

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HUBEI GRAND LIFE SCIENCE AND TECHNOLOGY CO., LTD,
Petitioner,

v.

VITAWORKS IP, LLC,
Patent Owner.

Case IPR2018-01766
Patent 9,428,450 B2

Before ERICA A. FRANKLIN, JENNIFER MEYER CHAGNON, and
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

MAJORS, *Administrative Patent Judge*.

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

I. INTRODUCTION

Hubei Grand Life Science and Technology Co., Ltd. (“Petitioner”),¹ on September 28, 2018, filed a Petition to institute *inter partes* review of claims 1 and 3–7 of U.S. Patent No. 9,428,450 B2 (Ex. 1001, “the ’450 patent”). Paper 2 (“Pet.”). Vitaworks IP, LLC (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 6 (“Prelim. Resp.”).

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless the Petition “shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” For the reasons stated below, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of at least one of claims 1 and 3–7 of the ’450 patent. Thus, we institute an *inter partes* review of claims 1 and 3–7 of the ’450 patent.

II. BACKGROUND

A. *Related Matters*

Petitioner states that it is a named defendant in *Vitaworks IP, LLC v. Hubei Grand Life Science and Technology Co., Ltd. et al.*, No. 2:17-cv-12358-CCC-MF (D.N.J. filed Dec. 1, 2017), a litigation in which the ’450 patent is asserted. Pet. 4. According to Petitioner, however, Plaintiff/Patent Owner has not served the complaint from that district court proceeding on Petitioner. *Id.* Petitioner also identifies two other pending litigations related

¹ Petitioner identifies a number of entities as the real parties-in-interest in this proceeding. Pet. 4. We do not repeat that listing here.

to the '450 patent. *Id.* at 5. Patent Owner identifies the same three proceedings. Paper 4, 1.

As for related matters before the Board, Petitioner identifies two other pending petitions for *inter partes* review, which were filed concurrently with the present Petition. Pet. 5. Those other petitions challenge U.S. Patent No. 9,428,451 B2 (“the '451 patent”) (IPR2018-01767) and U.S. Patent No. 9,573,890 B2 (“the '890 patent”) (IPR2018-01768). *Id.* Those other patents issued, respectively, from child and grand-child applications to the '450 patent.²

B. Background Technology and the '450 Patent

According to the '450 patent, the “invention relates to a cyclic process for the production of taurine from alkali isethionate and from alkali vinyl sulfonate in a high overall yield . . . by continuously converting the byproducts of the ammonolysis reaction, alkali ditaurinate and alkali tritaurinate, to alkali taurinate.” Ex. 1001, 1:6–11.

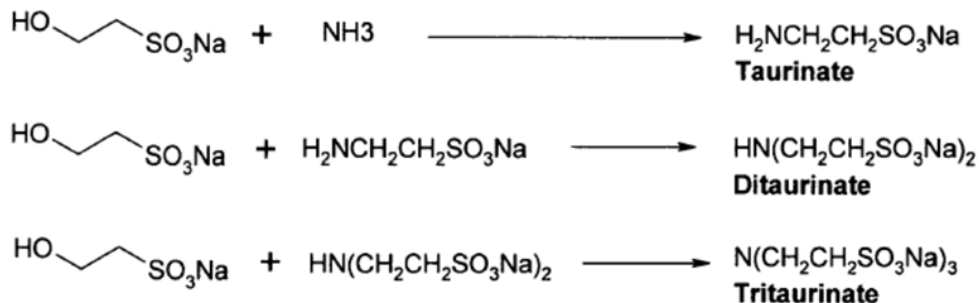
As explained in the '450 patent, “[t]aurine . . . is one of the amino sulfonic acids found in the tissues of many animals.” *Id.* at 1:15–17. “Taurine is an extremely useful compound because it has such pharmacological effects as detoxification effect, [and a] fatigue-relieving effect,” among others. *Id.* at 1:18–21. Thus, “taurine finds wide applications as an essential ingredient for human and animal nutrition.” *Id.* at 1:21–22.

² The '451 patent issued on a continuation-in-part (CIP) application to the application that issued as the '450 patent; the '890 patent issued on a CIP application of the application that issued as the '451 patent.

As further background, the '450 patent describes an existing method of producing taurine known as the "ethylene oxide process," which we may refer to in this Decision as the "EO process." *Id.* at 1:23–31; *see also id.* at 1:53–56 (describing, for example, the process in U.S. Patent No. 1,932,907 (Ex. 1016), wherein "sodium taurinate is obtained in a yield of 80% when sodium isethionate undergoes ammonolysis reaction in a molar ratio of 1:6.8 for 2 hrs at 240 to 250° C."). In this process, ethylene oxide is first reacted with sodium bisulfite to produce sodium isethionate, which is then subjected to an ammonolysis reaction to yield sodium taurinate, and the sodium taurinate, when neutralized with an acid (e.g., sulfuric acid), converts to taurine. *Id.* at 1:23–31.

According to the '450 patent, this EO process is "well established and widely practiced in commercial production." *Id.* at 1:32–33. Nevertheless, the '450 patent explains, "overall yield is not very high," and "the process generates a large amount of waste stream that is increasingly difficult to dispose of." *Id.* at 1:34–36.

The byproducts of the EO process include, among other compounds, alkali ditaurinate and alkali tritaurinate. Indeed, as explained in the '450 patent, "[f]rom these prior arts, it is therefore concluded that the ammonolysis of sodium isethionate invariably yields a mixture of sodium taurinate, sodium ditaurinate, and sodium tritaurinate." *Id.* at 2:9–12. This reaction is summarized below, and may be catalyzed by a basic alkali salt (e.g., sodium hydroxide or sodium carbonate).



Ex. 1003 ¶ 46 (Declaration of Dr. Mark A. Lipton); Ex. 2001 ¶ 45 (Declaration of Dr. Robert E. Maleczka). As depicted, sodium isethionate reacts in the presence of ammonia (NH₃) to produce a mixture of sodium taurinate, as well as sodium ditaurinate and sodium tritaurinate.³ By neutralizing with an acid, as noted above, the sodium taurinate can be converted to taurine and filtered out. Ex. 1001, 2:23–26 (describing a known technique wherein “[c]rude taurine is easily obtained [following neutralization of sodium taurinate in acid] by filtration from a crystalline suspension of taurine after cooling”); Ex. 1003 ¶¶ 33, 46; Ex. 2001 ¶ 46. The remaining waste supernatant, also known as the “mother liquor,” includes, *inter alia*, sodium ditaurinate and sodium tritaurinate as byproducts of the ammonolysis of sodium isethionate. Ex. 2001 ¶ 49.

With this background in mind, the ’450 patent proposes that the above-mentioned byproducts—particularly sodium ditaurinate and/or sodium tritaurinate—can be recycled and subjected to further ammonolysis

³ As Dr. Lipton explains, “[b]ecause ammonia has three hydrogen atoms that can be replaced by a substituent group, the amine formed in the ammonolysis reaction can be a primary, secondary, or tertiary amine, and a mixture of the three amines is usually formed.” Ex. 1003 ¶ 41. According to Dr. Lipton, “[t]he presence of excess ammonia in the ammonolysis reaction will favor the production of monoalkylated amines, or primary amines.” *Id.* ¶ 42 (citing Ex. 1020).

to increase the production of sodium taurinate and, hence, taurine. *See, e.g.*, Ex. 1001, 2:32–49. More specifically, the '450 patent discloses that “the mother liquor, consisting of taurine, monosodium ditaurinate, and monosodium tritaurinate, is suitable for recycling to the ammonolysis step to prepare sodium taurinate.” *Id.* at 2:59–62. According to the '450 patent, “[w]hen sodium ditaurinate and sodium tritaurinate are reacted with aqueous ammonia under ammonolysis reaction conditions, a mixture of similar compositions of sodium taurinate, ditaurinate, and tritaurinate is formed in an equilibrium state. This novel finding renders the cyclic process possible.” Ex. 1001, 2:44–49; *see also id.* at 3:67–4:3 (“[T]he inevitable byproducts of the ammonolysis step, i.e., sodium ditaurinate and sodium tritaurinate, can be continuously converted to sodium taurinate in each successive cycle.”).⁴

C. Prosecution History

During prosecution, the Examiner rejected the then-pending claims as obvious over German patent DD 219023 (DD '023 (Ex. 1007)). Ex. 1002, 149–150. According to the Examiner, DD '023 taught ammonolysis of sodium isethionate, which would produce alkali ditaurinate and alkali tritaurinate in the reaction mixture with ammonia, and that “those of ordinary skill would expect at least a portion of the ditaurinate . . . would convert to taurinate.” Ex. 1002, 150; *see also id.* at 151–152 (“[T]he recited ammonolysis step is inherent in DD 023 since the taurinate, ditaurinate, and tritaurinate species were in the reaction mixture with ammonia at the recited

⁴ Although the '450 patent discloses a cyclic or continuous process, the patent states that the “invention can be carried out discontinuously, semi-continuously, and continuously.” Ex. 1001, 5:44–46. The patent further indicates that its examples are not intended to be limiting. *Id.* at 5:50–51.

reaction conditions and any observed outcome or benefit from this step is an invariable aspect of DD 023.”) (emphasis omitted).

