

No. 18-

In the
Supreme Court of the United States

NIGEL R. PARKER AND SEPPÖ YLÄ-
HERTTUALA,

Petitioners

-against-

The Honorable ANDREI IANCU, in his official
capacity as Under Secretary of Commerce for
Intellectual Property and Director of the United
States Patent and Trademark Office,

Respondent

ON PETITION FOR A WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

J. MARK POHL
Counsel of Record
PHARMACEUTICAL PATENT
ATTORNEYS, LLC
55 Madison Avenue, 4th fl.
Morristown, New Jersey 07960
(973) 984-6159 x304
Mark.Pohl@LicensingLaw.Net

September 21, 2018

Attorneys for Petitioners

Question Presented

In *Dickinson v. Zurko*, 527 U.S. 150 (1999), this Court held that The United States Patent Office must support rejection with substantial evidence. See *Dickinson* at 152, citing 5 U.S.C. § 706(2)(E).

In the instant case, The Patent Office rejects Petitioners' patent claims based on either of two alleged antedating publications. Neither document, however, is of record. This appeal thus raises simple yet fundamental questions of agency overreach:

Whether the “substantial” evidence required to support agency action under 5 U.S.C. § 706(2)(E) must be evidence *of record*?

Whether agency rejection is “arbitrary” or “capricious” under 5 U.S.C. § 706(2)(A) if supported only by alleged evidence which is not of record and which the agency has not in fact considered?

Whether a document which is not publicly available is a “publication” under 35 U.S.C. § 102(b)?

Rule 14(b) Statement

A list of all parties to the proceeding in the court whose judgment is sought to be reviewed:

Nigel R. Parker Ph.D. and Seppo Ylä-Herttuala M.D., *Petitioners*. The real party in interest is the assignee of the instant patent applications, FKD Therapies Oy.

The Honorable Andrei Iancu, in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, *Respondent*.

Corporate Disclosure Statement

The real party in interest, FKD Therapies Oy, a Finnish company, hereby identifies The Frederick Paulsen Foundation, a privately-held Swiss foundation, as its ultimate parent company indirectly owning 100% of Petitioner's stock.

Table of Contents

QUESTION PRESENTED	I
RULE 14(B) STATEMENT	II
CORPORATE DISCLOSURE STATEMENT....	III
TABLE OF CONTENTS	IV
TABLE OF AUTHORITIES	V
TABLE OF APPENDIXES	VI
OPINIONS BELOW	1
JURISDICTION	2
STATUTORY PROVISION INVOLVED.....	3
STATEMENT OF THE CASE.....	4
STERMAN (DEC. 15, 2011) DOES NOT QUALIFY AS PRIOR ART UNDER 35 U.S.C. § 102(B).....	4
DIGITAL FILE DOI No. 10:1164/ RCCM.201103- 0554CR WAS CREATED ON 11/24/2011.....	5
THE BOARD CORRECTLY DISTINGUISHED BETWEEN STERMAN (DEC. 15, 2011) AND THE DIGITAL (DOI) FILE	8
THE BOARD’S <i>EX PARTE</i> INVESTIGATION CONFIRMS THAT THERE IS NO “EARLIER MANUSCRIPT”	10
THE ALLEGED MANUSCRIPT IS NOT A “PUBLICATION” 	11
ROUTINE BUSINESS PRACTICE CAN SHOW THE DATE OF PUBLICATION, BUT NOT THE SUBSTANCE OF THE PUBLICATION.....	12
THE FEDERAL CIRCUIT AFFIRMED PER CURIAM.....	13
ARGUMENT	13

THE DOI FILE DOES NOT QUALIFY AS ANTEDATING PRIOR ART	14
NEITHER THE DOI FILE NOR THE ALLEGED MANUSCRIPT ARE OF RECORD	15
THE ALLEGED MANUSCRIPT IS NOT A “PUBLICATION”	16
THE AGENCY’S REJECTION IS ARBITRARY AND CAPRICIOUS BECAUSE IT IS NOT SUPPORTED BY ANY EVIDENCE OF RECORD.....	16
CONCLUSION	17

Table of Appendixes

Appendix 1a – Decision of the United States Court of Appeals for the Federal Circuit, docket 2018-1088 (July 17, 2018)

Appendix 3a – Decision Of The Patent Trial & Appeal Board, docket 2016-008089 (Sept. 27, 2017)

Appendix 11a - Decision of the United States Court of Appeals for the Federal Circuit, docket 2017-2244 (July 17, 2018)

Appendix 13a - Decision Of The Patent Trial & Appeal Board, docket 2016-003044 (May 24, 2017)

Table of Authorities

Cases

<i>Chicago Firefighters Local 2 v. City of Chicago</i> , 249 F.3d 649 (7 th Cir. 2001).....	15
<i>Citizens to Preserve Overton Park v. Volpe</i> , 401 U.S. 402 (1971).....	9, 14
<i>Dickinson v. Zurko</i> , 527 U.S. 150 (1999).....	9, 11
<i>Eisenstadt v. Centel Corp.</i> , 113 F.3d 738 (7 th Cir. 1997).....	14
<i>In re Gartside</i> , 203 F.3d 1305 (Fed. Cir. 2000).....	15
<i>In re Hall</i> , 781 F.2d 897 (Fed. Cir. 1986).....	11, 16
<i>Kyocera Wireless Corp. v. Int’l Trade Comm’n</i> , 545 F.3d 1340 (Fed. Cir. 2008).....	12, 16
<i>Roberts v. City of Shreveport</i> , 397 F.3d 287 (5 th Cir. 2005).....	15
<i>Verdegaal Bros. v. Union Oil Co. of California</i> , 814 F.2d 628 (Fed. Cir. 1987).....	6, 17

Statutes

28 U.S.C. § 1254(1)	2
35 U.S.C. § 134(a)	2
35 U.S.C. § 141.....	2
5 U.S.C. § 706(2)	11, 17

Rules

Fed. R. Evid. Rule 803	12
------------------------------	----

Petitioners here petition for a *writ of certiorari* to review the two judgments of The United States Court of Appeals for the Federal Circuit entered on July 17, 2018 in Petitioners' two patent applications.

