
UNITED STATES
PATENT AND TRADEMARK OFFICE
uspto

Public Engagement Partnership Meeting Series

Introduction to patent challenge processes before PTAB

Ryan Flax, Lead Administrative Patent Judge

Cynthia Hardman, Administrative Patent Judge

September 4, 2024

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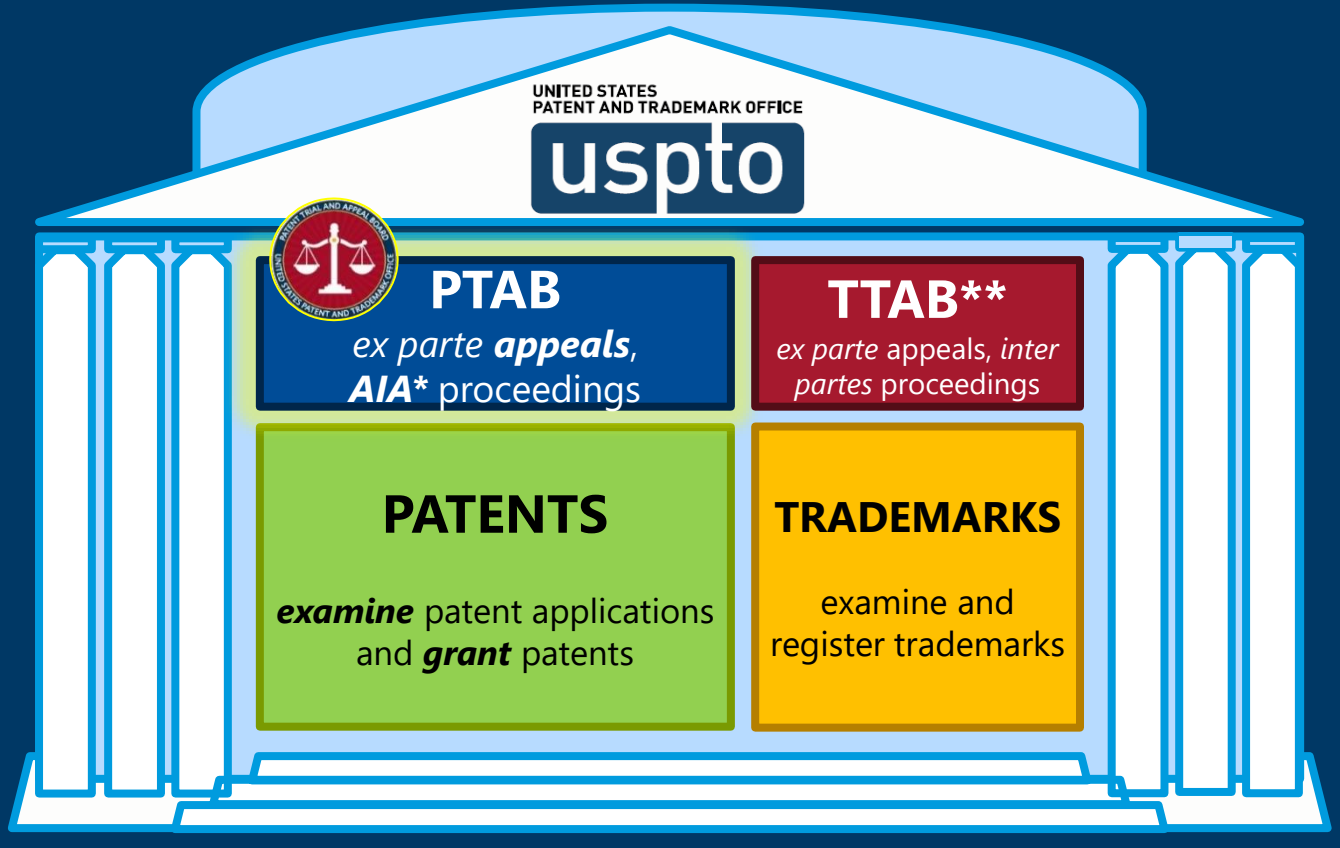
uspto UNITED STATES PATENT AND TRADEMARK OFFICE ®

(PTAB)

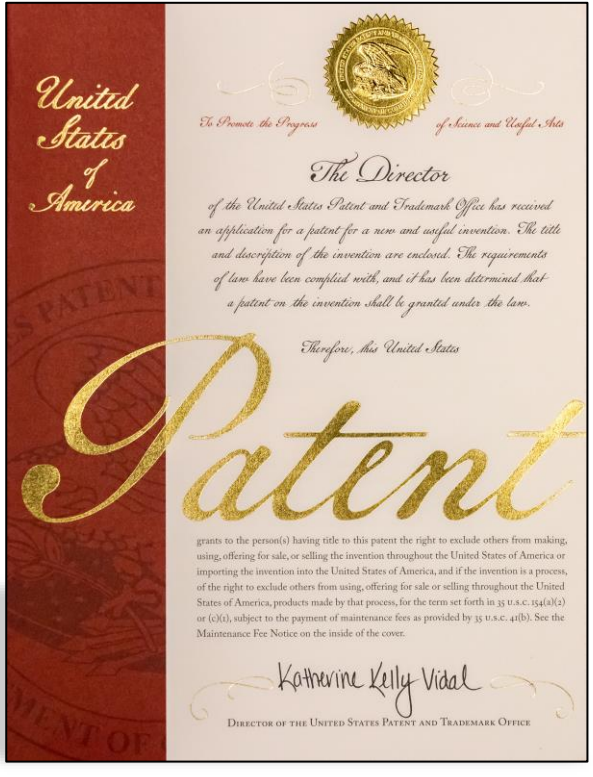
The Patent Trial and Appeal Board

What is the Patent Trial and Appeal Board?



* America Invents Act (AIA) **Trademark Trial and Appeal Board (TTAB)

A patent has issued – What can happen next?

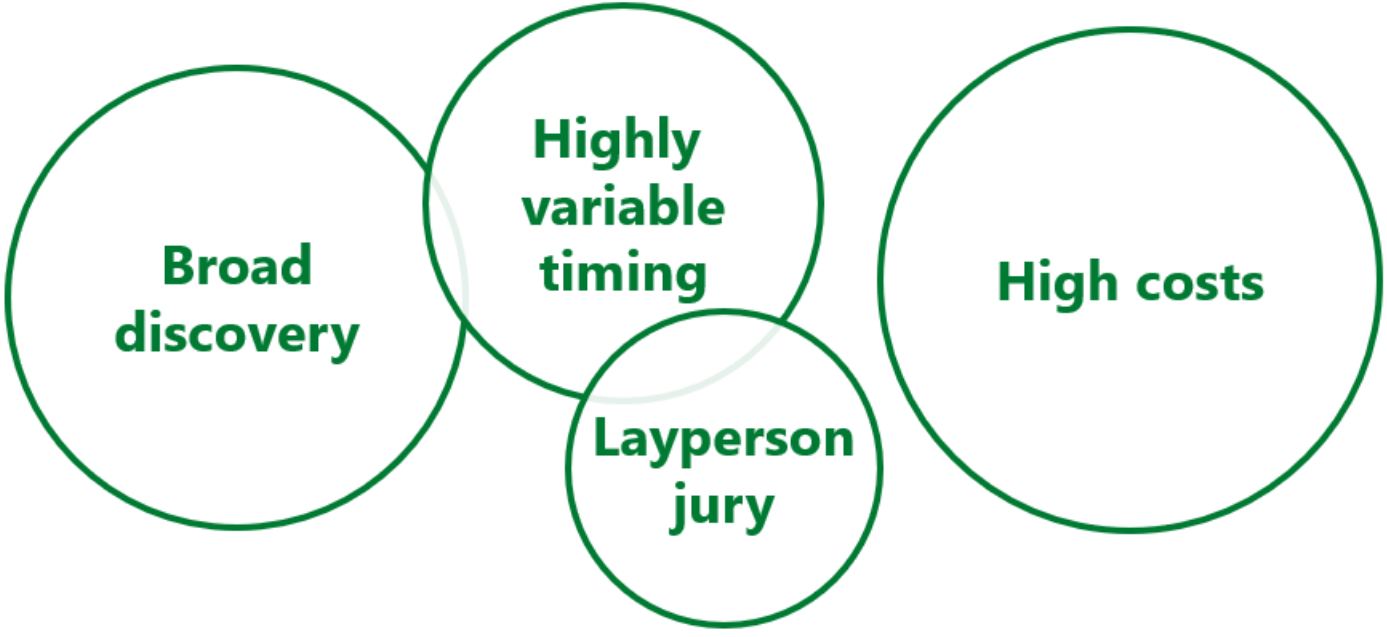


- Keep as asset, monetize, and/or license
- District Court trials
- *AIA trial proceedings*
- International Trade Commission proceedings

U.S. District Courts: Invalidity

CLEAR AND CONVINCING BURDEN OF PROOF

U.S. District Courts: Issues of Note



PTAB: Unpatentability

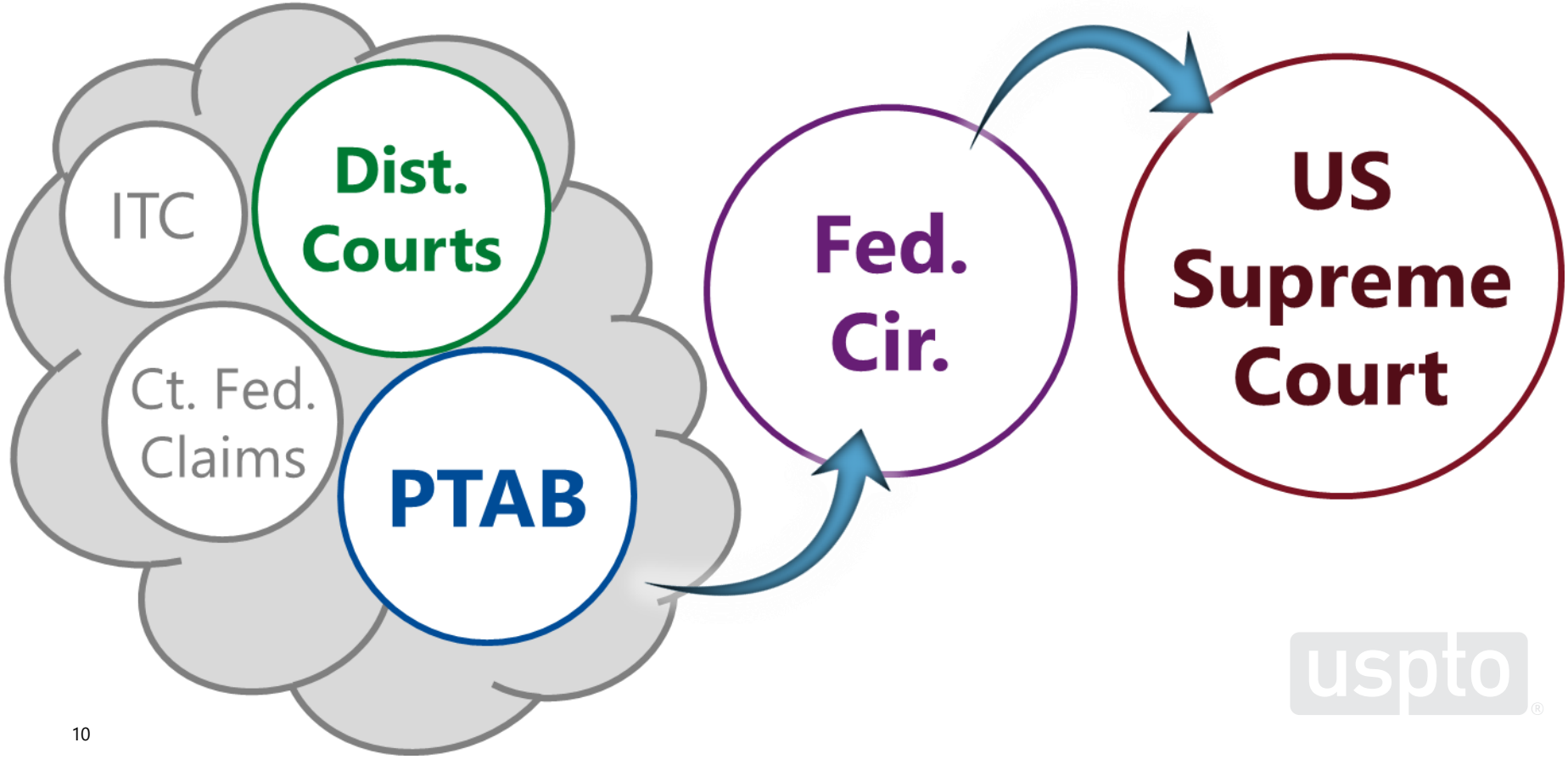
PREPONDERNACE OF THE EVIDENCE BURDEN OF PROOF

Inter Partes Review - IPR

Post Grant Review - PGR

PTAB: Issues of note

Patent proceedings forums



IPRs and PGRs

AIA Proceedings

What are AIA trial proceedings?

America Invents Act (AIA) – Congress revised the Patent Act to provide an additional forum to address patentability/validity disputes

AIA proceedings are intended to be **streamlined**, **efficient**, and **cost effective**

Who is involved in an AIA trial proceeding?

