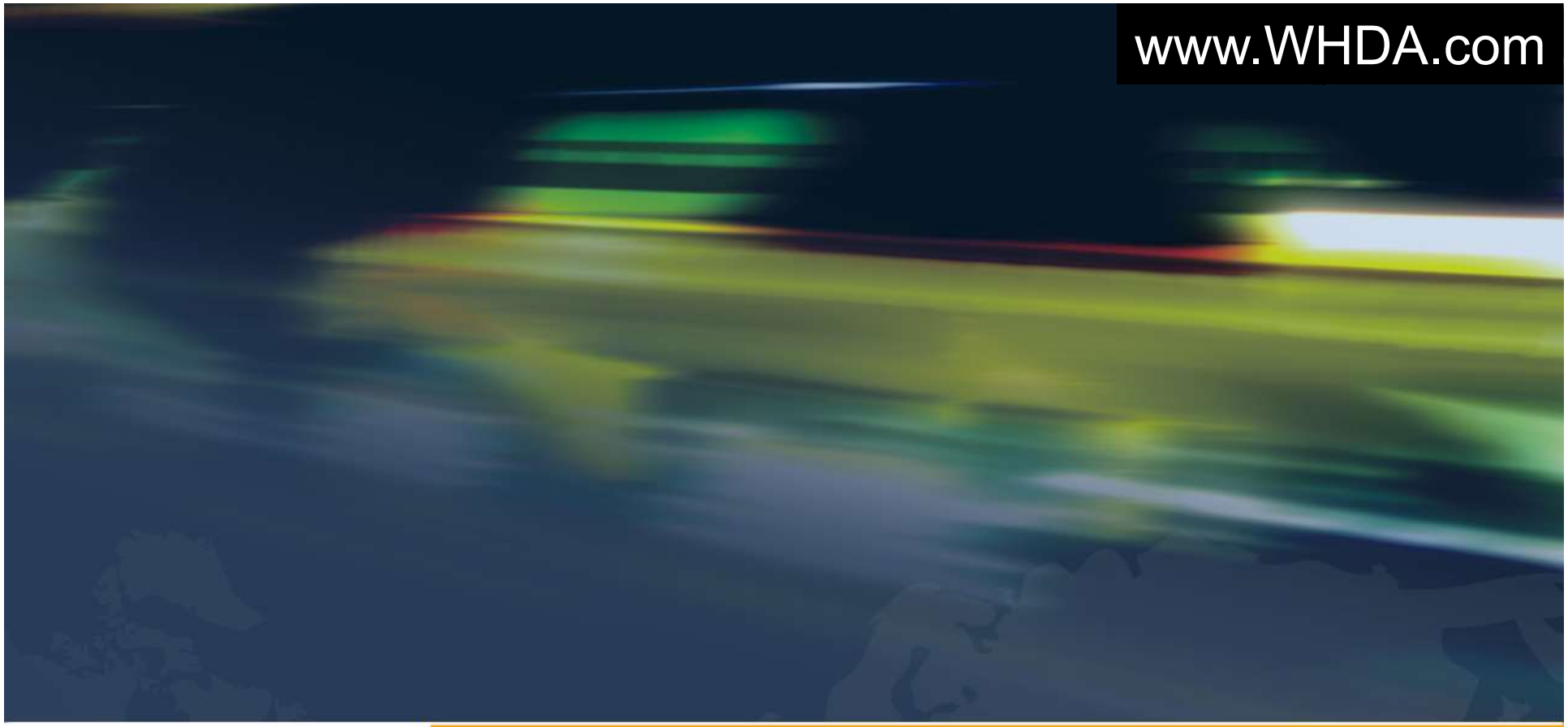


WESTERMAN HATTORI DANIELS & ADRIAN, LLP

ASPI-GRAPI Oct. 2019

Examen à l'USPTO: quelques rappels

Nicolas E. Seckel

Intellectual Property Law

Examen à l'USPTO: quelques rappels

- Négociation avec l'Examinateur US:
  1) Interprétation des revendications
  2) Preuves de fait c. arguments de droit
  3) Doctrines d'équité: estoppel, devoir de divulgation
- Calendrier de l'examen US:
  1) Notification non-finale vs. finale
  2) RCE c. appel
  3) Continuations et divisionnaires

Interprétation des revendications

- Pendant l'examen ou le réexamen: « broadest reasonable interpretation » (« BRI »)
  - Au vu de la description (en principe…)
  - Pour l'éviter: définition expresse dans la description
- Pendant les procédures contestées (« post-grant proceedings »): interprétation équilibrée
  - Au vu des revendications, de la description et du dossier d'examen, comme dans un litige au tribunal

=> En pratique: ne pas se braquer

Preuves de fait c. arguments de droit

- Les décisions de l'USPTO doivent être justifiées par des « preuves substantielles » (« substantial evidence »)
  - Une personne raisonnable accepterait ces preuves comme adéquates
  - Même en présence de preuves contraires
  - Déférence de la cour d'appel (cf. « clearly erroneous » = moindre déférence; « de novo » = aucune déférence)

=> En pratique: fournir des preuves

Doctrines d'équité

- « Prosecution History Estoppel »
  - Le dossier d'examen est une source indispensable pour l'interprétation d'un brevet US
  - Les amendements et les arguments sont des notifications au public
- Devoir de divulgation
  - Devoir de bonne foi
  - Faciliter l'examen