Opinions Below

Regarding patent application serial No. 13/932202, the opinion of The Court of Appeals for the Federal Circuit (docket 2018-1088) is not reported and is reproduced in the Appendix at 1a. The underlying opinion of The Patent Trial & Appeal Board (docket 2016-008089) is not reported and is reproduced in the Appendix at 3a.

Regarding patent application serial No. 14/030399, the opinion of The Court of Appeals for the Federal Circuit (docket 2017-2244) is not reported and is reproduced in the Appendix at 11a. The underlying opinion of The Patent Trial & Appeal Board (docket 2016-003044) is not reported and is reproduced in the Appendix at 13a.

Jurisdiction

The Patent Trial & Appeal Board enjoyed jurisdiction to hear an appeal of the rejection of the instant patent applications under 35 U.S.C. § 6(b).

The Court of Appeals for the Federal Circuit enjoyed jurisdiction to hear an appeal of The Patent Trial & Appeal Board under 35 U.S.C. § 141.

The judgments of the Court of Appeals were entered on July 17, 2018. No petition for rehearing was entered. This Court therefore enjoys jurisdiction under 28 U.S.C. § 1254(1).

Statutory Provision Involved

This case concerns the Federal Administrative Procedure Act, 5 U.S.C. § 706(2):

“The reviewing court shall ... (2) hold unlawful and set aside agency action, findings, and conclusions found to be -

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; [or]

* * *

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute.

Statement of the Case

The relevant facts are undisputed.

Sterman (Dec. 15, 2011) Does Not Qualify As Prior Art Under 35 U.S.C. § 102(b)

Petitioners filed two utility patent applications,¹ each asserting an effective filing date as of July 11, 2012.

One cannot patent something which is fully taught in an earlier publication. *See* pre-AIA 35 U.S.C. § 102(b).

The Examiner accordingly began examination by entering into the record a journal article, Daniel H. Sterman *et al.*, *A Trial of Intrapleural Adenoviral-Mediated Interferon- α 2b Gene Transfer for Malignant Pleural Mesothelioma*, 184 AMER. J. RESPIRATORY & CRITICAL CARE MED. 1395 (Dec. 15, 2011). The Examiner argued that Petitioners' patent claims were barred under pre-AIA 35 U.S.C. § 102(b) by Sterman *et al.* (Dec. 15, 2011).

The statute then in effect, however, afforded patent applicants a grace period. The statute said that to antedate, a prior publication must have been published "*more than one year prior to the date of the application for patent.*" *See* pre-AIA 35 U.S.C. § 102(b). In the instant case, Petitioners' patent applications assert an effective filing date of July 11, 2012. Therefore, to antedate, a publication must have been published before **July 11, 2011**.

¹ Patent Application Serial Nos. 13/932202 and 14/030399.

Sterman (Dec. 15, 2011), however, says on its face that it was published on December 15, 2011:



See Appx30.² Sterman (Dec. 15, 2011) was published five months *after* the July 11 cut-off date. Sterman (Dec. 15, 2011) therefore does not qualify as an antedating publication.³ See pre-AIA 35 U.S.C. § 102(b).

Digital File DOI No. 10:1164/rccm.201103-0554CR Was Created On 11/24/2011

Petitioners explained this to the Examiner. In response, the Examiner conceded that Sterman (Dec. 15, 2011) does not qualify as a prior art.

² “Appx” refers to the Appendix of record before the Court of Appeals below. In contrast, “_a” refers to the instant Appendix.

³ Pre-AIA 35 U.S.C. § 102 has seven subsections, (a) through (g). The Examiner correctly recognized that of these seven subsections, six do not apply here. The Examiner thus rejected the claims under only one subsection - subsection (b). Thus, for simplicity I here say “does not qualify as prior art” rather than a more verbose “does not qualify as prior art *under subsection (b)*” because only subsection (b) is at issue. The Board commented that Sterman (Dec. 15, 2011) might qualify as prior art under subsection (a). That commentary, however, is *dicta* because no rejection under subsection (a) was at issue below.

The Examiner, however, raised a new argument. Sterman (Dec. 15, 2011) says that it was published Dec. 15, 2011. It also says, “Originally Published in Press as DOI 10:1164/rccm.201103-0554CR on June 3, 2011. Internet address: www.atsjournals.org”:

Am J Respir Crit Care Med Vol 184. pp 1395–1399, 2011
Copyright © 2011 by the American Thoracic Society
Originally Published in Press as DOI: 10.1164/rccm.201103-0554CR on June 3, 2011
Internet address: www.atsjournals.org

See Appx31. The Examiner thus shifted position and rejected the patent applications not on Sterman (Dec. 15, 2011), but on the “DOI” digital file referred to in it.⁴

The Examiner, however, omitted from his rejection two critical pieces of evidence.

First, the Examiner did not make the DOI digital file of record. This is important because to reject a patent claim under 35 U.S.C. § 102(b), the antedating publication must show each and every limitation of the patent claim, and must do so in detail adequate to enable the skilled artisan to practice the claimed invention. See *e.g.*, *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). In the instant case, however, the digital DOI file is not of record. We thus cannot determine whether it teaches each limitation of these

⁴ “DOI” means Digital Object Identifier. A DOI number functions like an ISBN number does for books. A DOI number identifies a specific digital file (*e.g.*, a specific photograph or a particular Adobe Acrobat™ file). This is useful because the same digital file may be found in many different places on the internet. The DOI number indicates that all of these copies are identical.

patent claims. We thus cannot determine whether or not the DOI file anticipates these patent claims. *See Verdegall Bros.*

Second, the Examiner did not make of record evidence showing when the DOI file was in fact published. To address this evidentiary void, Petitioners obtained a copy of the DOI file from the publisher and examined the file's metadata. The metadata shows that the DOI file was created on Nov. 24, 2011 at 11:07 p.m. Appx62. The cut-off date for antedating publications, however, is July 11, 2011. *See* pre-AIA 35 U.S.C. § 102(b). The DOI file cannot possibly have been published *before* July 11, 2011 because it was not even created until the following November 24th. This metadata thus shows that the DOI file does not qualify as an antedating publication. *See* pre-AIA 35 U.S.C. § 102(b).