Petitioner

Files petition challenging a U.S. patent; must pay a filing fee

Carries legal burden to prove claims unpatentable

Patent Owner

Has opportunities to represent its interests

Panel

Typically three administrative patent judges

Types of AIA trial proceedings

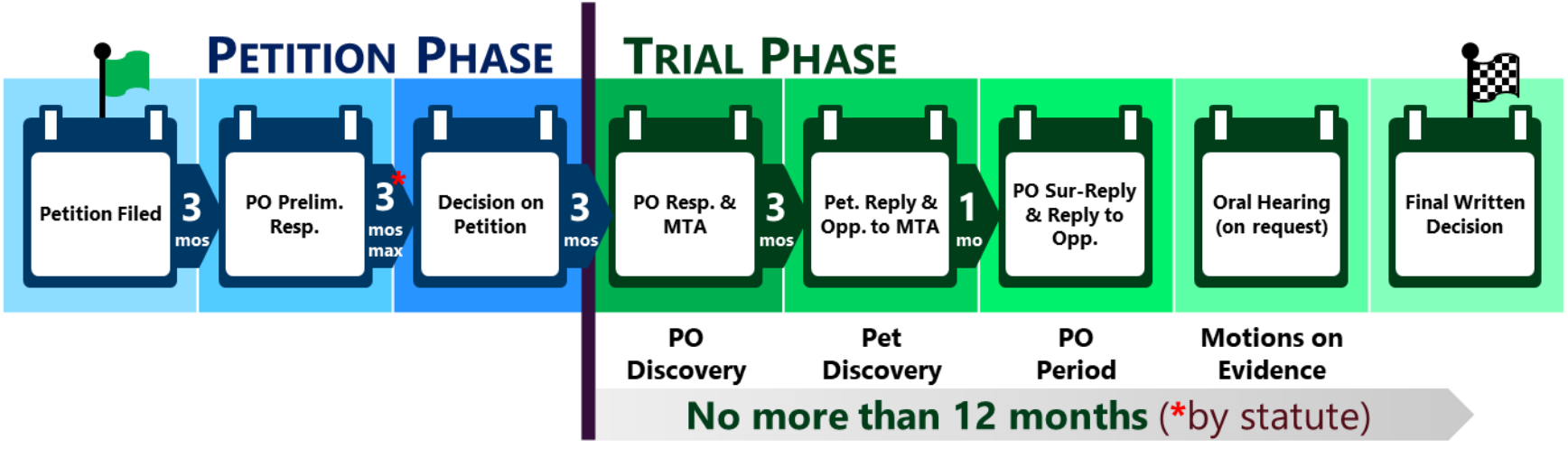
Inter Partes Review (IPR): can challenge claims based on prior art (patents or printed publications)

Post-Grant Review (PGR): can challenge claims based on prior art and other bases

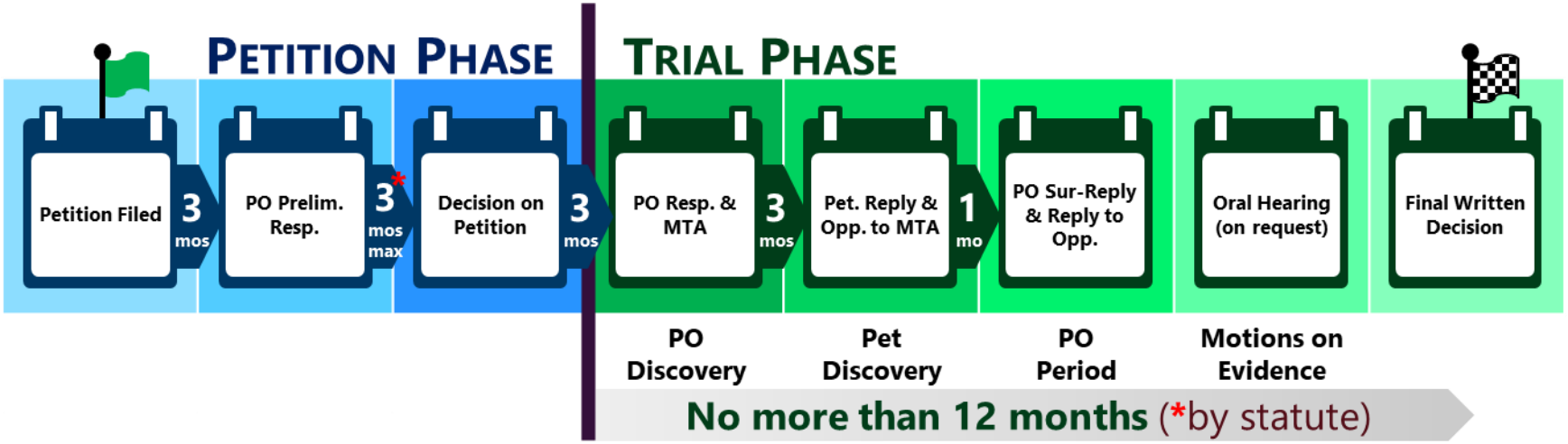
Comparison of IPR and PGR

Trial Type	Who Can File	Applicability	Availability	Basis
Inter partes review **(IPR)**	Person who is: (a) not the patent owner, (b) has not previously filed a civil action challenging the validity of a claim of the patent, and (c) has **not been served** with a complaint alleging infringement of the patent **more than 1 year prior** (exception for joinder).	**Any** patent.	For first-to-invent patents: **anytime** after patent grant or reissue. For first-inventor-to-file patents: from the **later** of: (a) **9 months** after patent **grant** or reissue; or (b) the date of **termination** of any **post grant** review.	Patent Act Sections 102 and 103 based on anticipation and obviousness over **patents** and **printed publications.**
Post-grant review **(PGR)**	Person who is: (a) not the patent owner, and (b) has not previously filed a civil action challenging the validity of a claim of the patent.	Patent issued ***after*** the AIA went into effect.	Must be filed **within 9 months** of patent grant or reissue.	Patent Act Sections 101, 102, 103, 112 (but not best mode), and double patenting.

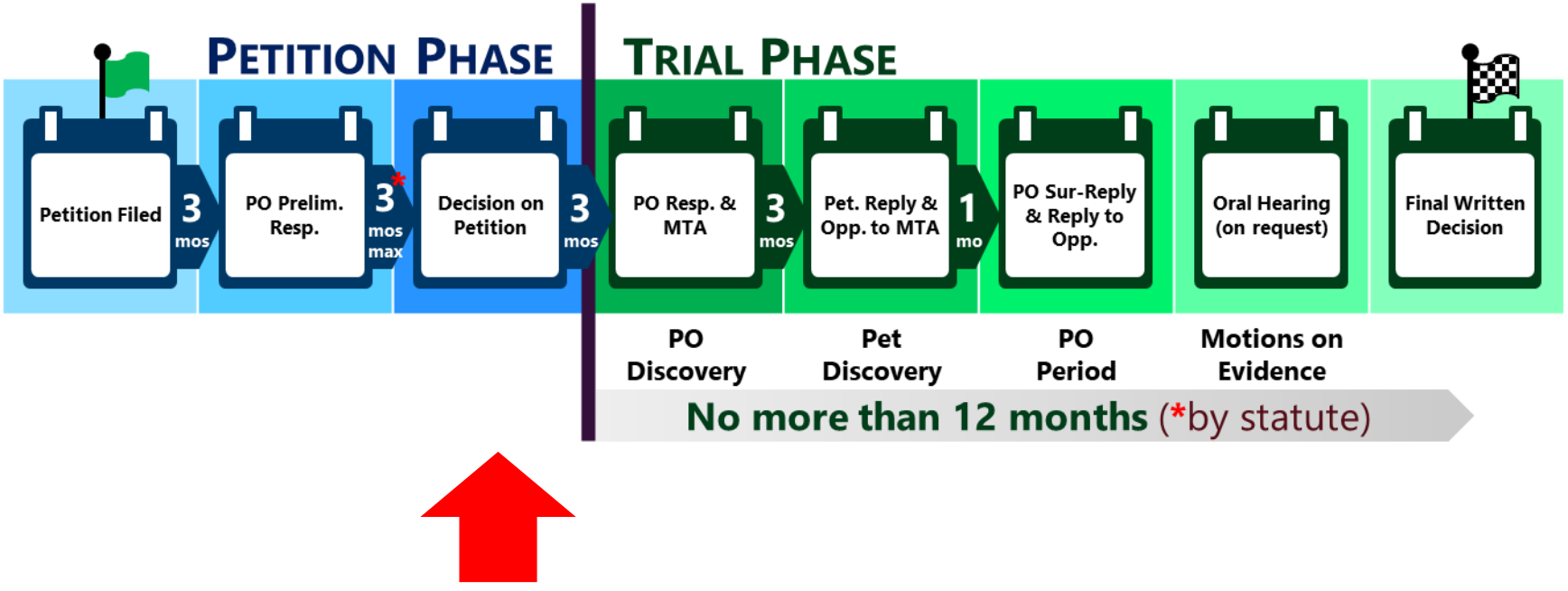
AIA proceeding timeline



Petition Phase: Briefing



Petition Phase: Institution



Overview of Institution Decision

The Board issues a **written decision** indicating whether it will start an AIA trial.

Petitioner must demonstrate a ***reasonable likelihood*** that it would prevail with respect to at least 1 of the claims challenged in IPR petition (PGR standard is *more likely than not*).

Overview of Institution Decision

Based on the record at institution, the Board generally provides parties **guidance about the Board's preliminary views** on the competing arguments.

This guidance allows parties to **focus their arguments** and may inform other options such as settlement, claim amendment, claim disclaimer, or request for adverse judgment on some claims or grounds.

Overview of Institution Decision

Party dissatisfied with the Board's institution decision **may request rehearing** (by the Board) as to points the Panel overlooked or misapprehended.

Party dissatisfied may alternatively request Director Review

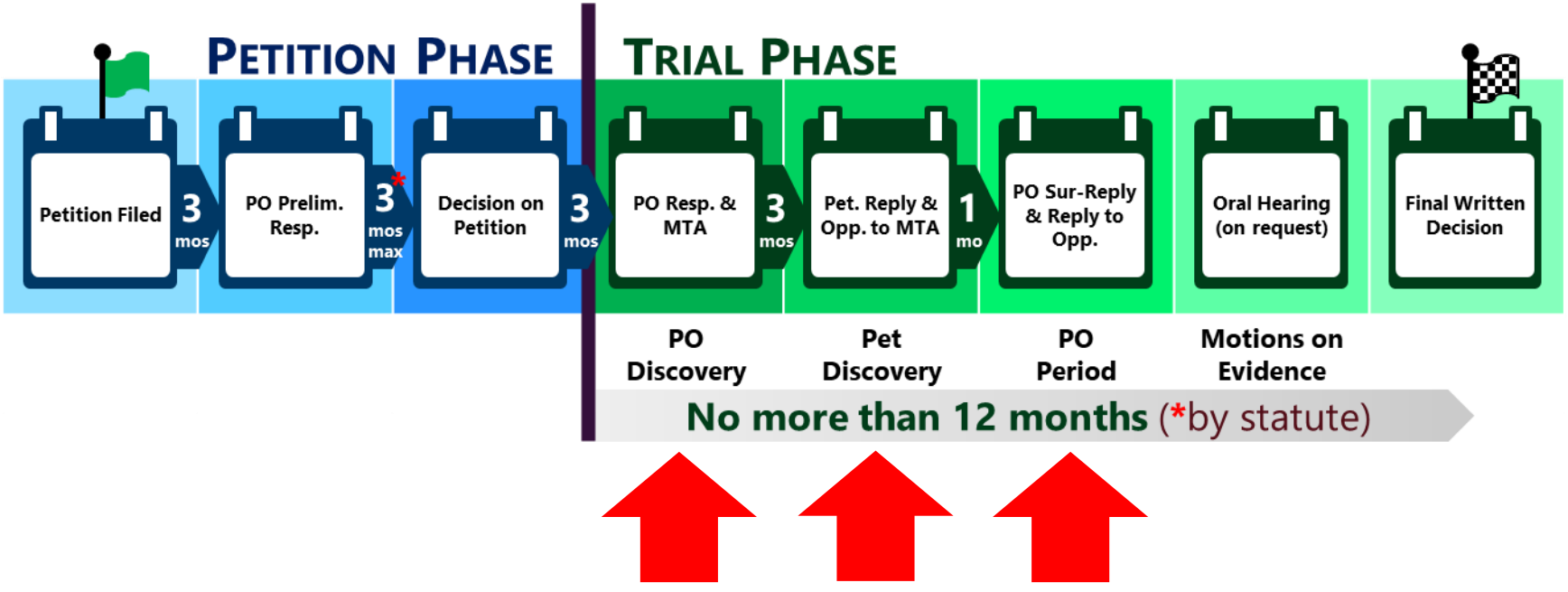
Institution decisions are **generally not appealable** to the Federal Circuit.