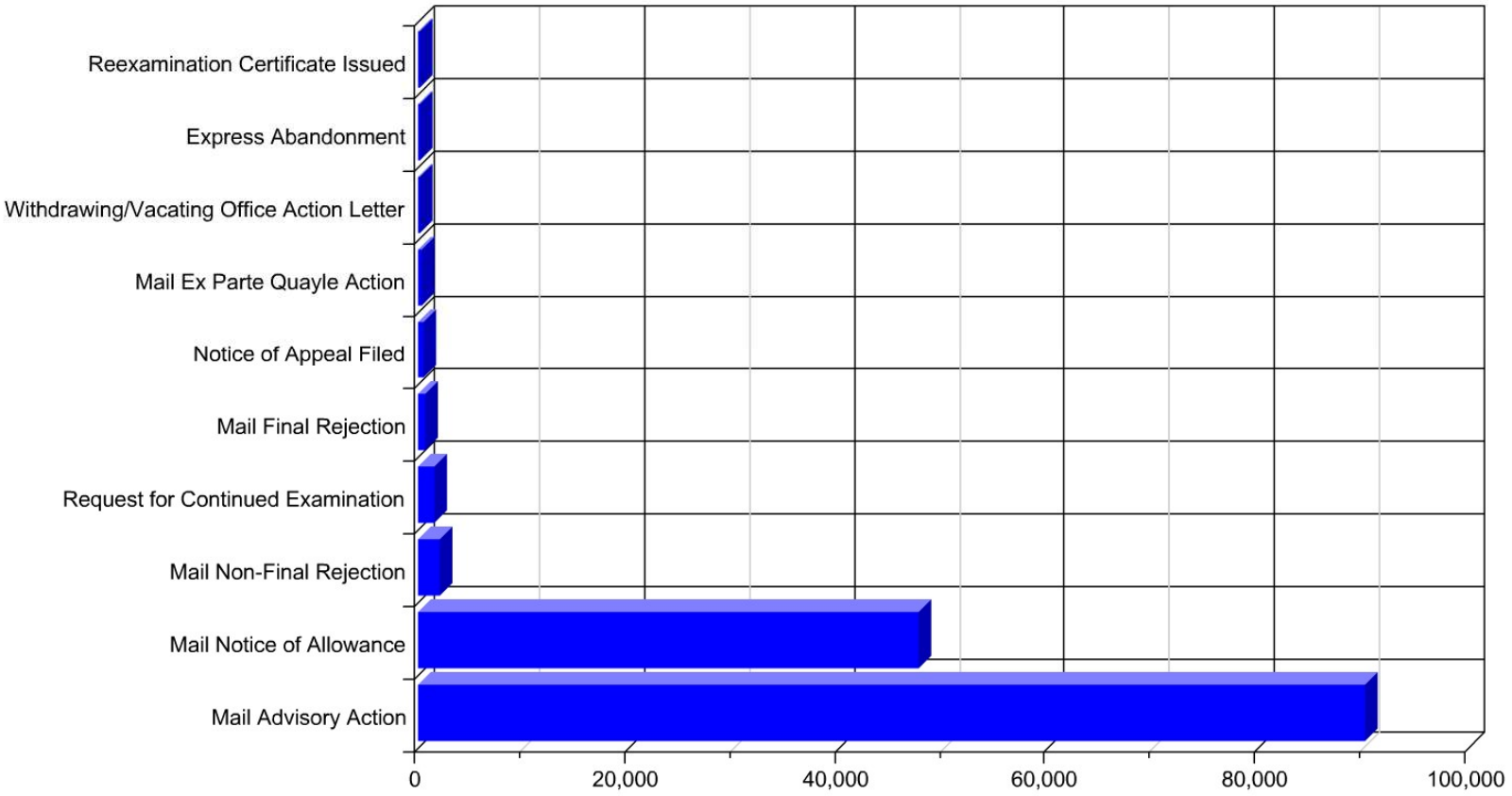
=> En pratique: ne rien cacher, mais faire court

Notification non-finale vs. finale

- Non-finale:
  - Amendement
  - Preuves de fait (documents, déclaration d'expert, etc.)
  - Interview
- Finale:
  - Traditionnelle: préparer la demande pour un appel
  - Advisory Action: trop tard pour une question nouvelle (« new issue »)
  - Programme pilote AFCP (question nouvelle simple)

=> En pratique: investir à la première notification

Examiners' Actions in Reply to After Final Responses



Source: USPTO (Sep 2018 to Aug. 2019)

RCE c. appel

- Appel
  - Suspensif
  - Long et cher
  - Conférence pré-mémoire d'appel, programme P3
- RCE
  - Eviter un appel
  - Reprendre l'examen sur une nouvelle stratégie

=> En pratique: RCE, le prix de la liberté (d'amender)

RCE c. appel

- Average pendency to appeal decision:
  - 71.2 months
- Average pendency including RCE:
  - 51.0 months
- Average pendency from RCE to action:
  - 2.4 months

Source: USPTO, Aug. 2019

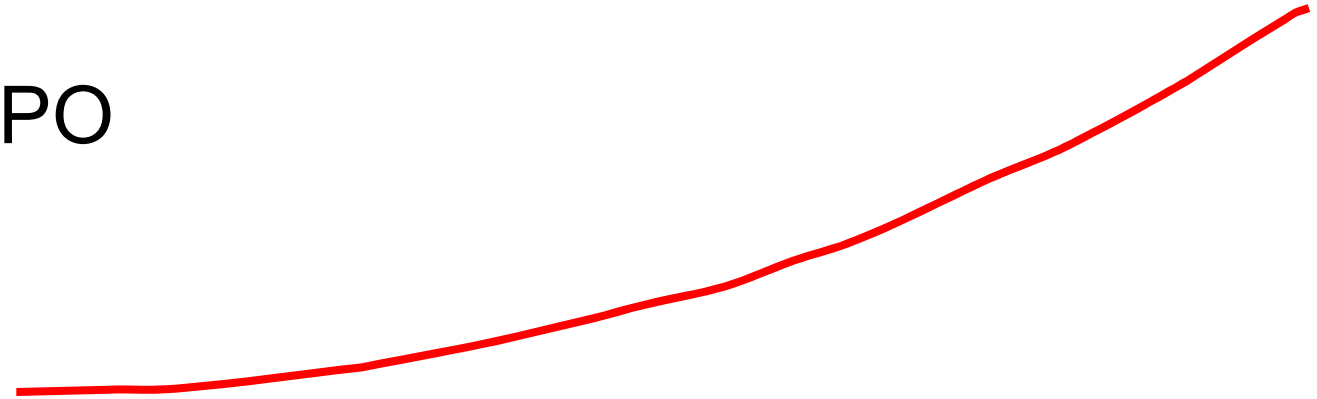
Continuations, divisionnaires

- Typologie:
  - Divisionnaire: invention différente
  - Continuation: même invention
- Utilisation
  - Optimiser la stratégie d'examen (rapidité, portée des revendications)
  - Accompagner la vie industrielle et commerciale de l'invention

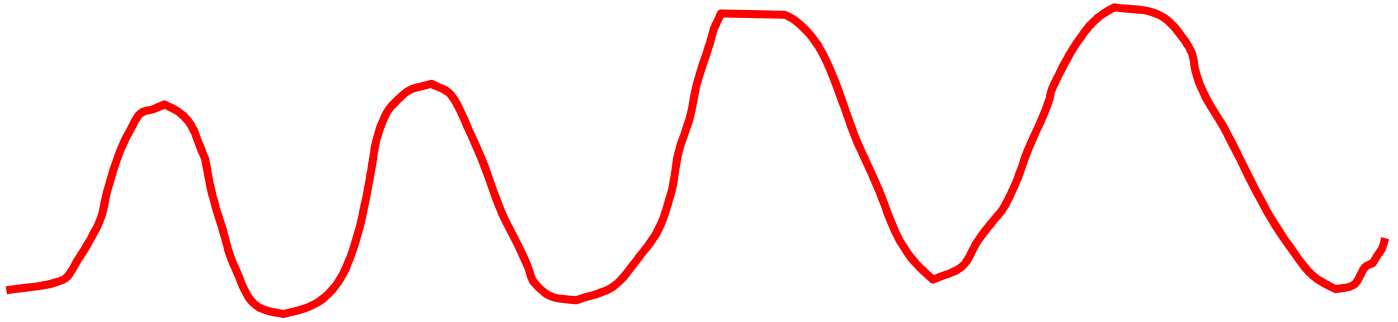
=> En pratique: bon rapport bénéfice/coût aux US