The applicant responded by amending claim 18 (issued claim 1) to add what is presently step (a) of claim 1. Ex. 1002, 160. Applicant acknowledged that “the ammonolysis of the byproducts is inherent in the process [of DD ’023] as you [i.e., the Examiner] clearly point out,” yet applicant argued that such inherent reaction did not result in sodium taurinate “in an amount significant to increase production yield under known reaction conditions.” *Id.* at 162. Applicant’s response cites previously “undisclosed results” related to “failed attempts to prepare taurinate from ditaurine and tritaurine under the ammonolysis conditions,” although no conditions or methodology for the purported testing is actually described. *Id.* at 162–163; Ex. 1003 ¶¶ 51–52; Ex. 2001 ¶ 34; Pet. 10. Applicant then argued that the claims now included an “extra step [that] is introduced before the ammonolysis . . . to convert alkali ditaurinate to di-alkali ditaurinate . . . by mixing the available starting materials with a solution of alkali hydroxide or alkali carbonate.” Ex. 1002, 163. With this “extra step,” applicant argued a higher yield of sodium taurinate could be obtained, that this step is “crucial for the success of the present process in the conversion of the byproducts to taurine,” and that the amended claims were, thus, “clearly distinguished from the inherent ammonolysis of the byproduct.” *Id.*

Following that response, the Examiner indicated that the claims as amended were allowable. Ex. 1002, 196. According to the Examiner, “the applied references fail to teach or suggest the required steps of adding an alkali hydroxide to a solution of alkali ditaurinate . . . to prepare a solution of dialkali ditaurinate . . . [i.e., step (a)], and adding an excess amount of ammonia to this to preform [*sic*, perform] an ammonolysis reaction.” *Id.*

D. Illustrative Claim

Petitioner challenges claims 1 and 3–7. Claim 1, the only independent claim, is illustrative and reads as follows:

1. A process for the production of taurine from alkali ditaurinate, or alkali tritaurinate, or their mixture, comprising:
 - (a) adding an alkali hydroxide to a solution of alkali ditaurinate, or alkali tritaurinate or their mixture, to prepare a solution of dialkali ditaurinate, or trialkali tritaurinate or their mixture,
 - (b) adding an excess amount of ammonia to a solution of dialkali ditaurinate, or dialkali^[5] tritaurinate, or their mixture, and subjecting the solution to ammonolysis reaction to yield a mixture of alkali taurinates,
 - (c) removing excess ammonia from (b) and neutralizing alkali taurinates with an acid to form a crystalline suspension of taurine, and
 - (d) recovering taurine by means of solid-liquid separation.

Ex. 1001, 8:6–20.

E. The Asserted Grounds of Unpatentability

Petitioner contends that claims 1 and 3–7 are unpatentable based on the grounds set forth in the table below. Pet. 13–14.

⁵ Petitioner notes that step (b) of claim 1 lists “dialkali tritaurinate” and that, in the context of the claim (*see* step (a)), the term in step (b) should be “trialkali tritaurinate.” Pet. 28 n.3. This issue is not decisive because, as explained herein, Petitioner has shown sufficient for institution purposes that at least dialkali ditaurinate would be present in the reactions taught or suggested by the prior art.

Grounds	Reference(s)	Basis	Claims
1	WO '071 ⁶	§ 102	1, 3–7
2	WO '071	§ 103	1, 3–7
3	Wu ⁷ and WO '071	§ 103	1, 3–7
4	Liu ⁸ and WO '071	§ 103	1, 3–7

Petitioner also relies on the Declaration of Dr. Mark A. Lipton (Ex. 1003), among other evidence. In response, Patent Owner relies on the Declaration of Dr. Robert E. Maleczka (Ex. 2001), among other evidence.

⁶ Heuer, WO 01/77071 A1, published Oct. 18, 2001 (Ex. 1009) (hereafter “WO '071”). WO '071 (Ex. 1010) is the apparent English translation of the international patent application, published in German. Ex. 1008 (Certification of translation for WO '071). As with other translated exhibits in this proceeding, Patent Owner does not contest the accuracy of the translations or sufficiency of the supporting certifications.

⁷ Wu Jiang et al., *Optimization on Ammonolysis in Manufacturing Method of Taurine*, 19:1 JOURNAL OF HUBEI POLYTECHNIC UNIVERSITY 23–26 (2004) (Ex. 1011) (hereafter “Wu”). Wu (Ex. 1012) is the apparent English translation of Wu, published in Chinese. Ex. 1013 (Certification of translation for Wu and Liu).

⁸ Liu Fuming, *Process Design of Taurine Ammonolysis*, 5:8 CHINA CHEMICAL TRADE 120 (2013) (Ex. 1014) (hereafter “Liu”). Liu (Ex. 1015) is the apparent English translation of Liu, published in Chinese. Ex. 1013 (Certification of translation for Wu and Liu).

III. ANALYSIS

A. *Overview of the Asserted References*

We provide overviews of WO '071, Wu, and Liu below. Pet. 14–19.

1. WO '071 (Ex. 1010)

WO '071 relates generally to “a method for producing ditaurine and salts thereof from taurine or its salts” in a reaction medium. Ex. 1010, 1.⁹

As background, WO '071 describes other processes for producing ditaurinate, including the process wherein “[d]itaurinate is [] formed in the reaction of hydroxyethyl sulfonate [i.e., isethionate] with ammonia under pressure.” Ex. 1010, 2. Citing downsides with other processes (e.g., lower yields of ditaurinate), WO '071 describes a “surprisingly simple method . . . [that] makes it possible to obtain ditaurinate from taurine in a targeted manner and with high yield.” *Id.*

WO '071 discloses a preferred temperature range for the reaction of “from 150 to 270°C” and especially “those [temperatures] in the range from 190 to 230°C.” Ex. 1010, 3. WO '071 further discloses that the reaction medium may include water, and preferably that aqueous sodium hydroxide or aqueous potassium hydroxide are used. *Id.* Moreover, WO '071 teaches that it is advantageous or necessary to add alkali hydroxide to the reaction mixture. *Id.* (describing addition of 0.1 to 15 moles of alkali hydroxide per mole of taurine). WO '071 also discloses that the reaction may be performed at various pressures, including atmospheric pressure, and pressures ranging from 0.9 to 40 bar. *Id.* at 4.

⁹ For purposes of the citations to the relied-upon prior art, we refer to the page numbers provided on the exhibit copies rather than the original pagination of the references.

WO '071 teaches that ammonia, produced in the reaction, may be separated from the reaction mixture. *Id.* at 3. WO '071 discloses, “[s]ince the equilibrium reaction may be displaced on the product side [i.e., toward ditaurinate] by the removal of the ammonia so formed, the conversion is dependent *inter alia* on the ammonia content in the reaction mixture.” *Id.* According to WO '071, “[a]fter carrying out the method . . . and separating the ammonia so formed, there is generally a mixture [] yielded which contains ditaurinate, taurinate, perhaps excess alkali hydroxide, perhaps water, perhaps free taurine, and perhaps other components in small amounts.” *Id.* at 4. WO '071 teaches that “[t]he reaction mixture may also be purified, e.g., neutralized or acidified, e.g. using mineral acids such as hydrochloric acid and sulfuric acid.” *Id.*

2. Wu (Ex. 1012)

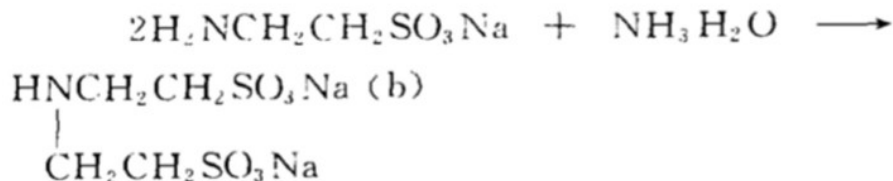
Wu relates to manufacturing methods for taurine by an ammonolysis of sodium hydroxyethyl sulfonate (i.e., sodium isethionate) and subsequent acidification of the reaction mixture. Ex. 1012, 4.

According to Wu, taurine “is the most abundant sulfur-containing free amino acid in body cells” and it “plays a vital role in the development of the brain, nerves, [and] internal organs,” among other body systems. *Id.* Moreover, taurine “helps enhance physical fitness, prevent disease, and relieve fatigue,” and it “has been added extensively to a variety of foods, particularly in infant formula.” *Id.*

Wu describes a reaction of ethylene oxide combined with sodium bisulfite to synthesize sodium isethionate. *Id.* Wu describes an ammonolysis reaction, wherein the sodium isethionate reacts with aqueous ammonia to generate sodium taurinate; the sodium taurinate, in the presence

of an acid, then forms taurine. *Id.* Wu states that “the average yield of product taurine is 41%.” Ex. 1012, 7.¹⁰

Wu further describes a “[s]ide reaction” of the ammonolysis of sodium isethionate, which produces “sodium ditaurinate [] expressed using the symbol (b).” *Id.*



Ex. 1012, 4 (partial reaction); Ex. 1003 ¶ 93. The above depiction of the reaction in Wu shows the formation of sodium ditaurinate (product “(b)”) in aqueous ammonia. Wu teaches that if “residues consisting primarily of (b) are fed again into the ammonolysis system, the total yield of the product [i.e., taurine] may very well increase.” Ex. 1012, 7.