Overview of Institution Decision

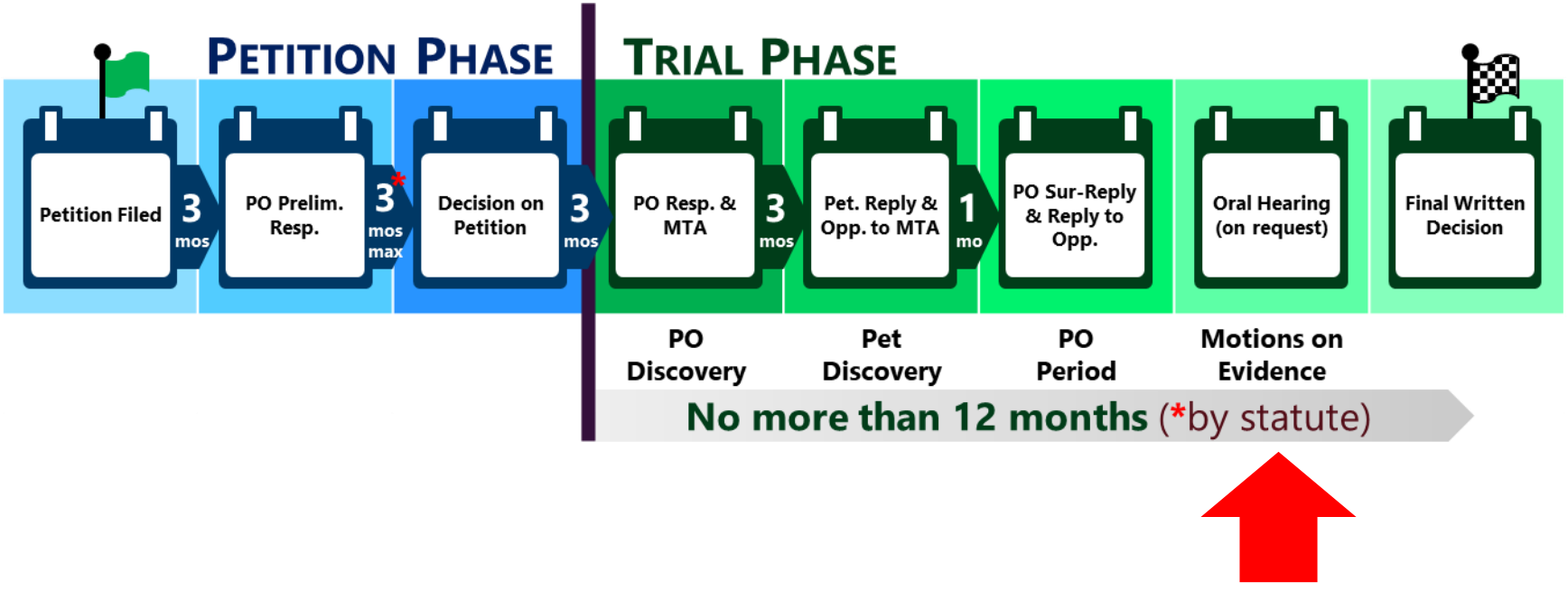
The Board will enter a **Scheduling Order** concurrent with a decision to institute a trial:

- Scheduling Order **sets due dates** for the trial to ensure completion within one year of institution
- A sample Scheduling Order is available in the **Trial Practice Guide** (www.uspto.gov/TrialPracticeGuideConsolidated)

Trial Phase: Briefing



Trial Phase: Evidence motions & hearing



mo·tion ('mō-shən)

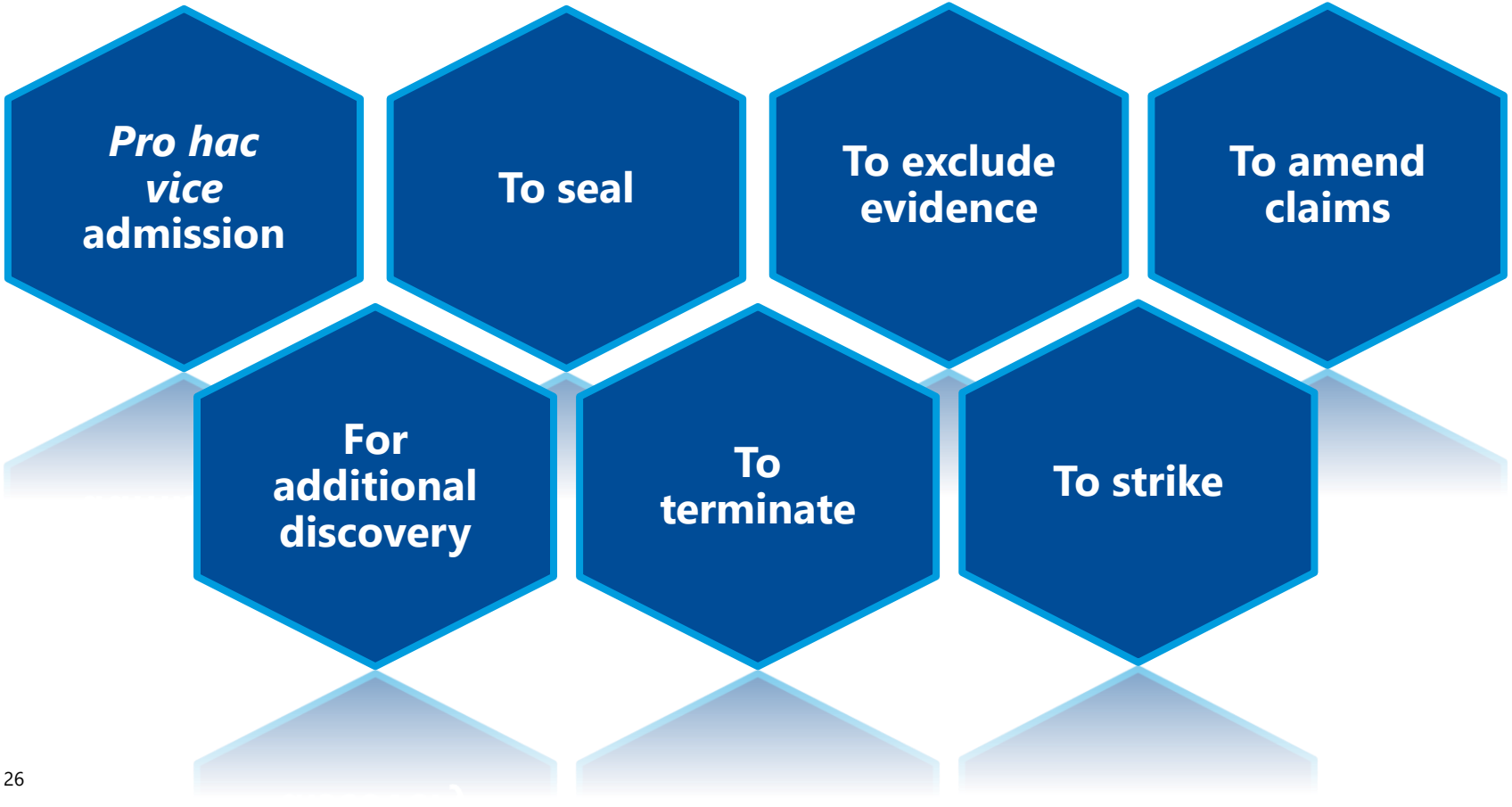
an **application**

made to a court or **judge**

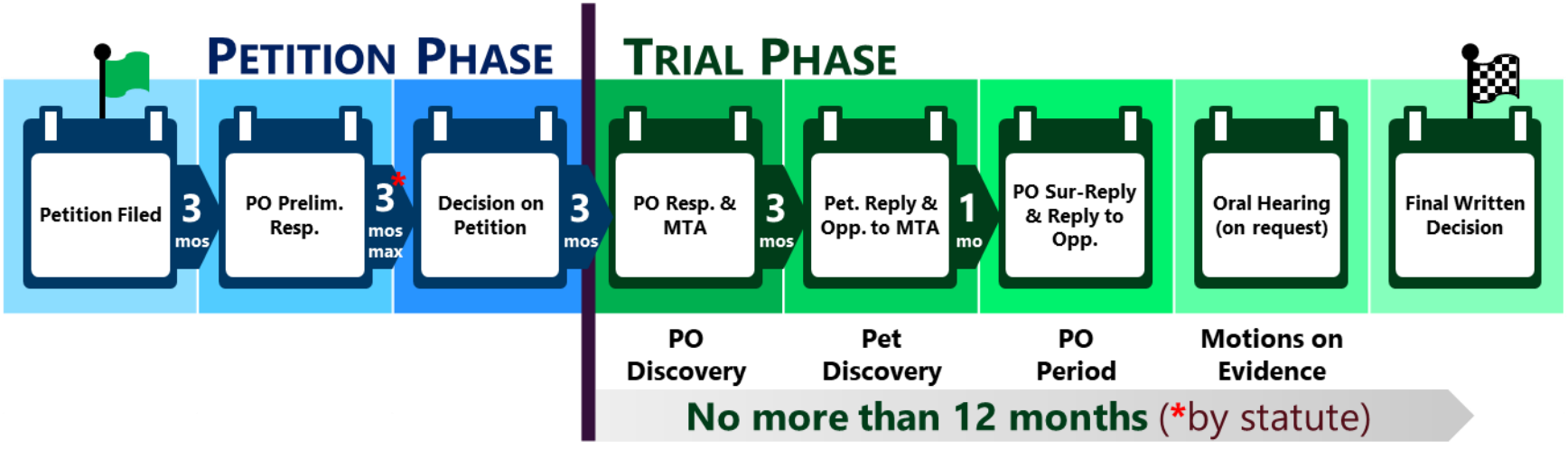
to obtain an **order**, **ruling**, or direction

www.merriam-webster.com/dictionary/motion

Common motions in AIA proceedings



Trial Phase: Final Written Decision



What are the possible outcomes?

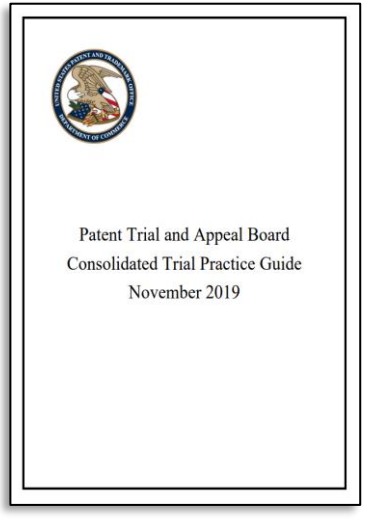
The outcome may be that all challenged claims are upheld, some challenged claims are upheld, or none of the challenged claims are upheld.

- All claims patentable: Every challenged claim upheld
- Mixed: At least one challenged claim, but not all, upheld
- All claims unpatentable: No challenged claim upheld

What happens next?

- Panel rehearing
- Director Review
- Appeal to the U.S. Court of Appeals for the Federal Circuit

Resources



The Patent Act – Title 35 of U.S. Code
(www.uspto.gov/web/offices/pac/mpep/consolidated_laws.pdf)

Rules – 37 C.F.R. Part 42 (§§ 42.1 – 42.224)
(www.govinfo.gov/content/pkg/CFR-2022-title37-vol1/pdf/CFR-2022-title37-vol1.pdf)

Trial Practice Guide (www.uspto.gov/TrialPracticeGuideConsolidated)

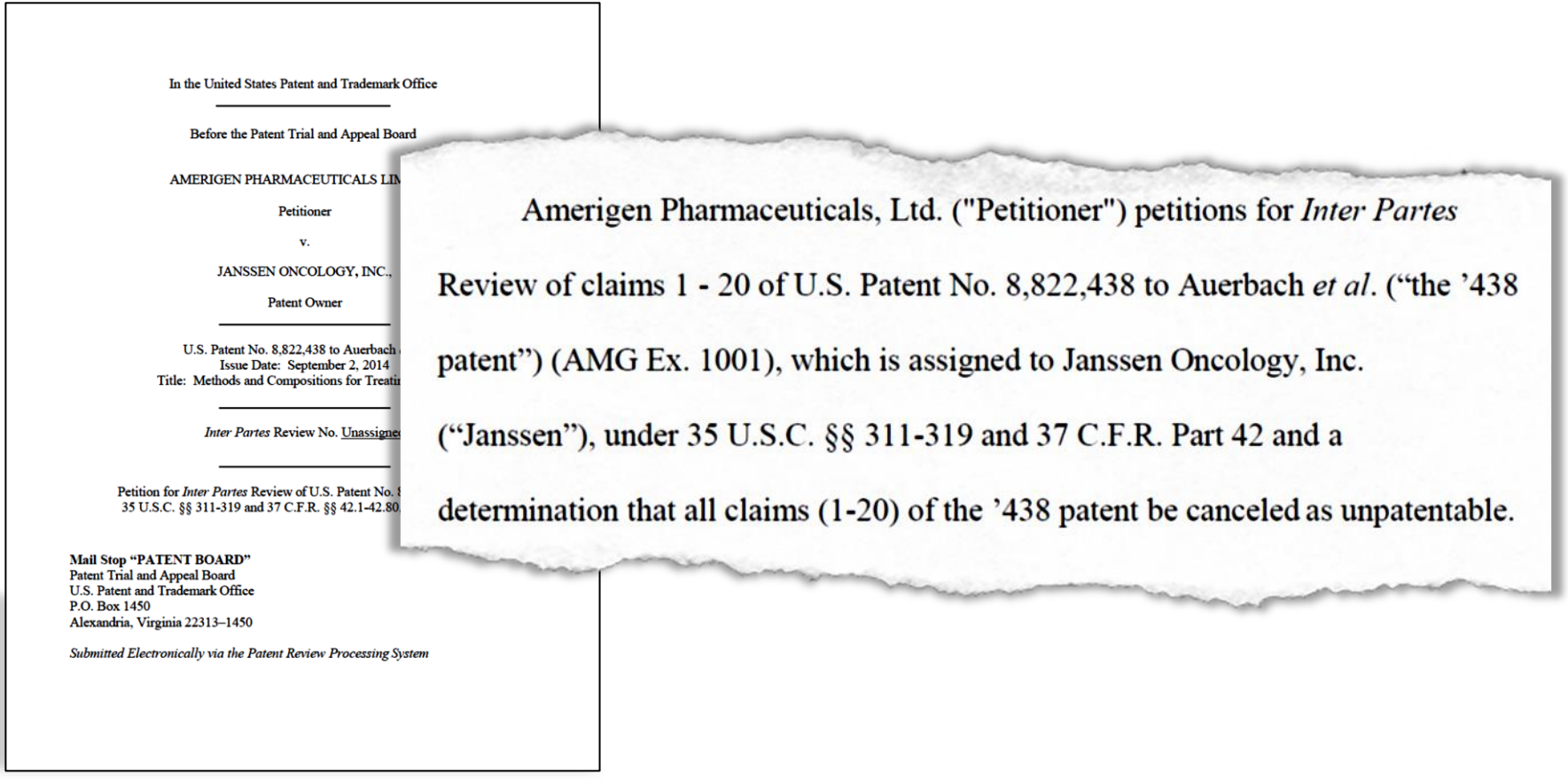
Amerigen Pharmaceuticals, Ltd. v. Janssen Oncology, Inc.