Conclusion:
Examination investment charts

- EPO



- USPTO



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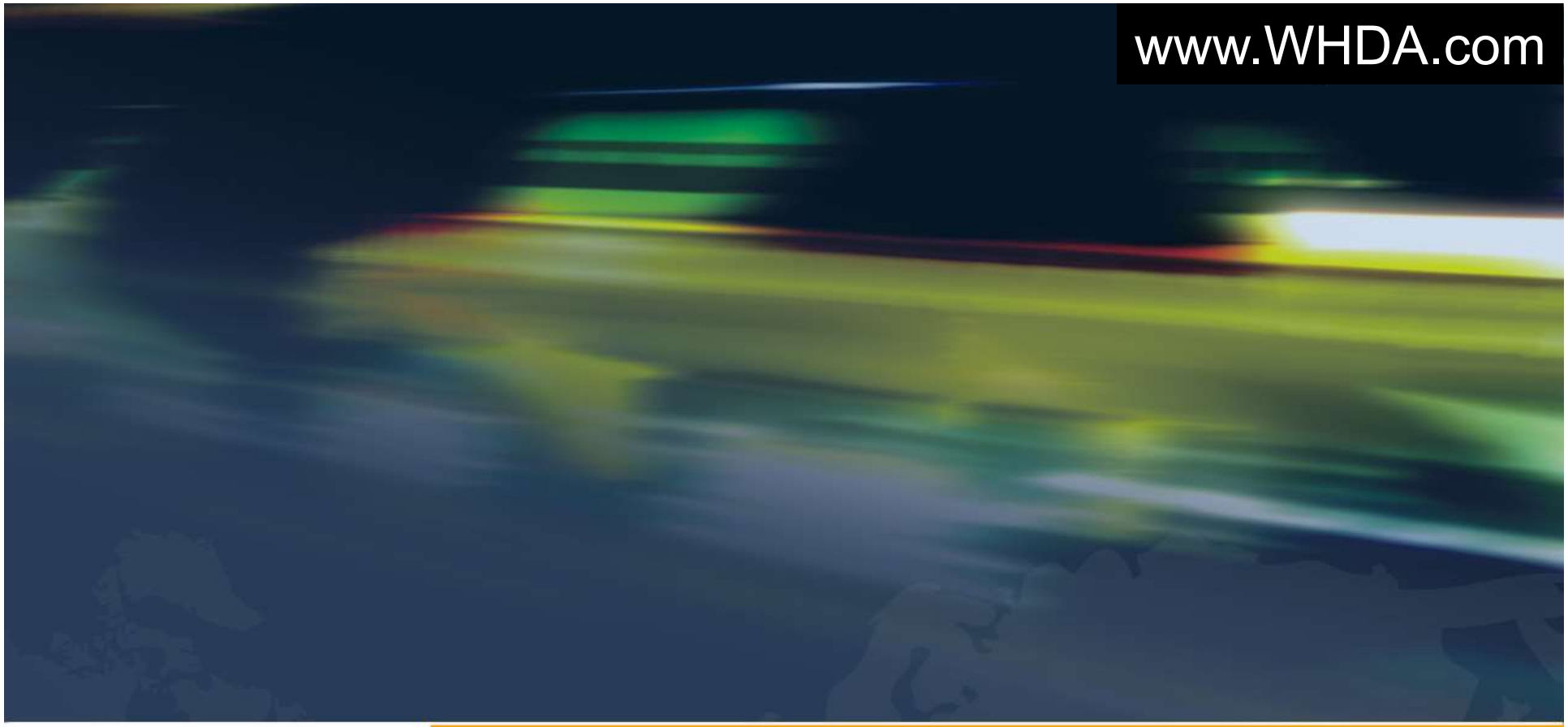

WESTERMAN HATTORI DANIELS & ADRIAN, LLP

ASPI-GRAPI Oct. 2019

Patent ineligibility (section 101): laws of nature

Nicolas E. Seckel

Intellectual Property Law

Basic diagnostic inventions are not patent-eligible

- Courts
  - Supreme Court (Mayo v. Prometheus 2012)
  - Fed. Cir. (Ariosa v. Sequenom 2015)
  - S. Ct. (Ariosa v. Sequenom, cert. denied 2016)
  - Fed. Cir. en banc order (Athena v. Mayo, en banc review denied 2019)
- USPTO
  - Vanda memo (therapies), Guidance examples
- Congress
  - Coon-Tillis draft bills

Athena v. Mayo
(Fed. Cir., en banc review denied 2019)

- 1. A method for diagnosing neurotransmission or developmental disorders related to [MuSK] in a mammal comprising the step of detecting in a bodily fluid of said mammal autoantibodies to an epitope of [MuSK].

=> Ineligible subject-matter under section 101

Athena v. Mayo
(Fed. Cir. en banc denied 2019)

- 7. A method according to claim 1, comprising
- contacting MuSK or an epitope or antigenic determinant thereof having a suitable label thereon, with said bodily fluid,
- immunoprecipitating any antibody/MuSK complex or antibody/MuSK epitope or antigenic determinant complex from said bodily fluid and
- monitoring for said label on any of said antibody/MuSK complex or antibody/MuSK epitope or antigen determinant complex,
- wherein the presence of said label is indicative of said mammal is suffering from said neurotransmission or developmental disorder related to [MuSK].

=> Ineligible subject-matter under section 101

Mayo v. Prometheus (S. Ct. 2012)

- 1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
- (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
- (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,
- wherein the level of 6-thioguanine less than about 230 pmol per 8x108 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and
- wherein the level of 6-thioguanine greater than about 400 pmol per 8x108 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

=> Ineligible subject-matter under section 101

Ariosa v. Sequenom (Fed. Cir. 2015)

- 1. A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises
- **amplifying** a paternally inherited nucleic acid from the serum or plasma sample and
- detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.

=> Ineligible subject-matter under section 101

Cleveland Clinic v. True Health (Fed. Cir. 2019) (non precedential)

- 11. A method of assessing a test subject's risk of having atherosclerotic cardiovascular disease, comprising
- comparing levels of myeloperoxidase in a bodily sample from the test subject with levels of myeloperoxidase in comparable bodily samples from control subjects diagnosed as not having the disease, said bodily sample being blood, serum, plasma, blood leukocytes selected from the group consisting of neutrophils, monocytes, sub-populations of neutrophils, and sub-populations of monocytes, or any combination thereo[f];
- wherein the levels of myeloperoxidase in the bodily [samples] from the test subject relative to the levels of [m]yeloperoxidase in the comparable bodily samples from control subjects is indicative of the extent of the test subject's risk of having atherosclerotic cardiovascular disease.

=> Ineligible subject-matter under section 101

Cleveland Clinic v. True Health (Fed. Cir. 2019) (non precedential)

- 1. A method of detecting elevated MPO mass in a patient sample comprising:
- a) obtaining a plasma sample from a human patient having atherosclerotic cardiovascular disease (CVD); and
- b) detecting elevated MPO mass in said plasma sample, as compared to a control MPO mass level from the general population or apparently healthy subjects, by **contacting** said plasma sample with anti-MPO antibodies and detecting binding between MPO in said plasma sample and said anti-MPO antibodies.

