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# Disclosures in the Grey Area

## View from the US

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# When does it become prior art?



35 U.S.C. 102(a)(1)

(a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—

- (1) the claimed invention was patented, described in a **printed publication**, or in public use, on sale, or otherwise **available to the public** before the effective filing date of the claimed invention; or

What is a printed publication?

When is it available to the public?

A reference is a “printed publication” if “*upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it.*” *In re Wyer*, 655 F.2d 221, 210 USPQ 790 (CCPA 1981) (quoting *I.C.E. Corp. v. Armco Steel Corp.*, 250 F. Supp. 738, 743, 148 USPQ 537, 540 (SDNY 1966))

# What level of public accessibility is required?

- ❖ A doctoral thesis indexed and shelved in a library is sufficiently accessible to the public to constitute prior art as a “printed publication.” *In re Hall*, 781 F.2d 897, 228 USPQ 453 (Fed. Cir. 1986).



- ❖ Even if access to the library is restricted, a reference will constitute a “printed publication” as long as a presumption is raised that the portion of the public concerned with the art would know of the invention. *In re Bayer*, 568 F.2d 1357, 196 USPQ 670 (CCPA 1978).

# What level of public accessibility is required?

*In re Cronyn*, 890 F.2d 1158, 13 USPQ2d 1070 (Fed. Cir. 1989) doctoral theses were shelved and indexed alphabetically by name with index cards kept in a shoe box listing only the student's name and thesis title. Held that the theses were not accessible to the public because the theses had not been either cataloged or indexed in a meaningful way since they could only be found by the researcher's name, but the name had no relationship to the subject of the thesis.



## ***Par-Amneal v. Jazz Pharma***

IPR2015-00546

(PTAB July 2016)

Also, five related proceedings between the same parties on five other patents.

# Invention

- **1.** Therapeutic method for treating a patient comprising: receiving prescriptions into a central computer; requiring entering the information into exclusive database; controlling distribution; ....
- **2.** Method of claim 1, wherein the controls for distribution are ... identifying the physician's name, license, and DEA registration information ...
- **POSA:** pharmacist or computer science plus familiarity with drug distribution procedures



## ***Par-Amneal v. Jazz Pharma***

IPR2015-00546 (PTAB July 2016)

### **Prior Art**

- XYREM – date-rape drug GHB
- Advisory Committee Art (ACA)
- Exs. 1003 – FDA Adv. Committee Transcript; 1004 – Prel. Clinical Safety Review; 1005 – Briefing Booklet prepared for Xyrem Advisory Committee Meeting in accordance with FACA; 1006 – Xyrem Video and Transcript

## Summary of Dates of Prior Art

- *May 3, 2001*: FDA Safety Review of Xyrem completed (Ex. 1004, 1)
- *May 3, 2001*: Sponsor's Xyrem Briefing Booklet submitted to Advisory Committee (Ex. 1005, 1)
- *May 3, 2001*: Sponsor's video of Xyrem prescription process submitted to Advisory Committee (Ex. 1005, 2 ¶ 5, 14, 312; Ex. 1006)
- *May 14, 2001*: Federal Register Notice of Xyrem Advisory Committee Meeting (Ex. 1015, Col. 2–3)
- *June 6, 2001*: Xyrem Advisory Committee Meeting (Ex. 1003)

# Holding

- POSITA is “interested in drug distribution, safety, and abuse prevention would have had reason to look to the Federal Register and FDA Advisory Committee meeting notices”. p 38.
- ACA was “publically accessible to an interested POSA exercising reasonable diligence more than one year before [filing date].” p. 39
- All limitations and steps disclosed in ACA.
- Obvious to combine ACA art

## What is a “printed” publication

- Oral presentations?
  - In *Massachusetts Institute of Technology v. AB Fortia*, 774 F.2d 1104, 227 USPQ 428, (Fed. Cir. 1985) a paper was orally presented to 50- 500 people at a conference open to all persons interested in the subject matter, with written copies distributed without restriction to any one who requested it. Six people requested copies – held to be a printed publication.

# Internet Publications, Press Releases and Drug Labels Oh My!

For any document the burden is on the party relying on the document to sufficiently demonstrate public dissemination and the date of “publication”. *In re Wyer*, 655 F.2d 221, 227 (C.C.P.A. 1981) (quoting *Philips Elec. & Pharm. Indus. Corp. v. Thermal & Electronics Indus., Inc.*, 450 F.2d 1164, 1171 (3d Cir. 1971)).