IPR2016-00286

U.S. Patent 8,822,438

Case file

Petition



In the United States Patent and Trademark Office

Before the Patent Trial and Appeal Board

AMERIGEN PHARMACEUTICALS LIM

Petitioner

v.

JANSSEN ONCOLOGY, INC.,

Patent Owner

U.S. Patent No. 8,822,438 to Auerbach
Issue Date: September 2, 2014
Title: Methods and Compositions for Treati

Inter Partes Review No. Unassigne

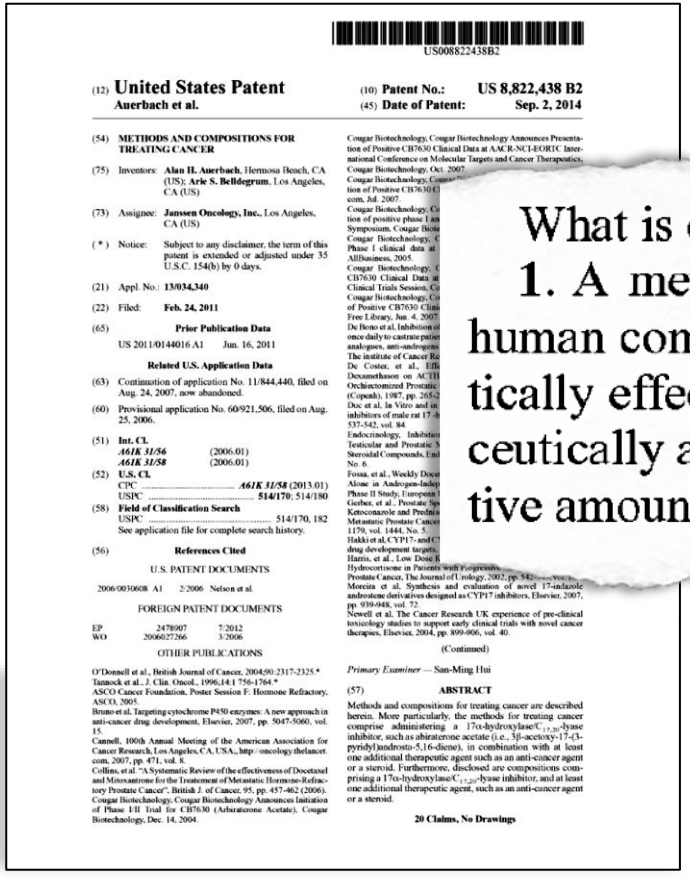
Petition for *Inter Partes* Review of U.S. Patent No.
35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.1-42.80

Mail Stop "PATENT BOARD"
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313–1450

Submitted Electronically via the Patent Review Processing System

Amerigen Pharmaceuticals, Ltd. ("Petitioner") petitions for *Inter Partes* Review of claims 1 - 20 of U.S. Patent No. 8,822,438 to Auerbach *et al*. ("the '438 patent") (AMG Ex. 1001), which is assigned to Janssen Oncology, Inc. ("Janssen"), under 35 U.S.C. §§ 311-319 and 37 C.F.R. Part 42 and a determination that all claims (1-20) of the '438 patent be canceled as unpatentable.

Challenged U.S. Patent 8,822,438



US008822438B2

(12) **United States Patent**
Auerbach et al.

(10) **Patent No.: US 8,822,438 B2**
(45) **Date of Patent: Sep. 2, 2014**

(54) **METHODS AND COMPOSITIONS FOR TREATING CANCER**

(75) Inventors: **Alan H. Auerbach**, Hermosa Beach, CA (US); **Arie S. Belldegrun**, Los Angeles, CA (US)

(73) Assignee: **Janssen Oncology, Inc.**, Los Angeles, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **13/034,340**

(22) Filed: **Feb. 24, 2011**

(65) **Prior Publication Data**

US 2011/0144016 A1 Jun. 16, 2011

Related U.S. Application Data

(63) Continuation of application No. 11/844,440, filed on Aug. 24, 2007, now abandoned.

(60) Provisional application No. 60/921,506, filed on Aug. 25, 2006.

(51) **Int. Cl.**
A61K 31/56 (2006.01)
A61K 31/58 (2006.01)

(52) **U.S. Cl.**
CPC ***A61K 31/58*** (2013.01)
USPC **514/170**; 514/180

(58) **Field of Classification Search**
USPC 514/170, 182
See application file for complete search history.

(56) **References Cited**

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Newell et al, The Cancer Research UK experience of pre-clinical toxicology studies to support early clinical trials with novel cancer therapies, Elsevier, 2004, pp. 899-906, vol. 40.

(Continued)

Primary Examiner — San-Ming Hui

(57) **ABSTRACT**

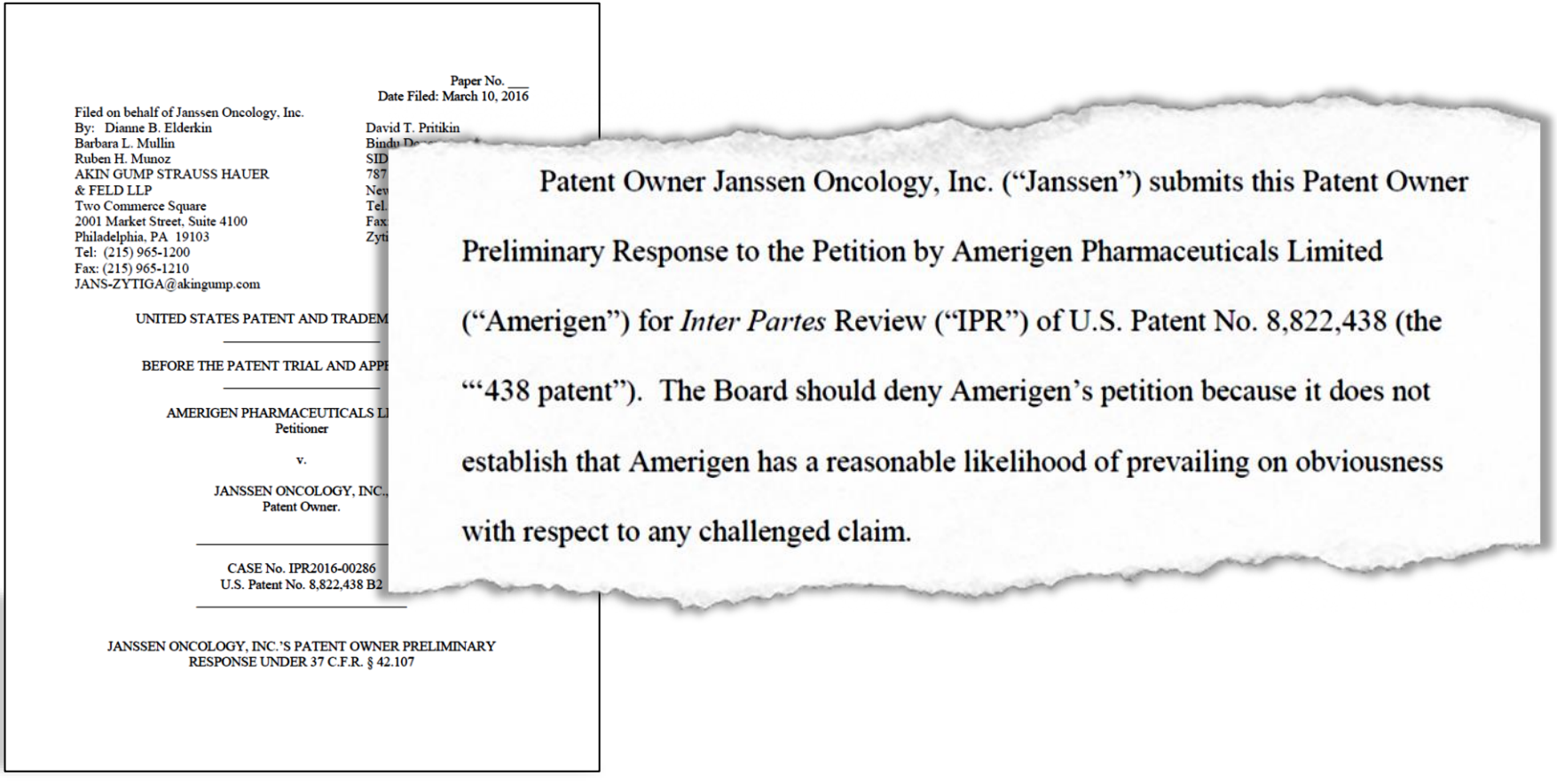
Methods and compositions for treating cancer are described herein. More particularly, the methods for treating cancer comprise administering a 17α-hydroxylase/$C_{17,20}$-lyase inhibitor, such as abiraterone acetate (i.e., 3β-acetoxy-17-(3-pyridyl)androsto-5,16-diene), in combination with at least one additional therapeutic agent such as an anti-cancer agent or a steroid. Furthermore, disclosed are compositions comprising a 17α-hydroxylase/$C_{17,20}$-lyase inhibitor, and at least one additional therapeutic agent, such as an anti-cancer agent or a steroid.

20 Claims, No Drawings

What is claimed is:

1. A method for the treatment of a prostate cancer in a human comprising administering to said human a therapeutically effective amount of abiraterone acetate or a pharmaceutically acceptable salt thereof and a therapeutically effective amount of prednisone.

Preliminary response



Paper No. ___
Date Filed: March 10, 2016

Filed on behalf of Janssen Oncology, Inc.
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UNITED STATES PATENT AND TRADEM...

BEFORE THE PATENT TRIAL AND APP...

AMERIGEN PHARMACEUTICALS L...
Petitioner

v.

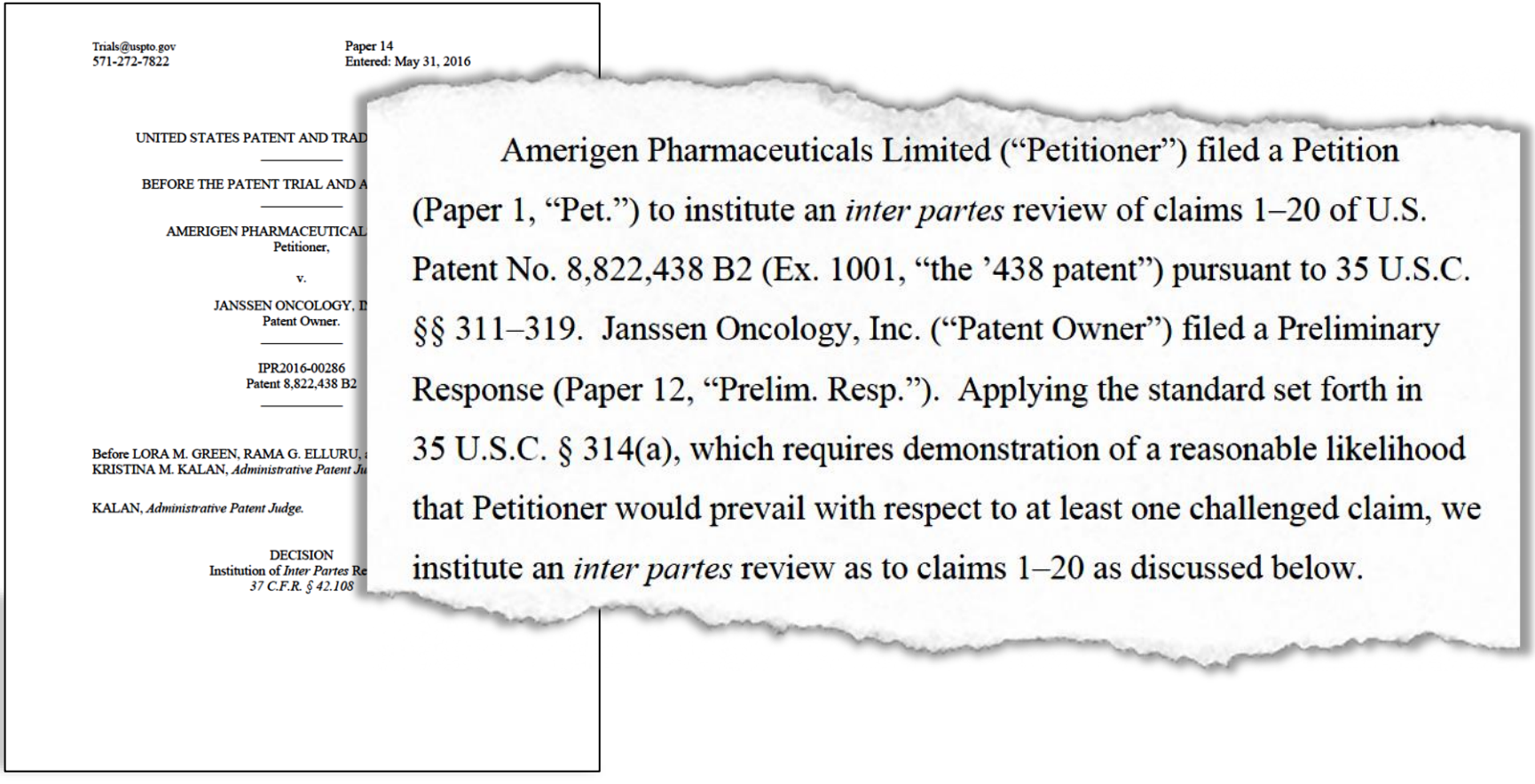
JANSSEN ONCOLOGY, INC.,
Patent Owner.