=> Ineligible subject-matter under section 101

Vanda v. West-Ward (Fed. Cir. 2018)

- A method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia, the method comprising the steps of:
- determining whether the patient is a CYP2D6 poor metabolizer by:
  - obtaining or having obtained a biological sample from the patient; and
  - performing or having performed a genotyping assay on the biological sample to determine if the patient has a CYP2D6 poor metabolizer genotype; and
- if the patient has a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount of 12 mg/day or less, and
- if the patient does not have a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount that is greater than 12 mg/day, up to 24 mg/day,
- wherein a risk of QTc prolongation for a patient having a CYP2D6 poor metabolizer genotype is lower following the internal administration of 12 mg/day or less than it would be if the iloperidone were administered in an amount of greater than 12 mg/day, up to 24 mg/day.

=> Eligible subject-matter under section 101

USPTO Vanda memo (2018)

- [I]t is not necessary for "method of treatment" claims that practically apply natural relationships to include nonroutine or unconventional steps to be considered patent eligible under 35 U.S.C. § 101

=> Why are diagnostics treated differently?

USPTO guidance example 29 (2016)

1. A method of detecting JUL-1 in a patient, said method comprising:
   a. obtaining a plasma sample from a human patient; and
   b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody.

=> Eligible subject-matter under section 101

2. A method of diagnosing julitis in a patient, said method comprising:
   a. obtaining a plasma sample from a human patient;
   b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and
   c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

=> Ineligible subject-matter under section 101

Fed. Cir. on USPTO guidance

- We have considered Example 29 and the arguments relating to it, but to the extent that Example 29–Claim 1 is analogous to the claims at issue, *Ariosa* must control. Accordingly, we decline to follow the PTO's Example 29…
  - Cleveland Clinic v. True Health (Fed. Cir., Apr 1, 2019) (non precedential)

Congress: Coon-Tillis (Apr. 2019)

- Statutorily abrogate judicially created exceptions to patent eligible subject matter in favor of exclusive statutory categories of ineligible subject matter.
- Define, in a closed list, exclusive categories of statutory subject matter which alone should not be eligible for patent protection. The sole list of exclusions might include the following categories, for example:
  - Fundamental scientific principles;
  - Products that exist solely and exclusively in nature;
  - Pure mathematical formulas;
  - Economic or commercial principles;
  - Mental activities.

Congress: Coon-Tillis (May 2019)

- No implicit or other judicially created exceptions to subject matter eligibility, including “abstract ideas,” “laws of nature,” or “natural phenomena,” shall be used to determine patent eligibility under section 101,
- and all cases establishing or interpreting those exceptions to eligibility are hereby abrogated.
- Section 100(k): The term “useful” means any invention or discovery that provides specific and practical utility in any field of technology through human intervention.

Athena v. Mayo, petition for certiorari (Oct 2, 2019)

QUESTION PRESENTED

Across eight opinions concurring or dissenting in the denial of rehearing en banc, the Federal Circuit unanimously agreed that the claims to a medical diagnostic method in this case should be patent-eligible. But the court split 7-5 on whether this Court's precedent foreclosed such a result or whether it was the Federal Circuit's own misinterpretation of that precedent that has denied patent protection to diagnostic tests. Numerous judges asked this Court to provide guidance.

The question presented is:

Whether a new and specific method of diagnosing a medical condition is patent-eligible subject matter, where the method detects a molecule never previously linked to the condition using novel man-made molecules and a series of specific chemical steps never previously performed.

Questions, comments?

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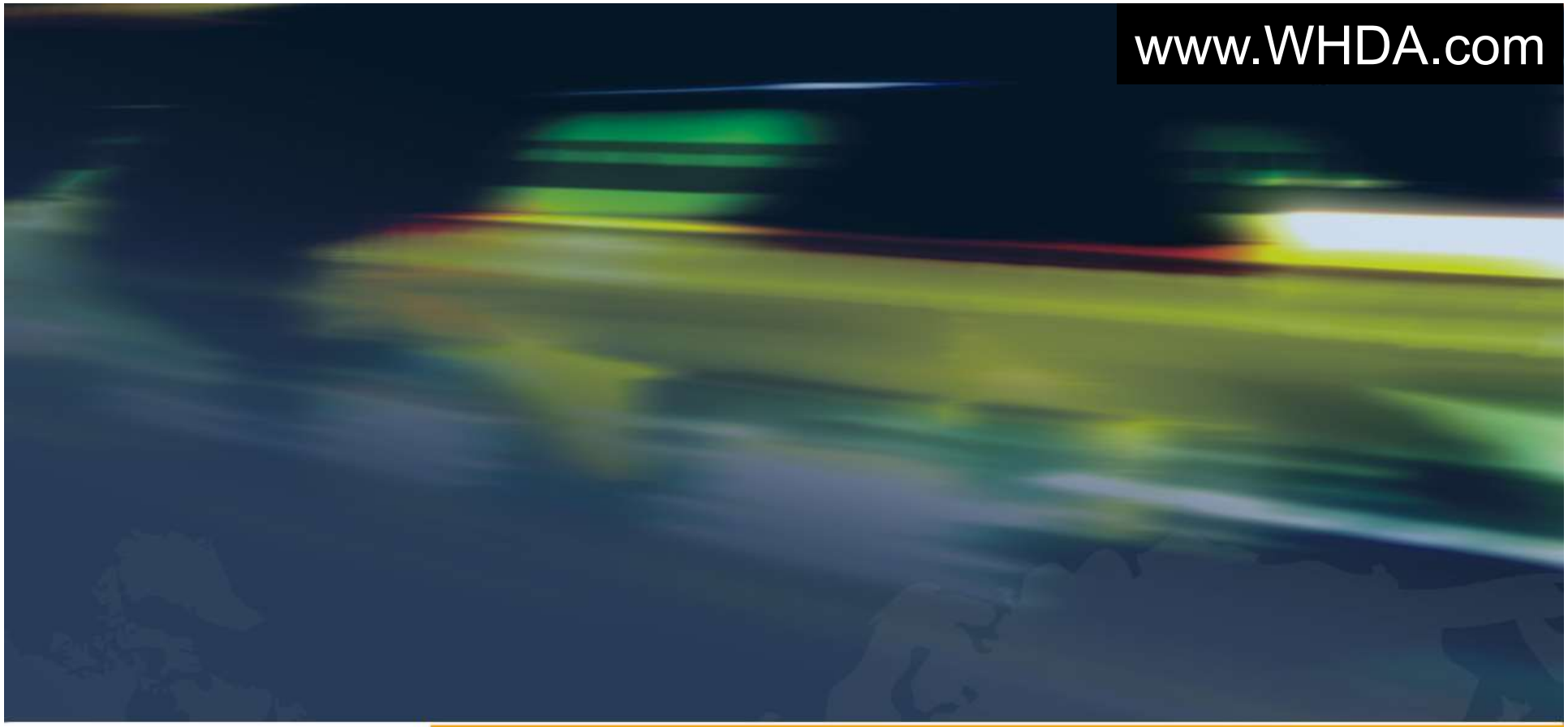

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ASPI-GRAPI Oct. 2019

Priority, provisionals representatives and assigns

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Intellectual Property Law

Priority, provisionals

- Priority in general
  - Foreign: section 119(a)
  - Continuation: section 120
  - Divisional: section 121
- Priority of US provisional
  - Section 119(e)

Paris Convention, article 4A(1)

- Celui qui aura régulièrement fait le dépôt d'une demande de brevet d'invention, d'un modèle d'utilité, d'un dessin ou modèle industriel, d'une marque de fabrique ou de commerce, dans l'un des pays de l'Union, ou son ayant cause, jouira, pour effectuer le dépôt dans les autres pays, d'un droit de priorité pendant les délais déterminés ci-après.

