

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

U.S. Patent No. 9,428,450

**PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 9,428,450 UNDER 37 C.F.R. § 42.100**

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TABLE OF CONTENTS

	<u>Page</u>
I. INTRODUCTION	1
II. GROUNDS FOR STANDING AND PROCEDURAL STATEMENT	3
III. MANDATORY NOTICES UNDER 37 C.F.R. §§ 42.8(b)(1)-(4)	4
A. Real Party-in-Interest	4
B. Related Matters	4
C. Lead and Back-Up Counsel	5
D. Notice of Service Information	6
IV. STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFOR	6
V. SUMMARY OF THE '450 PATENT	6
A. Overview of the '450 patent	6
B. Summary of the '450 Patent's Prosecution History	8
C. Level of Ordinary Skill in the Art	11
D. Claim Construction	12
VI. IDENTIFICATION OF CHALLENGE	12
VII. OVERVIEW OF THE FIELD AND PRIOR ART	14
A. Overview of the Field	14
B. Overview of the Prior Art	16
1. WO 071	16
2. Wu 2004	18
3. Liu 2013	19

VIII. DETAILED GROUNDS OF UNPATENTABILITY.....	20
A. Ground 1 – Claims 1 and 3-7 are Anticipated by WO 071	20
1. Anticipation legal standard	20
2. WO 071 anticipates claim 1	22
3. WO 071 discloses all limitations of claims 3-7	33
a) Claim 3	33
b) Claim 4	34
c) Claim 5	35
d) Claim 6	35
e) Claim 7	36
B. Ground 2 – Claims 1 and 3-7 are Obvious in Light of WO 071 and the Knowledge of a POSA	37
1. Obviousness legal standard	37
2. Claims 1 and 3-7 are obvious	39
C. Ground 3 – Claims 1 and 3-7 are Obvious in Light of Wu 2004 and WO 071	42
1. Claim 1 obvious	42
2. Claims 3-7 are obvious	49
a) Claim 3	49
b) Claim 4	50
c) Claim 5	51
d) Claim 6	51
e) Claim 7	52

D.	Ground 4 – Claims 1 and 3-7 are Obvious in Light of Liu 2013 and WO 071	53
1.	Claim 1 is obvious	53
2.	Claims 3-7 are obvious	60
a)	Claim 3	60
b)	Claim 4	61
c)	Claim 5	62
d)	Claim 6	62
e)	Claim 7	63
E.	Objective Indicia of Nonobviousness	64
IX.	CONCLUSION	64

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Amneal Pharms., LLC v. Supernus Pharms., Inc.</i> , IPR2013-00368, Paper 8 (P.T.A.B. Dec. 17, 2003).....	66
<i>Atlas Powder Co. v. Ireco, Inc.</i> , 190 F.3d 1342 (Fed. Cir. 1999).....	21
<i>Brown v. 3M</i> , 265 F.3d 1349 (Fed. Cir. 2001).....	22, 28, 30
<i>CCS Fitness, Inc. v. Brunswick Corp.</i> , 288 F.3d 1359 (Fed. Cir. 2002).....	12
<i>Cuozzo Speed Techs., LLC v. Lee</i> , 136 S. Ct. 2131 (2016).....	12
<i>Daiichi Sankyo, Co. v. Apotex, Inc.</i> , 501 F.3d 1254 (Fed. Cir. 2007).....	11
<i>DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.</i> , 464 F.3d 1356 (Fed. Cir. 2006).....	40
<i>Graham v. John Deere Co.</i> , 383 U.S. 1 (1966).....	39
<i>In re Gleave</i> , 560 F.3d 1331 (Fed. Cir. 2009).....	20
<i>In re Paulsen</i> , 30 F.3d 1475 (Fed. Cir. 1994).....	20
<i>In re Peterson</i> , 315 F.3d 1325 (Fed. Cir. 2003).....	40
<i>In re Zletz</i> , 893 F.2d 319 (Fed. Cir. 1989).....	12

Petition of *Inter Partes* Review of U.S. Patent No. 9,428,450

<i>King Pharm., Inc. v. Eon Labs, Inc.</i> , 616 F.3d 1267 (Fed. Cir. 2010).....	11
<i>KSR Int’l Co. v. Teleflex, Inc.</i> , 550 U.S. 398 (2007).....	11, 39, 40
<i>Perfect Web Techs., Inc. v. InfoUSA, Inc.</i> , 587 F.3d 1324 (Fed. Cir. 2009).....	40
<i>Philips Lighting N. Am. Corp. v. Wangs All. Corp.</i> , 727 Fed. Appx. 676 (Fed. Cir. 2018).....	49, 60
<i>Richardson v. Suzuki Motor Co.</i> , 868 F.2d 1226 (Fed. Cir. 1989).....	20
<i>Riverwood Int’l Corp. v. R.A. Jones & Co.</i> , 324 F.3d 1346 (Fed. Cir. 2003).....	32
<i>Schering Corp. v. Geneva Pharm.</i> , 339 F.3d 1373 (Fed. Cir. 2003).....	28, 32, 46, 58
<i>Scripps Clinic & Research Foundation v. Genentech, Inc.</i> , 927 F.2d 1565 (Fed. Cir. 1991) (overruled on other grounds)	24
<i>SmithKline Beecham Corp. v. Apotex Corp.</i> , 403 F.3d 1331 (Fed. Cir. 2005).....	28, 32, 46, 58
<i>Standard Havens Prod., Inc. v. Gencor Indus., Inc.</i> , 953 F.2d 1360 (Fed. Cir. 1991).....	20
<i>Titanium Metals Corp. of Am. v. Banner</i> , 778 F.2d 775 (Fed. Cir. 1985).....	21, 39
<i>Verdegaal Bros. v. Union Oil Co. of California</i> , 814 F.2d 628 (Fed. Cir. 1987).....	20
<i>Vitaworks IP, LLC v. Hubei Grand Life Science and Technology Co., Ltd. et al.</i> , No. 2:17-cv-12358-CCC-MF (D.N.J. filed Dec. 1, 2017)	4
<i>Vitaworks IP, LLC v. Qianjiang Yongan Pharmaceutical Co., Ltd., et al.</i> , No. 2:17-cv-06849-CCC-MF (D.N.J. filed Sept. 6, 2017).....	5

Petition of *Inter Partes* Review of U.S. Patent No. 9,428,450

Vitaworks, LLC v. Qianjiang Yongan Pharmaceutical Co., Ltd., et al.,
No. 2:16-cv-05321-CCC-MF (D.N.J. filed Aug. 31, 2016)5

STATUTES

35 U.S.C. § 102passim
35 U.S.C. § 103passim
35 U.S.C. §§ 311-3191
35 U.S.C. § 315(b).....4

OTHER AUTHORITIES

37 C.F.R. §§ 42.6.....69
37 C.F.R. §§ 42.8.....4, 5
37 C.F.R. § 42.22.....6
37 C.F.R. § 42.24.....68
37 C.F.R. § 42.63.....13
37 C.F.R. § 42.1001, 12
37 C.F.R. § 42.105.....69
37 C.F.R. § 42.106.....3

TABLE OF EXHIBITS

EXHIBIT	DESCRIPTION	ABBREVIATION
1001	U.S. Patent No. 9,428,450	'450 Patent
1002	File History of U.S. Patent Application No. 14/120,046, which issued as U.S. Patent No. 9,428,450 on August 30, 2016	'450 File History
1003	Declaration of Mark A. Lipton in Support of Petition for <i>Inter Partes</i> Review of U.S. Patent No. 9,428,450	Lipton Declaration
1004	Declaration of Min Chou, EdD	Chou Declaration
1005	<i>Vitaworks IP, LLC v. Hubei Grand Life Science and Technology Co., Ltd., et al.</i> , No. 17-cv-12358, Complaint (D.N.J. Dec. 1, 2017)	Complaint
1006	German Patent No. DD 219 023 A3	DD 023
1007	Translation of German Patent No. DD 219 023 A3	DD 023
1008	Certification for Translation of German Patent No. DD 219 023 A3 and International Publication No. WO 01/77071 A1	
1009	International Publication No. WO 01/77071 A1	
1010	Translation of International Publication No. WO 01/77071 A1	WO 071
1011	Jiang Wu & Zailin Guan. "Optimization on Ammonolysis in Manufacturing Method of Taurine," Journal of Hubei Polytechnic	Wu 2004 or Wu

EXHIBIT	DESCRIPTION	ABBREVIATION
	University, 19(1): 23-26 (February 2004)	
1012	Translation of Jiang Wu & Zailin Guan. "Optimization on Ammonolysis in Manufacturing Method of Taurine," Journal of Hubei Polytechnic University, 19(1): 23-26 (February 2004)	Wu 2004 or Wu
1013	Certification for Translation of Wu 2004 and Liu 2013	
1014	Fuming Liu, "Process Design of Taurine Ammonolysis," China Chemical Trade, no. 8: 120 (August 2013)	Liu 2013
1015	Translation of Fuming Liu, "Process Design of Taurine Ammonolysis," China Chemical Trade, no. 8: 120 (August 2013)	Liu 2013
1016	U.S. Patent No. 1,932,907	'907 Patent
1017	U.S. Patent No. 1,999,614	'614 Patent
1018	U.S. Patent Publication 2014/0121405	Chen
1019	Chapter 17 of Martin S. Silberberg, <i>Chemistry: The Molecular Nature of Matter and Change</i> (4th ed. 2006)	Silberberg
1020	Chapters 4 and 26 of Marc Loudon, <i>Organic Chemistry</i> (5th. ed. 2009)	Loudon
1021	Curriculum Vitae of Mark A. Lipton	

EXHIBIT	DESCRIPTION	ABBREVIATION
1022	O.M. Bondareva et al., <i>Synthesis of Taurine</i> , 42 <i>Pharm. Chem. J.</i> 142 (No.3, 2008).	Bondareva
1023	Copy of Springer's web page from which Document 3 may be obtained	
1024	National Library of Medicine catalog record of Document 3	
1025	WorldCat Record for Document 3	
1026	Indexing Information for Document 3 on Springer	
1027	Curriculum Vitae of Min Chou	
1028	Printout from the Stanford University Library Website	
1029	Printout from the University of California Los Angeles Library Website	
1030	Interlibrary Loan Request for Ex. 1011, Wu 2004	
1031	Translation of Chinese portion of Ex. 1030 (Interlibrary Loan Request) into English	
1032	Certification for Translation of Ex. 1031 (Interlibrary Loan Request)	
1033	Library of Congress Catalog record of Wu 2004	
1034	Copy of Wu 2004 obtained from Wanfang	

Petition of *Inter Partes* Review of U.S. Patent No. 9,428,450

EXHIBIT	DESCRIPTION	ABBREVIATION
1035	Translation of Ex. 1034 (Wu 2004 from Wanfang) into English	
1036	Certification for Translation of Ex. 1035 (Wu 2004 from Wanfang)	
1037	Bibliographic information of Wu 2004 from Wanfang	
1038	Translation of Ex. 1037 (Bibliographic information of Wu 2004) into English	
1039	Certification for Translation of Ex. 1038 (Bibliographic information of Wu 2004)	
1040	Copy of Liu 2013 obtained from Wanfang	
1041	Translation of Ex. 1040 (Liu from Wanfang) into English	
1042	Certification for Translation of Ex. 1041 (Liu from Wanfang)	
1043	Bibliographic information of Liu 2013 from Wanfang	
1044	Translation of Ex. 1043 (Bibliographic information of Liu 2013) into English	
1045	Certification for Translation of Ex. 1044 (Bibliographic information of Liu 2013)	
1046	MARC Record for Silberberg	

Petition of *Inter Partes* Review of U.S. Patent No. 9,428,450

EXHIBIT	DESCRIPTION	ABBREVIATION
1047	Library of University of California Riverside's catalog record of Silberberg	
1048	Paper band from front cover of Ex. 1020, Loudon	
1049	MARC Record for Loudon	

Hubei Grand Life Science and Technology Co., Ltd. (“Petitioner” or “HGL”), in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq.*, hereby requests that the United States Patent and Trademark Office proceed with an *inter partes* review (“IPR”) of Claims 1 and 3-7 of U.S. Patent No. 9,428,450 (the “’450 Patent”) (Ex. 1001).