## Internet publications, Press releases and Drug Labels

Establishing the date of public accessibility, i.e. publication date, is “*a case-by-case inquiry into the facts and circumstances surrounding the reference’s disclosure to members of the public*” *In re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004)

# Internet publications, Press releases and Drug Labels

## A date on a document may not be enough —

*Coalition for Affordable Drugs IV LLC v. Pharmacyclics, Inc.*, IPR2015-01076, Decision Denying Institution (Oct. 19, 2015). - The petitioner relied on a copy of a webpage from [www.clinicaltrials.gov](http://www.clinicaltrials.gov) disclosing the results of a clinical study. The webpage stated that it was “Updated: 2009\_02\_23.” The PTAB denied institution on the basis that the petitioner did not provide an “*explanation or evidence of what that date means*” or “*explain how the website disseminates information to the public or even when the website became available to the public.*” Petitioner did “*not satisfied its initial burden of coming forward with sufficient evidence to make a threshold showing that [the webpage] is a prior art printed publication.*”

# Internet publications, Press releases and Drug Labels

## Use of the archival services (Wayback Machine)

*Crestron Electronics, Inc. v. Intuitive Building Controls, Inc.*, IPR2015-01379, Institution Decision (PTAB Dec. 15, 2015) - The patent owner argued lack of public accessibility of a reference. PTAB held that “*it [is] reasonably likely that web pages locatable by crawlers of the Wayback Machine would be locatable to interested persons using typical search engines available at least one year before the critical date.*”



# Internet publications, Press releases and Drug Labels

- Use of the Wayback machine or other archival services show evidence of publication if supported by a Declaration from the archival service explaining how the service works and the relevancy of any dates...Maybe



# Internet publications, Press releases and Drug Labels

*ServiceNow, Inc. v. Hewlett-Packard Co.*, IPR2015-00707, Decision Denying Institution (PTAB Aug. 26, 2015).

Internet publications used as prior art in IPR Petition with the dates of the publications being supported by the Wayback Machine archive.

Institution denied on the basis that “*Petitioner fails to make the critical link between the alleged identification of the Collaborate References on the ‘download page’ and the exhibits relied upon in support of its asserted grounds....Petitioner fails to demonstrate Exhibits 1004–1006, which Petitioner relies upon..., were publicly accessible through the webpages included in Exhibit A to the Butler Affidavit more than one year prior to May 14, 2003.*”

# Internet publications, Press releases and Drug Labels

*ServiceNow, Inc. v. Hewlett-Packard Co.*, IPR2015-00707, Paper No. 12, Decision Denying Institution at 9-20 (PTAB Aug. 26, 2015).

Patent Owner also noted that the dates of the Wayback Machine capture were after the invention date.

Petitioner also pointed to the copyright dates on the references; however the PTAB held that “we are not persuaded that the presence of a copyright notice, without more, is sufficient evidence of public accessibility as of a particular date. “

# Internet publications, Press releases and Drug Labels

## So copyright dates are not useful?! - Sometimes

*Ericsson, Inc. v. Intellectual Ventures I LLC, IPR2014-00527, Paper No. 1, Petition at 7 (PTAB March 21, 2014).* – The patent owner objected to the authenticity of an article and moved to exclude, arguing that the date printed on the reference failed to prove public accessibility. The PTAB held that the copyright line on the first page sufficiently evidenced the publication date and public accessibility because “*IEEE is a well-known, reputable compiler and publisher of scientific and technical publications, and we take Official Notice that members in the scientific and technical communities who both publish and engage in research rely on the information published on the copyright line of IEEE publications.*”

# Internet publications, Press releases and Drug Labels

## *But...sometimes not.*

*TRW Automotive U.S. LLC, v. Magna Electronics Inc.*, IPR2014-01347, Paper No. 25, Final Written Decision at 5-12 (PTAB Jan. 6, 2016)

The PTAB refused to accept the copyright date of an IEEE article as proof of publication. The IEEE article did not include a statement that it had been published, but did include a copyright date, an IEEE inscription, and an ISBN number. In the final written decision, the PTAB found that the petitioner had failed to demonstrate that the reference qualified as a printed publication, stating that “*although the copyright notice is probative that IEEE owns a copyright to the article, it is not probative that the article was ever published by IEEE or anyone else.*”

# Internet publications, Press releases and Drug Labels

*TRW Automotive U.S. LLC, v. Magna Electronics Inc.*, IPR2014-01347, Paper No. 25, Final Written Decision at 5-12 (PTAB Jan. 6, 2016)

The PTAB also stated that “*the petitioner failed to prove that the number on the copyright line “is an ISBN, what an ISBN is, what an ISBN signifies, how an ISBN is assigned, who assigns it, or when and under what circumstances an ISBN is stamped onto something”*”

<https://www.isbn-international.org/content/what-isbn> “Any book made publicly available, whether for sale or on a gratis basis, can be identified by ISBN.”