EPC article 87

- (1) Celui qui a régulièrement déposé, dans ou pour
- a) un Etat partie à la Convention de Paris pour la protection de la propriété industrielle ou
- b) un membre de l'Organisation mondiale du commerce, une demande de brevet d'invention, de modèle d'utilité ou de certificat d'utilité, ou son ayant cause, jouit, pour effectuer le dépôt d'une demande de brevet européen pour la même invention, d'un droit de priorité pendant un délai de douze mois à compter de la date de dépôt de la première demande.

35 USC 119(a): foreign priority

- (a) An application for patent for an invention filed in this country by any person who has, or whose legal representatives or assigns have, previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, or in a WTO member country, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within 12 months from the earliest date on which such foreign application was filed.

35 USC 120: continuation

- An application for patent for an invention disclosed… in an application previously filed in the United States… which names an inventor or joint inventor in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application…

35 USC 121: divisional

- If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions…
- [A] divisional application… shall be entitled to the benefit of the filing date of the original application

35 USC 119(e): provisional

- An application for patent filed… for an invention disclosed… in a provisional application… by an inventor or inventors named in the provisional application, shall have the same effect… as though filed on the date of the provisional application…

Claiming priority or benefit: at least one common inventor

- MPEP 213.02(II): must name the same inventor or at least one common joint inventor
- Timing
  - Foreign priority: 12 months
  - Domestic priority: co-pendency with direct parent
- Benefit claim to multiple prior application is accepted

Prior foreign application ownership: must be filed by or on behalf of inventors

- Section 119(a): the prior foreign application must have been filed by
  1) the inventors, or
  2) the inventors' representatives or assigns
- Proof of the applicant's right to file
- Constructive trust and equitable assignment theories

Prior application not filed on behalf of inventors: Boston Scientific Scimed v. Medtronic (Fed. Cir. 2007)

Chronology:

1) MinTec filed two EP applications naming Cragg and Dake as inventors
2) Cragg and Dake assigned the inventions subject of the EP applications to MinTec (contract price: $800,000+)
3) Cragg and Dake filed a US application (pre-AIA) claiming priority to the EP applications
4) Cragg and Dake assigned the US applications to Scimed
5) Interference with Fogarty et al., who had assigned to Medtronic

Boston Scientific Scimed v. Medtronic (Fed. Cir. 2007)

Holding:

- MinTec did not file the two EP applications as "representative or assign" of the inventors Cragg and Dake under section 119(a)
- The US applicants (pre-AIA: inventors Cragg and Dake) have no right to claim priority of MinTec's EP applications
- Fogarty/Medtronic wins the interference

35 USC 118 (AIA): who may file a US patent application

- The inventor
- A person to whom the inventor has assigned
- A person to whom the invention… is under an obligation to assign
- A person who otherwise shows sufficient proprietary interest

Conclusion:
⇒ One common inventor
⇒ Ownership “on behalf” of the inventor(s)

Provisional priority claiming

- US provisional:
  - No claim required
  - No examination
  - Automatically abandoned after one year

Ariosa v. Illumina (Fed. Cir. 2018) Claim support for priority of provisional

- Ariosa petitioned for IPR against Illumina's patent based on Fan reference
  - Fan is a US published nonprovisional application
  - Fan claims priority of US provisional application under 35 USC 119(e)
- PTAB (2016): Fan is not entitled to the provisional filing date because the claims of Fan published nonprovisional do not have descriptive support in the Fan provisional
- Federal Circuit (2017, rehearing denied 2018): affirmed
- Supreme Court (Jun 24, 2019): certiorari denied

Why? “Hilmer” legacy (priority as a shield, not a sword)

- As to the applicant, section 119(e): priority claim to provisional gives an effective filing date only if invention claimed in the nonprovisional have descriptive support in the provisional
- As to third parties, 119(e) + pre-AIA 102(e) or AIA 102(a)(2): since a provisional is not published, the provisional gives an effective filing date only if the claims of the published application or patent have descriptive support in the provisional

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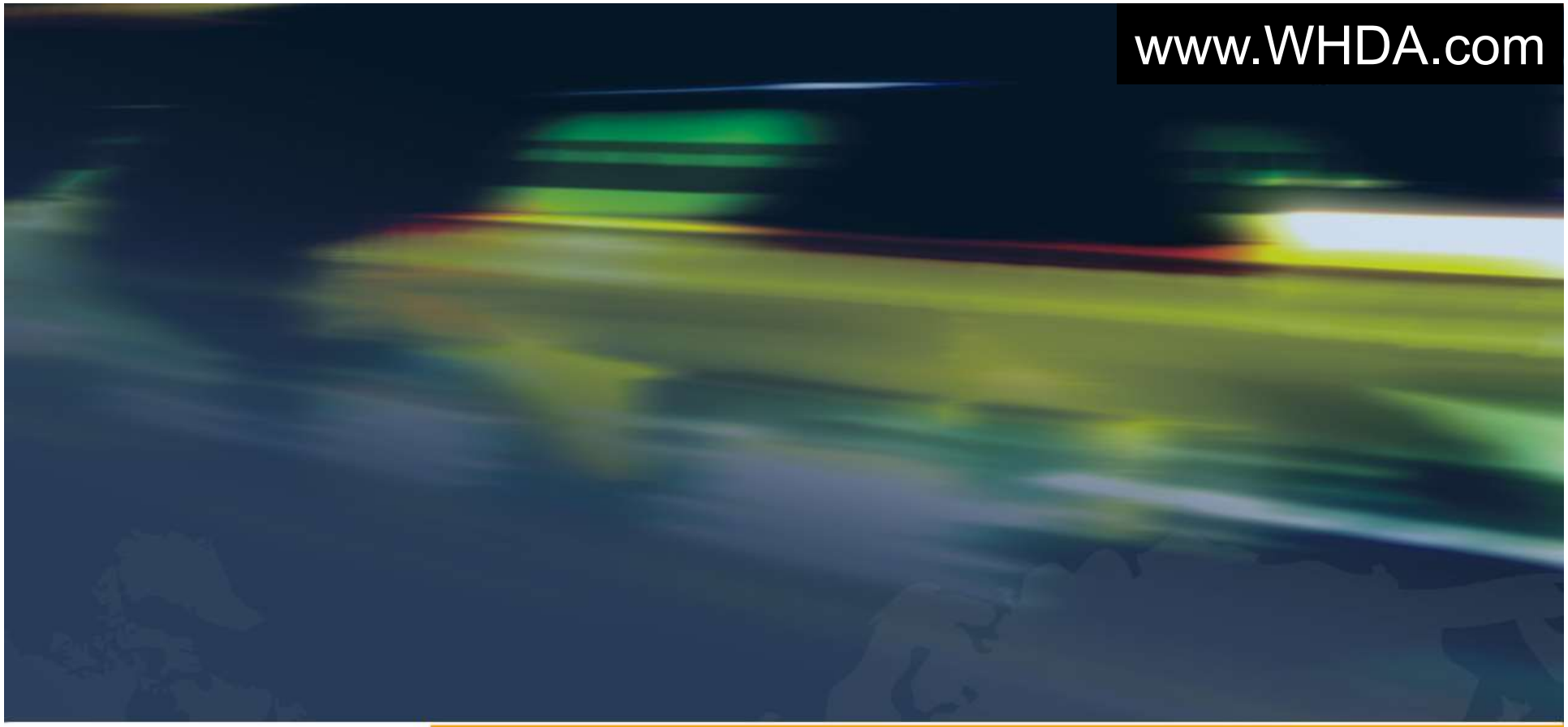