Petitioners made of record the DOI file metadata.⁵ In response, the Examiner obtained a copy of the DOI file and examined its metadata. Based on his investigation, the Examiner agreed that the DOI file was first created Nov. 24, 2011. The Examiner (correctly) says:

“Appellant is relying upon the ‘metadata’ contained within the PDF file which can be downloaded from the publishers website to indicate that PDF file was created on 11/24/2011. The Examiner does agree that the PDF file containing the work of Sterman, downloaded from the publisher’s website, is a PDF file created on 11/24/2011.”

⁵ N.B.: Petitioners made of record the metadata for the DOI file. Neither party has made of record the DOI file itself.

Appx72. The 11/24/2011 creation date disqualifies the DOI file as § 102(b) prior publication. The Examiner correctly recognized this. The Examiner thus did not bother to make the DOI file of record because it does not qualify as prior art. *See* pre-AIA § 102(b).

The Examiner nonetheless reiterated that he was rejecting the applications as anticipated by the DOI file. That rejection is legally flawed because it is based on a DOI file which the Examiner expressly found does not qualify as antedating § 102(b) prior art.⁶

The Board Correctly Distinguished Between Serman (Dec. 15, 2011) and the Digital (DOI) File

The Examiner rejected Petitioners' patent claims as anticipated by digital file number 10:1164/rccm.201103-0554CR. The Examiner, however, also found that the digital file was created on Nov. 24, 2011. Appx72. The DOI file thus does not qualify as antedating prior art as a matter of law. *See* pre-AIA 35 U.S.C. § 102(b).

Furthermore, assuming the DOI file qualified as antedating prior art, it does not support rejection because it is not of record.

Petitioners accordingly appealed to The Patent Trial & Appeal Board. The Board correctly found that the Dec. 15 publication (Appx31-32) "was published in the issue ... dated Dec. 15, 2011, which is less than a

⁶ The Examiner's rejection appears based on pecuniary self-interest. The Patent Office is self-funding. It retains applicants' filing fees for its own budget. The Examiner here raised a legally-flawed rejection and refuses further work *unless Petitioners pays further fees.*

year before the provisional filing dates” for Petitioners’ applications. 5a. The Board correctly found that Sterman (Dec. 15, 2011) does not qualify as antedating prior art. *See* 35 U.S.C. § 102(b).

The Board correctly found that the Dec. 15 publication and the digital file (DOI number 10:1164/rccm.201103-0554CR) “are not the same.” 9a. The Examiner correctly found that the DOI file “was created on 11/24/2011.” Appx72. The Board did not dispute this. The Board nonetheless affirmed rejection based on the DOI file. To support rejection, the Board disregarded the metadata. In so doing, the Board made two legal errors.

First, an agency cannot simply ignore adverse evidence. Rather, an agency’s review must be on the “*full*” administrative record.” *See Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 420 (1971) (emphasis mine). In the instant case, the metadata is of record, the Examiner reviewed it, and the Examiner made an undisputed factual finding that the DOI file “was created on 11/24/2011.” Appx72. The agency’s own Examiner having made this factual finding, the Board cannot simply ignore it. *See Overton Park*.

Second, assuming that the DOI file was published before the critical date, the DOI file nonetheless cannot support rejection because the DOI file is not of record.⁷ The Patent Office must support rejection with substantial evidence. *See Dickinson v. Zurko*, 527 U.S. 150, 152 (1999), *citing* 5 U.S.C. § 706(2)(E). In the instant case, the DOI file cannot constitute

⁷ N.B.: The DOI file metadata is of record. In contrast, the DOI file itself is not of record.

substantial evidence because it is not in evidence. *See id.*

The Board’s Ex Parte Investigation Confirms That There Is No “Earlier Manuscript”

The Examiner found that the DOI file was created on 11/24/2011. The DOI file thus does not qualify as antedating prior art. *See* pre-AIA 35 U.S.C. § 102(b). This is fatal to the Examiner’s rejection.

The Board tacitly recognized this. To rehabilitate the rejection, the Board of Appeals contacted the publisher *ex parte* to obtain a copy of an earlier publication. *See* 7a n.3. The Board, however, declines to make of record its *ex parte* communications with the publisher.⁸

As a threshold issue, you may find the Board’s *ex parte* investigation troubling because the Board is an appellate panel, not an investigator, and agency regulations forbid the parties from entering new evidence on appeal. Furthermore, the Board of Appeal is supposed to be impartial, not an advocate for the Examiner.

The Board’s pursuit of an *ex parte* fact-finding investigation implies that the Board disregarded its limited and ostensibly *impartial* role. The Board nonetheless came up empty-handed. Despite contacting the publisher directly, the Board failed to obtain any earlier manuscript.

The Board failed to obtain any earlier manuscript, despite contacting the publisher directly. The Board nonetheless says, “an earlier manuscript was

⁸ N.B.: The Board refers to an “attached email,” *see* 7a n.3, yet its opinion does not in fact include any attached emails, *see* 10a.

published online on June 4, 2011.” See 9a. The Board thus rejects the patent claims based on that alleged “earlier manuscript.” The alleged manuscript, however, is not of record and, in light of the publisher’s inability to provide a copy to the Board, apparently does to not exist.

The Board here errs as a matter of law by ignoring this Court’s mandate. This Court requires the agency to support rejection with substantial evidence. See *Dickinson v. Zurko*, 527 U.S. 150, 152 (1999), citing 5 U.S.C. § 706(2)(E). In the instant case, the Board’s alleged manuscript is not of record. It is thus not in evidence. It cannot constitute *substantial evidence* because it is not even *evidence*. See *id.* Indeed, the publisher’s inability to provide a copy of it implies that the Board’s alleged manuscript does not exist.

Furthermore, an agency cannot reject arbitrarily or capriciously. See 5 U.S.C. § 706(2)(A). In the instant case, the Board does not have a copy of its alleged manuscript. The Board thus apparently never read it. The Board nonetheless rejected based on an alleged manuscript which the Board never in fact read. This is the epitome of arbitrary or capricious action. See *id.*

In response, the Board speculates that its alleged manuscript should be similar to Serman (Dec. 15, 2011). The Board says, “it is reasonable [to speculate] that the phrase ‘Originally Published’ refers to this complete article.” See 6a. Without a copy of that alleged manuscript, however, that is mere speculation. And speculation is not evidence. Speculation thus cannot constitute the substantial evidence this Court requires. See *Dickinson*.