CASE No. IPR2016-00286
U.S. Patent No. 8,822,438 B2

JANSSEN ONCOLOGY, INC.'S PATENT OWNER PRELIMINARY RESPONSE UNDER 37 C.F.R. § 42.107

Patent Owner Janssen Oncology, Inc. ("Janssen") submits this Patent Owner Preliminary Response to the Petition by Amerigen Pharmaceuticals Limited ("Amerigen") for *Inter Partes* Review ("IPR") of U.S. Patent No. 8,822,438 (the "'438 patent"). The Board should deny Amerigen's petition because it does not establish that Amerigen has a reasonable likelihood of prevailing on obviousness with respect to any challenged claim.

PTAB's institution decision



Trials@uspto.gov
571-272-7822

Paper 14
Entered: May 31, 2016

UNITED STATES PATENT AND TRAD

BEFORE THE PATENT TRIAL AND A

AMERIGEN PHARMACEUTICAL
Petitioner,

v.

JANSSEN ONCOLOGY, I
Patent Owner.

IPR2016-00286
Patent 8,822,438 B2

Before LORA M. GREEN, RAMA G. ELLURU,
KRISTINA M. KALAN, *Administrative Patent Ju*

KALAN, *Administrative Patent Judge.*

DECISION
Institution of *Inter Partes* Re
37 C.F.R. § 42.108

Amerigen Pharmaceuticals Limited ("Petitioner") filed a Petition (Paper 1, "Pet.") to institute an *inter partes* review of claims 1–20 of U.S. Patent No. 8,822,438 B2 (Ex. 1001, "the '438 patent") pursuant to 35 U.S.C. §§ 311–319. Janssen Oncology, Inc. ("Patent Owner") filed a Preliminary Response (Paper 12, "Prelim. Resp."). Applying the standard set forth in 35 U.S.C. § 314(a), which requires demonstration of a reasonable likelihood that Petitioner would prevail with respect to at least one challenged claim, we institute an *inter partes* review as to claims 1–20 as discussed below.

Patent owner request for rehearing

Paper No. ___
Date Filed: June 14, 201[illegible]

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMERIGEN PHARMACEUTICALS LIMITED,
Petitioner

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner

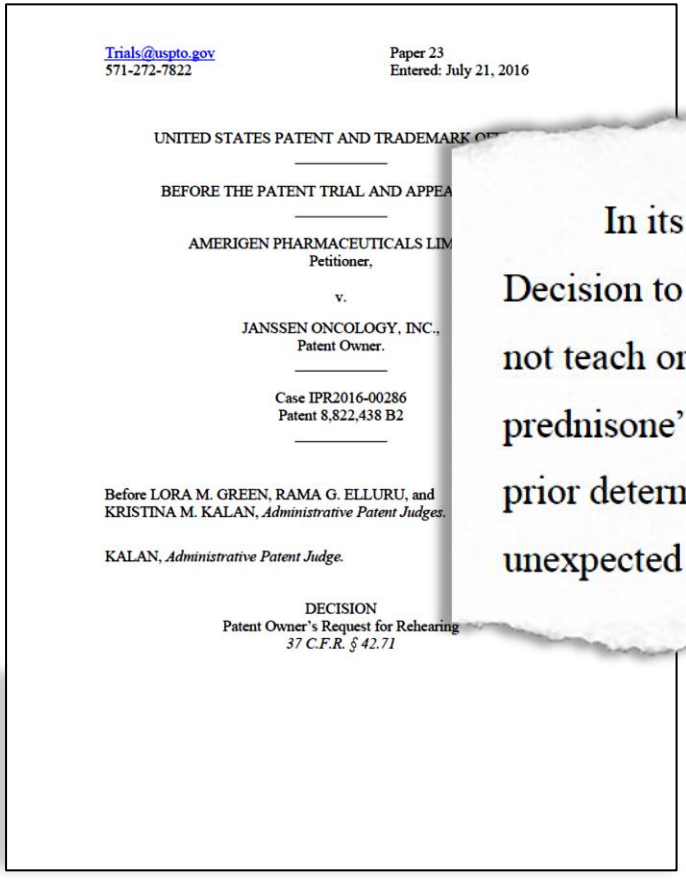
Case IPR2016-00286
Patent 8,822,438 B2

PATENT OWNER'S REQUEST FOR RECONSIDERATION PURSUANT TO 37 C.F.R. § 42.71(c)

(1) the Decision overlooks the petitioner's failure to proffer any evidence on the necessary element of administering a "therapeutically effective amount of prednisone," as well as petitioner's repeated admissions that this element, as properly construed by the Board to require an anti-cancer effective amount of prednisone, is neither taught nor suggested by the prior art; and

(2) the Decision fails to appropriately credit the Patent Office's prior finding of commercial success, instead inappropriately crediting petitioner's declaration refuting that finding, notwithstanding the statutory prohibition against instituting an *inter partes* review based on anything other than prior art patents and publications.

Denied



Trials@uspto.gov
571-272-7822

Paper 23
Entered: July 21, 2016

UNITED STATES PATENT AND TRADEMARK OF

BEFORE THE PATENT TRIAL AND APPEA

AMERIGEN PHARMACEUTICALS LIM
Petitioner,

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner.

Case IPR2016-00286
Patent 8,822,438 B2

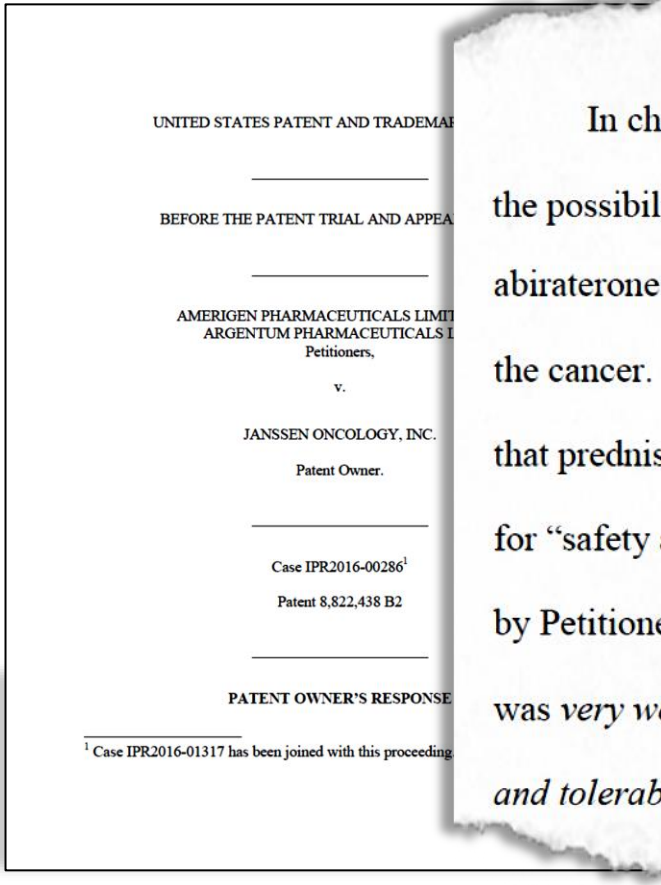
Before LORA M. GREEN, RAMA G. ELLURU, and KRISTINA M. KALAN, *Administrative Patent Judges.*

KALAN, *Administrative Patent Judge.*

DECISION
Patent Owner's Request for Rehearing
37 C.F.R. § 42.71

In its Request for Rehearing, Patent Owner contends that (1) the Decision to Institute ignores Petitioner's admissions that the prior art does not teach or suggest the claim element "a therapeutically effective amount of prednisone" (Req. 5–10); and (2) the Board fails to credit the Patent Office's prior determination of commercial success and Petitioner's admission of unexpected results (*id.* at 10–13). We disagree.

Patent owner's response



UNITED STATES PATENT AND TRADEMA

BEFORE THE PATENT TRIAL AND APPEA

AMERIGEN PHARMACEUTICALS LIMI
ARGENTUM PHARMACEUTICALS L
Petitioners,

v.

JANSSEN ONCOLOGY, INC.

Patent Owner.

Case IPR2016-00286[1]

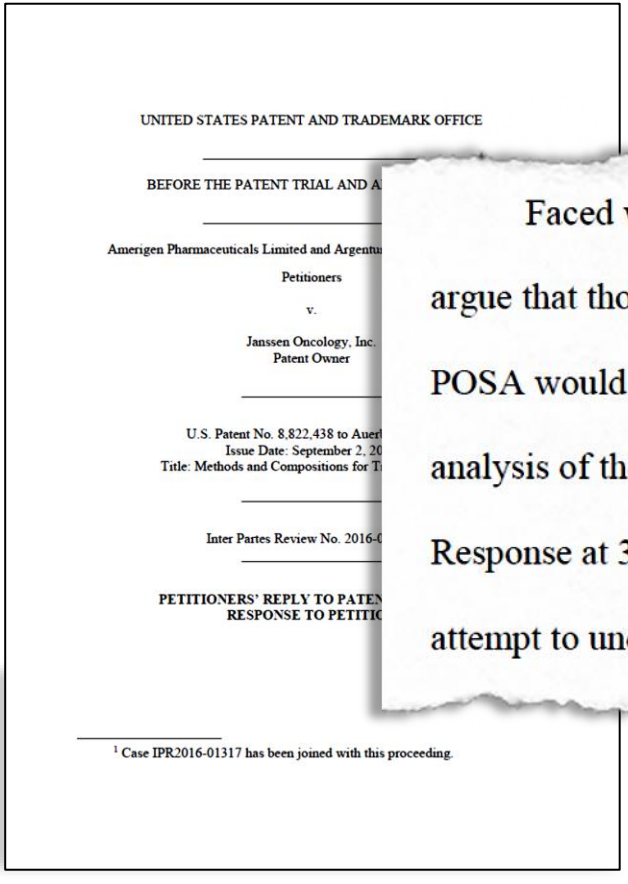
Patent 8,822,438 B2

PATENT OWNER'S RESPONSE

[1] Case IPR2016-01317 has been joined with this proceeding.

In challenging the claims, Petitioners point to no prior art that even hints at the possibility that the administration of prednisone in combination with abiraterone acetate could provide any surprising or unexpected benefit in treating the cancer. Petitioners thus side-step the benefit of the claimed invention to argue that prednisone would have been co-administered with abiraterone acetate therapy for "safety and tolerability" reasons. But the very prior art references relied upon by Petitioners show just the opposite: the prior art shows that abiraterone acetate was *very well-tolerated, meaning no further drug therapy was needed for "safety and tolerability" reasons*.

Petitioner's reply



UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND A

Amerigen Pharmaceuticals Limited and Argentu

Petitioners

v.

Janssen Oncology, Inc.
Patent Owner

U.S. Patent No. 8,822,438 to Auer
Issue Date: September 2, 20
Title: Methods and Compositions for T

Inter Partes Review No. 2016-0

PETITIONERS' REPLY TO PATEN
RESPONSE TO PETITIC

[1] Case IPR2016-01317 has been joined with this proceeding.

Faced with this clear teaching in the prior art, Patent Owner attempts to argue that those clear statements do not actually mean what they say, and that a POSA would have disregarded these unequivocal teachings, performed their own analysis of the underlying data, and reached a contrary conclusion. See PO Response at 39-41. The evidence, however, does not support Patent Owner's attempt to undo the teachings of the prior art. Instead, a POSA would have

Parties' motions (common ones)