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ASPI-GRAPI Oct. 2019

Reissue: descriptive support

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Intellectual Property Law

Reissue statute

- 35 USC 251: Whenever any patent is,
- Through error,
- deemed wholly or partly inoperative or invalid,
- by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent,
- the Director shall… reissue the patent

Case No. 1:
Forum v. Flow Valve (Fed. Cir. June 17, 2019)

- Original patent claims fixture for holding a workpiece during machining
- Claims "a plurality of arbors…"
- Description: "the body member 52 has a first arbor 58 and a second arbor 60…"

Original patent

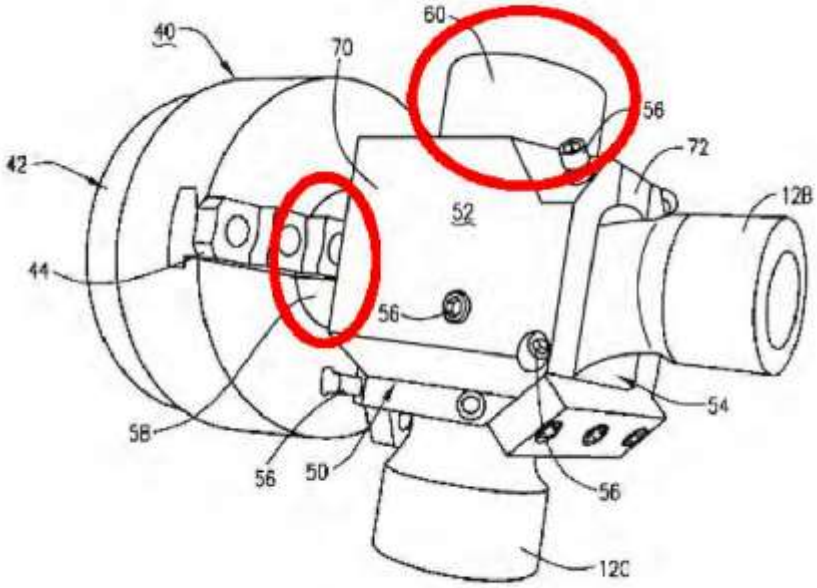


FIG. 4

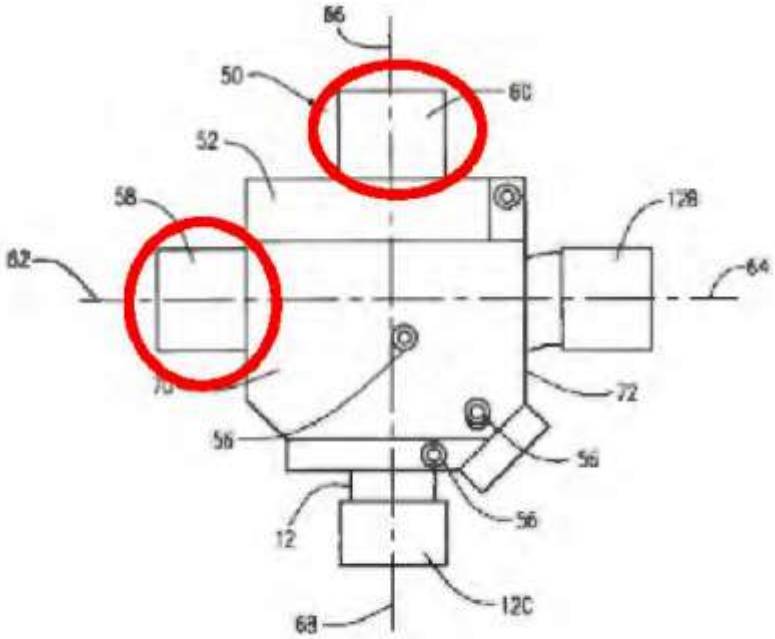


FIG. 5

Forum v. Flow Valve (Fed. Cir. 2019)

- Reissue application: “body pivotable to a second position…” (no recitation of an arbor)
- Note: a broadening reissue must be applied for within two years from original grant

Procedural history

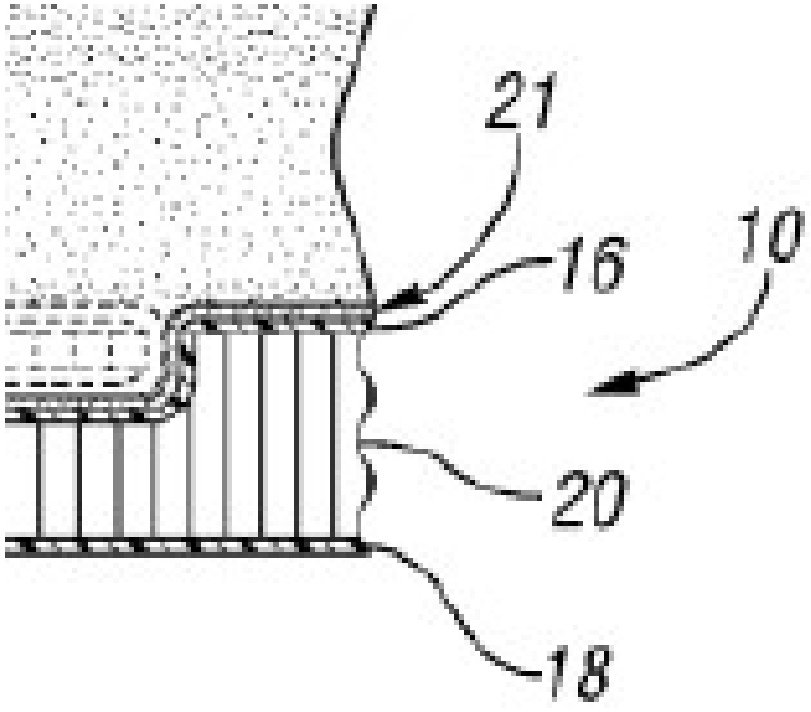
- Reissue patent granted
- Forum filed an invalidity declaratory judgment action
- District court: reissue claims invalid
  - the original patent must clearly and unequivocally disclose the newly claimed invention
- Fed. Cir.: affirmed
  - the description does not even suggest an arbor-less embodiment