The Alleged Manuscript Is Not a “Publication”

The proponent of an antedating publication must show that prior to the critical date, the reference was accessible to the artisan using reasonable diligence. *In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1986); *Kyocera Wireless Corp. v. Int’l Trade Comm’n*, 545 F.3d 1340, 1350 (Fed. Cir. 2008).

In the instant case, if the Board’s manuscript was accessible to the artisan, the artisan would be able to find it in the National Library of Medicine and on the publisher’s website. Neither, however, provides the alleged manuscript. Indeed, the Board could not get a copy despite contacting the publisher directly.

The artisan cannot obtain the alleged manuscript with reasonable diligence. It thus is not a “publication” under the statute. *See Kyocera, Hall*.

Routine Business Practice Can Show The Date of Publication, But Not the Substance of the Publication

The Board found that currently, the publisher publishes manuscripts on line as soon as they are accepted for publication. The Board thus argues that its alleged early manuscript was likely published on June 4, 2011. The Board here makes three legal errors.

First, the publisher’s *current* business practices fail to evince the publisher’s routine practices *in June 2011*.

Second, routine business practice may be used to establish *the date* a manuscript was published, but

cannot establish *the contents* of that manuscript. *See* Fed. R. Evid. Rule 803(6).⁹

Third, *the absence* of a transaction from routine business records tends to show that an alleged transaction did not occur. *See* Fed. R. Evid. Rule 803(7). In the instant case, the Board is unable to produce its alleged early manuscript, despite contacting the publisher directly. *See* 7a n.3. This implies that the alleged manuscript does not exist. *See* Fed. R. Evid. Rule 803(7).

The Federal Circuit Affirmed Per Curiam

The Board rejected based on digital DOI file and an alleged “earlier manuscript.” Neither document, however, is of record. The Board did not in fact have either document. The Board thus did not in fact read either document. The Board thus bases its rejection on evidence which is not of record, and which the Board did not read.

Further, the Examiner found that the DOI file was created on Nov. 24, 2011. It therefore does not qualify as antedating § 102(b) prior art as a matter of law. The Board’s inability to obtain its alleged earlier manuscript from the publisher implies that the manuscript does not exist. It also shows that the manuscript as a matter of law is not a “publication” under the statute. *See Kyocera*.

The Court of Appeals enjoyed jurisdiction to hear an appeal from The Patent Trial & Appeal Board under 35 U.S.C. § 141. The Court of Appeals affirmed. Perhaps recognizing that its decision is not

⁹ N.B.: While the Board’s argument echoes Fed. R. Evid. Rule 803, the Board did not expressly cite any authority for its position.

supported by any evidence of record, the Court declined to provide an opinion explaining its rationale.

Argument

Neither the DOI file nor the Board's alleged "earlier manuscript" constitutes substantial evidence supporting rejection.

The DOI File Does Not Qualify As Antedating Prior Art

The Examiner considered the metadata for digital DOI file number 10:1164/rccm.201103-0554CR. Based on that evidence, the Examiner found the DOI file was "created on 11/24/2011." Appx72. The Examiner's undisputed factual finding, based on evidence of record, shows that the DOI file does not qualify as an antedating publication. *See* pre-AIA § 102(b).

The Board responds by disregarding both the metadata and the Examiner's resulting finding. Rather, the Board argues that the DOI file was published on June 3, 2011 because Sterman (Dec. 15, 2011) says so. The Board here commits two legal errors.

First, an agency's review must be on the "full" administrative record. *See Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 420 (1971). An agency can *weigh* conflicting evidence. An agency cannot, however, simply *ignore* adverse evidence. In the instant case, the Board *ignores* the metadata, and *ignores* its own Examiner's finding that that the DOI file was "created on 11/24/2011." This is legal error. *See id.*

Second, even if we ignore the metadata, the DOI file as a matter of law does not support rejection because the Board commits a law student's error, basing its rejection on uncorroborated hearsay. A newspaper article can be used to prove the existence of the article. In contrast, using a newspaper article to prove the truth of its contents is hearsay. *See e.g., Eisenstadt v. Centel Corp.*, 113 F.3d 738, 742 (7th Cir. 1997) (Posner, C.J.); *Chicago Firefighters Local 2 v. City of Chicago*, 249 F.3d 649, 654 (7th Cir. 2001) (same); *Roberts v. City of Shreveport*, 397 F.3d 287, 295 (5th Cir. 2005) (same).

In the instant case, the Board tries to prove the DOI file publication date by relying on Stermann (Dec. 15, 2011). The board thus cites Stermann (Dec. 15, 2011) not to prove the existence of Stermann (Dec. 15, 2011), but to prove the truth of its contents, *i.e.*, to prove that digital file No. 10:1164/rccm.201103-0554CR was in fact published on June 3. The Board's use of Stermann (Dec. 15, 2011) is therefore hearsay. *See id.*

Further, the agency has not made the alleged June 3 document of record. The Board's hearsay evidence is thus uncorroborated.

Uncorroborated hearsay is not substantial evidence. *See Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229-30 (1938); *In re Gartside*, 203 F.3d 1305, 1312 (Fed. Cir. 2000). Uncorroborated hearsay thus fails as a matter of law to support rejection. *See Dickinson v. Zurko*, 527 U.S. 150, 152 (1999), *citing* 5 U.S.C. § 706(2)(E). The Board's rejection fails as a matter of law because it is based solely on uncorroborated hearsay.

Neither The DOI File Nor the Alleged Manuscript Are Of Record

The agency must support rejection with substantial evidence. *See Dickinson v. Zurko*, 527 U.S. 150, 152 (1999), *citing* 5 U.S.C. § 706(2)(E). In the instant case, neither the DOI file nor the Board's alleged manuscript is in evidence. Because neither is *evidence*, neither can be the *substantial* evidence this Court requires. Furthermore, the Board's inability to obtain a copy of the alleged manuscript - despite asking the publisher directly - implies that the alleged manuscript does not exist.

In response, the Board speculates that the DOI file and its alleged manuscript should be similar to the Dec. 15 document. The Board says, "it is reasonable [to speculate] that the phrase 'Originally Published' refers to this complete article." *See* 6a. Without having copies of the DOI file nor the Board's manuscript, however, we cannot see whether those documents are the same or not. The Board's allegation here is baseless speculation. And speculation is not evidence. It thus cannot constitute the substantial evidence this Court requires.