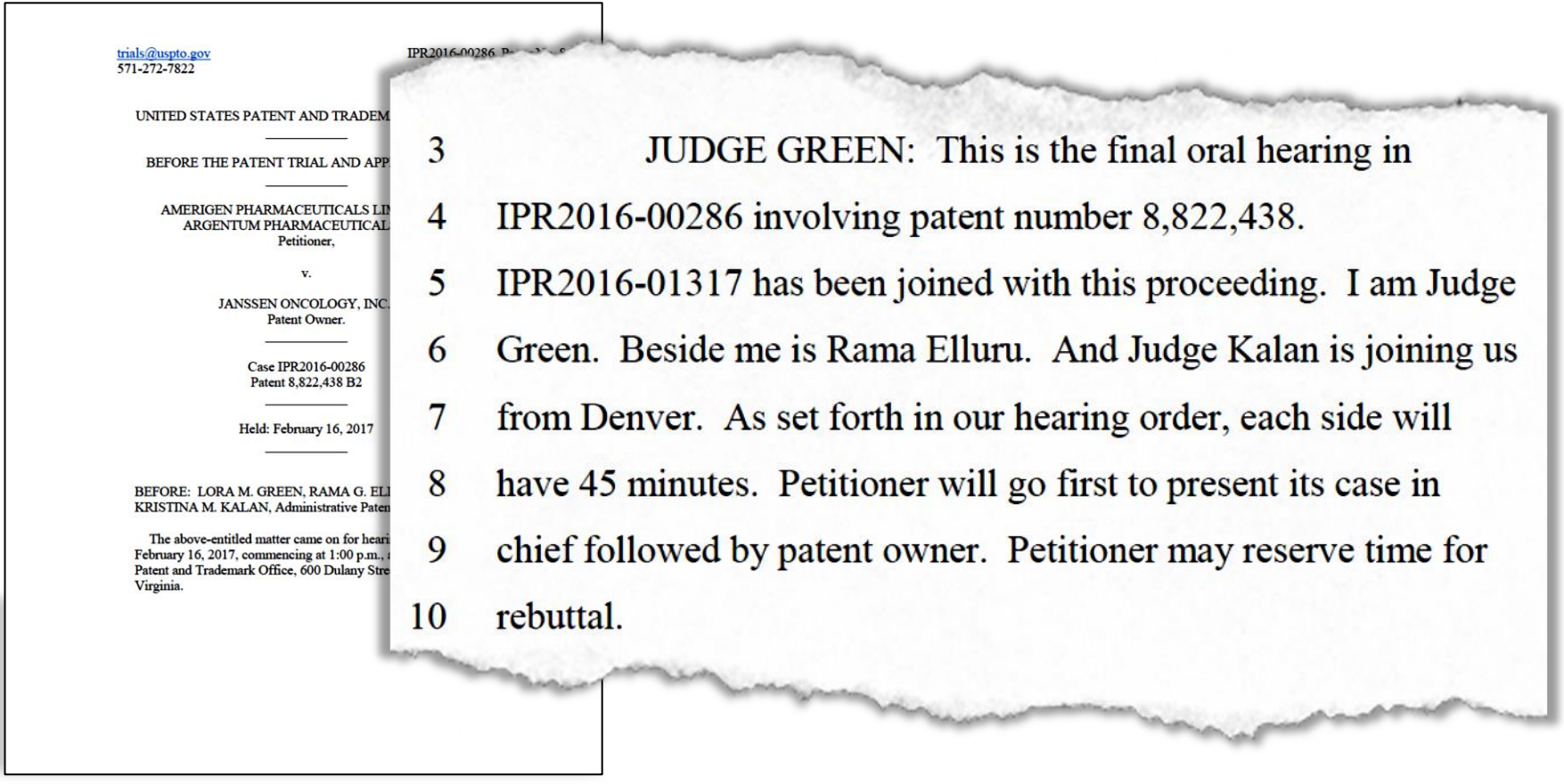
Both: for admission *pro hac vice*

PO: to exclude evidence

PO: to seal

PO: to file evidence

Oral argument



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571-272-7822

IPR2016-00286 P

UNITED STATES PATENT AND TRADEM

BEFORE THE PATENT TRIAL AND APP

AMERIGEN PHARMACEUTICALS LI
ARGENTUM PHARMACEUTICAL
Petitioner,

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JANSSEN ONCOLOGY, INC.
Patent Owner.

Case IPR2016-00286
Patent 8,822,438 B2

Held: February 16, 2017

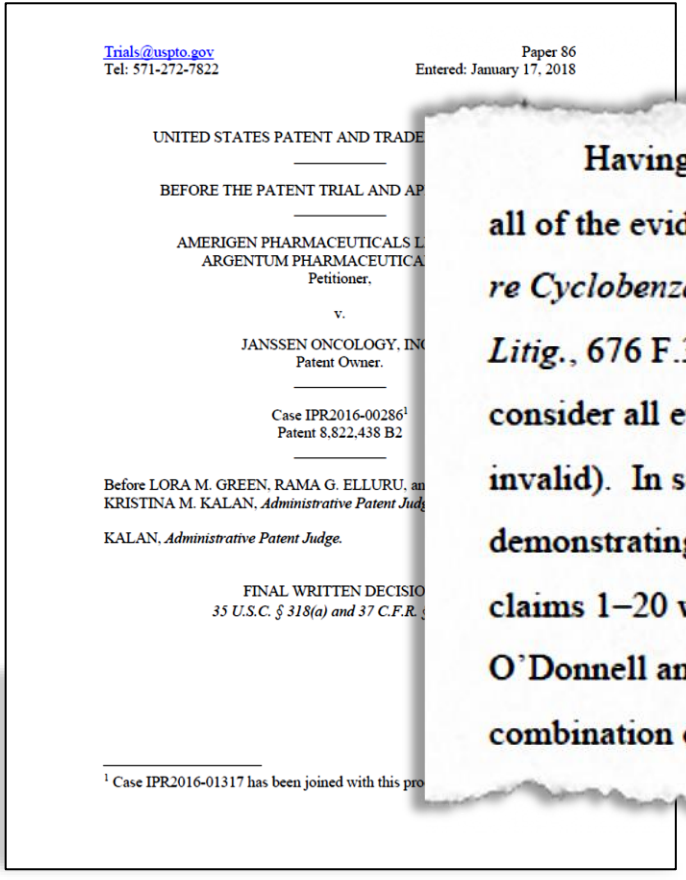
BEFORE: LORA M. GREEN, RAMA G. EL
KRISTINA M. KALAN, Administrative Paten

The above-entitled matter came on for heari
February 16, 2017, commencing at 1:00 p.m.,
Patent and Trademark Office, 600 Dulany Stre
Virginia.

JUDGE GREEN: This is the final oral hearing in IPR2016-00286 involving patent number 8,822,438. IPR2016-01317 has been joined with this proceeding. I am Judge Green. Beside me is Rama Elluru. And Judge Kalan is joining us from Denver. As set forth in our hearing order, each side will have 45 minutes. Petitioner will go first to present its case in chief followed by patent owner. Petitioner may reserve time for rebuttal.

Evidence

PTAB's final written decision



Trials@uspto.gov
Tel: 571-272-7822

Paper 86
Entered: January 17, 2018

UNITED STATES PATENT AND TRADE

BEFORE THE PATENT TRIAL AND AP

AMERIGEN PHARMACEUTICALS L
ARGENTUM PHARMACEUTICA
Petitioner,

v.

JANSSEN ONCOLOGY, IN
Patent Owner.

Case IPR2016-00286[1]
Patent 8,822,438 B2

Before LORA M. GREEN, RAMA G. ELLURU, an
KRISTINA M. KALAN, *Administrative Patent Judg*

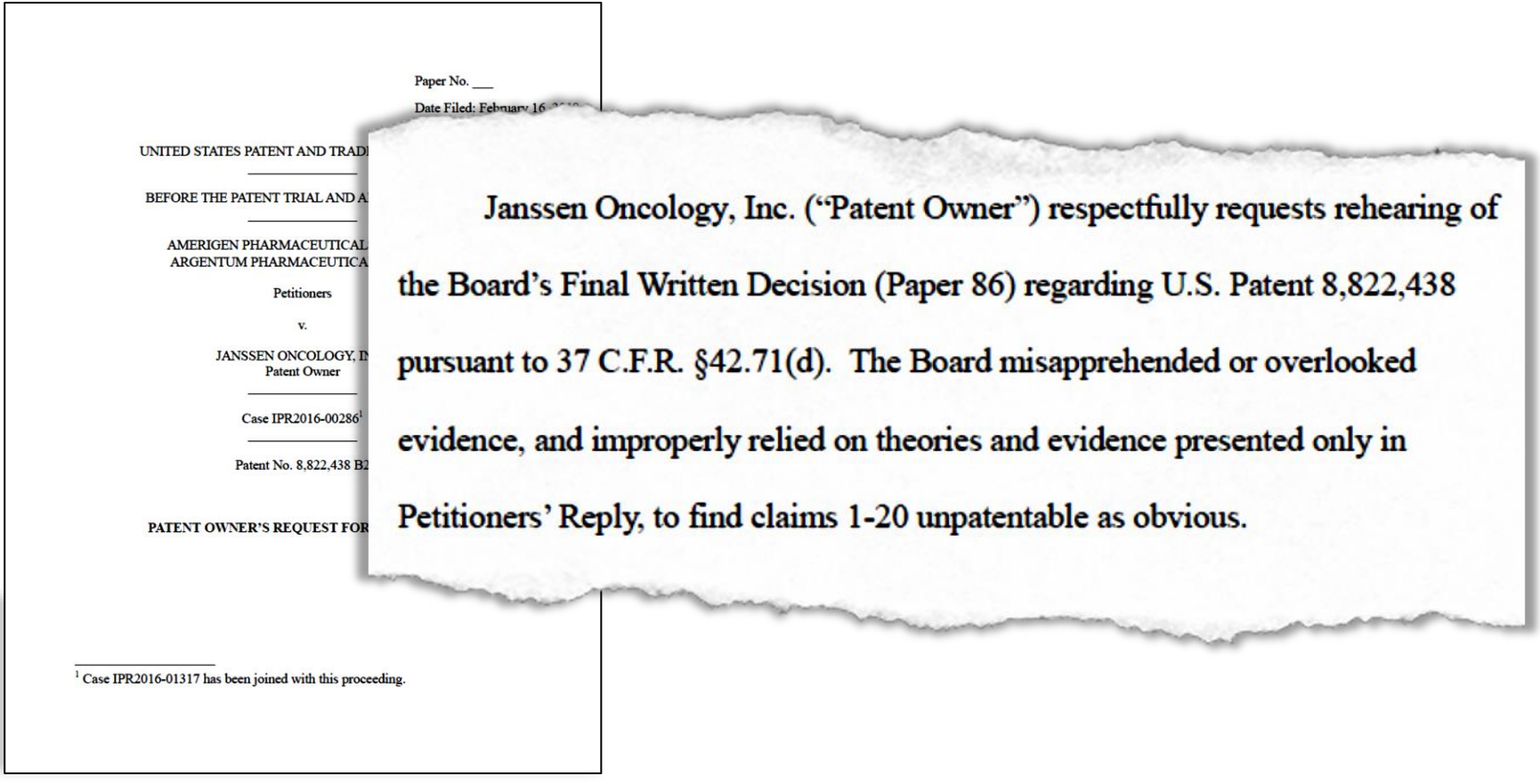
KALAN, *Administrative Patent Judge.*

FINAL WRITTEN DECISIO
35 U.S.C. § 318(a) and 37 C.F.R.

[1] Case IPR2016-01317 has been joined with this pro

Having considered the parties' arguments and evidence, we evaluate all of the evidence together to make a final determination of obviousness. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1075 (Fed. Cir. 2012) (stating that a fact finder must consider all evidence relating to obviousness before finding patent claims invalid). In so doing, we conclude that Petitioner has satisfied its burden of demonstrating, by a preponderance of the evidence, that the subject matter of claims 1–20 would have been obvious over the combination of Gerber and O'Donnell and that claims 1–4 and 6–11 would have been obvious over the combination of Gerber and Barrie.

Patent owner's request for rehearing



Paper No. ___

Date Filed: February 16

UNITED STATES PATENT AND TRADE

BEFORE THE PATENT TRIAL AND A

AMERIGEN PHARMACEUTICAL
ARGENTUM PHARMACEUTICA

Petitioners

v.

JANSSEN ONCOLOGY, I
Patent Owner

Case IPR2016-00286[1]

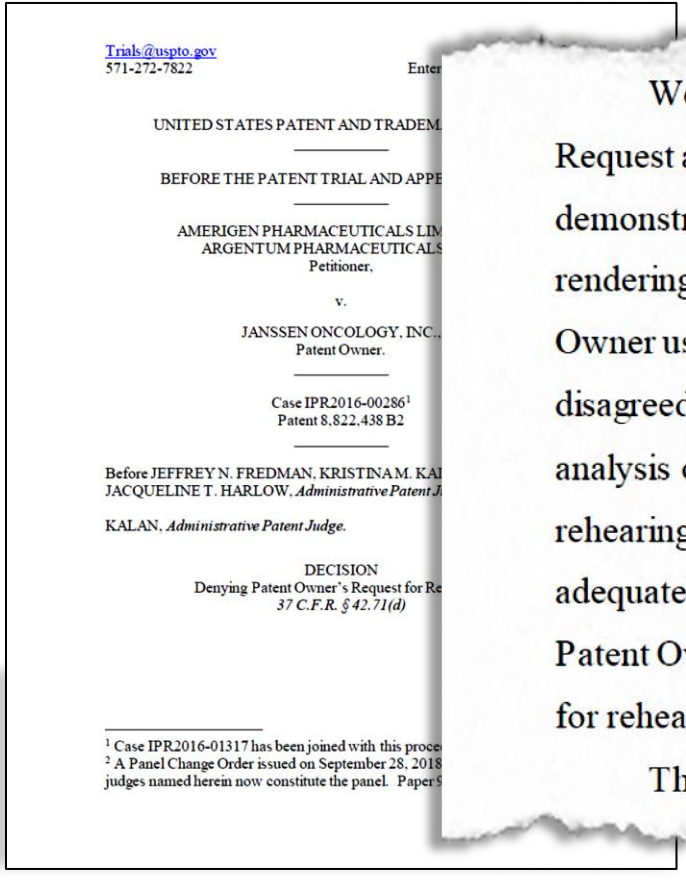
Patent No. 8,822,438 B2

PATENT OWNER'S REQUEST FOR

Janssen Oncology, Inc. ("Patent Owner") respectfully requests rehearing of the Board's Final Written Decision (Paper 86) regarding U.S. Patent 8,822,438 pursuant to 37 C.F.R. §42.71(d). The Board misapprehended or overlooked evidence, and improperly relied on theories and evidence presented only in Petitioners' Reply, to find claims 1-20 unpatentable as obvious.

[1] Case IPR2016-01317 has been joined with this proceeding.

Denied



Trials@uspto.gov
571-272-7822 Enter

UNITED STATES PATENT AND TRADEM

BEFORE THE PATENT TRIAL AND APPE

AMERIGEN PHARMACEUTICALS LIM
ARGENTUM PHARMACEUTICALS
Petitioner,

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner.