I. INTRODUCTION

The challenged claims of the ’450 patent are drawn to well-known processes of taurine synthesis. Taurine, whose chemical name is 2-aminoethanesulfonic acid, is an amino sulfonic acid naturally found in meat, fish, dairy products, and human milk. Taurine is essential to several of the human body’s metabolic processes as it aids the absorption of calcium, fat, and vitamins, and plays a vital role in the development of the brain, nerves, internal organs, and endocrine function of infants and children. In adults, taurine helps enhance physical fitness, prevent diseases, relieve fatigue, and increase productivity. As a result, taurine is widely added to a variety of foods and nutritional supplements around the world. (Ex. 1003, ¶¶ 37-38).

Taurine has been produced on an industrial scale for decades. Historically, the industrial synthesis of taurine has used one of two methods—(1) ethanolamine esterification or (2) hydroxyethyl sulfonate ammonolysis acidification, where the hydroxyethyl sulfonate—also known as isethionate—is typically prepared from

ethylene oxide. Compared to the former, the latter method has long been known to have a number of advantages, including higher yield of taurine, low production costs, and stable products. (Ex. 1003, ¶¶ 40, 44).

The '450 patent claims are directed to this latter method of industrial taurine synthesis. But, as noted, this method is not innovative nor novel; the synthesis of taurine through ammonolysis of an isethionate salt has been known for at least 80-plus years. The applicant of the '450 patent alleges that he discovered that the byproducts of this process—alkali ditaurinate and alkali tritaurinate—can undergo further ammonolysis to produce additional alkali taurinate (and in turn, taurine), and such discovery renders the claimed invention novel. But the identity of these byproducts have also been known for decades and, importantly, it was known that these byproducts, such as alkali ditaurinate, can convert to and from alkali taurinate through an equilibrium reaction. (Ex. 1003, ¶¶ 32, 45-46, 50). Shifting of a chemical equilibrium to favor the synthesis of one product over the others has been known in the art for many years, and applies directly to the reaction recited in the '450 patent claims. Indeed, the prior art makes clear that the byproducts of alkali isethionate ammonolysis, alkali ditaurinate and alkali tritaurinate, can undergo further ammonolysis to produce alkali taurinate and taurine. None of the other claim limitations, which are simple recitations of basic organic synthesis

techniques, impart patentability to the challenged claims of the '450 patent because they too are well known in the art.

Thus, the prior art discloses or suggests subjecting alkali ditaurinate and alkali tritaurinate to ammonolysis to produce alkali taurinate salt, which is then neutralized with an acid to form taurine. (Ex. 1003, ¶¶ 33, 46). Therefore, as discussed in more detail below, Petitioner is reasonably likely to demonstrate invalidity of the challenged claims over the prior art. For this reason, Petitioner respectfully requests that the Board grant the present Petition to institute an *inter partes* review of claims 1 and 3-7 of the '450 patent and to ultimately cancel the challenged claims.

II. GROUNDS FOR STANDING AND PROCEDURAL STATEMENT

Petitioner certifies that (1) the '450 patent is available for *inter partes* review, and (2) Petitioner is not barred or estopped from requesting *inter partes* review of any claim of the '450 patent on the grounds identified in this Petition. This Petition is filed in accordance with 37 C.F.R. § 42.106(a). A Power of Attorney and an Exhibit List are filed concurrently with this Petition. The required fee is paid through Deposit Account No. DA160605, and the Office is authorized to charge any fee deficiencies and credit any overpayment to that account.

III. MANDATORY NOTICES UNDER 37 C.F.R. §§ 42.8(B)(1)-(4)

A. Real Party-in-Interest

Hubei Grand Life Science and Technology Co., Ltd., Grand Pharmaceutical (China) Co., Ltd., China Grand Pharmaceutical (HK) Limited, Best Forward Group Limited, China Grand Pharmaceutical and Healthcare Holdings Limited, China Grand Enterprises, Inc., OUTWIT Investment Limited, Grand (Hong Kong) International Investments Holdings Limited, Beijing Grand Huachuang Investment Co. Ltd., and Wuhan Grand Hoyo Co., Ltd. are the real parties-in-interest. No other party has authority to direct or control Petitioner's actions or decisions relating to this Petition, and no other party has provided or will provide funding for the fees and costs of this Petition.

B. Related Matters

Petitioner is a named defendant in the following litigation involving the '450 patent: *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). This action is currently pending in the U.S. District Court for the District of New Jersey. Plaintiff Vitaworks IP, LLC is the Patent Owner of the '450 patent. Plaintiff served its complaint on defendant Wild Flavors, Inc., but has yet to effectuate service of its Complaint on Petitioner. Petitioner's Petition is timely filed pursuant to 35 U.S.C. § 315(b).

Petitioner advises that the '450 patent is subject to the following U.S.

District Court litigations, also currently pending in the District of New Jersey:

- *Vitaworks IP, LLC v. Qianjiang Yongan Pharmaceutical Co., Ltd., et al.*, No. 2:17-cv-06849-CCC-MF (D.N.J. filed Sept. 6, 2017); and
- *Vitaworks, LLC v. Qianjiang Yongan Pharmaceutical Co., Ltd., et al.*, No. 2:16-cv-05321-CCC-MF (D.N.J. filed Aug. 31, 2016).

In addition, Petitions for *Inter Partes* Review are being concurrently filed by Petitioner against U.S. Patent Nos. 9,428,451 and 9,573,890, both of which are related to the '450 patent and are also assigned to Patent Owner, Vitaworks IP, LLC.

C. Lead and Back-Up Counsel

Pursuant to 37 C.F.R. §§ 42.8(b)(3) and 42.10(a), Petitioner provides the following designation of counsel:

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D. Notice of Service Information

Please direct all correspondence regarding this Petition to lead and back-up counsel at the address shown above. Petitioner also consents to service by email at HGL-IPR@alston.com.

IV. STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFOR

In accordance with 37 C.F.R. § 42.22(a), Petitioner respectfully requests *inter partes* review and cancellation of Claims 1 and 3-7 of the '450 patent. Petitioner's full statement of the reasons for the relief requested is set forth in detail below, as supported by the Declaration of Mark A. Lipton, Ph.D. Dr. Lipton is currently an associate professor of organic chemistry at Purdue University, and has over 35 years of experience in organic synthesis. Dr. Lipton has particular expertise in the synthesis and chemistry of nitrogen-containing compounds, including amino acids.

V. SUMMARY OF THE '450 PATENT

A. Overview of the '450 patent

The '450 patent, titled "Process for Producing Taurine from Alkali Taurinates," issued on August 30, 2016. The '450 patent issued from U.S. patent application No. 14/120,046, filed on April 18, 2014 (the "Priority Date"). This application is the parent application of patent application No. 14/120,651, which issued as U.S. Patent No. 9,428,451, and patent application No. 15/228,539, which

Petition of *Inter Partes* Review of U.S. Patent No. 9,428,450

issued as U.S. Patent No. 9,573,890. Patent Nos. 9,428,451 and 9,573,890 are subject of Petitions for *Inter Partes* Review concurrently filed with this Petition. According to records at the U.S. Patent and Trademark Office, the '450 patent is currently assigned to Vitaworks IP, LLC.

The challenged claims of the '450 patent are directed to a process for producing taurine from alkali ditaurinate or alkali tritaurinate through ammonolysis. *See* Ex. 1001, Abstract. Independent claim 1 recites:

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 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.

All of these steps, however, are disclosed by the prior art.

Dependent claims 3 through 7, all of which depend from claim 1, recite specific, but routine conditions and parameters for the ammonolysis reaction.

Claim 3 requires that the alkali ditaurinate and alkali tritaurinate reactants are formed as byproducts of the ammonolysis of alkali isethionate or alkali vinyl sulfonate.

Claim 4 recites various suitable catalysts for the ammonolysis reaction.

Claim 5 specifies that the alkali metals recited in claim 1 are lithium, sodium, or potassium.

Claim 6 recites suitable acids for the neutralizing alkali taurinate in step (d) of claim 1.

Finally, claim 7 recites specific temperature and pressure conditions for the ammonolysis reaction.

Each recited limitation of claims 3-7, however, are disclosed by the prior art.

B. Summary of the '450 Patent's Prosecution History

During prosecution, the Examiner rejected the pending claims under 35 U.S.C. § 103 as obvious in light of the Abstract of German patent DD 219023 (DD 023). (Ex. 1007, Ex. 1002 at 103–105). The Examiner noted that DD 023 teaches ammonolysis of sodium isethionate, and the reaction mixture comprises di- and tri-taurinates. Furthermore, the Examiner noted that while DD 023 does not

specifically teach ammonolysis of alkali ditaurinate and alkali tritaurinate, these species were in a reaction mixture with ammonia, and a person of ordinary skill in the art (“POSA”) would have expected at least a portion of these species would convert to alkali taurinate. (*Id.*)

In response, the Patent Owner admitted that several limitations recited in the challenged claims were known in the art before the Priority Date. First, the Patent Owner admitted that the ammonolysis of sodium isethionate to produce taurine “has been known since 1933” and was disclosed in U.S. Patent No. 1,932,907. (Ex. 1002 at 138). Second, the Patent Owner admitted “[i]t is known in the literature that alcohols can react with ammonia to yield invariably a mixture of primary, secondary, and ternary amines,” and in the case of taurine, increasing the molar ratio of ammonia to alcohol would yield smaller amounts of the byproducts ditaurine and tritaurine. (Ex. 1002 at 139). Third, the Patent Owner admitted that the cited patents and literature all teach the ammonolysis of sodium isethionate to sodium taurinate, along with the formation of sodium ditaurinate and sodium tritaurinate. (Ex. 1002 at 140). Yet, the Patent Owner argued that the invention of the application lies within the “new reaction” of ditaurinate and tritaurinate with ammonia to yield sodium taurinate. (Ex. 1002 at 143). The Examiner rejected Patent Owners argument, issuing a final rejection and maintaining the obviousness rejection under 35 U.S.C. § 103. The Examiner specifically noted that the

ammonolysis step recited in the pending claims to be anticipated by DD 023, because ditaurinate and tritaurinate species were admitted by the Patent Owner to be in the reaction mixture of DD 023, therefore any ammonolysis of ditaurinate and tritaurinate is “an invariable aspect of DD 023.” (Ex. 1002 at 151–152).

The Patent Owner argued in response that ammonolysis of sodium ditaurinate and sodium tritaurinate, as disclosed by DD 023, will not result in the formation of sodium taurinate. For support, the Patent Owner allegedly conducted its own testing showing no formation of sodium taurinate from sodium ditaurinate and sodium tritaurinate under “known ammonolysis conditions.” (Ex. 1002 at 163). The Patent Owner provided no details of the testing carried out, particularly the conditions of the ammonolysis reactions, but instead provided the Examiner only the results. (*Id.*) The Patent Owner then argued that an extra step of mixing the sodium ditaurinate and sodium tritaurinate with alkali hydroxide or alkali carbonate is “crucial” for the conversion of byproducts to taurine. (Ex. 1002 at 163). The Patent Owner went on to add what is now step (a) in claim 1 to the then-pending claim 18 (which issued as claim 1): “adding an alkali hydroxide to a solution of alkali ditaurinate and alkali tritaurinate or their mixture to prepare a solution of dialkali ditaurinate and trialkali tritaurinate or their mixture.” (Ex. 1002 at 160).

In allowing the pending claims to issue, the Examiner's Notice of Allowance stated that the prior art fails to teach or suggest "adding an alkali hydroxide to a solution of alkali ditaurinate and alkali tritaurinate or their mixture to prepare a solution of dialkali ditaurinate and trialkali tritaurinate or their mixture; and adding an excess amount of ammonia." (Ex. 1002 at 196). As demonstrated below, however, the addition of alkali hydroxide, which functions as a catalyst in an ammonolysis reaction, along with excess ammonia, was not only routine, but was known to be advantageous in the synthesis of taurine before the Priority Date.