The Alleged Manuscript Is Not a "Publication"

The proponent of an antedating publication must show that prior to the critical date, the reference was accessible to the artisan using reasonable diligence. *In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1986); *Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1340, 1350 (Fed. Cir. 2008).

In the instant case, neither the Examiner nor the Board nor the Petitioner can get a copy of the Board's alleged manuscript. The artisan thus cannot obtain

it with reasonable diligence. It thus is not a “publication” as a matter of law. *See Kyocera, Hall*.

The Agency’s Rejection is Arbitrary and Capricious Because It is Not Supported By Any Evidence of Record

To reject a patent claim under 35 U.S.C. § 102(b), the antedating prior art publication must show each and every limitation of the patent claim, and must do so in detail adequate to enable the skilled artisan to practice the claimed invention. *See e.g., Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

In the instant case, the agency cannot explain where each limitation of Petitioner’s patent claims is taught in the DOI file, nor in its alleged “earlier manuscript.” The agency cannot do so because the agency has not made either document of record. Not having either document, the Board apparently never read either document. The Board thus rejects based on alleged documents *it apparently never read*. This is the epitome of arbitrary or capricious agency action. *See* 5 U.S.C. § 706(2)(A).

Conclusion

The DOI file and the Board’s alleged “early manuscript” are not of record. Further, the alleged manuscript is not cataloged, nor available directly from the publisher, and apparently does not even exist. Petitioner respectfully asks this Court to grant *certiorari* to clarify that evidence which is not of record, and which may not in fact exist, is not the “substantial” evidence this Court requires. *See Dickinson v. Zurko*, 527 U.S. 150, 152 (1999), *citing* 5 U.S.C. § 706(2)(E).

Respectfully submitted,

/s/

J. MARK POHL

Counsel of Record

PHARMACEUTICAL PATENT ATTORNEYS, LLC

55 Madison Avenue, 4th floor

Morristown, New Jersey 07960

(973) 984-6159 x304

Attorneys for Petitioner

APPENDIX

NOTE: This disposition is nonprecedential.

United States Court of Appeals
for the Federal Circuit

IN RE: NIGEL PARKER, SEPP0 YLA-
HERTTUALA,
Appellants

2018-1088

Appeal from the United States Patent and
Trademark Office, Patent Trial and Appeal Board in
No. 13/932,202.

JUDGMENT

J. MARK POHL, Pharmaceutical Patent Attorneys,
LLC, Morristown, NJ, argued for appellants.

MARY BETH WALKER, Office of the Solicitor,
United States Patent and Trademark Office,
Alexandria, VA, argued for appellee Andrei Iancu.

Also represented by NATHAN K. KELLEY,
THOMAS W. KRAUSE, WILLIAM LAMARCA.

THIS CAUSE having been heard and considered, it is ORDERED and ADJUDGED:

PER CURIAM (PROST, Chief Judge, NEWMAN and LINN, Circuit Judges).

AFFIRMED. See Fed. Cir. R. 36.

ENTERED BY ORDER OF THE COURT

July 17, 2018

/s/ Peter R. Marksteiner

Date

Peter R. Marksteiner

Clerk of Court

UNITED STATES PATENT AND TRADEMARK
OFFICE

BEFORE THE PATENT TRIAL AND APPEAL
BOARD

Ex parte NIGEL PARKER and SEPPO YLA-
HERTTUALA

Appeal 2016-008089
Application 13/932,202^{1,2}
Technology Center 1600

Before RICHARD M. LEOVITZ, ULRIKE W.
JENKS, and RICHARD J. SMITH, *Administrative
Patent Judges.*

LEOVITZ, *Administrative Patent Judge.*

DECISION ON APPEAL

This appeal involves claims directed to methods of treating a cancerous organ comprising administering a chemotherapeutic agent and a recombinant virus, where the recombinant virus comprises a homeomimetic transgene. The Examiner rejected the claims under 35 U.S.C. §§ 102(b) and 103. We have jurisdiction under 35 U.S.C. § 6(b). The rejections are affirmed.

¹ The Appeal Brief ("Appeal Br.") identifies FGD Therapies as the real party-in-interest.

² "The '202 Application."

STATEMENT OF THE CASE

The claims stand rejected by the Examiner as follows:

1. Claims 1-9, 11-19 and 21-30 under pre-AIA 35 U.S.C. § 102(b) as anticipated by Sterman (*A Trial of Intrapleural Adenoviral-mediated Interferon- α 2b Gene Transfer for Malignant Pleural Mesothelioma*, 184 AM. J. RESPIR. CRIT. CARE MED. 1395-99 (2011)); issue of Dec. 15, 2011). Ans. 2.

The Examiner found that Sterman was originally published as DOI: 10.1164/rccm.201103-0554CR on June 3, 2011, which is more than a year before the provisional application 61/670,330 filing date of July 11, 2012, and the provisional application 61/692,828 filing date of August 24, 2012, to which the '202 Application claims benefit.

2. Claim 10 under pre-AIA 35 U.S.C. § 103(a) as obvious over Sterman in view of Giaccone (*Pleural mesothelioma: combined modality treatments* 13, Suppl. 4 EUR. SOC. MED. ONCOL. 217-25, (2002)). Ans. 3-4.

3. Claims 11, 12 and 20 under pre-AIA 35 U.S.C. § 103(a) as obvious over Sterman in view of Lengyel (*Ovarian Cancer Development and Metastasis* 177(3) AMER. J. PATHOL. 1053-64. (Sep. 2010)). Ans. 5.

The '202 Application is the parent application of continuation application 14/030,399 which was the subject of Appeal 2016-003044 to the PTAB. A decision on the appeal was decided on May 24, 2017, affirming the Examiner's rejection. The decision has been appealed to the Federal Circuit Court of

Appeals. Appellants did not list this related appeal in their Appeal Brief.

CLAIMED SUBJECT MATTER

Independent claim 1 is representative and reads as follows:

1. In a method of treating a human diagnosed as having cancerous organ by administering chemotherapeutic agent, the improvement comprising administering to said human a recombinant virus, said recombinant virus comprising a homeomimetic transgene.