Case IPR2016-00286[1]
Patent 8,822,438 B2

Before JEFFREY N. FREDMAN, KRISTINA M. KAL
JACQUELINE T. HARLOW, *Administrative Patent J*

KALAN, *Administrative Patent Judge.*

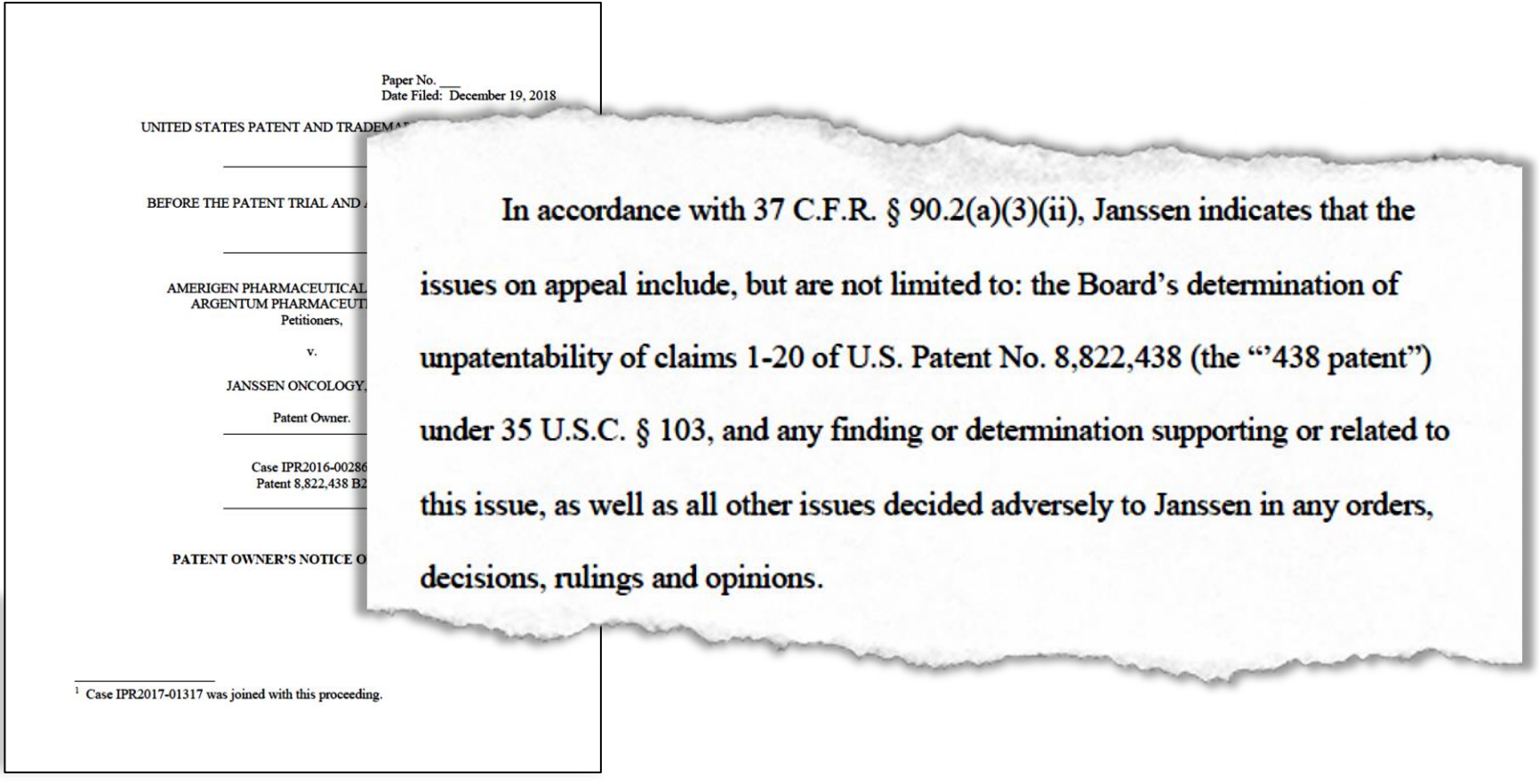
DECISION
Denying Patent Owner's Request for Re
37 C.F.R. § 42.71(d)

[1] Case IPR2016-01317 has been joined with this proce
[2] A Panel Change Order issued on September 28, 2018
judges named herein now constitute the panel. Paper 9

We have reviewed and considered the arguments in Patent Owner's Request and conclude that Patent Owner has not carried its burden of demonstrating that the Board misapprehended or overlooked any matters in rendering the Final Written Decision. 37 C.F.R. § 42.71(d). Rather, Patent Owner uses its Request as an opportunity to argue positions with which we disagreed in our Final Written Decision. Merely disagreeing with our analysis or conclusions does not serve as a proper basis for a request for rehearing. Patent Owner also uses its Request to raise matters without adequately demonstrating where those matters previously were raised. Thus, Patent Owner's challenge does not meet the standard set forth for a request for rehearing.

The Request for Rehearing is *denied*.

Patent owner's appeal



Paper No. ___
Date Filed: December 19, 2018

UNITED STATES PATENT AND TRADEM

BEFORE THE PATENT TRIAL AND

AMERIGEN PHARMACEUTICAL
ARGENTUM PHARMACEUT
Petitioners,

v.

JANSSEN ONCOLOGY,

Patent Owner.

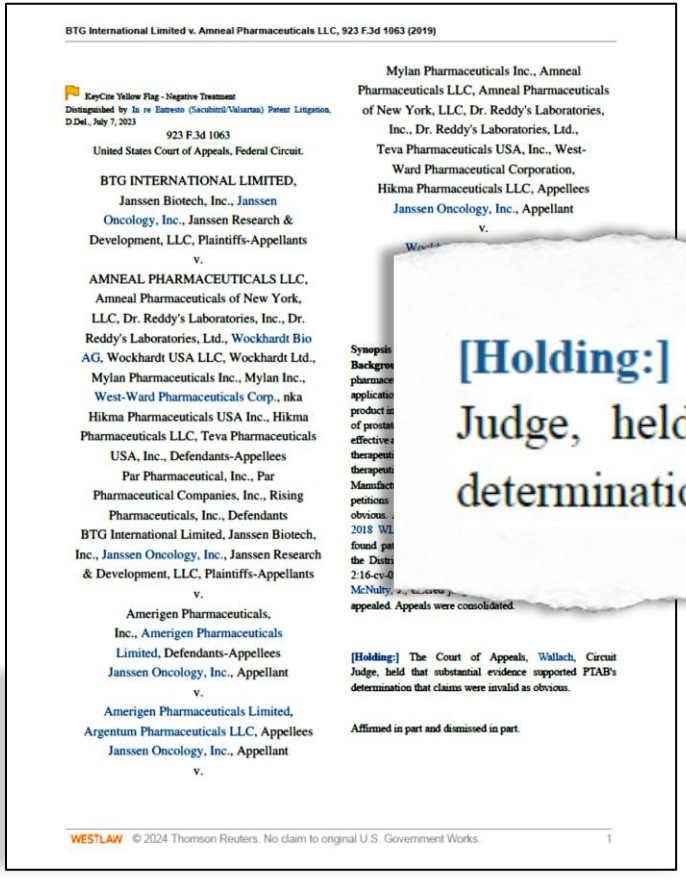
Case IPR2016-00286
Patent 8,822,438 B2

PATENT OWNER'S NOTICE O

[1] Case IPR2017-01317 was joined with this proceeding.

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Janssen indicates that the issues on appeal include, but are not limited to: the Board's determination of unpatentability of claims 1-20 of U.S. Patent No. 8,822,438 (the "'438 patent") under 35 U.S.C. § 103, and any finding or determination supporting or related to this issue, as well as all other issues decided adversely to Janssen in any orders, decisions, rulings and opinions.

Federal Circuit holding



BTG International Limited v. Amneal Pharmaceuticals LLC, 923 F.3d 1063 (2019)

KeyCite Yellow Flag - Negative Treatment
Distinguished by In re Entresto (Sacubitril/Valsartan) Patent Litigation, D.Del., July 7, 2023

923 F.3d 1063
United States Court of Appeals, Federal Circuit.

BTG INTERNATIONAL LIMITED, Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, Plaintiffs-Appellants
v.
AMNEAL PHARMACEUTICALS LLC, Amneal Pharmaceuticals of New York, LLC, Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd., Wockhardt Bio AG, Wockhardt USA LLC, Wockhardt Ltd., Mylan Pharmaceuticals Inc., Mylan Inc., West-Ward Pharmaceuticals Corp., nka Hikma Pharmaceuticals USA Inc., Hikma Pharmaceuticals LLC, Teva Pharmaceuticals USA, Inc., Defendants-Appellees
Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc., Rising Pharmaceuticals, Inc., Defendants
BTG International Limited, Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, Plaintiffs-Appellants
v.
Amerigen Pharmaceuticals, Inc., Amerigen Pharmaceuticals Limited, Defendants-Appellees
Janssen Oncology, Inc., Appellant
v.
Amerigen Pharmaceuticals Limited, Argentum Pharmaceuticals LLC, Appellees
Janssen Oncology, Inc., Appellant
v.
Mylan Pharmaceuticals Inc., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC, Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd., Teva Pharmaceuticals USA, Inc., West-Ward Pharmaceutical Corporation, Hikma Pharmaceuticals LLC, Appellees
Janssen Oncology, Inc., Appellant
v.

Synopsis
Background
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petitions
obvious.
2018 WL
found pat
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2:16-cv-0
McNulty,
appealed. Appeals were consolidated.

[Holding:] The Court of Appeals, Wallach, Circuit Judge, held that substantial evidence supported PTAB's determination that claims were invalid as obvious.

Affirmed in part and dismissed in part.

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[Holding:] The Court of Appeals, Wallach, Circuit Judge, held that substantial evidence supported PTAB's determination that claims were invalid as obvious.

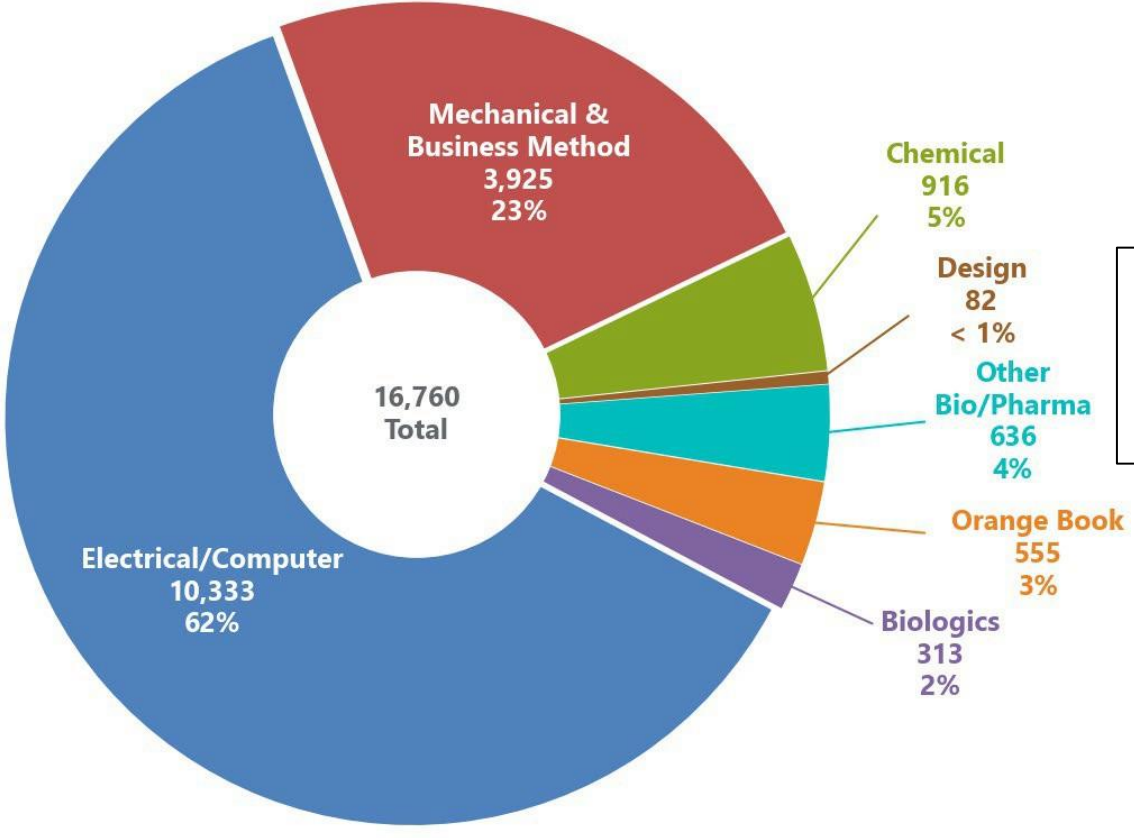
PTAB Orange Book patent/biologic patent study

FY24 Q2 Update (through March 31, 2024)

Statistics

AIA petitions filed by technology

(Sept. 16, 2012 to Mar. 31, 2024)