Case No. 2:
In re Global IP Holdings (Fed. Cir. July 5, 2019)

- Global's '233 patent claims composite panels for vehicle floors (two skins and cellular core)
- Original patent claim: "thermoplastic skins" and "thermoplastic core"

Original patent

16, 18: skins
20: core



Case No. 2:
In re Global IP Holdings (Fed. Cir. 2019)

- Reissue application: replace “thermoplastic” by “plastic”
- Note: a broadening reissue must be applied for within two years from original grant

USPTO

- Examiner: final rejection for lack of written description (new matter)
- PTAB: affirmed

Federal Circuit

- Sufficient description "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date"
  - Predictability is a factor
  - Lack of criticality is a factor (not needed to overcome prior art)
- Vacated and remanded

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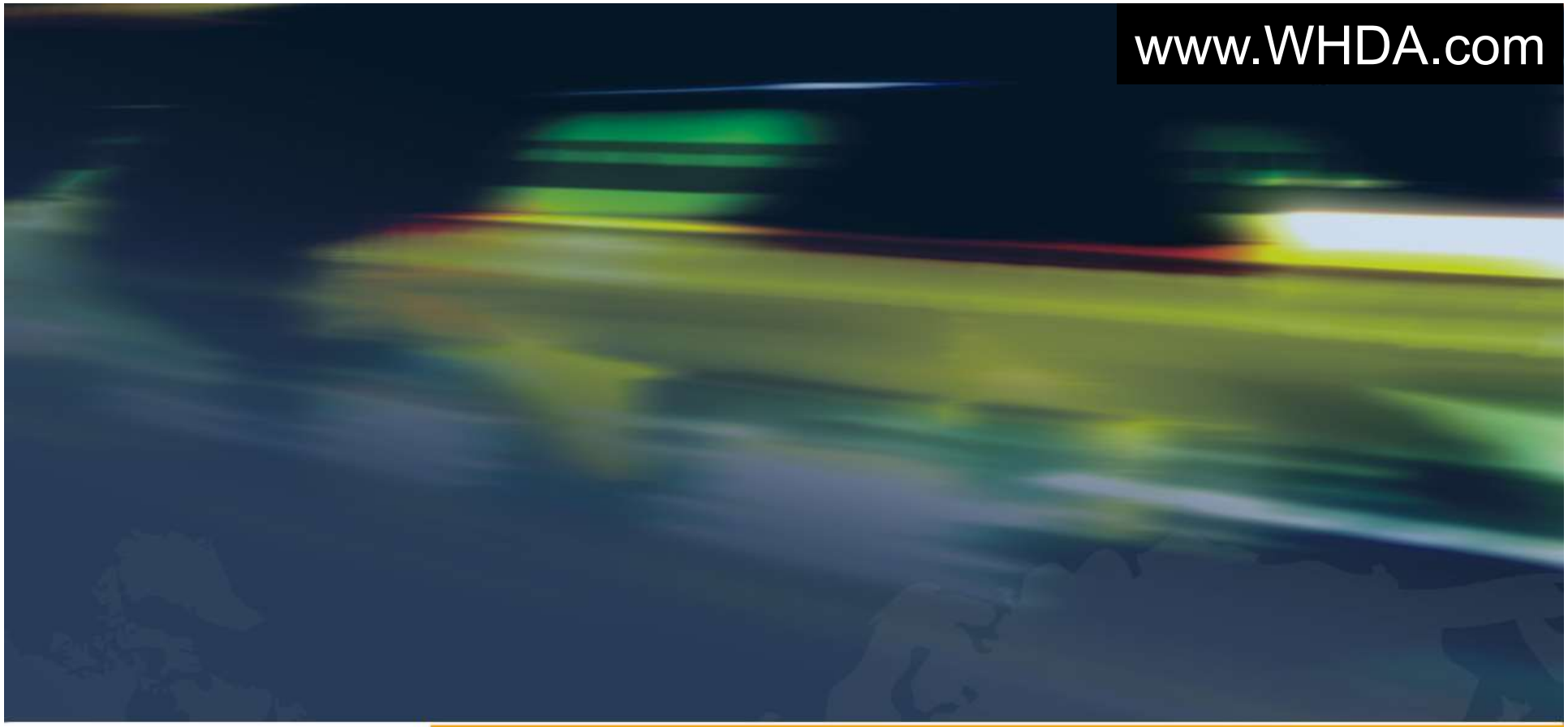

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ASPI-GRAPI Oct. 2019

Broadest reasonable interpretation (consistent with the specification)

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Intellectual Property Law

Broadest reasonable interpretation (BRI)

- MPEP 2111: During patent examination, the pending claims must be given their broadest reasonable interpretation consistent with the specification
- Objective: establish a clear record of what applicant intends to claim
- Approved by the courts (see Phillips v AWH, Fed. Cir. 2005)

Limits of BRI

- Must be consistent with ordinary and customary meaning
- Must be consistent with use in the specification and drawings
  - But no importation of limitations from the specification
- Must be consistent with any special definition or disavowal of scope in the specification
  - The definition or disavowal must be sufficiently clear (not “for example”, “preferably”, etc.)

When is BRI used?

- Initial examination
- Reissue, reexam
  - Except expired patent (the claims cannot be amended)
- Early post-grant proceedings (2012-2018, validated by S. Ct. in Cuozzo v. Lee, 2016)
  - But for petitions filed on or after Nov 11, 2018: ordinary (balanced) interpretation

Why stop using BRI in post-grant proceedings?

- Strengthen the rights of the patent owner in post-grant proceedings
- More predictability and uniformity
- Increase the importance of post-grant proceedings
  - More opportunities for issue preclusion (collateral estoppel) in subsequent district court litigation

Example: “roofing or building” material

Claim 1 is one of two independent claims. It reads:

A method of making a roofing or building cover material, which comprises treating an extended length of substrate, comprising the steps of:

***

2131 (2016). It is not reasonable to read the claims as limited to materials that either have been or are to be coated or saturated with asphalt or asphalt mix.