REJECTIONS

Appellants contend that Sterman "does not qualify as prior art" because it was published December 15, 2011, which "is less than one year before the priority date of the instant application." Appeal Br. 1. Appellants have presented no other patentability argument for Rejections 1, 2, and 3. Consequently, the appeal from all three rejections turns on the issue of whether Sterman is prior art to the rejected claims.

The '202 Application in this appeal claims benefit to a provisional applications filed July 11, 2012 and August 24, 2012, respectively. Sterman was published in the issue of *American Journal of Respiratory and Critical Care Medicine* dated Dec. 15, 2011, which is less than a year before the provisional filing dates and thus constitutes prior art under pre-AIA 35 U.S.C. § 102(a) ("(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign

country, before the invention thereof by the applicant for a patent"). Because Appellants did not establish that the authors of Sterman were not "others," Appellants' statement that Sterman "does not qualify as prior art" is not factually correct. A rejection under § 102(a), however, was not made by the Examiner. The Examiner found that Sterman is prior art under pre-AIA 35 U.S.C. § 102(b) based on the statement in Sterman that it was "Originally Published in Press as DOI: 10.1164/rccm.201103-0554CR on June 3, 2011" which is more than a year before the July 11, 2012 provisional application filing date. Final Act. 6. Because the complete journal article was published in December of 2011, it is reasonable that the phrase "Originally Published" refers to this complete article, rather than just a part of it, such as an abstract only. We find that such statement constitutes sufficient evidence that the manuscript and the experiments therein relied upon by the Examiner to establish unpatentability of the claimed subject matter was available on June 3, 2011.

Appellants argue that the only material from Sterman that was published on June 3, 2011 was the abstract. Reply Br. 4. Appellants contend that the Examiner conceded that only the abstract was available. *Id.*, 5.

The Examiner made no such concession. Rather, the Examiner directed Appellants' attention to the publisher's guidelines which expressly states "Manuscripts accepted for publication will immediately (within 48 hours of acceptance) be published online in the Articles in Press section of the A.JRCCM." Ans. 8. Appellants contend that the "publisher's previous publication guidelines could

potentially be legally relevant here. In contrast, the publisher's current guidelines provide no information on how the publisher in fact treated the Sterman manuscript six years ago." Reply Br. 5. We disagree. There is no evidence that the policy has changed.³ The journal guidelines reproduced by the Examiner stating that manuscripts are "published online in the Articles in Press section" is fully consistent with the statement in Sterman, published Dec. 15, 2011, that the complete journal article was "Originally Published in Press ... on June 3, 2011" containing the experiments relied upon by the Examiner to establish unpatentability. Appellants have not provided evidence that the statement in the Dec. 15, 2011 journal article about being originally published in press on June 3, 2011 is any less than what it says to be true.

³ It seemed rather simple to confirm with the publisher of the journal that the manuscript was available as indicated in the printed statement that accompanied the publication on December 15, 2011. We did just that, and as indicated in the attached email, the publisher advised us that "just abstracts" are not posted. However, it is unnecessary to rely on this email because, as explained in this Decision, Appellants did not establish that the statement "Originally Published in Press ... on June 3, 2011" means that only the abstract of the journal article was published.

Appellants' allegation that the guidelines are not of record is not persuasive. The Examiner's citation to the guidelines is responsive to the new argument made by Appellants in the Appeal Brief for apparently the first time concerning the editing and creation of the PDF file for the Dec. 15 2011 journal article. *See* Ans. 7-8. We could not find this argument made earlier, e.g., in Appellants' Remarks filed July 13, 2015.

The Examiner clearly identified where the information concerning the guidelines appeared. Ans. 8. Appellants had the opportunity to respond to the Examiner's finding in their Reply Brief, and did. Reply Br. 5. Appellants did not explain why Examiner's response to Appellants' new argument is improper and should be ignored when it is of record in the Answer and Appellants are on notice of it. Indeed, Appellants introduced new evidence in this appeal regarding the creation of the Sterman pdf file.

Under 37 C.R.F. § 41.37(c)(2), the "brief shall not include any new or non-admitted amendment, or any new or non-admitted affidavit or other Evidence."

Appellants further argue that the pdf of the Sterman publication is freely available to download from the publisher's website and that "[t]he 'Document Properties' for that pdf file says the file was created on Nov. 24, 2011 - shortly before the Dec. 15 edition was published." Appeal Br. 3. Based on this date, Appellants contend

the metadata on the article pdf file shows that publisher created that file on Nov. 24, 2011, after the critical date. That file could not

possibly have been published before the critical date because it did not exist before the critical date.

Id., 6.

We do not see the relevance of the date of when the final publication was created to the finding by the Examiner that an earlier manuscript was published online on June 4, 2011. To the contrary, the fact that the final version was created months later is consistent with the statement in the Sterman publication that an earlier manuscript was available online after acceptance. Appellants appear to have confused the pdf available today with the online manuscript availability on June 4, 2011; these are not the same.

Appellants also contend:

What was published on June 3, 2011, however, appears to have been merely the Abstract only, not the entire paper. Searching "Sterman 2011" on the www.atsjournals.org website identifies six articles, including the instant one. Clicking on the link to "10.1164/rccm.201103-0554CR" leads to a page with only the Abstract:

Id., 7.

Appellants' argument is not persuasive. The "link" directs to a page with the abstract and tabs for "Full Text", "References", "Suppl. Materials", "Cited by", and "PDF." Consequently, we find Appellants' argument that the aforementioned "link" establishes that only the abstract was available on the disputed

date is unavailing because the link contains the complete publication as published on Dec. 15, 2011. There is no evidence that this is the same link available on June 3, 2011.

In sum, there is no persuasive evidence before us that the disclosure in Sterman's December 15, 2011 publication indicating it was "Originally Published in Press as DOI: 10.1164/rccm.201103-0554CR on June 3, 2011" was not the complete, albeit unedited for publication, manuscript and the disclosure of the experiments relied by the Examiner to reject the claims. To the extent we have considered Appellants' new argument and new evidence regarding the creation of the December 15, 2011 pdf file, we find it unpersuasive because such argument and new evidence do not rebut the finding that an earlier manuscript was publicly available on the journal website at the cited DOI number.

SUMMARY

For the foregoing reasons, Rejections 1, 2, and 3 of all pending claims are affirmed. No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

NOTE: This disposition is nonprecedential.