C. Level of Ordinary Skill in the Art

A person of ordinary skill in the art ("POSA") is a hypothetical person presumed to be aware of all pertinent art, to think along with the conventional wisdom in the art, and to have ordinary creativity. *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1281 (Fed. Cir. 2010) (citing *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421 (2007)). Factors that may be considered for determining the level of a skilled practitioner include: the educational level of the inventor; types of problems encountered in the art; prior art solutions to these problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field. *Daiichi Sankyo, Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007) (citations omitted).

Here, a POSA at the time of the alleged invention (April 18, 2014) would have an advanced degree, such as 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.*

D. Claim Construction

Petitioner believes that no claim terms or phrases require specific construction for the purpose of this IPR. Therefore, pursuant to 37 C.F.R. § 42.100(b), the challenged claims are accorded their broadest reasonable interpretation in light of the specification of the '450 patent. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2146 (2016). This means that the words of the claim are given their plain meaning from the perspective of a POSA unless that meaning is inconsistent with the specification. *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989). Indeed, there is a "heavy presumption" that a claim term carries its ordinary and customary meaning. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). Here, each claim term of the '450 patent carries its ordinary and customary meaning.

VI. IDENTIFICATION OF CHALLENGE

Inter partes review is requested in view of the following references:

- **Exhibit 1009** (German) and **Exhibit 1010** (English): International Publication No. WO 01/77071 to Lutz Heuer (“WO 071”);
- **Exhibit 1011** (Chinese) and **Exhibit 1012** (English): Journal of Hubei Polytechnic University 2004, Vol. 19, No. 1, pp. 23-26 by Wu, et al. (“Wu 2004”);
- **Exhibit 1014** (Chinese) and **Exhibit 1015** (English): China Chemical Trade 2013, Vol. 8, page 120 by Liu Fuming (“Liu 2013”);

Each of these patents and printed publications is prior art to the ’450 patent.

Pursuant to 37 C.F.R. §42.63(b), Exhibit 1008 contains an affidavit attesting that a professional translator and interpreter fluent in the English and German languages translated WO 071 (Ex. 1010), and Exhibit 1013 contains an affidavit attesting that a professional translator and interpreter fluent in the English and Chinese languages translated Wu 2004 (Ex. 1012) and Liu 2013 (Ex. 1015).

Ground	Proposed Statutory Rejections for the Challenged Claims
1	Claims 1 and 3-7 are anticipated by WO 071 (Ex. 1010) pursuant to 35 U.S.C. § 102.
2	Claims 1 and 3-7 are rendered obvious by a combination of WO 071 (Ex. 1010) in view of the knowledge of a POSA.

Ground	Proposed Statutory Rejections for the Challenged Claims
3	Claims 1 and 3-7 are rendered obvious by a combination of Wu 2004 (Ex. 1012) in view of WO 071 (Ex. 1010) pursuant to 35 U.S.C. § 103.
4	Claims 1 and 3-7 are rendered obvious by a combination of Liu 2013 (Ex. 1015) in view of WO 071 (Ex. 1010) pursuant to 35 U.S.C. § 103.

VII. OVERVIEW OF THE FIELD AND PRIOR ART

A. Overview of the Field

By the Priority Date of the '450 patent, various processes for synthesizing taurine had been known for decades. The synthesis of taurine by subjecting isethionate to an ammonolysis reaction has been known for at least eighty years. *See, e.g.*, U.S. Patent Nos. 1,932,907 (the “'907 patent,” Exhibit 1016) and 1,999,614 (the “'614 patent,” Exhibit 1017). In this process, isethionic acid (hydroxyethanesulphonic acid) reacts with ammonia in an autoclave in the presence of a neutral or alkaline catalyst such as hydroxides of alkali metals or alkaline earth metals. This reaction produces a series of aminoalkylsulphonic acids, including taurine (2-aminoethanesulfonic acid). (Ex 1017, 1:32-55). In the '450 patent, this process is recognized as “well established and widely practiced in commercial production.” (Ex. 1001, 1:23-32).

The mechanism of this ammonolysis reaction was also well known before the Priority Date. It was known that this reaction takes place with (1) the elimination of water and (2) replacement of the hydroxyl group by the amino- or alkyl-amino group, after which a series of aminoalkylsulphonic acids are formed. (Ex. 1017, 1:49-55; *see also* Ex. 1016, 1:35-42 (same)). In the case of ammonolysis of isethionic acid, the aminoalkylsulphonic acids formed were known to be taurine, ditaurine, and tritaurine. (Ex. 1007 at 1, abstract; Ex. 1012 at 4; Ex. 1015 at 6). The specification of the '450 patent recognizes that the prior art makes clear that the ammonolysis of sodium isethionate “invariably” yields a mixture of the sodium salts of taurine, ditaurine, and tritaurine. (Ex. 1001, 2:9-13; Ex. 1003, ¶¶ 41-46).

In addition, it was known before the Priority Date that this ammonolysis reaction can be continuous. (Ex. 1017, 2:1-2; Ex. 1016, 1:43-44 Ex. 1015 at 6; Ex. 1012 at 7); *see also* U.S. Patent Publication No. 2014/0121405 at Abstract (“Chen” Exhibit 1018) (Ex. 1003, ¶¶ 48-49). Moreover, it was well-known that after the ammonolysis reaction and after taurine has been separated from the resultant reaction mixture, the reaction mixture containing the remaining byproducts, including ditaurinate and tritaurinate salts, can be added back into the reaction system to undergo further ammonolysis to produce additional taurine. (Ex. 1012 at 7; Ex. 1015 at 6; Ex. 1018 at Abstract; ¶ [0008]; (Ex. 1003, ¶¶ 48-49). The prior

art also teaches that this reaction mixture containing the remaining byproducts, also called “mother liquor,” contains contaminants that can damage and pollute the environment. (Ex. 1015 at 6). Finally, the prior art teaches that ditaurinate salts can be produced from taurinate salts. (Ex. 1010 at 3; Ex. 1003, ¶ 50).

B. Overview of the Prior Art

1. WO 071

WO 071 to Lutz Heuer, Ex. 1010, titled “Method for Producing Ditaaurine and Salts Thereof,” was published under the Patent Cooperation Treaty (PCT) on October 18, 2001. WO 071 has an international filing date of March 28, 2001, and claims priority to German patent application DE 100 17 313.6, which was filed on April 10, 2000. Because WO 071 was published on October 18, 2001, before the Priority Date of the ’450 patent, WO 071 qualifies as prior art to the ’450 patent under 35 U.S.C. § 102(a)(1). In addition, WO 071 designated the United States as a contracting state, and because WO 071 has an effective filing date of April 10, 2000, WO 071 also qualifies as prior art to the ’450 patent under 35 U.S.C. § 102(a)(2).

WO 071 was cited by Patent Owner in an information disclosure statement (IDS) filed on April 18, 2014 during the prosecution of the ’046 application (which led to the ’450 patent), and was mentioned in the specification. (Ex. 1002 at 25;

Ex. 1001 at 1). It was, however, never relied upon by the Examiner in any office actions.

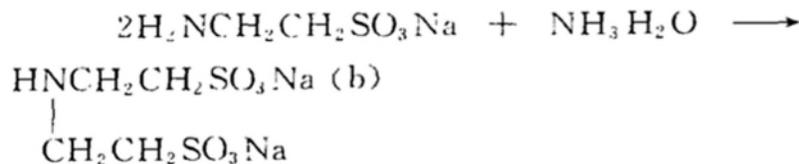
WO 071 discloses a process of making ditaurine and ditaurine salts from taurine or taurine salts. (Ex. 1010 at 2; Ex. 1003, ¶ 55). This process, which WO 071 characterizes as “surprisingly simple,” involves preparing ditaurine and its salts by heating taurine or its salts in the presence of a reaction medium. (Ex. 1010 at 2). WO 071 further discloses that this reaction medium may be, for example, water, molten alkali hydroxides, or other molten electrolytes and, preferably, the reaction medium is sodium hydroxide, potassium hydroxide, aqueous sodium hydroxide solution or aqueous potassium hydroxide solution. (*Id.* at 3; Ex. 1003, ¶ 55).

WO 071 also discloses that the ammonia resulting from the disclosed reaction can be separated by distillation with water. (Ex. 1010 at 3; Ex. 1003, ¶ 74). Furthermore, WO 071 teaches that this reaction is an equilibrium reaction, and the reaction may be made to favor the product (ditaurine) side by the removal of ammonia. (Ex. 1010 at 3, Ex. 1003, ¶¶ 56, 60-63). Therefore, the conversion from taurine to ditaurine is dependent on the ammonia content in the reaction mixture. (Ex. 1010 at 3; Ex. 1003, ¶ 60-63).

2. Wu 2004

Wu 2004, Ex. 1012 titled “Optimization on Ammonolysis in Manufacturing Method of Taurine,” was published in the February 2004 edition of Journal of Hubei Polytechnic University, Vol. 19, No. 1. According to Min Chou, EdD, an academic librarian with more than thirty years of experience in the library profession, Wu 2004 was publicly available and accessible by no later than May 28, 2004. (Ex. 1004, ¶ 52). Therefore, Wu 2004 qualifies as prior art to the ’450 patent under 35 U.S.C. § 102(a)(1). Wu 2004 was not cited by Patent Owner or the Examiner during prosecution.

Like the ’450 patent, Wu 2004 is also directed to the process of producing taurine from ammonolysis of sodium isethionate. (Ex. 1012 at 4; Ex. 1003, ¶ 93). Wu 2004 discloses that in addition to sodium taurinate, this ammonolysis reaction also produces sodium ditaurinate, which is designated by the symbol “(b)” as shown below:



(Ex. 1012 at 4; Ex. 1003, ¶ 94). Wu 2004 also discloses that after the ammonolysis reaction and after sodium taurinate is separated from the reaction mixture, if the remaining reaction mixture consisting primarily of sodium ditaurinate is fed back

into the ammonolysis system again, the total yield of taurine “may very well increase.” (Ex. 1012 at 7; Ex. 1003, ¶ 95).

3. Liu 2013

Liu 2013, Ex. 1015 titled “Process Design of Taurine Ammonolysis,” was published in the August 2013 edition of China Chemical Trade Journal, Vol. 8. Liu 2013 would have been publicly available and accessible by no later than September 13, 2013. (Ex. 1004, ¶ 65). Therefore, Liu 2013 qualifies as prior art to the ’450 patent under 35 U.S.C. § 102(a)(1). Liu 2013 was not cited by Patent Owner or the Examiner during prosecution of the ’046 application (which led to the ’450 patent).

Liu 2013 also relates to the ammonolysis of sodium isethionate to produce taurinate, which is then neutralized with sulfuric acid to produce taurine. (Ex. 1015 at 6; Ex. 1003, ¶ 107). Liu 2013 also discloses that after crude taurine is extracted from the reaction mixture, the remaining mixture (*i.e.*, mother liquor) contains many components, including taurine, sodium isethionate that did not participate in the ammonolysis, and sodium ditaurinate. (Ex. 1015 at 6; Ex. 1003, ¶ 109). Moreover, Liu 2013 discloses, in a section labeled “Application of Mother Liquor Recycle in Production,” that the mother liquor can participate again in ammonolysis, and if sodium ditaurinate is also fed again into ammonolysis, the generation yield of taurine would increase. (Ex. 1015 at 6; Ex. 1003, ¶¶ 109-10).

VIII. DETAILED GROUNDS OF UNPATENTABILITY

A. Ground 1 – Claims 1 and 3-7 are Anticipated by WO 071

1. Anticipation legal standard

A prior art reference anticipates a claim “if each and every element as set forth in the claim is found, either expressly or inherently described, in [the] single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the patent claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). While the elements of a prior art reference “must be arranged or combined in the same way as in the claim, the reference need not satisfy an *ipsissimis verbis* test.” *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009) (citation omitted). In addition, “a prior art reference must be considered together with the knowledge of one of ordinary skill in the pertinent art” at the time the application was filed. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (citation omitted); *see also Application of Preda*, 401 F.2d 825, 826 (C.C.P.A. 1968) (“[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.”).

