PATENT OWNER
UNITED THERAPEUTICS CORPORATION

IPR2016-00006

U.S. Patent No. 8,497,393

November 29, 2016

UT Ex. 2061

Petitioner Bears the Burden of Proving Invali[d]

- "In an inter partes review, the burden of persuasion is on the petitioner to prove 'unpatentability by a preponderance of th[e] evidence,' 35 U.S.C. § 316(e), and that burden never shifts to [] patentee."

  - *In re Magnum Oil Tools International, Inc.* (Fed. Cir. 2016), citing *Dynamic Drinkware*, 800 F.3d at 137[]

- "[T]he petitioner continues to bear the burden of proving unpatentability after institution, and must do so by a prepon[] of the evidence at trial."

  - *In re Magnum Oil Tools International, Inc.* (Fed. Cir. 201[]

- "[T]he Board has an obligation to assess the question anew a[] based on the totality of the record."

Prior Art at Issue

- The only prior art treprostinil examples in this IPR are (a) t
  single example in Moriarty 2004 of treprostinil acid (Ex. 10
  13) and (b) the single example in Phares WO 2005/007081
  diethanolamine salt of treprostinil, form B (Ex. 1005, pp. 8

- Kawakami and Ege do not disclose treprostinil or any pros
  derivative and do not disclose how to purify such compou
  specifically.

- To the extent Petitioner's evidence shifts burden of produ
  Patent Owner need only present sufficient evidence to reb
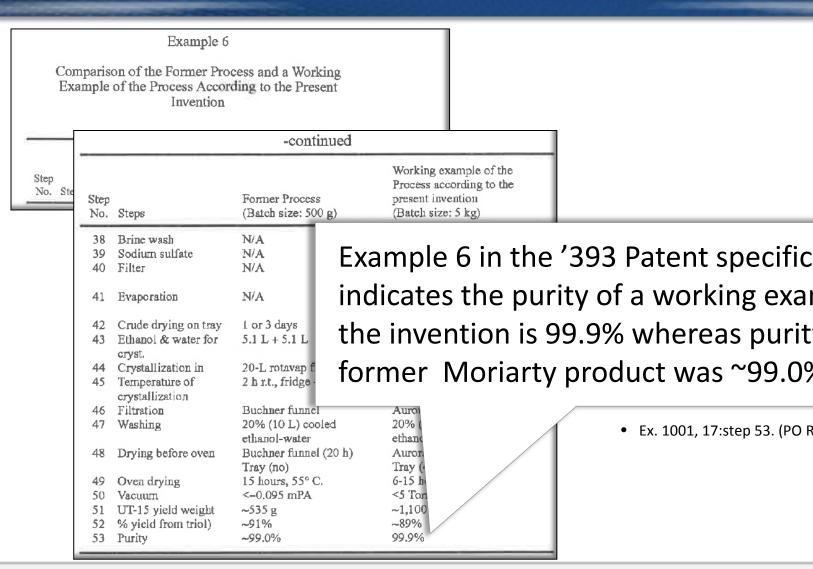 evidence relied upon by Petitioner.

Claim Construction in an IPR Analysis

- "While it is true that, as a general rule, the words of a patent claim
  be given their plain, ordinary and accustomed meaning to one of o
  skill in the relevant art, *Toro Co. v. White Consol. Indus., Inc.*, 199 F.
  1295, 1299 (Fed. Cir. 1999), *a court must nevertheless examine the*
  remaining intrinsic evidence to determine whether the patentee ha
  forth an explicit definition of a term contrary to its ordinary meanin
  disclaimed subject matter, or has otherwise limited the scope of the
  claims."

  - *Day Intern., Inc. v. Reeves Brothers, Inc.*, 260 F.3d 1343, 1349 (Fed. Cir. 2001) (emphasis added) (PO Resp.

- The Federal Circuit in *SafeTCare Mfg* incorporated limitations into
  construction where the specification repeatedly indicated that the
  invention operated by "pushing (as opposed to pulling) forces," and
  characterized the "pushing forces" as "an important feature of the
  present invention."

  - *SafeTCare Mfg., Inc. v.Tele-Made, Inc.*, 497 F.3d 1262, 1269-70 (Fed. Cir. 2007)(PO Re

Proper Claim Construction Requires Consideration of Impurities Present In The Product

Example 6

Comparison of the Former Process and a Working
Example of the Process According to the Present
Invention

Step No.	Ste

-continued

Step No.	Steps	Former Process (Batch size: 500 g)	Working example of the Process according to the present invention (Batch size: 5 kg)
38	Brine wash	N/A	
39	Sodium sulfate	N/A	
40	Filter	N/A	
41	Evaporation	N/A	
42	Crude drying on tray	1 or 3 days	
43	Ethanol & water for cryst.	5.1 L + 5.1 L	
44	Crystallization in	20-L rotavap f	
45	Temperature of crystallization	2 h r.t., fridge	
46	Filtration	Buchner funnel	Auro
47	Washing	20% (10 L) cooled ethanol-water	20% ethan
48	Drying before oven	Buchner funnel (20 h) Tray (no)	Auror Tray (
49	Oven drying	15 hours, 55° C.	6-15 h
50	Vacuum	<−0.095 mPA	<5 Tor
51	UT-15 yield weight	~535 g	~1,100
52	% yield from triol)	~91%	~89%
53	Purity	~99.0%	99.9%

Example 6 in the '393 Patent specific
indicates the purity of a working exar
the invention is 99.9% whereas purit
former Moriarty product was ~99.0%

- Ex. 1001, 17:step 53. (PO R

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