Wu also suggests that sodium carbonate should be added to the reaction environment as a catalyst for an ammonolysis reaction. Ex. 1012, 6 (“As a universal catalyst of high-pressure ammonolysis, the feeding amount of sodium carbonate is certain to be another factor in the reaction.”)¹¹ Wu discloses that “[t]he basic reaction temperature was around (140-260)°C.” Ex. 1012, 5. Wu further discloses that after ammonolysis occurs in an autoclave, “the ammonia is expelled,” then concentrated sulfuric acid is used to adjust the pH to acidic, and a sample is taken to determine the sample’s taurine content. *Id.* at 4.

¹⁰ According to Dr. Lipton, “with certain of [Wu’s] ammonolysis conditions, the taurine yield can reach above 97%.” Ex. 1003 ¶ 96; Ex. 1012, 6–7.

¹¹ Sodium carbonate is a strong base that forms sodium hydroxide in water. Ex. 1003 ¶ 97.

3. Liu (Ex. 1015)

Liu relates to ammonolysis and a method for the large-scale production of taurine, a product Liu describes as having “been applied extensively in the pharmaceutical and food industries.” Ex. 1015, 6. Liu further “explains the process of producing taurine using the ethylene oxide method [i.e., the EO process], the theoretical analysis of ammonolysis, [and] the applications of the mother liquor in production.” *Id.*

Liu describes the reaction of ethylene oxide and sodium bisulfite under alkaline conditions (30% sodium hydroxide) to produce 2-sodium isethionate. Ex. 1015, 6. That product then undergoes an initial ammonolysis reaction at high temperature and pressure (18–19.5 MPa, 265–270°C) to generate 2-sodium aminoethanesulfonate (i.e., sodium taurinate). *Id.* Liu further teaches that a neutralization of sodium taurinate in sulfuric acid generates sodium sulfate and taurine, which may then be extracted. *Id.* According to Liu, “[c]omponent analysis of the mother liquor indicates that it contains many components,” including, *inter alia*, remaining 2-sodium isethionate, sodium sulfate, and “sodium ditaurinate.” *Id.* Liu explains that this mother liquor, if released, “becomes highly concentrated contaminated emissions, damaging and polluting the environment.” *Id.*

Liu then describes an “Application of Mother Liquor Recycle in Production.” Ex. 1015, 6 (bold-font omitted). Liu teaches that “[t]he 2-sodium isethionate that does not participate in ammonolysis follows the production system into the next process.” *Id.* According to Liu, “[e]xcluding a small amount that undergoes a secondary reaction, the majority exists in the mother liquor in the form of 2-sodium isethionate,” and “[t]he mother liquor can undergo the corresponding processing and purification to participate again in ammonolysis in the form of sodium

isethionate.” *Id.* Moreover, Liu discloses, “sodium ditaurinate is also generated during the ammonolysis process.” *Id.* According to Liu, “[t]his sodium ditaurinate also exists in the mother liquor system,” and “[i]f this sodium ditaurinate is fed again into ammonolysis, the proportion of 2-sodium isethionate in the reaction product can be increased, increasing generation yield.” *Id.*

Liu further teaches that “[a]mmonolysis process reaction yield can be increased from 70%-80% to 85%-95%.” Ex. 1015, 6. And, Liu discloses, the “equipment operations are stable, reducing the discharge of waste liquids and overall production costs.” *Id.*

B. *Person of Ordinary Skill in the Art*

Petitioner proposes the following qualifications for the person of ordinary skill in the art:

[A] POSA at the time of the alleged invention . . . would have an advanced degree, such as a Master’s or Ph.D., in the field of organic chemistry or a closely related field. (Ex. 1003, ¶ 17). A POSA would also have at least five years of experience with organic synthesis of nitrogen-containing compounds, and would understand basic chemistry principles and organic synthesis techniques. *Id.*

Pet. 12. For its part, Patent Owner agrees in substance with Petitioner’s proposal. Prelim. Resp. 12; Ex. 2001 ¶¶ 20–22.

The parties agree regarding the skilled artisan’s qualifications, and we find that the proposals are consistent with the relied-upon prior art. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required where the prior art itself reflects an appropriate level and a need for testimony is not shown) (internal quotation marks and citation omitted). We, thus, adopt for

purposes of this Decision the parties' proposed qualifications for the person of ordinary skill in the art.

C. Claim Construction

In an *inter partes* review, we interpret claim terms in an unexpired patent based on the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b) (2018); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (affirming the broadest reasonable construction standard in *inter partes* review proceedings).¹² Under that standard, we presume a claim term carries its “ordinary and customary meaning,” which “is the meaning that the term would have to a person of ordinary skill in the art in question” at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). We need only construe terms in controversy, and only to the extent necessary to resolve that controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

Whether the claims require a “second” ammonolysis step

In the Petition and the Patent Owner's Preliminary Response, neither party contends that the claims require any express construction. Pet. 12

¹² The Final Rule changing the claim construction standard in IPR proceedings does not apply here, as the Petition was filed before the rule's effective date, November 13, 2018. *See Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 51,340, 51,340, 51,344 (Oct. 11, 2018). Nevertheless, we do not perceive on this record that the construction would be different if the standard in the above-noted Final Rule were applied.

(“[N]o claim terms or phrases require specific construction for the purpose of this IPR.”); Prelim. Resp. 11 (“Vitaworks agrees with Petitioner’s position that none of the claim terms of the ’450 Patent requires interpretation for purposes of deciding whether or not to institute a proceeding.”). After Patent Owner’s Preliminary Response was filed, however, an issue arose related to whether the claims require a “second” or “subsequent” ammonolysis step. *See* Paper 8, 5 (Petitioner’s Reply to Patent Owner’s Preliminary Response);¹³ Paper 9, 1–3 (Patent Owner’s Sur-Reply).

According to Petitioner, the question whether the claims require a “second” ammonolysis step is “not an issue of claim construction,” but instead goes to Patent Owner’s attempt to distinguish the cited prior art. Paper 8, 5–6. In particular, Petitioner contends Patent Owner is urging that the claims require a “second” ammonolysis step because Patent Owner argues that the prior art discloses a first ammonolysis reaction, but does not describe “precise conditions” for a second ammonolysis reaction. *Id.* at 6. In any event, Petitioner contends “the claims themselves” confirm that a second ammonolysis step is not required. *Id.* at 5 (citing, e.g., dependent claim 2).

Patent Owner responds that “[t]he claims at issue in all three patents [challenged in the three-related IPRs] require a ‘second’ or subsequent ammonolysis reaction.” Paper 9, 1. According to Patent Owner, a “first” ammonolysis is one conducted first in time and without any ditaurinate. *Id.*

¹³ The Board held a conference call with counsel for the parties, and the Board authorized further pre-institution briefing on two issues: (i) whether statements of Patent Owner in other proceedings were inconsistent with positions taken in the Preliminary Response; and (ii) whether the claims require a second ammonolysis step. Paper 8; Paper 9.

(citing known reactions where ditaurinate is one of several products of ammonolysis of isethionate). Patent Owner contends that “[i]n all the challenged claims ditaurinate is present in the reaction mixture before ammonolysis [and] therefore they all read on a second ammonolysis.” *Id.*

We are unpersuaded, for purposes of this Decision, that independent claim 1 of the ’450 patent requires a second ammonolysis step. Claim 1 expressly recites one, and only one, ammonolysis reaction, which appears in step (b). Claim 1 also does not specify that ditaurinate (as recited in the claim preamble and step (a)) must come from any particular source or earlier reaction as suggested by Patent Owner’s argument.

Claim 1 may “read on” the ammonolysis of a ditaurinate, itself produced as one of the byproducts of a “first” ammonolysis reaction of, for example, sodium isethionate.¹⁴ Indeed, such a process is claimed in dependent claim 3. Ex. 1001, 8:24–27. In that context, the reaction of a ditaurinate in excess ammonia might be characterized as a “second” ammonolysis as argued by Patent Owner. Paper 9, 1–2.

But what a claim may “read on” (i.e., encompass) is not the same as what the claim *requires*. And, as Petitioner demonstrates persuasively, claim 1 is broader and does not necessarily require that ditaurinate be produced from a first ammonolysis reaction. Dependent claim 2 recites that the ditaurinate or tritaurinate (from claim 1’s preamble and/or step (a)) is prepared from diethanolamine or triethanolamine. Paper 8, 5; Ex. 1001, 8:21–23; *see also id.* at 3:37–55 (describing preparation of sodium

¹⁴ As recited in claim 1, dialkali ditaurinate is prepared with addition of alkali hydroxide to a solution of alkali ditaurinate (step (a)), and in step (b), a solution comprising dialkali ditaurinate is subjected to ammonolysis.

ditaurinate from diethanolamine reacted with thionyl chloride, followed by sulfonation). Dependent claim 2, thus, indicates that ditaurinate in claim 1 need not be the product of a “first” ammonolysis step. Hence, the ammonolysis reaction recited in claim 1’s step (b) need not be a “second” ammonolysis step. Patent Owner’s response to claim 2, describing this as “a semantics argument,” does not demonstrate persuasively why Petitioner’s argument—at least as to the breadth and interpretation of claim 1—is wrong. Paper 9, 2.