# Internet publications, Press releases and Drug Labels

*Mylan Pharmaceuticals Inc. v. Boehringer Ingelheim International GMBH* Case IPR2016-01566 (Institution Decision, February 3, 2017)

Institution denied on the basis that Mylan failed to provide sufficient evidence to support a threshold showing that a drug label was a printed publication.

Mylan relied on a drug label marked as “includes a cover page stating it is the “FINAL PRINTED LABELING” and “Revised January 2001.”

# Internet publications, Press releases and Drug Labels

*The label “does not contain any source identifying information, e.g. as an FDA-approved label, or other indicia of when the document became publicly available...For example, the Glucophage® Label submitted by Petitioner contains no indicia that it (1) is a certified copy of a public record, (2) is copied from an official 2001 publication such as the United States Pharmacopoeia–National Formulary, (3) is copied from a recognized periodical published in 2001 such as the Physicians’ Desk Reference, or (4) otherwise bears the hallmarks of a self authenticating document published in 2001...Exhibit 1004 indicates the label was revised in January 2001, but it bears no source identifying information from the FDA, a copyright date, or any other indicia of a publication date.”*



# Internet publications, Press releases and Drug Labels

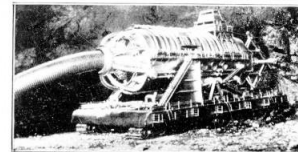
*Need to tell a good story!!*

*BioMarin Pharmaceuticals Inc.  
v. Genzyme Therapeutic  
Products IPR2013-00534*

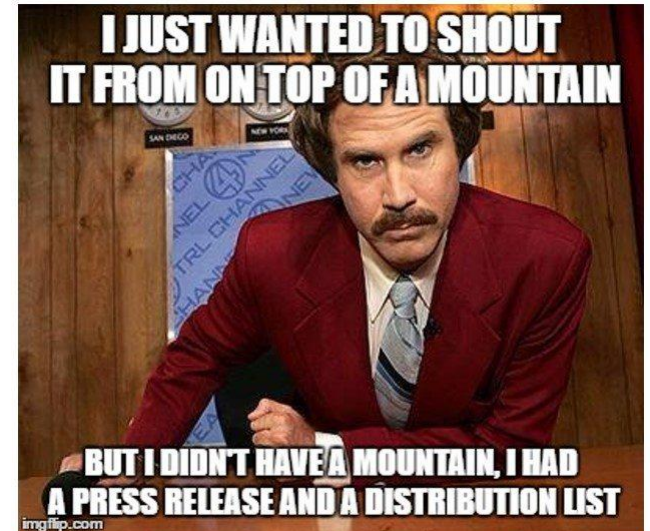
**PTAB Final Written Decision,  
February 23, 2015**



## FAKE RADIO 'WAR' STIRS TERROR THROUGH U.S.



# Internet publications, Press releases and Drug Labels



# Internet publications, Press releases and Drug Labels

*BioMarin Pharmaceuticals Inc. v. Genzyme Therapeutic Products* IPR2013-00534 PTAB Final Written Decision, February 23, 2015

- The petitioner relied upon a press release by Duke University reporting the U.S. Food and Drug Administration (“FDA”) approval of Duke University’s application for Orphan Drug Designation for a new therapy for Pompe disease, using the claimed method.
- The patent owner sought to exclude the press release as hearsay and not qualifying as a printed publication.

# Internet publications, Press releases and Drug Labels

*BioMarin Pharmaceuticals Inc. v. Genzyme Therapeutic Products* IPR2013-00534 PTAB Final Written Decision, February 23, 2015

Petitioner supported the authenticity of the press release by:

- showing publication on two different archived sites;
- obtaining a second copy that was published in a newspaper with a clear publication date;
- had a private investigator go to the Duke University library and obtain a copy of the original archived press release.



**WHAT'S  
YOUR  
STORY?**



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