“An anticipatory reference, however, need not duplicate word for word what is in the claims. Anticipation can occur when a claimed limitation is ‘inherent’ or

otherwise implicit in the relevant reference.” *Standard Havens Prod., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1369 (Fed. Cir. 1991). Inherency does not require knowledge, recognition, or appreciation of the inherent characteristic or property in the prior art reference by a POSA at the time the invention was made. Indeed, “[i]nherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. . . . the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.” *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999). Moreover, the anticipating reference must describe the claimed invention sufficiently to enable the POSA to carry out the invention without undue experimentation. *In re Gleave*, 560 F. 3d 1331, 1334 (Fed. Cir. 2009).

Finally, to anticipate a claim that recites a range, a prior art reference need only provide one example within that range. *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 782 (Fed. Cir. 1985) (“It is also an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is ‘anticipated’ if *one* of them is in the prior art.”) (citation omitted). Put simply, the anticipating prior art reference need not recite the entire claimed range.

2. WO 071 anticipates claim 1

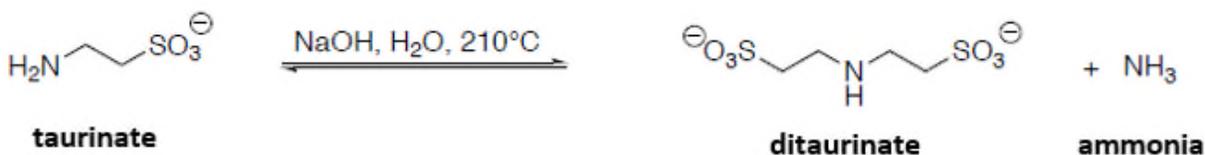
WO 071 expressly or inherently discloses every limitation of claim 1 of the '450 patent, as set forth in further detail below.

The Preamble of Claim 1

Claim Limitation	Disclosure in WO 071 (Ex. 1010)
A process for the production of taurine from alkali ditaurinate or alkali tritaurinate, or their mixture, comprising,	<p>Ex. 1010 at 2: “The method for the production of ditaurine and its salts according to the present invention is characterized in that taurine or its salts or mixtures thereof are heated to temperatures in the range from 130 to 300°C in the presence of a reaction medium.”</p> <p>Ex. 1010 at 3: “The resulting ammonia may, for example, be separated by distillation with water.”</p>

Claim 1 of the '450 patent, as made clear by its preamble, is directed to a process of producing taurine from alkali ditaurinate, alkali tritaurinate, “or” their mixture. Because the claim language uses “or,” its plain and ordinary meaning requires that only one alkali ditaurinate, alkali tritaurinate, or their mixture need to be disclosed in the prior art to anticipate. *See Brown v. 3M*, 265 F.3d 1349, 1351 (Fed. Cir. 2001) (“When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art.”).

WO 071 discloses the reverse process, a reaction of producing ditaurine and its salts – which includes alkali ditaurinate – from taurine or its salt. (Ex. 1010 at 2; Ex. 1003, ¶ 55). WO 071 also discloses this reaction proceeds in heat and in the presence of a reaction medium. (Ex. 1010 at 2; Ex. 1003, ¶ 55). In Example 1, this reaction medium is sodium hydroxide solution at 210°C. (Ex. 1010 at 6; Ex. 1003, ¶ 57). WO 071 explains that ammonia is generated in the disclosed reaction and, more importantly, this reaction is an equilibrium reaction. (Ex. 1010 at 3; Ex. 1003, ¶¶ 57-58). The POSA would understand that this reaction can therefore be represented in the schematic diagram below:



Ex. 1003, ¶¶ 57, 66-67).

As of the Priority Date, a POSA would have understood that an equilibrium reaction necessarily proceeds both ways – forward and reverse. (Ex. 1003, ¶ 57-63, 67). A POSA would also understand that an equilibrium reaction can be shifted to increase yield of either the products or reagents. (*Id.*) In accordance with Le Châtelier’s Principle, “whenever the concentration of a component changes, *the equilibrium system reacts to consume some of the added substance or produce some of the removed substance.*” (Ex. 1019 at 45-46). Furthermore, the

Principle of Microscopic Reversibility, another principle that a POSA would have readily been aware of, provides that “if a reaction occurs by a certain mechanism, the reverse reaction under the same conditions occurs by the exact reverse of that mechanism.” (Ex. 1020 at 81).¹ By the Priority Date, a POSA would have readily been aware of both Le Châtelier’s Principle and the Principle of Microscopic Reversibility. (Ex. 1003, ¶ 62).²

¹ Ex. 1019 is an excerpt from the chemistry textbook *Chemistry, The Molecular Nature of Matter and Change*, Fourth Edition, by Martin S. Silberberg. This textbook was used to teach basic university chemistry courses such as Chemistry 101. (Ex. 1003, ¶ 61). Ex. 1019 was published and became publicly available in 2006. (Ex. 1004, ¶ 86). Ex. 1020 is an excerpt from the chemistry textbook *Organic Chemistry*, Fifth Edition, by Marc Loudon. This textbook was used to teach basic university organic chemistry courses such as Chemistry 262, an undergraduate level organic chemistry class. (Ex. 1003, ¶ 42). Ex. 1020 was published and became publicly available in 2009. (Ex. 1004, ¶ 96).

² In considering whether WO 071 provides an anticipatory disclosure of the claimed invention, extrinsic evidence, such as Silberberg and Loudon, can be used to “educate the decision-maker to what the reference meant to persons of ordinary

Indeed, WO 071 confirms that the conversion of its disclosed equilibrium reaction is affected by the amount of ammonia in the reaction mixture, and that the reaction can be predictably “displaced on the product side by the removal of the ammonia so formed.” (Ex. 1010 at 3). Therefore, a POSA would have understood that this equilibrium reaction can also be predictably displaced towards the reagent side by adding ammonia into the reaction system. (Ex. 1003, ¶¶ 61-62, 67). Also, WO 071’s disclosure that the reaction’s conversion of taurine or its salt ranges from 1% to 70% indicates that this equilibrium can be significantly displaced towards the reagent side, to produce up to 99% taurine or its salt. (Ex. 1010 at 3; Ex. 1003, ¶ 60). Consequently, a POSA would understand that by disclosing the process of producing ditaurine or its salt and ammonia from taurine or its salt in an equilibrium reaction, WO 071 necessarily discloses the process of producing taurine or its salt from ditaurine and its salt, as every equilibrium reaction is reversible. (Ex. 1003, ¶¶ 59, 61-63, 67). Thus, WO 071’s disclosure provides sufficient information to enable a POSA to start with the reaction products (*e.g.*,

skill in the field of the invention,” but it may not be used “to fill gaps in the reference.” *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991) (overruled on other grounds).

ditaurinate and ammonia) and produce from them taurinate by a reversal of the reaction for set forth in the examples. (Ex. 1003, ¶ 63).

For these reasons, WO 071 discloses the preamble of claim 1, namely “a process for the production of taurine from alkali ditaurinate or alkali tritaurinate, or their mixture.”

Step (a) of claim 1

Claim Limitation	Disclosure in WO 071 (Ex. 1010)
(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,	Ex. 1010 at 3: “The reaction medium may be, for example, water, molten alkali hydroxides or other molten electrolytes such as sodium sulfate or mixtures thereof. Preferably, sodium hydroxide, potassium hydroxide, aqueous sodium hydroxide solution or aqueous potassium hydroxide solution are used.” Ex. 1010 at 6-7, Examples 1 to 6.

As discussed above, WO 071 discloses the equilibrium reaction of producing ditaurine or its salt from taurine or its salt. A POSA would also read WO 071 as necessarily disclosing the reverse process of producing taurine or its salt from ditaurine and its salt, through the same equilibrium reaction. (Ex. 1003, ¶¶ 59, 61, 67). WO 071 also discloses that this equilibrium reaction should proceed in a reaction medium that preferably contains an alkali hydroxide such as sodium hydroxide, potassium hydroxide, aqueous sodium hydroxide solution, or aqueous potassium hydroxide solution. (Ex. 1010 at 3). All disclosed examples of WO 071 proceed in a reaction medium containing sodium hydroxide. A POSA would

understand that the reverse reaction can also proceed in the same reaction medium, meaning that any ditaurinate in the reaction system can be mixed with the alkali hydroxide in the reaction medium. (Ex. 1003, ¶¶ 67, 70).

A POSA would also recognize that the alkali hydroxide in the reaction medium ensures the reaction environment is basic, and with fundamental chemistry principles in mind, a POSA would have readily understood that this reaction medium accelerates the forward and reverse reactions of an equilibrium by the same factor. (Ex. 1003, ¶¶ 63, 70). A POSA would also have known that an ammonolysis reaction has to proceed in a basic environment. (Ex. 1003, ¶ 43). WO 071 therefore inherently discloses to a POSA that an alkali hydroxide can be added to a solution of alkali ditaurinate (ditaurine salt) and ammonia, which through the reverse of the forward reaction disclosed in Example 1 of WO 071, react to produce taurine or its salt. (Ex. 1003, ¶ 70).

Step (a) of Claim 1 of the '450 patent also recites that the reaction of alkali ditaurinate, or alkali tritaurinate or their mixture with the alkali hydroxide produces “dialkali ditaurinate, or trialkali tritaurinate or their mixture.” While WO 071 does not mention dialkali ditaurinate or trialkali tritaurinate, their formation is inherently disclosed because dialkali ditaurinate or trialkali tritaurinate will inevitably form when alkali hydroxide is added to alkali ditaurinate or alkali tritaurinate. (Ex. 1003, ¶¶ 71-72). *See SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331,

1345 (Fed. Cir. 2005) (Claimed compound anticipated where practicing the prior art inherently results in at least trace amounts of that compound); *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1378 (Fed. Cir. 2003) (claimed metabolite anticipated where metabolite is inevitably formed in accordance with the prior art).

Finally, because the claim language uses “or,” its plain and ordinary meaning requires that only one alkali ditaurinate, alkali tritaurinate, or their mixture need to be disclosed in the prior art to anticipate. *See Brown*, 265 F.3d at 1351. For these reasons, a POSA would read WO 071 as necessarily disclosing 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. (Ex. 1003, ¶¶ 71-72).

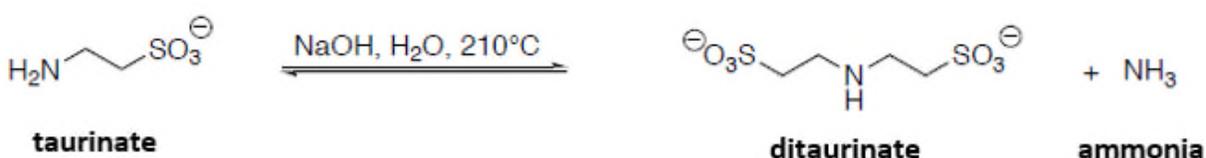
Step (b) of claim 1

Claim Limitation³	Disclosure in WO 071 (Ex. 1010)
b) adding an excess amount of ammonia to a solution of dialkali ditaurinate, or dialkali tritaurinate, or their	Ex. 1010 at 3: “The resulting ammonia may, for example, be separated by distillation with water.”

³ Petitioner notes that the term “dialkali tritaurinate” in step (b) of claim 1 lacks antecedent basis. Petitioner believes the correct term, in the context of the claim 1, should have instead read “trialkali tritaurinate,” and will therefore treat the claim as such.

Claim Limitation ³	Disclosure in WO 071 (Ex. 1010)
mixture, and subjecting the solution to ammonolysis reaction to yield a mixture of alkali taurinates,	

As discussed above, WO 071 discloses the equilibrium reaction represented in the schematic diagram below:



(Ex. 1003, ¶ 57). WO 071 also discloses that the conversion of its disclosed equilibrium reaction is affected by the amount of ammonia in the reaction mixture, and that the reaction can be “displaced on the product side by the removal of the ammonia so formed.” A POSA would appreciate that the reaction can also be displaced on the reagent side, to generate taurinate or its salt (including alkali taurinate) by adding excess ammonia into the reaction system (*i.e.* undergoing an ammonolysis reaction). (Ex. 1010 at 3; Ex. 1003, ¶¶ 61-62, 73). A POSA would also have known that the presence of excess ammonia would favor the formation of taurinate, the primary amine, over secondary or tertiary amines. (Ex. 1020 at 102; Ex. 1003, ¶ 42). Further, in light of WO 071’s disclosure that the reaction may be carried out continuously to produce additional ditaurine with the removal

of the ammonia formed during the reaction, a POSA would understand that, based on Le Châtelier’s Principle, taurine or taurine salt is predictably and necessarily produced through the reverse reaction by adding excess ammonia to the reaction mix under the same reaction conditions. (Ex. 1003, ¶¶ 61-62, 73).