For the above reasons, we conclude for purposes of this Decision that the challenged claims of the ’450 patent do not require both “first” and “second” ammonolysis reactions, except to the extent such steps are required explicitly or by implication in the claims (i.e., dependent claim 3).

D. Principles of Law

To show anticipation, each and every claim element, arranged as in the claim, must be found in a single prior art reference. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359 (Fed. Cir. 2008). The prior art need not, however, use the same words as the claims in order to find anticipation. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009). It is permissible to take into account not only the literal teachings of the prior art reference, but also the inferences the skilled artisan would draw from the reference. *Eli Lilly and Co. v. Los Angeles Biomedical Res. Inst. at Harbor-UCLA Med. Ctr.*, 849 F.3d 1073, 1074–75 (Fed. Cir. 2017); *In re Preda*, 401 F.2d 825, 826 (CCPA 1968).

A 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 to the person of ordinary skill

in the art at the time of the invention. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). “[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR*, 550 U.S. at 418. “[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine elements in the way the claimed new invention does.” *Id.*

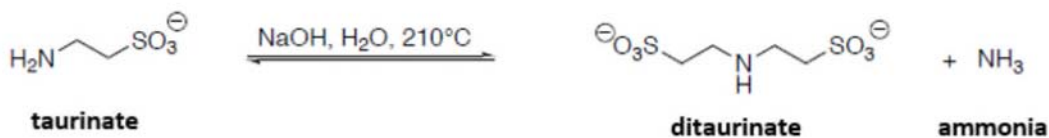
E. Ground 1: Anticipation By WO '071

Petitioner contends that claim 1 (and dependent claims 3–7) are unpatentable as anticipated by WO '071. Pet. 20–37.

Claim 1

WO '071 generally describes the production of ditaurine (or its salts) from taurine (or its salts). Ex. 1010, 1; *see supra* Section III(A)(i).

Fundamental to Petitioner's anticipation challenge is the assertion that WO '071 describes not only a forward reaction, wherein ditaurinate is produced from a reaction of taurinate, but the *reverse* reaction as well—producing taurinate from ditaurinate. Pet. 22–23. According to Petitioner, “[t]he POSA would understand that this reaction can . . . be represented in the schematic diagram below:”



Id. at 23; *see also* Ex. 1003 ¶ 57. The above diagram, which is not expressly shown in WO '071, illustrates a reaction at equilibrium, with two reactions proceeding at the same time: one proceeding in one direction (right-facing arrow) where ditaurinate and ammonia are produced from taurinate, and another proceeding in the reverse direction (left-facing arrow) where taurinate is produced from ditaurinate and ammonia. Ex. 1003 ¶¶ 57–59; Ex. 1010, 6 (Examples). As depicted, the reaction takes place in a medium comprising sodium hydroxide and water, and at a temperature of 210°C. Ex. 1003 ¶¶ 57–59; Ex. 1010, 2 (disclosing reaction media, temperatures, and addition of alkali hydroxides), 6–7 (Examples and Table 1).

Although the focus of WO '071 is generating ditaurinate (not taurinate or taurine, as in claim 1), Petitioner relies on WO '071's teaching that the reaction is an "equilibrium reaction." Pet. 23; Ex. 1010, 3 ("Since the *equilibrium reaction* may be displaced on the product side by the removal of the ammonia so formed, the conversion is dependent . . . on the ammonia content in the reaction mixture.") (emphasis added). So, Petitioner reasons, "a POSA would have understood that an equilibrium reaction necessarily proceeds both ways – forward and reverse." Pet. 23; Ex. 1003 ¶¶ 66–67. Also, Petitioner contends, "[a] POSA would also understand," applying well-known principles of chemistry, "that an equilibrium reaction can be shifted to increase yield of either the products or reagents." Pet. 23.¹⁵

¹⁵ Petitioner cites, for example, Le Châtelier's Principle that, "whenever the concentration of a component changes, *the equilibrium system reacts to*

Accordingly, reading WO '071 in light of these principles, Petitioner contends that “a POSA would have understood that this equilibrium reaction can also be predictably displaced towards the reagent side [i.e., toward taurinate] by adding ammonia into the reaction system.” Pet. 25.

In terms of whether WO '071 describes claim 1's four steps (a–d), Petitioner argues the following points. Petitioner contends that step (a) is satisfied because the reverse reaction “can also proceed in the same reaction medium,” which in WO '071's examples includes addition of sodium hydroxide—an alkali hydroxide as claimed. Pet. 26–27. According to Petitioner, although “dialkali ditaurinate” is not mentioned in WO '071, its formation “is inherently disclosed because dialkali ditaurinate . . . will inevitably form when alkali hydroxide is added to alkali ditaurinate,” particularly in a basic environment. *Id.* For step (b), Petitioner contends, a “POSA would appreciate that the reaction can also be displaced on the reagent side, to generate taurinate or its salt . . . by adding excess ammonia into the reaction system.” *Id.* at 29. And, for steps (c) and (d), Petitioner asserts that WO '071 discloses separating ammonia by distillation, and neutralizing the reaction mixture with an acid (Pet. 30), which, according to Petitioner, “inevitably would form crystalline taurine, which can then easily be recovered through solid-liquid separation using known techniques in the art” (Pet. 32).

consume some of the added substance or produce some of the removed substance.” Pet. 23–24 (quoting Ex. 1019, 45–46) (Petitioner's emphasis); *see also* Ex. 1020 (describing the Principle of Microscopic Reversibility: “if a reaction occurs by a certain mechanism, the reverse reaction under the same conditions occurs by the exact reverse of that mechanism”).

Patent Owner responds with several arguments of its own. Patent Owner contends that WO '071 “expressly teaches the opposite process” of claim 1 and, thus, cannot anticipate. Prelim. Resp. 17–18.

Patent Owner also contends that, even if the “literal teaching of WO '071 is considered in reverse, it would not anticipate the claims.” *Id.* at 19. That is so, Patent Owner argues, because literally running the reaction in reverse would add only a “stoichiometric amount of ammonia,” therefore not adding and removing *excess* ammonia as claimed. *Id.* Moreover, Patent Owner contends the WO '071 reaction, when literally reversed, would add the alkali hydroxide after the ammonia/ammonolysis reaction, not before, as with steps (a) and (b) of claim 1. *Id.* at 20. Regarding addition of alkali hydroxide, Patent Owner argues that nothing in WO '071 suggests a need to add an amount sufficient to ensure that fully deprotonated taurinates (e.g., dialkali ditaurinate) are formed.¹⁶ *Id.* at 21. Finally, Patent Owner contends WO '071's process does not in fact neutralize the reaction to form taurine or recover taurine in crystalline form as required with claim 1. *Id.* Because claim 1 is not anticipated by WO '071, Patent Owner contends neither are dependent claims 3–7. *Id.* at 22.

We are skeptical that Petitioner is reasonably likely to succeed in establishing anticipation of claim 1 by WO '071. As Patent Owner notes,

¹⁶ Patent Owner seemingly acknowledges, however, that the amounts of sodium hydroxide added in WO '071 are sufficient to convert some monosodium ditaurinate to the deprotonated form. Prelim Resp. 21; Ex. 2001 ¶¶ 33 (opining that at pH 5–8, monoalkali ditaurinate is predominantly present, while at pH > 9, dialkali ditaurinate is a predominant form), 119 (calculating WO '071's pH range for the reaction at between 8 to 14). Notably, the claims do not recite that any particular proportion of the ditaurinates or tritaurinates be in the dialkali- or trialkali-form.

Petitioner cites no authority where anticipation according to a reverse-reaction theory was supported or found. Prelim. Resp. 18. On the other hand, Petitioner cites WO '071's disclosure that the formation of ditaurinate from taurinate/taurine in the reaction media is an "equilibrium reaction." Pet. 23; Ex. 1010, 3. And, the anticipation analysis is not restricted to only a reference's literal descriptions. Pet. 20–21 (citing cases). Further to that point, Petitioner provides evidence (e.g., opinion of Dr. Lipton) seeking to explain how a skilled artisan would "have understood" WO '071's teachings, including on whether WO '071's method necessarily involves both the forward and the reverse reaction—wherein ditaurinate reacts with ammonia under the same reaction conditions to produce taurinate. Pet. 22–25; Ex. 1003 ¶¶ 66–68.