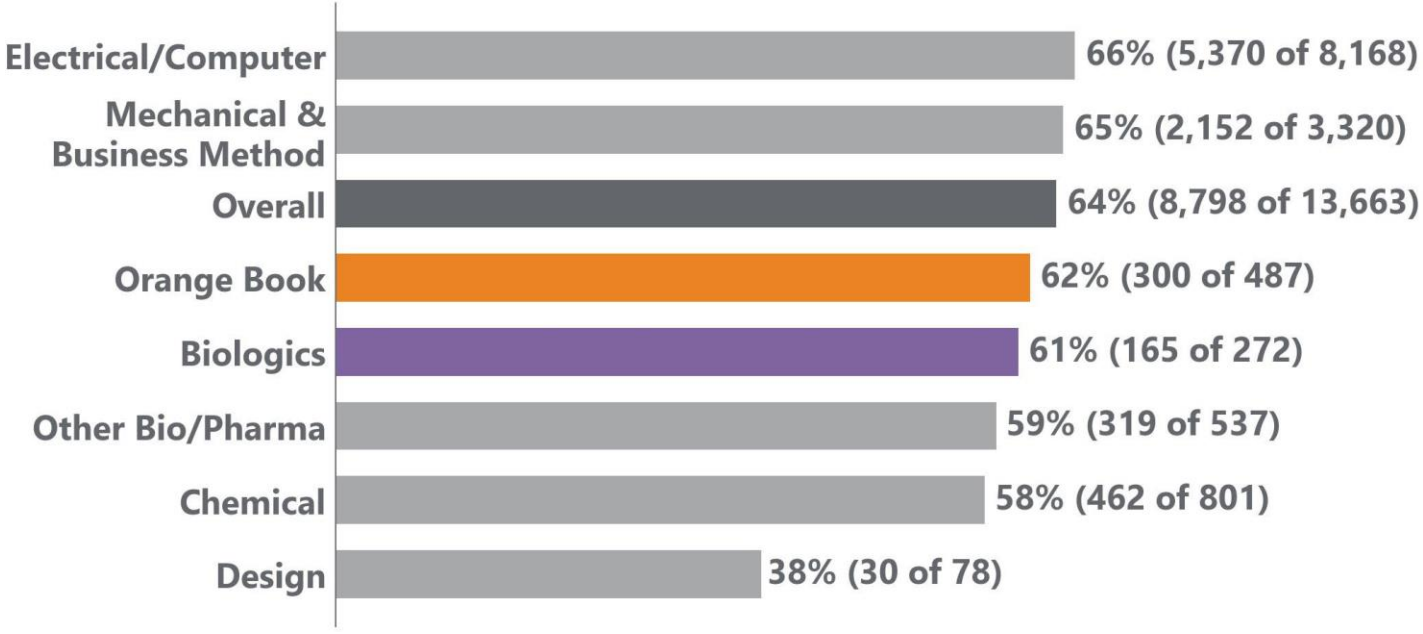
3% of all AIA petitions challenge **Orange Book patents**

2% of all AIA petitions challenge **biologic patents**

Includes all trial types

Institution rates by technology

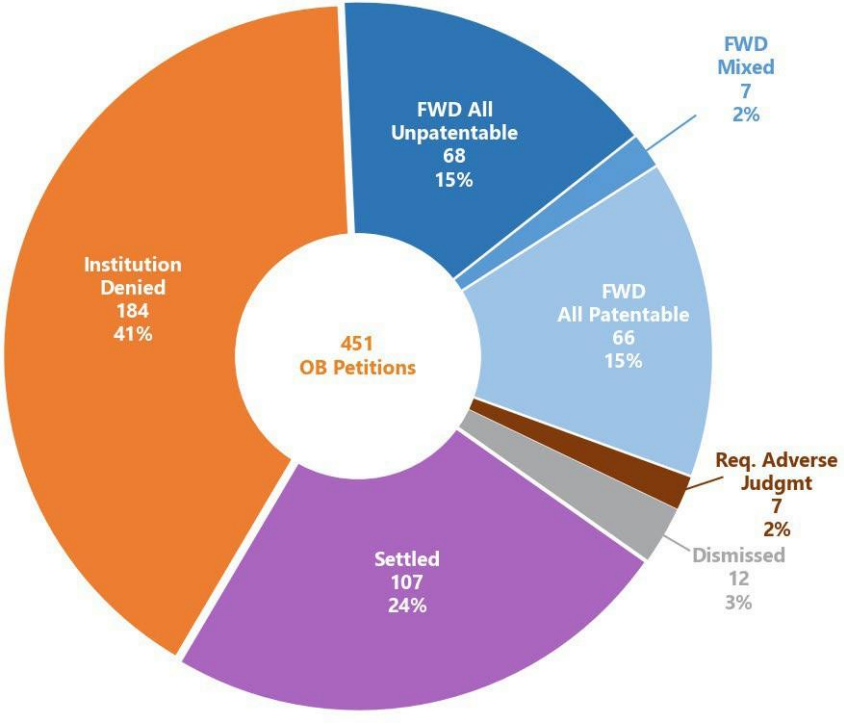
(Sept. 16, 2012 to Mar. 31, 2024)



The institution rate for **biologic patents (61%)** is similar to the institution rate for **Orange Book patents (62%)**

Institution rate for each technology is calculated by dividing petitions instituted by decisions on institution (i.e., petitions instituted plus petitions denied). The outcomes of decisions on institution responsive to requests for rehearing are excluded.

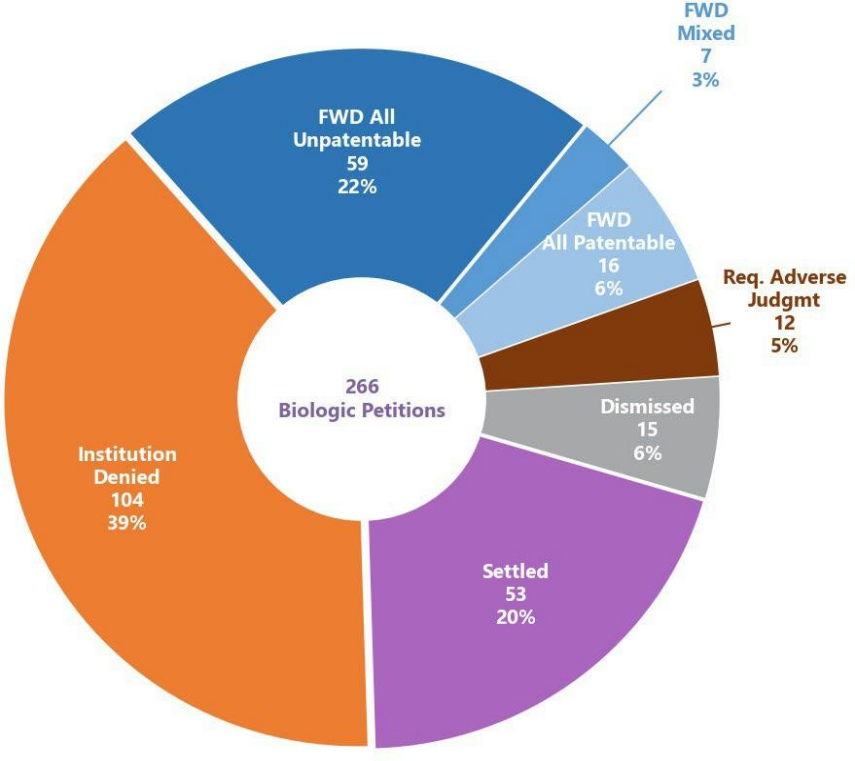
Outcomes of AIA petitions challenging Orange Book patents (Sept. 16, 2012 to Mar. 31, 2024)



The outcomes of decisions on institution responsive to requests for rehearing are included.

Joined and pending petitions are excluded.

Outcomes of AIA petitions challenging biologic patents (Sept. 16, 2012 to Mar. 31, 2024)

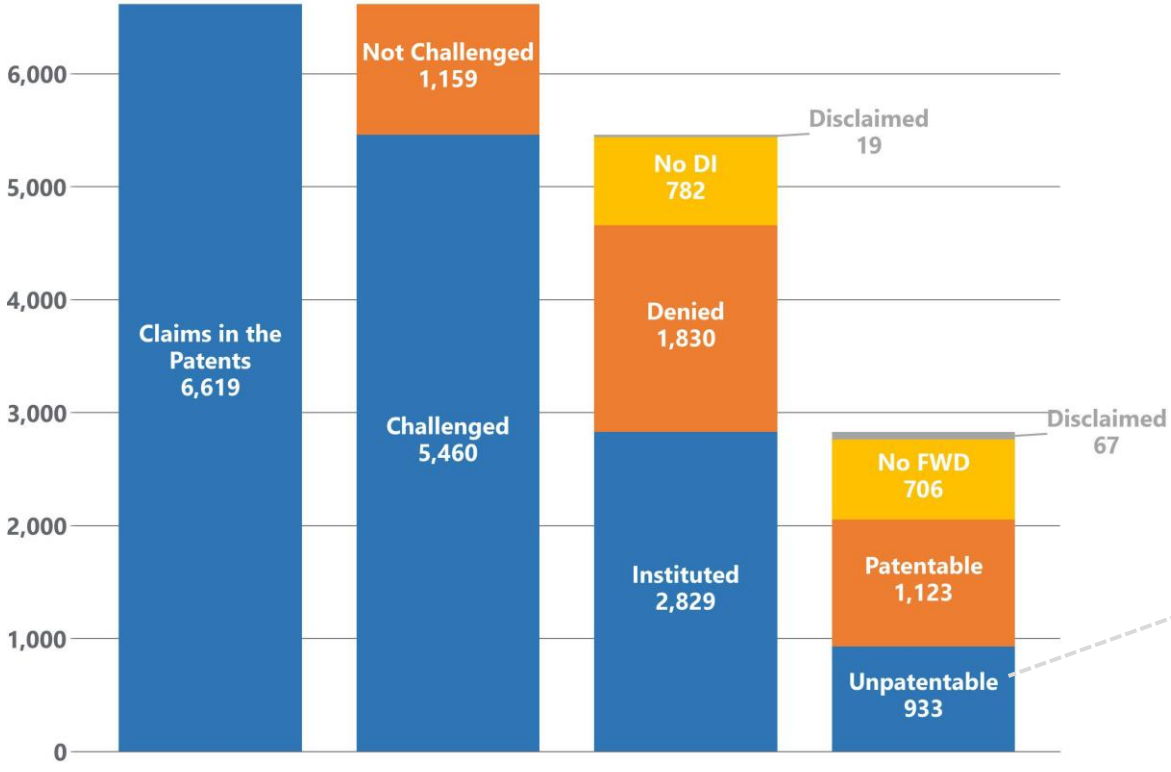


The outcomes of decisions on institution responsive to requests for rehearing are included.

Joined and pending petitions are excluded.

Claim outcomes for Orange Book patents

(Sept. 16, 2012 to Mar. 31, 2024)



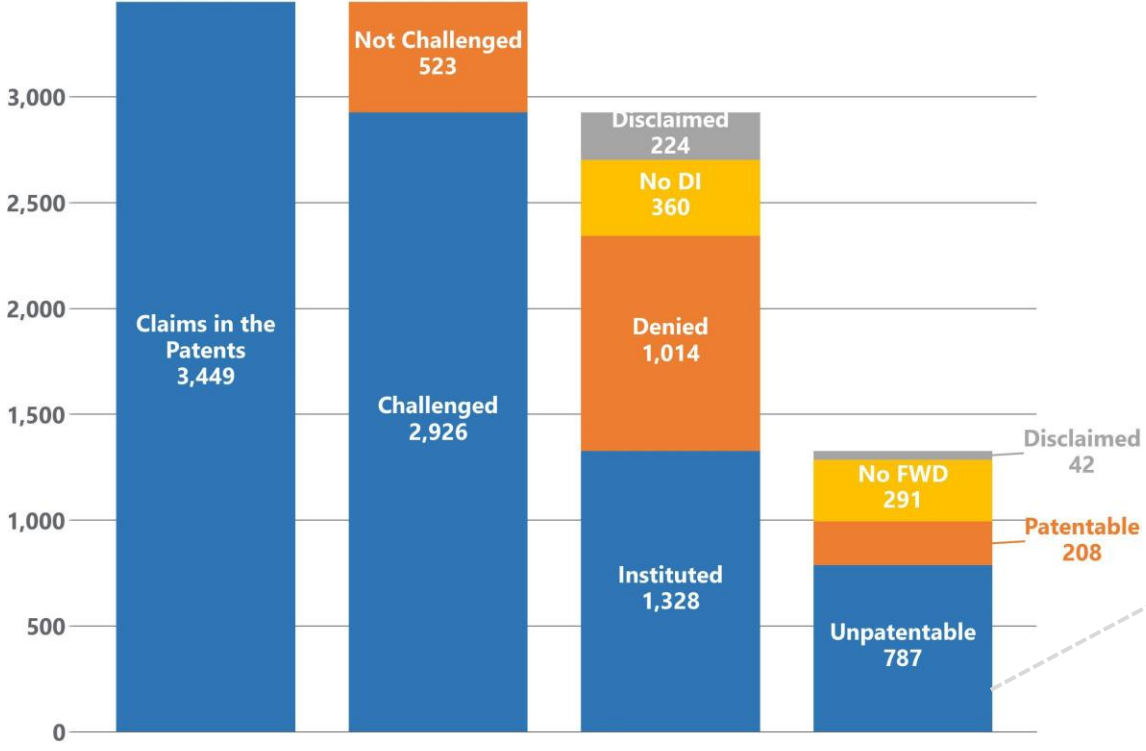
*"No DI" and "No FWD" means the claim was challenged but not addressed in a DI/FWD, e.g., due to settlement.

Orange Book patents:

17% of challenged claims and 33% of instituted claims were found unpatentable by a preponderance of the evidence

Claim outcomes for biologic patents

(Sept. 16, 2012 to Mar. 31, 2024)



*"No DI" and "No FWD" means the claim was challenged but not addressed in a DI/FWD, e.g., due to settlement.

Biologic patents:

27% of challenged claims and 59% of instituted claims were found unpatentable by a preponderance of the evidence

Questions?


UNITED STATES PATENT AND TRADEMARK OFFICE
DEPARTMENT OF COMMERCE