United States Court of Appeals
for the Federal Circuit

**IN RE: NIGEL PARKER, SEPO YLA-
HERTTUALA,**

Appellants

2017-2244

Appeal from the United States Patent and
Trademark Office, Patent Trial and Appeal Board in
No. 14/030,399.

JUDGMENT

J. MARK POHL, Pharmaceutical Patent Attorneys,
LLC, Morristown, NJ, argued for appellants.

MARY BETH WALKER, Office of the Solicitor,
United States Patent and Trademark Office,
Alexandria, VA, argued for appellee Andrei Iancu.

Also represented by NATHAN K. KELLEY,
THOMAS W. KRAUSE, WILLIAM LAMARCA.

THIS CAUSE having been heard and considered, it is ORDERED and ADJUDGED:

PER CURIAM (PROST, *Chief Judge*, NEWMAN and LINN, *Circuit Judges*).

AFFIRMED. See Fed. Cir. R. 36.

ENTERED BY ORDER OF THE COURT

July 17, 2018

/s/ Peter R. Marksteiner

Date

Peter R. Marksteiner

Clerk of Court

UNITED STATES PATENT AND TRADEMARK
OFFICE
BEFORE THE PATENT TRIAL AND APPEAL
BOARD

Ex parte NIGEL PARKER and SEPPO YLA-
HERTTUALA

Appeal 2016-003044

Application 14/030,399^{1,2}

Technology Center 1600

Before RICHARD M. LEBOVITZ, ULRIKE W.
JENKS, and RACHEL H. TOWNSEND,
Administrative Patent Judges.

LEBOVITZ, *Administrative Patent Judge.*

DECISION ON APPEAL

This appeal involves claims directed to methods of treating a cancer comprising administering a chemotherapeutic agent and a recombinant virus, where the recombinant virus comprises a homeomimetic transgene. The Examiner rejected the claims under 35 U.S.C. §§ 102(b). We have jurisdiction under 35 U.S.C. § 6(b). The rejections are affirmed.

¹ The Appeal Brief ("Appeal Br.") identifies FKD Therapies Oy, Kuopio Finland, as the real-party-in-interest.

² "The '399 Application."

STATEMENT OF THE CASE

Appellants appeal from the Examiner's final rejection of claims 1-9, 11-19, and 21-30 under pre-AIA 35 U.S.C. § 102(b) as anticipated by Sterman (*Am. J. Respir. Crit. Care Med.*, 184: 1395-99, 2011; issue of Dec. 15, 2011). Final Action ("Final Act."; Jan. 14, 2015) 2.

The Examiner found that Sterman was originally published as DOI: 10.1164/rccm.201103-0554CR on June 3, 2011, which is more than a year before the provisional application 61/670,330 filing date of July 11, 2012 to which the '399 Application claims benefit. *Id.* at 2-3.

CLAIMED SUBJECT MATTER

Independent claim 1 is representative and reads as follows:

1. In a method of treating a human diagnosed as having cancerous organ by administering chemotherapeutic agent, the improvement comprising administering to said human a recombinant virus, said recombinant virus comprising a homeomimetic [spelled throughout the '399 Application as "homomimetic"] transgene, said recombinant virus administered to a site remote from said cancerous organ.

CLAIM INTERPRETATION

There are four independent claims. Claims 1 and 11 are directed to methods of treating a human that has a "cancerous organ." Claim 21 is directed to a method of treating "organ cancer." Claim 30 is directed to a

method of treating "cancer." The interpretation of "cancerous organ" and "organ cancer" are in dispute.

The Examiner construed "cancerous organ" and "organ cancer" as cancer involving the tissues of an organ ("malignant pleural mesothelioma is a malignant cancer which in later stages involves the lung tissue and as such qualifies as a 'lung cancer'"). Final Act. 4. Appellants contend "internal organs derive from embryonic endoderm. . . . Organ cancer is cancer of an organ, i.e., endoderm-derived tissue." Appeal Br. 7.³ Appellants distinguish an "organ cancer" from a cancer of a mesothelioma which is a sac which covers internal organs. *Id.* Appellants argue that an organ cancer must arise from cancerous cells of the organ ("Lung cancer is a different [sic, cancer?], arising not from cancerous mesothelium cells, but from cancerous lung cells."). *Id.* at 8. *See also* Reply Br. 1-2.

Appellants did not provide adequate factual support for the argument that an organ is derived from endodermal cells. It is well-known that not all organs derive from the endoderm. For example, the brain is an organ and it arises from the ectoderm and the spleen and heart, also organs, arise from the mesoderm.⁴

³ Appellants did not number the pages of the Appeal Brief. The numbering used throughout this Decision begins with the title page of the Appeal Brief numbered as page 1.

⁴ <http://discovery.lifemapsc.com/library/review-of-medical-embryology/chapter-25-germ-layers-and-their-derivatives>. Accessed April 2, 2017.

Nonetheless, regardless of the embryonic origin of an "organ," the issue is whether the terms "cancerous organ" or "organ cancer" require the cancer to have *originated* in the organ.

During patent examination proceedings, claim terms are given "the broadest reasonable meaning ... in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." In *re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

The Specification does not provide a definition of either term. Thus, we turn to the ordinary usage of these terms.

In the term "organ cancer," "organ" is used as an adjective to describe the type of cancer, namely, the cancer is associated with an organ, namely, the organ has cancerous cells present in it. Neither word requires the cancer of the organ to have originated in the organ. For example, the cancer could have metastasized to, or invaded a particular organ, and the cancerous cells would still would be present in the organ.

In the term "cancerous organ," "cancerous" is an adjective and thus describes the organ as being "affected" with a cancer.⁵ Again, neither word in the

⁵ <http://www.thefreedictionary.com/cancerous>. Accessed April 2, 2017.

term "cancerous organ" requires the cancer to have a specific history; a "cancerous organ" can result from cells that originated in the organ, or, from cells originating from another location in the body that subsequently invaded the organ.

We have not been directed to a definition in the Specification, or an extrinsic definition, that would guide us to a narrower interpretation, particularly the interpretation urged by Appellants that cancer must originate in the organ to qualify as an organ cancer or cancerous organ. Consequently, we adopt the Examiner's claim construction as the broadest reasonable interpretation of the disputed terms and construe "organ cancer" and "cancerous organ" to mean that cancer is present in the organ.