Even if we agree, however, that Petitioner's evidence is sufficient for institution purposes to show that WO '071 discloses the forward, and the reverse reactions, more is necessary to establish anticipation of claim 1. For example, as Patent Owner points out, the method described in WO '071 does not, in fact, appear to include a step of "adding excess ammonia" as in claim 1's step (b) or "recovering taurine by means of solid-liquid separation" as in step (d). Whether a step of adding excess ammonia would have been straightforward or routine for a skilled artisan having a reason to produce taurine by applying established principles of chemistry (e.g., Le Châtelier's Principle) for an equilibrium reaction, in order to drive the reaction toward production of taurinate/taurine, presents a different question. And here, Petitioner's invocation of what the skilled artisan would "appreciate" about the reverse reaction in WO '071, and particularly how the reaction "can be" modified to emphasize the production of the reagent (i.e., taurine), which "can then easily be recovered . . . using known techniques in the art," seem

to be rationales better suited, not to anticipation, but to obviousness, which is the subject of Petitioner's Ground 2 challenge. Pet. 23, 25, 29, and 32.

Notwithstanding our skepticism on the anticipation challenge, because we find that the Petition demonstrates a reasonable likelihood of success in establishing that at least one of claims 1 and 3–7 are unpatentable for obviousness (*see* Grounds 2–4, discussed below), we include Ground 1 in the institution of trial. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018).

F. Ground 2: Obviousness Over WO '071 And Knowledge Of The Ordinarily Skilled Person

Petitioner contends that claim 1 (and dependent claims 3–7) are unpatentable for obviousness over WO '071 and the skilled artisan's knowledge. Pet. 37–42. Petitioner cross-references, in pertinent part, its discussion of WO '071's teachings referenced above related to anticipation. Pet. 39–40.

1. Claim 1

Petitioner contends that, insofar as WO '071's reaction that produces ditaurinate proceeds in one direction, while the reaction of claim 1 proceeds in an opposite direction, the skilled artisan would appreciate that, as an "equilibrium reaction," the WO '071 reaction actually proceeds in both directions. Pet. 40. And, Petitioner contends, "[a] POSA would also understand that an equilibrium reaction can be shifted to increase yield of either product or reagent" using "[w]ell-established chemistry principles." *Id.*; Ex. 1003 ¶¶ 58–59, 60–63, and 86–87.

With this appreciation of WO '071 and basic principles of chemistry, Petitioner argues, the skilled artisan seeking to produce taurine in high yield would have reason to displace WO '071's reaction to the reagent side

through the addition of ammonia. Pet. 41. Petitioner contends the skilled artisan's attention "would be drawn to the fact that ditaurinate is a standard byproduct from the widely-practiced taurine synthesis process through ammonolysis." *Id.* (citing, e.g., Ex. 1001, 2:9–12; Ex. 1003 ¶ 89). Based on the disclosed conversion rates in WO '071 (1% to 70%), Petitioner and its declarant assert that the skilled artisan "would understand [this] to mean that this equilibrium can be significantly displaced . . . to produce up to 99% taurine or its salt" from the reaction of ditaurinate and ammonia. Pet. 41; Ex. 1003 ¶¶ 89–90.

With the equilibrium reaction, Petitioner contends a presence of excess ammonia will drive the reaction in reverse and would favor the formation of the primary amine (sodium taurinate) over the secondary or tertiary amines (ditaurinate or tritaurinate). Pet. 41; Ex. 1003 ¶ 42. The skilled artisan would, according to Petitioner, have also had a reasonable expectation of success in driving this reverse reaction, and generating high taurine yield from ditaurinate because the equilibrium reaction consumes ammonia under the same conditions (e.g., reaction media) in WO '071. *Id.* at 41–42; Ex. 1003 ¶¶ 86–90.¹⁷ Moreover, Petitioner contends, applying well-known techniques, such as those recognized as such in the '450 patent itself, the skilled artisan would have neutralized the desired product (sodium taurinate) with an acid to produce crystalline taurine and recovered the

¹⁷ Petitioner explains that the addition of alkali hydroxide (as in WO '071) "ensures the reaction environment is basic," and that "a POSA would have readily understood that this [basic] reaction medium accelerates the forward and reverse reactions of an equilibrium by the same factor." Pet. 27; *see also* Ex. 1003 ¶ 43 ("[A]s reflected in the prior art, a POSA would know that ammonolysis reactions must proceed in a basic environment.").

taurine through solid-liquid separation. Pet. 31–32; Ex. 1001, 2:21–26; Ex. 1003 ¶¶ 74–76.

Petitioner supports its positions with the teachings of WO '071, disclosures in secondary references (e.g., Exs. 1019 and 1020), descriptions of prior art and background knowledge as evidenced in the '450 patent, and Dr. Lipton's testimony. *See, e.g.*, Ex. 1003 ¶¶ 41–44, 65–76. We determine, for purposes of this Decision, that Petitioner's argument and evidence is sufficient to establish a reasonable likelihood of success in showing that at least claim 1 of the '450 patent is unpatentable as obvious over WO '071 and the knowledge of the skilled artisan.

We agree on the present record that the skilled artisan would have likely understood, from WO '071's disclosure of an "equilibrium reaction," that the reaction proceeds in both directions. We are further persuaded that a skilled artisan, having a reason to produce taurine and with knowledge of the reaction described in WO '071, would have displaced the reaction towards the production of taurinate by adding ammonia to ditaurinate in the reaction environment.¹⁸ Just as WO '071 describes that the equilibrium reaction may be driven toward production of ditaurinate/ditaurine by removing ammonia, the skilled artisan would understand and reasonably expect, according to well-known principles of chemistry, that adding excess ammonia would drive the reaction in the opposite direction. *See, e.g.*, Ex. 1003 ¶¶ 61, 86–90.

¹⁸ Although the method of WO '071 is aimed at producing ditaurinate or ditaurine and improving the yield of those products, we do not agree that the skilled artisan would read its teachings so narrowly. The record here is replete with evidence about the known benefits of taurine and describing methods for its production (*see, e.g.*, Pet. 1–2; Ex. 1001, 1:15–22; Ex. 1012, 4; Ex. 1015, 6), thus reflecting reasons for the skilled artisan to have formed taurine and to have improved on existing methods capable of producing it.

WO '071 suggests the use of an alkaline reaction media including the addition of alkali hydroxide, and Petitioner presents evidence that this same reaction media would apply to help accelerate the reaction, whether proceeding forward or in reverse. *See, e.g., id.* ¶ 70; Ex. 1010, 3. Petitioner cites evidence that the combination of sodium ditaurinate with alkali hydroxides in a basic environment, required for an ammonolysis reaction to occur, will convert at least some of the sodium ditaurinate to dialkali ditaurinate. Pet. 27–28; Ex. 1003 ¶¶ 70–72; *see also supra* n.16. Petitioner's argument and evidence is, thus, sufficient, for purposes of this Decision, to show to a reasonable likelihood that claim 1's step (a) would be met in the reverse reaction of WO '071 as proposed by Petitioner. Claim 1's step (b) is discussed above regarding the proposed reason to displace the reaction in reverse by addition of excess ammonia. And Petitioner's evidence and argument is also sufficient, at this stage, to support a determination that claim 1's steps (c) and (d) are suggested in WO '071 or simply routine techniques the skilled artisan would predictably use for neutralizing and removing the desired reaction product—in this case, taurine. Pet. 31–32; Ex. 1001, 2:21–26; Ex. 1003 ¶¶ 74–76.

Below we address Patent Owner's arguments, none of which is persuasive in demonstrating that the Petition does not establish a reasonable likelihood of success on the challenge to claim 1 under Ground 2.

Patent Owner argues that an ordinarily skilled person, interested in producing taurine, would not look to WO '071. Prelim. Resp. 22–23. According to Patent Owner, WO '071 relates to the production of ditaurinate, “destroying taurine” in the process, and “a POSA need only read WO '071's cover page to conclude that they need not read further.” *Id.* at 23. Moreover, Patent Owner contends, WO '071 “distinguishes its process

from [the] underlying process used in the '450 Patent,” wherein isethionate is reacted with ammonia to produce taurinate and byproducts, such as ditaurinate (i.e., part of the conventional EO process). *Id.* at 24. The POSA looking to produce taurine would, Patent Owner argues, “be stopped cold” by those disclosures in WO '071. *Id.*

We disagree. First, it is axiomatic that prior art should be read in its entirety, and considered for all that it teaches and suggests to the skilled artisan. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1547, 1554 (Fed. Cir. 1983); *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986) (holding “the prior art as a whole must be considered”); *Dystar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1361 (Fed. Cir. 2006) (prior art is “viewed through the eyes of an ordinary artisan”). So, based on the current record, we do not find that the ordinarily skilled person would immediately stop reading WO '071 upon coming to a disclosure that indicates an allegedly different objective or desired reaction product than that produced with the claimed method.

Second, the skilled artisan is “a person of ordinary creativity, not an automaton.” *KSR*, 550 U.S. at 421. Relevant to the inquiry here, the skilled person, at least based on WO '071's disclosure of an “equilibrium reaction” would likely recognize WO '071's teachings as not strictly limited to only the forward reaction where ditaurinate and ammonia are produced. To the contrary, applying knowledge about equilibrium reactions and well-established principles of chemistry, the skilled person would know that the reaction can readily be shifted to favor the reverse direction to produce taurinate from ditaurinate and excess ammonia. *Id.* at 415, 418 (holding the obviousness requires “an expansive and flexible approach” and “can take

account of the inferences and creative steps that a person of ordinary skill in the art would employ.”).

Third, it is true, as Patent Owner notes, WO '071 describes its method of producing ditaurinate as advantageous over other methods (e.g., the EO process). Prelim. Resp. 24; Ex. 1010, 2. But, as discussed above, claim 1 does not require that the ditaurinate come from any particular source or prior reaction (e.g., ammonolysis of isethionate). *See* Section III(C). Moreover, we agree the skilled person, having a reason to produce taurine by driving the equilibrium reaction in reverse, would be drawn to known sources of ditaurinate. Pet. 41. Because taurine is the desired reaction product under Petitioner's Ground 2 challenge, the skilled person would not seek to drive WO '071's reaction in a forward direction to produce ditaurinate, as that would, on balance, consume and reduce taurine yield.

Patent Owner also argues that WO '071 only briefly mentions an “equilibrium reaction” and, Patent Owner contends, that disclosure is taken out of context to allege disclosure of the reverse reaction. Prelim. Resp. 24–25. According to Patent Owner (and Dr. Maleczka) equilibrium can be impacted by many factors. *Id.* at 26. Patent Owner contends “the statement in WO '071 that the reaction is in equilibrium is unsupported by data.” *Id.* (citing Ex. 2001 ¶¶ 60–69, 75, 76, and 106). And, Patent Owner argues, that the reaction of WO '071 is in equilibrium is “questionable because the results achieved in WO '071 never exceeded a yield of 64% ditaurinate,” yet Petitioner and its declarant Dr. Lipton somehow read the reverse reaction as capable of producing higher yields of taurine (i.e., as high as 99%). Prelim. Resp. 26–27.

On the question of whether the WO '071 reaction is an equilibrium reaction, and whether the skilled artisan would interpret the relevant

disclosures in WO '071 as suggesting the reverse reaction, Patent Owner's arguments do not avoid institution on the record here. Those issues, at this stage, are essentially disagreements among the parties' declarants about how WO '071 would be understood by those skilled in the art and what, if any, expectations related to a reverse reaction and product yields would reasonably be predicted from such a reaction. Based upon our review, we consider those disagreements to present genuine issues of material fact better left to resolution through trial on a more developed record. 37 C.F.R. § 42.108(c) (requiring that genuine issues of material fact created by testimonial evidence at the institution stage be viewed in the light most favorable to the petitioner).

Patent Owner also asserts that there are other differences between the claimed invention and the process of WO '071. Prelim. Resp. 25–26. These differences include, according to Patent Owner, adding alkali hydroxide to deprotonate ditaurinate or tritaurinate *before* ammonolysis, and the neutralization of the resulting material with acid *after* ammonolysis as claimed. *Id.* As explained above, we find the Petition has shown, sufficient for institution, that those elements are disclosed or inherent upon the combination of a ditaurinate and an alkaline hydroxide in a basic reaction environment (as suggested in WO '071), and otherwise involve conventional techniques within the skilled person's knowledge for purifying the desired reaction product (acidification and solid-liquid separation). Pet. 26–28, 31–32; *see, e.g.*, Ex. 1001, 2:21–26; Ex. 1003 ¶¶ 74–76.

2. Claims 3–7

Petitioner cites evidence to demonstrate that each of the limitations that dependent claims 3–7 add to claim 1 is disclosed in WO '071. Pet. 33–37, 42. For example, for claim 3, Petitioner cites WO '071's disclosure of a

typical EO process, where ditaurinate is produced from reaction of hydroxyethyl sulfonate (isethionate) with ammonia.¹⁹ Pet. 33; Ex. 1010, 2. For claim 4, Petitioner cites WO '071's teaching of the use of catalysts, especially alkali hydroxides as advantageous. Pet. 34; Ex. 1010, 3. According to Petitioner, the skilled artisan would recognize such catalysts operate similarly, whether the reaction is proceeding forward or backward. Pet. 34; Ex. 1003 ¶¶ 79–80. For claim 6, Petitioner cites WO '071's disclosure that the reaction mixture can be neutralized with sulfuric acid, and Petitioner otherwise contends that neutralizing of reaction mixtures containing taurinate and ditaurinate is well known in the art. Pet. 35; Ex. 1010, 4; Ex. 1001, 2:21–24; Ex. 1003 ¶ 82.

Patent Owner argues claim 3 is not obvious because the cited portion of WO '071 relates to a discussion of the traditional process (ammonolysis of isethionate), which WO '071 allegedly dismisses in favor of making ditaurinate from taurine. Prelim. Resp. 27–28. Hence, Patent Owner contends, “it is difficult to imagine that a POSA would look to that very same [allegedly dismissed] process.” *Id.* at 29. For claim 4, Patent Owner contends WO '071 does not mention adding an alkaline catalyst “to a reaction mixture prior to ammonolysis.” *Id.* at 28. And, for claim 6, Patent Owner argues WO '071 does not teach “neutralizing with an acid after ammonolysis as claimed.” *Id.*

¹⁹ Patent Owner does not provide any separate argument regarding dependent claims 5 and 7. Prelim. Resp. 27–28. Accordingly, we do not repeat here Petitioner's assertions as to those claims, assertions with which we generally agree, for purposes of institution, that Petitioner has established a reasonable likelihood of success in demonstrating the unpatentability of those claims over the asserted art. Pet. 35–37.

Patent Owner's arguments as to claims 4 and 6 are unpersuasive at this stage to overcome Petitioner's showing of a reasonable likelihood of success in demonstrating the unpatentability of those claims over the combined prior art. Petitioner contends that the catalyst would work the same whether the reaction runs in a forward direction or in reverse, and further contends that a skilled artisan would recognize that the reaction environment must be rendered basic in order for an ammonolysis reaction to proceed, thus suggesting the introduction of alkali hydroxide/catalyst prior to addition of excess ammonia. Pet. 27; *see also* Ex. 1003 ¶¶ 43, 97 (regarding adding a base to ensure the reaction environment is basic for ammonolysis). Patent Owner provides insufficient persuasive evidence otherwise. As to claim 6, Patent Owner's argument fails to adequately account for the well-known techniques identified by Petitioner of purifying and neutralizing sodium taurinate with acids—as would predictably be done with the product of the reverse reaction in WO '071. Ex. 1001, 2:21–24; Ex. 1003 ¶ 82.

As for claim 3, the Petition's obviousness analysis is rather threadbare, referring to the discussion provided for anticipation under Ground 1. Pet. 42. The Petition's discussion of claim 3 under Ground 1 simply identifies that sodium ditaurinate is one of several known byproducts of ammonolysis of isethionate. *Id.* at 33. Little in the way of specific analysis is provided for claim 3 (under Ground 1 or Ground 2) to explain why the skilled artisan would combine the byproduct of the traditional EO process with a reverse reaction of WO '071. The Petition's assertion (related to analysis of claim 1) that the skilled artisan “would be drawn to the fact that ditaurinate is a standard byproduct from the widely-practiced taurine synthesis process through ammonolysis” does not connect clearly

that assertion to claim 3. Thus, at this stage of the proceeding, we do not find that Petitioner has established a reasonable likelihood of success in demonstrating that claim 3 is unpatentable over WO '071.

G. Ground 3: Obviousness Over Wu And WO '071

Petitioner contends that claims 1 and 3–7 are unpatentable as obvious over Wu (Ex. 1012) and WO '071 (Ex. 1010). Pet. 42–52.

1. Claim 1

An overview of Wu is provided above. See Section III(A)(ii). Petitioner cites, *inter alia*, Wu's teaching of an ammonolysis reaction, wherein sodium isethionate is reacted with ammonia in the presence of an alkaline catalyst to produce sodium taurinate and, in a side reaction, sodium ditaurinate. Pet. 43; Ex. 1012, 4. Petitioner further emphasizes Wu's teaching that when residues "consisting primarily of (b) [i.e., sodium ditaurinate produced in the above-noted side-reaction] are fed again into the ammonolysis system, the total yield of the product [i.e., taurine] may very well increase." Pet. 43; Ex. 1003 ¶ 95.

Turning to steps (a–d) of claim 1, Petitioner contends those steps are disclosed in the combination of Wu and WO '071. For step (a), Petitioner contends, *inter alia*, that Wu teaches that sodium carbonate, as a strong base that forms sodium hydroxide in water, is a universal catalyst for an ammonolysis reaction. Pet. 44–45 ("a POSA would have known that because ammonia is a weak base, an ammonolysis reaction must proceed in a basic environment."); Ex. 1003 ¶¶ 43, 97; Ex. 1012, 4, 6. When the residues, comprising primarily sodium ditaurinate, are fed again into the ammonolysis system as suggested in Wu (Ex. 1012, 4), Petitioner contends that step (a) would be met and that dialkali ditaurinate would be "necessarily

present” based on conversion of at least some sodium ditaurinate to dialkali ditaurinate in the presence of the alkali hydroxide (e.g., sodium carbonate) added to the system. Pet. 45; Ex. 1003 ¶¶ 71–72.

For step (b), Petitioner notes that “Wu . . . does not explicitly disclose the mechanism through which ditaurinate produces taurine through ammonolysis.” Pet. 46. Petitioner, however, contends that the skilled person would understand such a mechanism and reaction from WO ’071—where the “equilibrium reaction” suggests ditaurinate reacts with ammonia in the presence of a reaction medium to produce a taurine salt. *Id.*; Ex. 1003 ¶¶ 66–67, 99. Accordingly, Petitioner contends Wu and WO ’071 together suggest “adding an excess amount of ammonia to a solution of dialkali ditaurinate . . . and subjecting the solution to ammonolysis reaction to yield a mixture of alkali taurinates.” Pet. 46; Ex. 1003 ¶¶ 98–99.²⁰

²⁰ In additional briefing, Patent Owner contends the Petition is deficient in establishing the addition of “excess ammonia” for step (b)’s ammonolysis. Paper 9, 6. Evidence in the present record, however, suggests adding excess ammonia is merely standard procedure for ammonolysis and, Petitioner contends, Patent Owner admits this in other proceedings. *See* Ex. 1060 (Patent Owner’s Second Amended Complaint) ¶ 128 (chart purporting to show satisfaction of claim 1’s step (b) with an assertion that “[t]he addition of excess ammonia to perform ammonolysis is standard operating procedure”); *see, e.g.*, Ex. 1001, 53–58 (describing prior art (Ex. 1016) as conducting ammonolysis of isethionate in a molar ratio of 1:6.8). Patent Owner contends its Complaint does not say excess ammonia is standard for a *second* ammonolysis, yet this contention is unpersuasive in view of Patent Owner’s apparent reading of claim 1’s step (b) as being the allegedly required second ammonolysis step. Paper 9, 1–2. In any event, the Petition provides a reason to add excess ammonia, for example, in displacing the WO ’071 reaction in reverse according to known principles of chemistry. Pet. 29–30; Ex. 1003 ¶¶ 61–62, 73.

For steps (c) and (d), Petitioner contends those steps are disclosed in Wu. Pet. 46–47. According to Petitioner, Wu teaches excess ammonia is expelled from the system following the reaction, and that the reaction mixture is neutralized with sulfuric acid so that a taurine sample may be taken and analyzed. *Id.* at 47 (citing Ex. 1012, 4). Further Petitioner contends, neutralizing the reaction mixture of taurinates with acid to form a crystalline taurine suspension, and removing taurine through solid-liquid separation is a well-known technique—again, as admitted in the ’450 patent. Pet. 47 (citing Ex. 1001, 2:21–24); Ex. 1003 ¶ 96.

Petitioner contends the skilled artisan would have been motivated to combine the disclosures of Wu and WO ’071 based on a desire to improve taurine yields and to reduce waste of known byproducts. Pet. 48. According to Petitioner, Wu specifically suggests recycling the ditaurinate, otherwise a waste product, for another round of ammonolysis, and provides an express suggestion that taurine yield will improve in doing so. *Id.*; Ex. 1012, 4. And, Petitioner contends, the skilled artisan would read WO ’071 as “confirming that sodium ditaurinate will in fact produce additional taurine through ammonolysis”—thus further providing a reasonable expectation of success in the recycling process suggested in Wu, and arriving at the subject matter of claim 1. Pet. 48–49; Ex. 1003 ¶¶ 63, 67, 99–102; Ex. 1010 2, 3.

On the present record, we conclude that Petitioner’s argument and evidence is sufficient to establish a reasonable likelihood that claim 1 is unpatentable as obvious over Wu and WO ’071 for the reasons given by Petitioner, and as explained above. Petitioner’s argument is adequately supported for institution purposes by, *inter alia*, disclosures in the cited references, and opinion testimony explaining how those disclosures would

be understood and combined to arrive at the subject matter of claim 1. We address Patent Owner's arguments below.

Patent Owner argues that Petitioner "does not explain why a POSA would combine these teachings" in Wu and WO '071, and "a POSA has absolutely no reason to look to a disclosure of WO '071 for explaining or improving a process of making taurine." Prelim. Resp. 28. We do not agree with Patent Owner on the record here.

As an initial matter, Wu's teachings are not limited to only the process of making taurine using ammonolysis of isethionate (the EO process), as Patent Owner suggests. Prelim. Resp. 28. To the contrary, Wu discloses more. Indeed, it suggests reusing one of the byproducts (sodium ditaurinate) in a further round of ammonolysis, and that doing so should increase taurine yield. Ex. 1010, 4. To the extent the teachings of the references are being "combined," Petitioner relies on WO '071, in effect, to evidence that a further chemical reaction expressly encouraged in Wu—feeding ditaurinate into the ammonolysis system again—is likely to produce more taurinate, and taurine, just as predicted in Wu. In other words, WO '071 better illustrates that Wu's method is likely to work and improve taurine yields, and we do not read Petitioner's challenge as requiring fundamental changes to Wu's method, including the suggested recycling of ditaurinate for a subsequent ammonolysis reaction.

Patent Owner's argument that a skilled artisan would have no reason to consider WO '071, because that reference describes a reaction that consumes rather than produces taurine, is unpersuasive for reasons addressed above for Ground 2. Prelim. Resp. 29–32. Patent Owner's argument is premised on a narrow reading of WO '071, and fails to grapple persuasively with WO '071's disclosure that ditaurinate may be produced

from taurinate in an equilibrium reaction and what that would mean to the skilled artisan. Ex. 1010, 3; *see, e.g.*, Ex. 1003 ¶¶ 66–67.

Patent Owner contends Wu “only truly discloses the first ammonolysis reaction” and “did not actually run the [second ammonolysis] reaction or obtain an increased yield.” Prelim. Resp. 32–33. A lack of detail and experimental data for the second ammonolysis reaction in Wu is a factor to be considered. But the fact remains that Wu suggests recycling the ditaurinate from the first ammonolysis reaction through another round of ammonolysis is likely to improve taurine yields. Ex. 1010, 4; Ex. 1003 ¶ 100. The alleged lack of detail for the second-run ammonolysis suggested in Wu can reasonably be attributed to an assumption that ammonolysis conditions are largely routine, or that the skilled artisan would merely employ substantially the same conditions described in Wu for the first ammonolysis. Ex. 1003 ¶¶ 96–97. The ’450 patent also broadly discloses that sodium ditaurinate will convert to sodium taurinate under vague ammonolysis conditions. *See, e.g.*, Ex. 1001, 2:44–48 (“when sodium ditaurinate and sodium tritaurinate are reacted with aqueous ammonia under ammonolysis reaction conditions, a mixture of sodium taurinate, ditaurinate,” and other byproducts is formed.)²¹ And, in spite of the alleged lack of detailed conditions for Wu’s second ammonolysis, Petitioner bolsters its challenge by citing WO ’071’s suggested reaction conditions, which Petitioner and Dr. Lipton assert would be recognized by the ordinarily

²¹ *In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994) (holding “the Board’s observation that appellant did not provide the type of detail in his specification that he now argues is necessary in prior art references supports the Board’s finding that one skilled in the art would have known how to implement the features of the references.”).

skilled person as also suitable for forming taurinate from the ammonolysis of ditaurinate. Pet. 41–42, 45–46; Ex. 1003 ¶¶ 42, 86–90, and 99–100.

Patent Owner argues Wu’s yield of taurine “was much lower than even other art cited by Petitioner.” Prelim. Resp. 33. According to Patent Owner, Wu’s average yield was only 41%. *Id.* This argument is not persuasive in showing that Petitioner has not met its institution burden. None of the challenged claims requires any particular average yield of taurine be achieved. Also, Wu’s reported average yield of 41% appears to account for only the first-pass ammonolysis, not the second-pass that Wu encourages—and suggests is likely to improve taurine yields. Ex. 1010, 7. Even if Wu’s average yields were lower than other methods in the prior art, we are unpersuaded that would negate the skilled artisan’s desire to improve them, such as by considering the allegedly higher yields of taurine that Petitioner and its expert contend the skilled person would think possible from the reverse reaction of WO ’071. *See, e.g.*, Ex. 1003 ¶¶ 60, 89–90.

Finally, Patent Owner contends Wu and WO ’071 do not recognize the importance of pH in the claimed invention. Prelim. Resp. 34. According to Patent Owner, Wu “expressly teaches that pH is not a factor.” *Id.* Here too, this argument is unpersuasive in avoiding institution. The challenged claims do not recite any particular pH or pH range. Inasmuch as claim 1’s step (a) requires alkali hydroxide be added in a sufficient amount to convert some monoalkali ditaurinate to dialkali ditaurinate, as explained above, Petitioner provides evidence that alkali hydroxide is added in the reaction environment of the cited prior art methods and that the reaction environment is rendered basic for ammonolysis to proceed. *See, e.g.*, Ex. 1003 ¶¶ 43, 71–72, and 80 (“ammonolysis reactions described in prior art references all take

place in basic environments”).²² In such reaction environments, we are persuaded for purposes of this Decision that at least some sodium ditaurinate would convert to dialkali ditaurinate. *Id.*

2. Claims 3–7

Petitioner contends that dependent claims 3–7 would have been obvious over Wu and WO ’071. Pet. 49–53. Petitioner relies principally on disclosures in Wu to address the limitations that dependent claims 3–7 add to claim 1. *Id.* After considering Petitioner’s argument and evidence in support of this challenge to claims 3–7, we conclude Petitioner has established a reasonable likelihood that those claims are unpatentable.

Patent Owner argues that claim 3 is nonobvious because one would not look to combine Wu with WO ’071. Prelim. Resp. 35. That argument is addressed above regarding claim 1. For claims 4 and 6, Patent Owner contends nothing in Wu mentions pH or adding alkali hydroxide during a second ammonolysis, or neutralizing with acid after a second ammonolysis. *Id.* at 36. This argument is also addressed above at least to the extent Wu is reasonably read as suggesting repetition of the ammonolysis steps and conditions. Ex. 1003 ¶¶ 96–97. Moreover, as Petitioner notes, neutralizing taurinates with an acid following ammonolysis to purify the desired reaction product is a known and conventional technique, as even the ’450 patent

²² We observe that in pending district court proceedings, consistent with Petitioner’s arguments and evidence, Patent Owner asserts that “without adding alkali hydroxide to the mixture of alkali ditaurinate and alkali tritaurinate to create a basic mixture, the reaction of ammonolysis cannot and will not proceed.” Ex. 1060, 34 (claim chart from Patent Owner’s Second Amended Complaint related to claim 1, step (a)).

acknowledges. Pet. 52; Ex. 1001, 2:21–24. In short, Patent Owner’s argument on the dependent claims is unavailing on this record.

H. Ground 4: Obviousness Over Liu and WO ’071

Petitioner’s challenge to claims 1 and 3–7 as obvious over Liu (Ex. 1015) and WO ’071 (Ex. 1010) is similar to Ground 3, with Liu providing similar disclosures to those cited above in Wu. Pet. 53–63.

A summary of Liu is provided above. *See* Section III(A)(iii). Petitioner cites, *inter alia*, Liu’s teaching of the synthesis of taurine from sodium isethionate. Pet. 53; Ex. 1015, 6. According to Petitioner, Liu teaches an addition reaction, in which sodium isethionate is formed under alkaline conditions with 30% sodium hydroxide and then sodium isethionate undergoes ammonolysis to produce sodium taurinate, which is neutralized with sulfuric acid to form taurine. Pet. 53; Ex. 1015, 6; Ex. 1003 ¶¶ 107–108. Petitioner contends Liu teaches that the remaining reaction mixture—the mother liquor—contains sodium ditaurinate and other compounds. Pet. 53–54; Ex. 1015, 6.

Petitioner highlights Liu’s disclosure that sodium ditaurinate in the mother liquor can be fed again into an ammonolysis reaction to help increase yield, which Liu suggests may jump to 85%–95%. Pet. 54; Ex. 1015, 6 (“[S]odium ditaurinate also exists in the mother liquor system. If this sodium ditaurinate is fed again into ammonolysis, the proportion of 2-sodium isethionate in the reaction product can be increased, increasing generation yield.”); *see also id.* (suggesting that, with recycling of the mother liquor, “[a]mmonolysis process reaction yield can be increased from 70%-80% to 85%-95% . . . [while] reducing the discharge of waste liquids and overall production costs”). Petitioner relies on the reverse reaction of

WO '071 in further support of the Ground 4 challenge in much the same way as for Ground 3. Pet. 55, 57. Petitioner also relies on essentially the same reasons for combining Liu and WO '071 with a reasonable expectation of success as detailed above. Pet. 58–59 (describing, for instance, a desire to increase taurine yields and reduce waste from byproducts).

We have reviewed Petitioner's argument and evidence in support of the challenge to claims 1 and 3–7 over the combination of Liu and WO '071, and, on this record, Petitioner has established a reasonable likelihood that it would prevail in showing unpatentability of one or more of those claims. Our reasoning here parallels the reasoning explained above for Ground 3. In short, like Wu, Liu suggests recycling the ditaurinate byproduct from an initial ammonolysis reaction for use in a second ammonolysis reaction to improve taurine yields. Ex. 1015, 5. We are persuaded, for purposes of this Decision, that the skilled artisan would add alkali hydroxide to ditaurinate to render the environment basic and to catalyze the second ammonolysis reaction, and to later neutralize the reaction product with acid to purify and extract taurine with a reasonable expectation of improving yield and reducing waste materials. Ex. 1003 ¶¶ 107–116; *see supra* Section III(G).

Patent Owner argues the ditaurinate produced in Liu's reaction is neutralized with an acid and, at acidic pH, the ditaurinate could be in the form of deprotonated ditaurine or monoalkali ditaurinate—not dialkali ditaurinate. Prelim. Resp. 36–37. But this argument is unpersuasive because it does not account for the evidence that the skilled artisan, in order to render a reaction environment suitable for subsequent ammonolysis of sodium ditaurinate (something Liu discloses can be done to improve yield), would know that a basic environment should be used and take steps to make it so, such as adding alkali hydroxides. Ex. 1003 ¶ 108 (“This highly basic

reaction system is advantageous for the subsequent ammonolysis reaction, which as I explained . . . must occur in a basic environment.”).

Patent Owner next contends that Liu’s mention of recycling the mother liquor in a second ammonolysis reaction “is not an enabling description.” Prelim. Resp. 37. Yet disclosures in prior art publications are presumed to be enabled for the ordinarily skilled person absent persuasive evidence to the contrary, which Patent Owner does not provide on this record. *In re Antor Media Corp.*, 689 F.3d 1282, 1287–88 (Fed. Cir. 2012); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003).

Patent Owner contends that Liu actually discloses that sodium ditaurinate undergoes an ammonolysis reaction and forms sodium isethionate—not sodium taurinate like the reverse reaction allegedly disclosed in WO ’071. Prelim. Resp. 38. Hence, Patent Owner contends, “[t]his chemistry is completely different” and a “POSA would have an incomprehensible time reconciling such conflicting art.” *Id.* We agree with Patent Owner insofar as the particular disclosure in Liu is somewhat unclear in suggesting that if ditaurinate is fed again through ammonolysis, the proportion of 2-sodium isethionate in the reaction product can increase. Ex. 1015, 6. On this point, Patent Owner’s declarant opines that Dr. Lipton fails to appreciate the chemistry of Liu and its differences. Ex. 2001 ¶¶ 126–127. On the other hand, Dr. Lipton reads Liu’s teachings as reasonably clear and as suggesting that ditaurinate, when re-fed into an ammonolysis reaction of sodium isethionate, will increase taurine yield as illustrated with the reverse reaction from WO ’071. Ex. 1003 ¶¶ 109, 112–113. Resolution of this issue and the competing interpretations of the alleged experts on the relevant teachings of Liu will be left to trial.

Patent Owner, advancing essentially the same arguments as raised above for Ground 3, urges that Liu and WO '071 are not combinable and that a skilled artisan looking to produce taurine would have no reason to consider WO '071. Prelim. Resp. 39–42. Those arguments are not persuasive on this record for reasons explained previously. *See supra* Sections III(F)–(G).

Patent Owner contends neither Liu nor WO '071 disclose adding excess ammonia to a solution of *dialkali* ditaurinate. Prelim. Resp. 41. However, as explained above, we are persuaded for purposes of this Decision that at least some de-protonated species (i.e., dialkali ditaurinate) would necessarily be present when sodium ditaurinate is combined in a basic reaction environment, which is necessary for ammonolysis. As also explained above, the evidence here suggests that adding excess ammonia is standard protocol for an ammonolysis reaction, and Petitioner provides reasons for adding excess ammonia (e.g., to drive the WO '071 reaction toward production of taurinate/taurine).

Finally, Patent Owner contends there is no reason for the combination of Liu and WO '071 to obtain greater yields, because Liu already provides up to 95% yields while WO '071's yields are allegedly no better than 64%. Prelim. Resp. 42. This argument goes to whether a skilled person would understand WO '071's reaction as potentially providing improved yields of taurinate above 95% (including up to 99%). Dr. Lipton opines that is how the skilled artisan would interpret the reference (Ex. 1003 ¶¶ 60, 89–90); Dr. Maleczka opines that Dr. Lipton's interpretation is incorrect (Ex. 2001 ¶¶ 63–64). The disagreement between the parties' declarants on this issue is not sufficient to avoid institution on this record. 37 C.F.R. § 42.108(c).

Patent Owner's arguments as to dependent claims 3, 4, and 6 are also unavailing at this stage, for the reasons explained above concerning essentially the same arguments raised as to Ground 3.

IV. CONCLUSION

For the foregoing reasons, we determine Petitioner has established a reasonable likelihood of prevailing on its assertions that one or more of claims 1 and 3–7 of the '450 patent are unpatentable.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314, an *inter partes* review of claims 1 and 3–7 of the '450 patent is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314 and 37 C.F.R. § 42.4(b), *inter partes* review of the '450 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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