As discussed above, the fact that claim 1 recites alkali tritaurinate in addition to alkali ditaurinate does not prevent WO 071 from anticipating this claim. *See Brown*, 265 F.3d at 1351. For these reasons, WO 071 discloses adding an excess amount of ammonia to a solution of dialkali ditaurinate, or dialkali tritaurinate, or their mixture, and subjecting the solution to ammonolysis reaction to yield a mixture of alkali taurinates.

Step (c) of claim 1

Claim Limitation	Disclosure in WO 071 (Ex. 1010)
(c) removing excess ammonia from (b) and neutralizing alkali taurinates with an acid to form a crystalline suspension of taurine, and	<p>Ex. 1010 at 4:</p> <p>“The reaction mixture may also be purified, e.g. neutralized or acidified, e.g. using mineral acids such as hydrochloric acid and sulfuric acid, acetic acid, and taurine, perhaps.”</p> <p>Ex. 1010 at 6, Example 1:</p> <p>“The reaction mixture was analyzed after cooling, the addition of 160 g water, and ammonia removed via distillation.”</p> <p>Ex. 1010 claims 9, 10.</p>

As shown in the chart above, WO 071 discloses each limitation of Step (c). In WO 071, after the reaction, the excess ammonia is removed from the reaction system. (Ex. 1003, ¶ 74). A POSA would have known that excess ammonia should be removed at the end of the reaction, regardless of the direction in which the reaction had proceeded. (*Id.*). WO 071 also discloses that the reaction mixture should be neutralized with an acid after the reaction, so the desired product, taurinate or ditaurinate, can be neutralized to form taurine or ditaurine, respectively. (Ex. 1003, ¶ 75). The '450 patent also admits the neutralization of the sodium taurinate with an acid is known and disclosed in the prior art. (Ex. 1001, 2:21-24). *See Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1354 (Fed. Cir. 2003) (“This court and its predecessor have held that a statement by an applicant during prosecution identifying certain matter not the work of the inventor as ‘prior art’ is an admission that the matter is prior art.”).

Based on the WO 071 disclosures discussed above, along with the fact that the chemical principles involved were well-known, a POSA art would have readily appreciated that after neutralization with an acid, the taurine generated would inevitably be crystalline. (Ex. 1003, ¶ 75). *See SmithKline Beecham*, 403 F.3d at 1345; *Schering*, 339 F.3d at 1378.

Step (d) of claim 1

Claim Limitation	Disclosure in WO 071 (Ex. 1010)
(d) recovering taurine by means of solid-liquid separation.	<p>Ex. 1010 at 4: “After carrying out the method according to the invention and separating the ammonia so formed, there is generally a mixture is yielded which contains ditaurinate, taurinate, perhaps excess alkali hydroxide, perhaps water, perhaps free taurine, and perhaps other components in small amounts (for example less than 5% by weight).”</p> <p>“The reaction mixture may also be purified”</p>

WO 071 discloses that after equilibrium reaction is carried out, the resulting reaction mixture contains ditaurinate, taurinate and free taurine, and this mixture may be purified. (Ex. 1010 at 4). As of the Priority Date, a POSA would have considered solid-liquid separation as one of the most common and easiest methods for separating and purifying a solid from a liquid phase, and it was well-known in the art that taurine can be recovered through solid-liquid separation as part of the purification of the reaction mixture. (Ex. 1003, ¶ 76). This is especially true because, as discussed above, WO 071 discloses neutralizing the taurinates in the reaction mixture with an acid, which inevitably would form crystalline taurine, which can then easily be recovered through solid-liquid separation using known techniques in the art. (Ex. 1003, ¶¶ 75-76). Moreover, the '450 patent admits that it was well known to a POSA to recover taurine through a solid-liquid separation, such as crystallization. (Ex. 1001, 2:21-26).

Accordingly, for the reasons set forth above, WO 071 anticipates all the limitations of claim 1 of the '450 patent.

3. WO 071 discloses all limitations of claims 3-7

a) Claim 3

Claim Limitation	Disclosure in WO 071 (Ex. 1010)
The process according to claim 1, wherein alkali ditaurinate, alkali tritaurinate, and their mixture are the byproducts in the production of taurine by the ammonolysis reaction of alkali isethionate or alkali vinyl sulfonate.	Ex. 1010 at 2: “Ditaurinate is also formed in the reaction of hydroxyethyl sulfonate with ammonia under pressure and at temperatures from 195 to 245°C within 3 to 5 hours of reaction time (DRP 612.994, DRP 646.707 and DD-A 219 023). This results in up to 33.7% ditaurinate in addition to 21.1% taurinate.”

WO 071 discloses all limitations of claim 3. Specifically, WO 071 discloses that ditaurinate is formed as a byproduct in the ammonolysis reaction of hydroxyethyl sulfonate (isethionate), which produces taurine. (Ex. 1010 at 2; Ex. 1003, ¶ 78). WO 071 also cites DD 023, which discloses that, in addition to ditaurinate, tritaurinate is also formed in the same reaction. (Ex. 1010 at 2; Ex. 1007 at Abstract; Ex. 1003, ¶¶ 77-78). Furthermore, the '450 patent admits that it was known that the ammonolysis of sodium isethionate “invariably” yields a mixture of sodium taurinate, sodium ditaurinate, and sodium tritaurinate. (Ex. 1001, 2:9-13). Accordingly, WO 071 anticipates claim 3. (Ex. 1003, ¶¶ 77-78).

b) Claim 4

Claim Limitation	Disclosure in WO 071 (Ex. 1010)
The process according to claim 1, wherein the catalysts for the ammonolysis reaction are sodium hydroxide, potassium hydroxide, lithium hydroxide, sodium carbonate, potassium carbonate, lithium carbonate, sodium sulfate, sodium sulfite, potassium sulfate, and potassium sulfite.	Ex. 1010 at 3: “The reaction medium may be, for example, water, molten alkali hydroxides or other molten electrolytes such as sodium sulfate or mixtures thereof. Preferably, sodium hydroxide, potassium hydroxide, aqueous sodium hydroxide solution or aqueous potassium hydroxide solution are used.” Ex. 1010 Examples 1 to 6. Ex. 1010 claims 3, 6.

As discussed above with respect to the limitations of claim 1(a), WO 071 discloses an equilibrium reaction of producing ditaurine or its salt from taurine or its salt. This reaction should proceed in a reaction medium that is water, molten alkali hydroxides, or other molten electrolytes. (Ex. 1010 at 3). WO 071 also discloses that the use of alkali hydroxide is advantageous, if not required. (*Id.*). A POSA would recognize that the disclosed species, such as alkali hydroxide, in the reaction medium functions as catalysts in this reaction for both the forward and reverse equilibrium reactions. (Ex. 1003, ¶¶ 79-80). The '450 patent also admits that alkali hydroxide such as sodium hydroxide functions as a catalyst in

ammonolysis reactions, and had been disclosed as a catalyst in the prior art. (Ex. 1001, 1:63-2:3). Accordingly, WO 071 anticipates claim 4.⁴ (Ex. 1003, ¶¶ 79-80).

c) Claim 5

Claim Limitation	Disclosure in WO 071 (Ex. 1010)
The process according to claim 1, wherein alkali metals are lithium, sodium, and potassium.	Ex. 1010 at 3: “Insofar as ditaurinate salts are produced according to the invention, they represent preferably alkali or ammonium salts, in particular sodium, ammonium or potassium salts.” Ex. 1010 at 6-7, Examples 1 to 6.

As shown in the chart above, WO 071 specifies that the alkali salts of ditaurinate (and in turn, taurinate) and hydroxide are sodium or potassium salts. (Ex. 1010 at 3). Further, all species disclosed in Examples 1 to 6 of WO 071 are sodium salts. WO 071 therefore anticipates claim 5. (Ex. 1003, ¶ 81).

d) Claim 6

Claim Limitation	Disclosure in WO 071 (Ex. 1010)
The process according to claim 1, wherein the acids are sulfuric acid, hydrochloric acid, nitric acid, hydrobromic acid, sulfurous acid, sulfur dioxide, and carbon dioxide.	Ex. 1010 at 4: “The reaction mixture may also be purified, e.g. neutralized or acidified, e.g. using mineral acids such as hydrochloric acid and sulfuric acid, acetic acid, and taurine, perhaps.” Ex. 1010, claim 10.

⁴ Petitioner notes that while claim 4 depends from claim 1, the term catalysts is not recited in claim 1 and therefore lacks antecedent basis.

As shown in the chart above, WO 071 discloses that mineral acids such as hydrochloric acid and sulfuric acid can be used to neutralize the reaction mixture. (Ex. 1010 at 4). The '450 patent also admits that the neutralization of the reaction mixture containing taurinate and ditaurinate with an acid, and specifically sulfuric acid, is known and disclosed in the prior art. (Ex. 1001, 2:21-24). WO 071 therefore discloses all limitations of claim 6. (Ex. 1003, ¶ 82). Claim 6 is therefore anticipated.

e) Claim 7

Claim Limitation	Disclosure in WO 071 (Ex. 1010)
The process according to claim 1, wherein the ammonolysis reaction is carried out at a temperature from 150 to 280°C. and under a pressure from autogenous to 260 bar.	<p>Ex. 1010 at 3: “The preferred temperatures according to the invention, are those in the range from 150 to 270°C, in particular those in the range from 190 to 230°C.”</p> <p>Ex. 1010 at 4: “The method of the invention may be performed at various pressures. . . . It is also possible, in particular in the presence of low-boiling components, to work in a closed vessel under the pressure that develops automatically at the reaction temperature. It is also possible to work at other pressures, e.g. in the range from 0.9 to 40 bar.”</p>

As demonstrated in the above chart, WO 071 discloses that ditaurinate is formed in an ammonolysis reaction of hydroxyethyl sulfonate (*i.e.*, isethionate), where the temperature is between 195 to 245°C (Ex. 1010 at 2). In addition, WO 071 discloses an equilibrium reaction where ditaurinate reacts with ammonia to

form taurinate. (Ex. 1003, ¶¶ 55-57). As of the Priority Date, a POSA would have understood that the reaction conditions disclosed in WO 071, including the reaction medium, pressure, and temperature, would be the same for both the forward and reverse reactions. (Ex. 1020 at 81; Ex. ¶¶ 63, 70). Consequently, a POSA would have understood that the temperature and pressure range disclosed by WO 071 for the forward reaction equally apply to the reverse ammonolysis reaction as well. (Ex. 1003, ¶¶ 63, 70, 83). As shown in the chart above, WO 071 discloses specific temperature ranges (150 to 270°C, in particular 190 to 230°C) and pressure ranges (autogenous, and 0.9 to 40 bar). Each of these ranges fall within the ranges recited by claim 7. (Ex. 1003, ¶ 83). Accordingly, WO 071 anticipates claim 7. (Ex. 1003, ¶¶ 83-84); *see also Titanium Metals*, 778 F.2d at 782. (“It is also an elementary principle of patent law that when, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is ‘anticipated’ if *one* of them is in the prior art”) (emphasis in original).

In sum, WO 071 discloses each and every limitations of claims 3-7, and therefore anticipates these claims.

B. Ground 2 – Claims 1 and 3-7 are Obvious in Light of WO 071 and the Knowledge of a POSA

1. Obviousness legal standard

The obviousness inquiry under § 103 is set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966): “[T]he scope and content of the prior art are to be

determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved.” Under this criteria, therefore, a claim is unpatentable 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. *See* 35 U.S.C. § 103(a); *KSR*, 550 U.S. at 415-16 (2007). The party challenging the patent must also show a POSA would have a reason to combine the elements as recited in the claims with a reasonable expectation of success in practicing the claimed invention. *KSR*, 550 U.S. at 418-19. The reason to combine the prior art could be provided by the “normal desire of scientists or artisans to improve upon what is already generally known.” *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003).