REJECTION

The claims are directed to methods of treating cancer comprising administering 1) a chemotherapeutic agent and 2) a recombinant virus to a human, where the recombinant virus comprises a homeomimetic transgene. Appellants elected IFN-alpha as the species of the homeomimetic transgene⁶ and lung as the species of cancerous organ. Ans. 2.

⁶ A homomimetic transgene is defined in the '399 Application as "a transgene which codes for a polypeptide which mimics an effect of a naturally-occurring human polypeptide." '399 Application 2:18-20.

The Examiner found that Sterman teaches "methods of treating malignant pleural mesothelioma (MPM) in human patients by intrapleural catheter infusion of a saline solution comprising an adenoviral vector encoding interferon-alpha 2b, wherein patients receiving the treatment exhibited antitumor immune responses and in some cases stable disease or even tumor regression " *Id.* at 3. The patients had also received a chemotherapeutic agent. *Id.* Because the Examiner found that all limitations of the claim are described by Sterman, the Examiner concluded the claim is anticipated. *Id.*

Appellants contend that mesothelioma is not an organ cancer or a cancerous organ. Appeal Br. 7-8. Appellants state:

Organ cancer is cancer of an organ, *i.e.*, endoderm-derived tissue. In contrast, mesothelioma is, as the name implies, cancer of the mesothelium-derived sac that covers many internal organs. The two types of cancers differ in location (one occurs in the organ, the other in the surrounding sac) and biology (endoderm and mesoderm cells differ).

Id.

Appellants also contend that lung cancer must arise from cancerous lung cells, not mesothelioma cells which migrate into the lung. *Id.* at 9.

Discussion

The broadest reasonable interpretation of "organ cancer" and

"cancerous organ" is of a cancer that is present in an organ, which in this case would be the elected organ, the lung. Contrary to Appellants' interpretation, the

claims do not require the cancer to originate from the cells of the organ. Accordingly, the issue in the anticipation rejection is whether the mesothelioma described by Sterman is present in lung tissue.

The Examiner relied upon an online publication (at <https://www.pleuralmesothelioma.com/cancer/staging.php>) ("pleuralmesothelioma.com") describing the staging of mesothelioma to establish that the lung contains mesothelioma cells in Stage T2. Final Act. 4; Ans. 5. According to this publication, at Stage T2:

The tumor involves the pleural lining of the chest wall on one side of the chest, as well as the pleural lining of the diaphragm, mediastinum and the lung. The cancer has also grown into at least one of the following:

- The diaphragm muscle
- Tissue of the lung itself

Stage T2 occurs in Stages II through IV of mesothelioma (pleuralmesothelioma.com). Sterman specifically discloses that several of the treated patients were in Stages III and IV (Sterman 1396, Table 1). Stage III and Stage IV patients would have Stage T2 cancer where the mesothelioma is in the lung tissue. Thus, the Examiner had sufficient factual basis to conclude that Sterman treated lung cancer. Final Act. 4; Ans. 5. Appellants have not provide adequate arguments or evidence to rebut this fact-based determination.

Appellants contend that the migration of cells into the lung is not a lung cancer. Appeal Br. 8. However, such claim construction is not the broadest reasonable interpretation of the claim. Accordingly,

this argument does not persuade us that the Examiner erred.

Remote

Claim 1 requires that the "recombinant virus [is] administered to a site remote from said cancerous organ " Appeal Br. 7. The Examiner found that Sterman describes "intrapleural catheter infusion of a saline solution comprising an adenoviral vector encoding interferon-alpha 2b." Ans. 3. The Examiner also found that "intrapleural catheter infusion involves the delivery of the vector to the intrapleural space, the space between the mesothelium and the lung, and as such qualifies as a site 'remote' from a cancerous [lung] organ." *Id.* Appellants respond that "Sterman's mesothelium is cancerous, so Sterman teaches administration directly onto cancerous tissue, not 'remote' from it." Reply Br. 5.

This argument does not demonstrate error because the rejection is based on administration of the transgene to the intrapleural space which is at a remote location to the lung.

Is Sterman prior art?

Appellants contend that "Sterman (Dec. 15, 2011) was first published in December 2011 and therefore does not qualify as prior art." Reply Br. 7.

The '399 Application in this appeal claims benefit to a provisional application filed July 11, 2012. Sterman was published in the issue of *American Journal of Respiratory and Critical Care Medicine* dated Dec. 15, 2011, which is less than a year before the provisional filing date and thus constitutes prior art under pre-AIA 35 U.S.C. § 102(a). Consequently, Appellants'

statement that Sterman "does not qualify as prior art" has no factual support in this record.

The Examiner found that Sterman is prior art under pre-AIA 35 U.S.C. § 102(b) based on the statement in Sterman that it was "Originally Published in Press as DOI: 10.1164/rccm.201103-0554CR on June 3, 2011" which is more than a year before the July 11, 2012 provisional filing date.

See Ans. 2. Appellants argue, without providing the Board with any evidence in this proceeding, that the only material published was the abstract. Reply Br. 7. Appellants contend that the DOI document is of record "in the parent case," but did not identify the "parent case" nor provide the Board, as a courtesy, with such document. *Id.*

Sterman clearly states "Originally Published in Press," indicating that the article was itself published. Appellants had the opportunity throughout this proceeding to provide evidence to the Examiner that it was only the abstract which was published, but did not. For example, the Sterman rejection was made by the Examiner in a non-final Office Action entered June 11, 2014. Appellants responded to the rejection on Sept. 10, 2014 without making the allegation that Sterman is not prior art to their application and without providing evidence that the Examiner erred in finding Sterman's publication date to be June 3, 2011.

Nonetheless, Sterman is prior art under pre-AIA 35 U.S.C. § 102(a). Consequently, even if Sterman was not published more than before the provisional filing date of the '399 Application, it is still prior art to the application.

SUMMARY

For the foregoing reasons, the anticipation rejection of independent claims 1, 11, 21, and 30 is affirmed. Dependent claims 2-9, 12-19, and 22-29 were not argued separately and fall with the independent claims. 37 C.F.R. § 41.37(c)(iv)(1)

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED