034 ¶¶ 69, 219; Ex. 1071, 4; Ex. 1072, 12; Ex. 1030, 4).

Among other rationales offered, Petitioner asserts that a POSA would have had a reasonable expectation of success in combining the prior art to provide a subcutaneous device that delivers to a patient a 162 mg fixed dose of tocilizumab. *Id.* at 41 (citing Ex. 1034 ¶¶ 222–226). Petitioner argues that a POSA would have been able to following Morichika's teachings "to create a concentrated formulation of tocilizumab that would fit into an autoinjector or pre-filled syringe." *Id.*

Based on our review of the current record, we determine that Petitioner has shown sufficiently for institution that a POSA would have had a reason to use one of the disclosed subcutaneous administration devices in Kivitz to contain and deliver the tocilizumab subcutaneous dose disclosed in NCT '653, as exemplified in Morichika, with a reasonable expectation of success. In particular, we find persuasive, at this stage in the proceeding, Petitioner's argument and evidence that: (a) a POSA would have understood that the dosing regimen disclosed in NCT '653 necessarily involved using a subcutaneous administration device to administer the subcutaneous 162 mg fixed dose of tocilizumab; (b) Kivitz discloses the specific subcutaneous administration devices recited by the challenged dependent claims and explains that those devices have been used to deliver monoclonal antibody formulations with success; and (c) a POSA would have been able to successfully follow Morichika's teachings to provide a concentrated formulation of tocilizumab that would fit into an autoinjector or pre-filled syringe. *See* Pet. 36–41; Ex. 1004 ¶¶ 212–215, 222–227.

Accordingly, based on the information presented at this stage of the proceeding, we determine that Petitioner has shown sufficiently that there is a reasonable likelihood that it would prevail in showing that claims 1–8 are rendered obvious by the combination of NCT '653, Morichika, and Kivitz.

III. CONCLUSION

For the foregoing reasons, we conclude that Petitioner has established a reasonable likelihood of prevailing in its assertion that claims 1–8 of the '677 patent are unpatentable. Accordingly, we institute an *inter partes* review of all of the challenged claims on all of the asserted grounds.

Our determination in this Decision is not a final determination on either the patentability of any challenged claims or the construction of any claim.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–8 of the '677 patent on all grounds set forth in the Petition is instituted, commencing on the entry date of this decision; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of review.

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