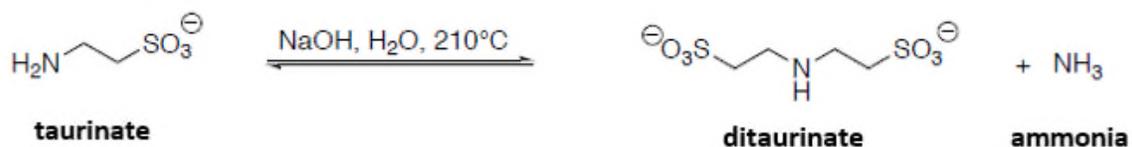
The obviousness analysis does not require express teachings, but may be based on the common sense, inferences, and creative steps expected of a person of ordinary skill in the art. (*KSR*, 550 U.S. at 415-16). The “expansive and flexible approach” in *KSR*, in fact, is consistent with long-standing Federal Circuit practice that “not only permits, but *requires*, consideration of common knowledge and common sense.” *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co*, 464 F.3d 1356, 1367 (Fed. Cir. 2006). In sum, “a court must ask

whether the improvement is more than the predictable use of prior art elements according to their established functions.” *KSR*, 550 U.S. at 417.

2. Claims 1 and 3-7 are obvious

As discussed above, all limitations of claims 1 and 3-7 of the '450 patent are disclosed in WO 071. These claims are also rendered obvious by WO 071 combined with the knowledge of a POSA. *See Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1329 (Fed. Cir. 2009) (an obviousness analysis “may include recourse to logic, judgment, and common sense available to the person of ordinary skill that do not necessarily require explication in any reference or expert opinion.”).

WO 071 discloses the reaction of producing ditaurine and its salts – which includes alkali ditaurinate – from taurine or its salt. [Ex. 1010 at 2; Ex. 1003, ¶¶ 55-57]:



WO 071 discloses that this reaction proceeds in the presence of a catalyst, such as sodium hydroxide in a reaction medium, and ammonia is generated in this reaction. (Ex. 1010 at 3; Ex. 1003, ¶¶ 55-57). WO 071 also discloses that the product from this reaction can be crystallized through neutralization by an acid,

which can be separated through solid-liquid separation. (Ex. 1010 at 4-5; Ex. 1003, ¶¶ 75-76). WO 071, therefore, discloses all steps recited in claim 1 of the '450 patent, and the only difference between the reaction disclosed in WO 071 and that recited in claim 1 is the direction of the reaction – *i.e.*, instead of disclosing the production of taurine from ditaurinate and ammonia, as recited in claim 1, WO 071 discloses the opposite reaction. (Ex. 1003, ¶¶ 67-68).

WO 071, however, discloses that reaction it describes is an equilibrium reaction. (Ex. 1010 at 3; Ex. 1003, ¶ 56). By the Priority Date, a POSA would have understood that an equilibrium reaction necessarily proceeds in both directions – forward and reverse. (Ex. 1003, ¶¶ 58-59). A POSA would also understand that an equilibrium reaction can be shifted to increase yield of either the product or reagent. (Ex. 1003, ¶¶ 60-63, 86-87). Well-established chemistry principles such as Le Châtelier's Principle dictates that “whenever the concentration of a component changes, *the equilibrium system reacts to consume some of the added substance or produce some of the removed substance.*” (Ex. 1019 at 45-46). Furthermore, the Principle of Microscopic Reversibility, another principle that a POSA would have readily been aware of, provides that with “*if a reaction occurs by a certain mechanism, the reverse reaction under the same conditions occurs by the exact reverse of that mechanism.*” (Ex. 1020 at 81; Ex. 1003, ¶¶ 61-62).

With these fundamental principles in the POSA's mind, the POSA's attention would be drawn to the fact that ditaurinate is a standard byproduct from the widely-practiced taurine synthesis process through ammonolysis. (Ex. 1001, 1:24-34, 2:9-12; Ex. 1003, ¶ 89). The POSA would also be drawn to WO 071's disclosure that the conversion of taurine from its reaction ranges from 1% to 70%, which a POSA would understand to mean that this equilibrium can be significantly displaced on the reagent side, to produce up to 99% taurine or its salt. (Ex. 1010 at 3; Ex. 1003, ¶¶ 89-90). Therefore, a POSA desiring to increase the yield of taurine and make the taurine synthesis process more efficient would have been motivated to apply fundamental chemistry principles, such as Le Châtelier's Principle and the Principle of Microscopic Reversibility, to reverse the equilibrium reaction disclosed in WO 071—that is, shift the equilibrium by adding ammonia into that reaction. (Ex. 1010 at 3; Ex. 1003, ¶¶ 89-90). A POSA would also have known that the presence of excess ammonia would favor the formation of taurinate, the primary amine, over secondary or tertiary amines. (Ex. 1003, ¶ 42). In doing so, the POSA would have had a reasonable expectation that taurine would be produced at a very high yield because the equilibrium system disclosed in WO 071 will consume the ammonia by the exact reverse mechanism under which the ditaurinate was initially produced in WO 071. (Ex. 1003, ¶ 90). Accordingly, it would have

been obvious for a POSA to reverse the equilibrium reaction disclosed in WO 071, and the POSA would expect to be successful. (Ex. 1003, ¶¶86-90).

For this reason, WO 071 combined with a POSA's knowledge render claim 1 of the '450 patent obvious. The additional limitations recited in dependent claims 3-7 are also taught or suggested by WO 071 as shown in Ground 1 above, rendering these dependent claims obvious as well.

C. Ground 3 – Claims 1 and 3-7 are Obvious in Light of Wu 2004 and WO 071

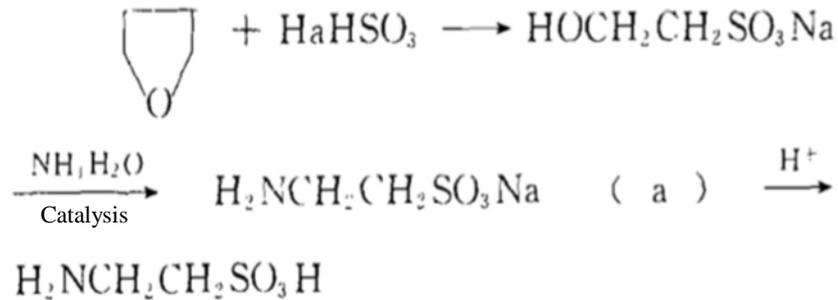
In addition to the challenges noted above, claims 1 and 3-7 are also rendered obvious under 35 U.S.C. § 103 when in light of Wu 2004 (Ex. 1012) and WO 071 (Ex. 1010).

1. Claim 1 obvious

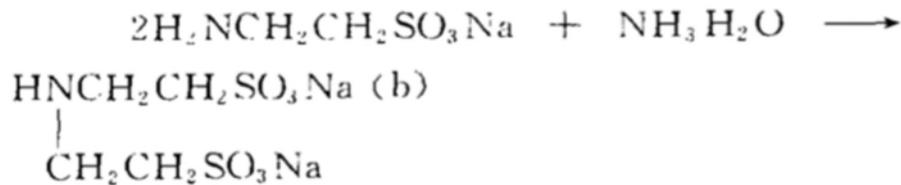
Preamble of Claim 1

Claim Limitation	Prior Art Disclosure
A process for the production of taurine from alkali ditaurinate or alkali tritaurinate, or their mixture, comprising,	Ex. 1012 at 4, 7.

Wu 2004 (Ex. 1012) discloses the synthesis of taurine from sodium isethionate, wherein the sodium isethionate is first synthesized from ethylene oxide and sodium bisulfite in an addition reaction. (Ex. 1012 at 4). This reaction is summarized in the schematic diagram below:



(Ex. 1012 at 4; Ex. 1003, ¶ 93). In addition, Wu 2004 also discloses a “side reaction,” in which sodium ditaurinate is also formed in the same reaction:



(Ex. 1012 at 4; Ex. 1003, ¶ 94). The structure of sodium ditaurinate shown on the product side of this reaction, and sodium ditaurinate is characterized as (b). (Ex. 1003, ¶ 94).

Wu 2004 also discloses that after taurine is separated from the reaction system, if residues “consisting primarily of (b) are fed again into the ammonolysis system, the total yield of the product may very well increase.” (Ex. 1012 at 7; Ex. 1003, ¶ 95). Consequently, a POSA understands that Wu 2004 discloses a process of producing taurine from alkali ditaurinate, and discloses the limitations recited in the preamble of claim 1. (Ex. 1003, ¶¶ 93-97).

Step (a) of claim 1

Claim Limitation	Prior Art Disclosure
(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,	Ex. 1012 at 6, 7.

Wu 2004 discloses that this ammonolysis reaction should proceed in the presence of sodium carbonate, a strong base that forms sodium hydroxide in the presence of water. (Ex. 1012 at 6, Ex. 1003, ¶¶ 96-98). Wu 2004 also discloses that after the ammonolysis reaction, the residues containing sodium ditaurinate can be fed into the reaction system to undergo ammonolysis again. (Ex. 1012 at 7, Ex. 1003, ¶¶ 95, 98). The '450 patent also admits that this residue “invariably” contains a mixture of the sodium salts of taurine, ditaurine and tritaurine. (Ex. 1001, 2:9-13). Therefore, Wu 2004 teaches that an alkali hydroxide is added to a solution of alkali ditaurinate, or alkali tritaurinate or their mixture. (Ex. 1003, ¶ 97). In addition, 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). A POSA would also have understood that the presence of sodium carbonate, a strong base, ensures that the reaction environment is basic, and that

another strong base such as sodium hydroxide can also ensure that the reaction environment is basic. (Ex. 1003, ¶ 97).

Although Wu 2004 does not expressly mention the formation of dialkali ditaurinate or trialkali tritaurinate as recited in claim 1(a), after the addition of the alkali hydroxide, these species are necessarily present in both because they will inevitably form when the byproducts alkali ditaurinate or alkali tritaurinate are added back into the ammonolysis system, which contains alkali hydroxide. (Ex. 1003, ¶ 71-72). See *SmithKline Beecham*, 403 F.3d at 1345; *Schering*, 339 F.3d at 1378.

Consequently, all limitations of claim 1(a) are disclosed by Wu 2004.

Step (b) of claim 1

Claim Limitation	Prior Art Disclosure
(b) adding an excess amount of ammonia to a solution of dialkali ditaurinate, or dialkali tritaurinate, or their mixture, and subjecting the solution to ammonolysis reaction to yield a mixture of alkali taurinates,	Ex. 1012 at 4, 7. Ex. 1010 at 2, 3.

As discussed above, Wu 2004 discloses that residues containing sodium ditaurinate can be fed back into the reaction system to undergo ammonolysis again in order to produce sodium taurinate (and in turn, taurine). (Ex. 1012 at 7, Ex.

1003, ¶ 95). The residues, after alkali hydroxide is added, inevitably contains dialkali ditaurinate, or trialkali tritaurinate. (Ex. 1003, ¶¶ 71-72).

Wu 2004 does not explicitly disclose the mechanism through which ditaurinate produces taurine through ammonolysis. As discussed above, WO 071 discloses the equilibrium reaction where ditaurinate salt reacts with ammonia in the presence of a reaction medium to produce taurine salt. (Ex. 1010 at 2, 3; Ex. 1003, ¶¶ 66-67, 99). Therefore, in light of the disclosures from Wu 2004 and WO 071, a POSA would appreciate that sodium ditaurinate, as a byproduct from the ammonolysis of sodium isethionate, can undergo further ammonolysis in the presence of a suitable reaction medium to generate sodium taurinate, which can be neutralized to form taurine. (Ex. 1003, ¶¶ 98-100).

Consequently, Wu 2004 and WO 071 together disclose adding an excess amount of ammonia to a solution of dialkali ditaurinate, or dialkali tritaurinate, or their mixture, and subjecting the solution to ammonolysis reaction to yield a mixture of alkali taurinates. (Ex. 1003, ¶¶ 98-99).

Step (c) of claim 1

Claim Limitation	Prior Art Disclosure
(c) removing excess ammonia from (b) and neutralizing alkali taurinates with an acid to form a crystalline suspension of taurine, and	Ex. 1012 at 4, 7.

Wu 2004 discloses that after the ammonolysis reaction takes place in an autoclave, excess ammonia is to be “expelled” from the system. (Ex. 1012 at 4). Concentrated sulfuric acid is then added to the system, and a taurine sample is taken for analysis. (Ex. 1012 at 4). A POSA would understand that when concentrated sulfuric acid is added, sodium taurinate is protonated and therefore neutralized, forming a crystalline suspension of taurine. (Ex. 1003, ¶ 96). Therefore, Wu 2004 discloses all limitations recited in step (c) of claim 1.

Step (d) of claim 1

Claim Limitation	Prior Art Disclosure
(d) recovering taurine by means of solid-liquid separation.	Ex. 1012 at 4, 7.

Wu 2004 discloses that after concentrated sulfuric acid is added to the reaction system, a taurine sample is taken for analysis. (Ex. 1012 at 4). A POSA would understand that taurine would have crystalized in solution after the sulfuric acid is added, and would be separated from the system through solid-liquid separation as it is “taken” for analysis, a technique the ’450 patent admits to be well known in the prior art. (Ex. 1001, 2:21-24; Ex. 1003, ¶ 96). Therefore, Wu 2004 discloses that taurine is recovered by means of solid-liquid separation. (Ex. 1003, ¶ 96).

A POSA would have been motivated to combine Wu 2004 and WO 071, both of which disclose processes of taurine synthesis. (Ex. 1003, ¶¶ 100-101). *See*

Philips Lighting N. Am. Corp. v. Wangs All. Corp., 727 Fed. Appx. 676, 681-81

(Fed. Cir. 2018) (finding reason to combine references that are “substantially pertinent to solving precisely the same problem addressed by the [patent in suit]”).

Wu 2004 discloses that sodium ditaurinate, the byproduct from ammonolysis of sodium isethionate, can be fed into the ammonolysis reaction again to increase the yield of taurine – the desired product of the ammonolysis reaction. (Ex. 1012 at 4, 7; Ex. 1003, ¶¶ 94-95). Synthesis of taurine through ammonolysis of isethionate is a well-known method and, as the '450 patent acknowledges, a POSA would look to improve the yield of taurine from the process disclosed in Wu 2004 and reduce waste from the byproducts. (Ex. 1001, 1:23-36; Ex. 1003, ¶ 101). At the same time, a POSA would be motivated to further increase the yield of taurine, and WO 071 confirms that sodium ditaurinate can react with ammonia to form sodium taurinate (and in turn taurine after neutralization with an acid), and discloses this reaction's mechanism of action. (Ex. 1010 at 2, 3; Ex. 1003, ¶¶ 63, 67, 99). A POSA looking to maximize the yield of taurine synthesis would therefore combine Wu 2004 and WO 071 to improve and maximize the yield of taurine by subjecting the sodium ditaurinate byproduct to ammonolysis again. (Ex. 1003, ¶¶ 100-01).

A POSA would also have had a reasonable expectation of success. (Ex. 1003, ¶ 102). Wu 2004 expressly discloses that by feeding sodium ditaurinate into the ammonolysis system again, the total yield of taurine may very well increase,

and reach more than 97%. (Ex. 1012 at 6, 7; Ex. 1003, ¶¶ 95-96). Moreover, WO 071 discloses the reaction in which sodium ditaurinate would react with ammonia to produce taurine, confirming that sodium ditaurinate will in fact produce additional taurine through ammonolysis. (Ex. 1010 at 2, 3; Ex. 1003, ¶¶ 63, 67, 99). WO 071 also discloses that the conversion of taurine from its reaction ranges from 1% to 70%, which a POSA would understand to mean that this equilibrium can be significantly displaced on the reagent side, to produce up to 99% taurine or its salt. (Ex. 1010 at 3; Ex. 1003, ¶ 60). Consequently, a POSA would have expected to successfully combine Wu 2004 and WO 071 to achieve the subject matter of claim 1. (Ex. 1003, ¶ 102)

Accordingly, claim 1 would have been obvious and therefore unpatentable.

2. Claims 3-7 are obvious

As discussed above, all limitations of claims 3-7 of the '450 patent are disclosed by WO 071. These limitations are also disclosed by Wu 2004.

a) Claim 3

Claim Limitation	Prior Art Disclosure
The process according to claim 1, wherein alkali ditaurinate, alkali tritaurinate, and their mixture are the byproducts in the production of taurine by the ammonolysis reaction of alkali	Ex. 1012 at 4.

Claim Limitation	Prior Art Disclosure
isethionate or alkali vinyl sulfonate.	

Wu 2004 discloses that sodium ditaurinate is formed in a “side reaction” from the ammonolysis of sodium isethionate, and that the byproducts of this side reaction can then be put back into the ammonolysis process. (Ex. 1012 at 4). Furthermore, the ’450 patent admits that the prior art makes clear that the ammonolysis of sodium isethionate “invariably” yields a mixture of sodium taurinate, sodium ditaurinate, and sodium tritaurinate. (Ex. 1001, 2:9-13). Therefore, Wu 2004 discloses the additional limitation required by claim 3. (Ex. 1003, ¶¶ 94-95).

b) Claim 4

Claim Limitation	Prior Art Disclosure
The process according to claim 1, wherein the catalysts for the ammonolysis reaction are sodium hydroxide, potassium hydroxide, lithium hydroxide, sodium carbonate, potassium carbonate, lithium carbonate, sodium sulfate, sodium sulfite, potassium sulfate, and potassium sulfite.	Ex. 1012 at 4, 6.

Wu 2004 discloses that the ammonolysis reaction uses sodium carbonate as the catalyst, which necessarily forms sodium hydroxide in the ammonolysis reaction. (Ex. 1012 at 4, 6; Ex. 1003, ¶ 97). Therefore, Wu 2004 discloses the additional limitations required by claim 4. (Ex. 1003, ¶ 97.).

c) Claim 5

Claim Limitation	Prior Art Disclosure
The process according to claim 1, wherein alkali metals are lithium, sodium, and potassium.	Ex. 1012 at 4, 5, 6.

Wu 2004 discloses that sodium salts of the reaction species, such as isethionate, taurinate, and ditaurinate as well as carbonate, are used in the reactions. (Ex. 1012 at 4-6). Therefore, Wu 2004 discloses the additional limitations required by claim 5. (Ex. 1003, ¶¶ 93, 94, 97, 104).

d) Claim 6

Claim Limitation	Prior Art Disclosure
The process according to claim 1, wherein the acids are sulfuric acid, hydrochloric acid, nitric acid, hydrobromic acid, sulfurous acid, sulfur dioxide, and carbon dioxide.	Ex. 1012 at 4.

Wu 2004 discloses that at the end of the disclosed ammonolysis process, concentrated sulfuric acid is used to adjust to pH to 3.5 at which point a sample is taken. (Ex. 1012 at 4). The '450 patent also admits the neutralization of the reaction mixture containing taurinate and ditaurinate with an acid, and specifically sulfuric acid, is known and disclosed in the prior art. (Ex. 1001, 2:21-24).

Therefore, Wu 2004 discloses the additional limitations required by claim 6. (Ex. 1003, ¶¶ 96, 104).

e) Claim 7

Claim Limitation	Prior Art Disclosure
The process according to claim 1, wherein the ammonolysis reaction is carried out at a temperature from 150 to 280°C. and under a pressure from autogenous to 260 bar.	Wu 2004, Ex. 1012 at 5.

Wu 2004 discloses that the ammonolysis reaction temperature ranges between 140 to 260°C, and pressure ranges between 7 to 9 MPa (70 to 90 bar). (Ex. 1012 at 5). Therefore, Wu 2004 discloses the additional limitations required by claim 7. (Ex. 1003, ¶ 104).

For these reasons, claims 3-7 are obvious. Each limitation recited in claims 3-7 is disclosed in the prior art directed to synthesizing taurine and used in the prior art according to its established use or function in producing taurine, and the

disclosed use or function for each of these limitations is the same as that disclosed in the '450 patent. *KSR*, 550 U.S. at 417.

D. Ground 4 – Claims 1 and 3-7 are Obvious in Light of Liu 2013 and WO 071

All challenged claims of the '450 patent are also obvious in light of Liu 2013 and WO 071.

1. Claim 1 is obvious

Preamble of Claim 1

Claim Limitation	Prior Art Disclosure
A process for the production of taurine from alkali ditaurinate or alkali tritaurinate, or their mixture, comprising,	Ex. 1015 at 6.

Liu 2013 (Ex. 1015) discloses the synthesis of taurine from sodium isethionate, wherein the sodium isethionate is first synthesized from ethylene oxide and sodium bisulfite in an addition reaction, in alkaline conditions with 30% sodium hydroxide. (Ex. 1015 at 6; Ex. 1003, ¶ 107). Sodium isethionate then undergoes an ammonolysis reaction under heat and pressure to form sodium taurinate, which is then neutralized with sulfuric acid to form taurine and sodium sulfate. (Ex. 1015 at 6, Ex. 1003, ¶¶ 107-08).

Liu 2013 also discloses that after the neutralization reaction, taurine and sodium sulfate are separated, and the remaining reaction mixture contains many

components including sodium ditaurinate. (Ex. 1015 at 6; Ex. 1003, ¶ 109). The sodium ditaurinate can then be fed again into the ammonolysis reaction, and can help increase generation yield of taurine, which according to Liu 2013 reaches 85% to 95%. (Ex. 1015 at 6; Ex. 1003, ¶ 109). Consequently, a POSA understands that Liu 2013 discloses a process of producing taurine from alkali ditaurinate, and discloses the limitations recited in the preamble of claim 1. (Ex. 1003, ¶ 111).

Step (a) of claim 1

Claim Limitation	Prior Art Disclosure
(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,	Ex. 1015 at 6. Ex. 1010 at 2, 3.

Liu 2013 discloses the addition reaction where ethylene oxide and sodium bisulfite reacted to produce sodium isethionate takes place in 30% sodium hydroxide, and a POSA understands that this sodium hydroxide is part of the reaction environment, and will remain in the reaction system during the ammonolysis reaction, the very next reaction, which takes places in the same reaction system:

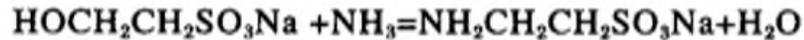
I. Main Principles of the Ethylene Oxide Method

1. Addition Reaction



Under alkaline conditions (30% sodium hydroxide), an addition reaction occurs between ethylene oxide and sodium bisulfite solution (40-50%) at 66-88°C, generating 2-sodium isethionate.

2. Ammonolysis



At a high temperature and pressure (18-19.5 MPa, 265-270°C), 2-sodium isethionate and ammonia react to generate 2-sodium aminoethanesulfonate and water;

(Ex. 1015 at 6, Ex. 1003, ¶¶ 107-09). Furthermore, WO 071 discloses that the equilibrium reaction in which ditaurinate undergoes ammonolysis to produce taurine takes place in a reaction medium that is preferably, if not required to be, sodium hydroxide. (Ex. 1010 at 3; Ex. 1003, ¶ 55). It was known before the Priority Date, as admitted by the '450 patent specification, that the prior art makes clear that the ammonolysis of sodium isethionate “invariably” yields a mixture of the sodium salts of taurine, ditaurinate, and tritaurinate. (Ex. 1001, 2:9-13). Liu 2013 and WO 071 therefore both disclose to a POSA the addition of alkali hydroxide to a solution of alkali ditaurinate or alkali tritaurinate (Ex. 1003, ¶¶ 70, 107). Moreover, a POSA would have known that an ammonolysis reaction must proceed in a basic environment, and that sodium hydroxide, a strong base that is cheap and readily available, would have been an obvious choice to add to the reaction system to keep the reaction environment basic. (Ex. 1003, ¶ 43).

Although Liu 2013 does not expressly mention the formation of dialkali ditaurinate or trialkali tritaurinate, after the addition of the alkali hydroxide, these

species are necessarily present in both because they will inevitably form when the byproducts alkali ditaurinate or alkali tritaurinate are added back into the ammonolysis system, which contains alkali hydroxide. (Ex. 1003, ¶¶ 71-72); *see SmithKline Beecham*, 403 F.3d at 1345; *Schering*, 339 F.3d at 1378.

Step (b) of claim 1

Claim Limitation	Prior Art Disclosure
(b) adding an excess amount of ammonia to a solution of dialkali ditaurinate, or dialkali tritaurinate, or their mixture, and subjecting the solution to ammonolysis reaction to yield a mixture of alkali taurinates,	Ex. 1015 at 6. Ex. 1010 at 2, 3.

Liu 2013 discloses that the solution containing sodium ditaurinate can be fed back into the reaction system to undergo ammonolysis again in order to produce sodium taurinate (and in turn, taurine). (Ex. 1015 at 6, Ex. 1003, ¶ 109). The solution, after alkali hydroxide is added, inevitably contains dialkali ditaurinate or trialkali tritaurinate. (Ex. 1003, ¶ 71-72). A POSA would also have known to add excess ammonia to the reaction because excess ammonia would favor the formation of taurinate, the primary amine, over secondary and tertiary amines. (Ex. 1003, ¶ 41).

Liu 2013 does not explicitly disclose the mechanism through which ditaurinate produces taurine through ammonolysis. As discussed above, WO 071 discloses the equilibrium reaction where ditaurinate salt reacts with ammonia in the presence of a reaction medium to produce taurine salt. (Ex. 1010 at 2, 3; Ex. 1003, ¶¶ 70, 88, 112). Therefore, in light of the disclosures from Wu 2004 and WO 071, a POSA would appreciate that sodium ditaurinate, as a byproduct from the ammonolysis of sodium isethionate, can undergo further ammonolysis in the presence of a suitable reaction medium to generate sodium taurinate, which can be neutralized to form taurine. (Ex. 1003, ¶¶ 70, 109, 113).

Consequently, Liu 2013 and WO 071 together disclose adding an excess amount of ammonia to a solution of dialkali ditaurinate, or dialkali tritaurinate, or their mixture, and subjecting the solution to ammonolysis reaction to yield a mixture of alkali taurinates. (Ex. 1003, ¶¶ 73, 107, 111-12).

Step (c) of claim 1

Claim Limitation	Prior Art Disclosure
(c) removing excess ammonia from (b) and neutralizing alkali taurinates with an acid to form a crystalline suspension of taurine, and	Ex. 1015 at 6.

Liu 2013 discloses that after the ammonolysis reaction, excess ammonia is then removed through the “ammonia absorption system.” (Ex. 1015 at 6; Ex.

1003, ¶ 109). Liu 2013 also discloses that the sodium taurinate produced in the ammonolysis reaction is then neutralized with sulfuric acid to form taurine. (Ex. 1015 at 6; Ex. 1003, ¶¶ 108-09). A POSA would appreciate that after sodium taurinate is neutralized with sulfuric acid, it inevitably crystallizes and forms a crystalline suspension. (Ex. 1003, ¶ 107). Consequently, Liu 2013 discloses all limitations recited in claim 1(c).

Step (d) of claim 1

Claim Limitation	Prior Art Disclosure
(d) recovering taurine by means of solid-liquid separation.	Ex. 1015 at 6.

Liu 2013 discloses that after the neutralization reaction, taurine, along with sodium sulfate, is separated from the reaction mixture. (Ex. 1015 at 6; Ex. 1003, ¶ 109). A POSA would understand that the neutralized taurine can easily be separated through solid-liquid separation, a technique the '450 patent admits to be well known in the prior art. (Ex. 1001, 2:21-24; Ex. 1003, ¶ 76). Therefore, Liu 2013 discloses that taurine is recovered by means of solid-liquid separation.

A POSA would have been motivated to combine Liu 2013 and WO 071, both of which disclose processes of taurine synthesis. (Ex. 1003, ¶¶ 113-14). *See Philips Lighting*, 727 Fed. Appx. 676. Liu 2013 discloses that sodium ditaurinate, the byproduct from ammonolysis of sodium isethionate, can be fed into the

ammonolysis reaction again to increase the yield of taurine – the desired product of the ammonolysis reaction. (Ex. 1015 at 6; Ex. 1003, ¶ 109). Synthesis of taurine through ammonolysis of isethionate is a well-known method and, as the '450 patent acknowledges, a POSA would look to improve the yield of taurine from the process disclosed in Liu 2013 and reduce waste from the byproducts. (Ex. 1001, 1:23-36; Ex. 1003, ¶¶ 113-14). At the same time, a POSA would be motivated to further increase the yield of taurine, and WO 071 confirms that sodium ditaurinate can react with ammonia to form sodium taurinate (and in turn taurine after neutralization with an acid), and discloses this reaction's mechanism of action. (Ex. 1010 at 2, 3; Ex. 1003, ¶¶ 63, 67, 112). A POSA looking to maximize the yield of taurine synthesis would therefore combine Liu 2013 and WO 071 to improve and maximize the yield of taurine by subjecting the sodium ditaurinate byproduct to ammonolysis again. (Ex. 1003, ¶ 113-14).

A POSA would also have had a reasonable expectation of success. (Ex. 1003, ¶ 115). Liu 2013 expressly discloses that by feeding sodium ditaurinate into the ammonolysis system again, the total yield of taurine may very well increase, and reach as high as 95%. (Ex. 1015 at 6; Ex. 1003, ¶ 109). Moreover, WO 071 discloses the reaction in which sodium ditaurinate would react with ammonia to produce taurine, confirming that sodium ditaurinate will in fact produce additional taurine through ammonolysis. (Ex. 1010 at 2, 3; Ex. 1003, ¶¶ 63, 67, 112). WO

071 also discloses that the conversion of taurine from its reaction ranges from 1% to 70%, which a POSA would understand to mean that this equilibrium can be significantly displaced on the reagent side, to produce up to 99% taurine or its salt. (Ex. 1010 at 3; Ex. 1003, ¶ 60). Consequently, a POSA would have expected to successfully combine Liu 2013 and WO 071. (Ex. 1003, ¶ 115).

Accordingly, claim 1 would have been obvious and therefore unpatentable.

2. Claims 3-7 are obvious

As discussed above, all limitations of claims 3-7 of the '450 patent are disclosed by WO 071. These limitations are also disclosed by Liu 2013.

a) Claim 3

Claim Limitation	Prior Art Disclosure
The process according to claim 1, wherein alkali ditaurinate, alkali tritaurinate, and their mixture are the byproducts in the production of taurine by the ammonolysis reaction of alkali isethionate or alkali vinyl sulfonate.	Ex. 1015 at 6.

Liu 2013 discloses that sodium ditaurinate is formed from the ammonolysis reaction of sodium isethionate. (Ex. 1015 at 6). Furthermore, the '450 patent admits that the prior art makes clear that the ammonolysis of sodium isethionate “invariably” yields a mixture of sodium taurinate, sodium ditaurinate, and sodium

tritaaurinate. (Ex. 1001, 2:9-13). Therefore, Liu 2013 discloses the additional limitation required by claim 3. (Ex. 1003, ¶¶ 108-09).

b) Claim 4

Claim Limitation	Prior Art Disclosure
The process according to claim 1, wherein the catalysts for the ammonolysis reaction are sodium hydroxide, potassium hydroxide, lithium hydroxide, sodium carbonate, potassium carbonate, lithium carbonate, sodium sulfate, sodium sulfite, potassium sulfate, and potassium sulfite.	Ex. 1015 at 6.

Liu 2013 discloses that the addition reaction, through which sodium isethionate is formed and which takes place right before the ammonolysis reaction, proceeds in alkaline conditions with 30% sodium hydroxide. (Ex. 1015 at 6; Ex. 1003, ¶¶ 107-08). A POSA would appreciate that the ammonolysis reaction should also take place in the presence of sodium hydroxide. (Ex. 1003, ¶¶ 107-09). In addition, WO 071 also discloses that the use of alkali hydroxide in the ammonolysis reaction is advantageous, if not required. (Ex. 1010 at 3; Ex. 1003, ¶¶ 55, 70). A POSA would also have known that an ammonolysis reaction must proceed in a basic environment, and that sodium hydroxide would have been a

clear choice to add to the reaction system to keep the reaction environment basic.

(Ex. 1003, ¶¶ 43, 80). Therefore, Liu 2013 discloses the additional limitation required by claim 4.

c) Claim 5

Claim Limitation	Prior Art Disclosure
The process according to claim 1, wherein alkali metals are lithium, sodium, and potassium.	Ex. 1015 at 6.

Liu 2013 discloses that sodium salts of the reaction species, such as isethionate, taurinate, and ditaurinate, as well as sodium hydroxide, are used in the reactions. (Ex. 1015 at 6; Ex. 1003, ¶¶ 107-109, 117). Liu 2013 discloses the additional limitation required by claim 5.

d) Claim 6

Claim Limitation	Prior Art Disclosure
The process according to claim 1, wherein the acids are sulfuric acid, hydrochloric acid, nitric acid, hydrobromic acid, sulfurous acid, sulfur dioxide, and carbon dioxide.	Ex. 1015 at 6.

Liu 2013 discloses that after the ammonolysis reaction, a neutralization reaction takes place in which sodium taurinate is neutralized with sulfuric acid to

generate taurine and sodium sulfate. (Ex. 1015 at 6; Ex. 1003, ¶¶ 107-08). The '450 patent also admits the neutralization of the reaction mixture containing taurinate and ditaurinate with an acid, and specifically sulfuric acid, is known and disclosed in the prior art. (Ex. 1001, 2:21-24). Therefore, Liu 2013 discloses the additional limitation required by claim 4.

e) Claim 7

Claim Limitation	Prior Art Disclosure
The process according to claim 1, wherein the ammonolysis reaction is carried out at a temperature from 150 to 280°C. and under a pressure from autogenous to 260 bar.	Ex. 1015 at 6.

Liu 2013 discloses that the ammonolysis reaction temperature at 270°C, and pressure ranges between 18 to 19.5 MPa (180 to 195 bar). (Ex. 1015 at 6; Ex. 1003, ¶ 117). Therefore, Liu 2013 discloses the additional limitation required by claim 4.

Accordingly, for the same reasons discussed above that claim 1 is obvious, claims 3-7 are also obvious. Each limitation recited in claims 3-7 is disclosed in the prior art directed to synthesizing taurine and used in the prior art according to its established use or function in producing taurine, and the disclosed use or

function for each of these limitations is the same as that disclosed in the '450 patent. *KSR*, 550 U.S. at 417.

E. Objective Indicia of Nonobviousness

Patent Owner bears the burden of proof in establishing objective indicia of nonobviousness. To date, Patent Owner has not come forward with any such evidence. To the extent Patent Owner does assert any objective indicia in this proceeding, detailed consideration of Patent Owner's evidence should not be undertaken until Petitioner has had an opportunity to respond to it. *Amneal Pharms., LLC v. Supernus Pharms., Inc.*, IPR2013-00368, Paper 8, at 12-13 (P.T.A.B. Dec. 17, 2003).

IX. CONCLUSION

For these reasons, Petitioner has demonstrated by a preponderance of the evidence that claims 1 and 3-7 of the '450 patent are unpatentable over the various prior art references cited herein, and respectfully requests that *inter partes* review be instituted.

Petition of *Inter Partes* Review of U.S. Patent No. 9,428,450

Dated: September 28, 2018

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24 *et seq.*, the undersigned certifies that this document complies with the type-volume limitations. This document contains 13,612 words as calculated by the “Word Count” feature of Microsoft Word, the word processing program used to create it, and manually counting words in images that excerpt text.

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CERTIFICATE OF SERVICE

The undersigned certifies, in accordance with 37 C.F.R. § 42.105 and § 42.6(e), that service was made on the Patent Owner as detailed below.

Date of Service September 28, 2018

Manner of Service Priority Mail Express®

Document Served Petition for *Inter Partes* Review of U.S. Pat. No. 9,428,450

Power of Attorney

Exhibit 1001 – Exhibit 1049

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