It is true that the preferred embodiments in the '757 patent focus on roofing materials that are or will be coated or saturated with asphalt or asphalt mix. *See, e.g.*, '757 patent, col. 7, lines 27–54. But that is not enough to narrow the claim scope in the IPR. The claims are plainly

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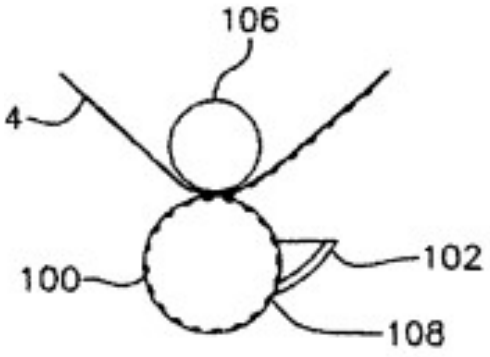
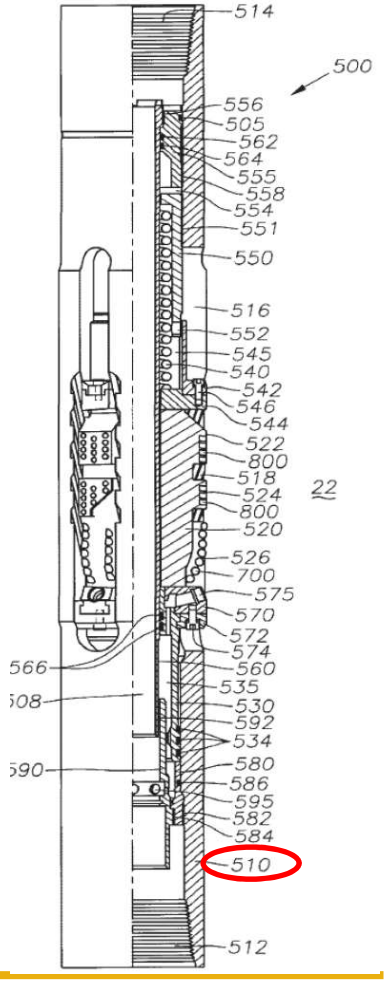


Fig. 1

Counter-example: drilling tool “body"

- Claim: drilling tool comprising a body and a pivotable arm that engages the body
- IPR petitioner: body is not specified, so it can reasonably be a mandrel and cam sleeve
- Patentee: body means “outer housing”
- CAFC: description consistently describes body, mandrel, ring, arms, etc. separately
- BRI is not “broadest not inconsistent with” the description, but “broadest consistent with” the description
- PTAB anticipation decision is reversed



In re Smith Int’l, Inc. (Fed. Cir. 2017)

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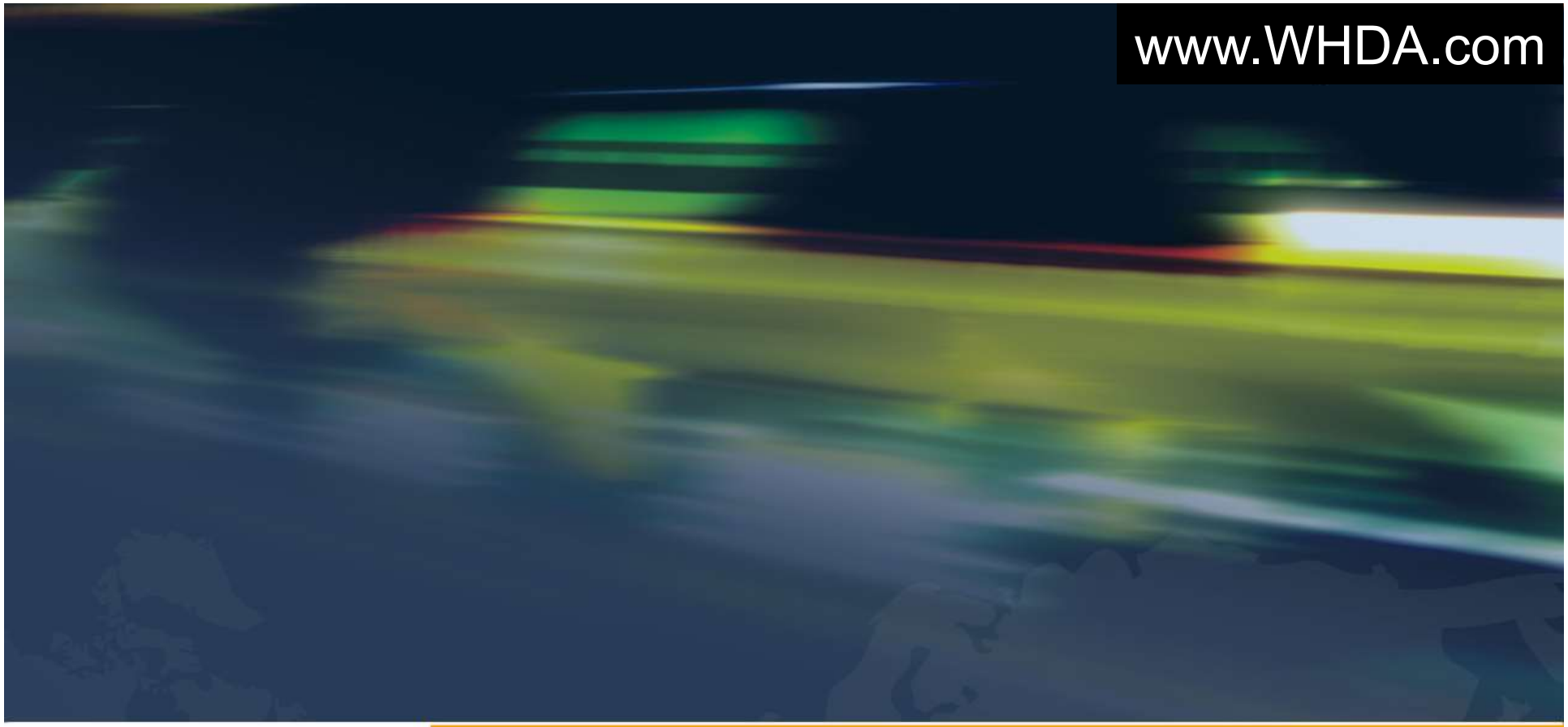

WESTERMAN HATTORI DANIELS & ADRIAN, LLP

ASPI-GRAPI Oct. 2019

"STRONGER" patent act of 2019

Nicolas E. Seckel

Intellectual Property Law

“STRONGER” patent act

- Currently a bill = a proposed law, not passed, not signed (S. 2082)
- “STRONGER”: Support Technology & Research for Our Nation’s Growth and Economic Resilience Patents Act of 2019
- Pro-patentee, anti-PTO reviews

Content

- Facilitate injunctive relief
  - Presumption of entitlement (overturn Ebay 2006)
- Improve USPTO funding
  - Stop fund diversion to Federal government's general budget
- Assist patentees in post-grant proceedings
  - Variety of procedural protections for patentees

Post-grant proceedings (PGPs)

- Ordinary and customary meaning interpretation
- Presumption of validity
- Petition only if standing for declaratory judgement (an actual controversy)
- Real party of interest is any party that makes a financial contribution
- PTAB stay if appealable final decision in district court or ITC

Prospects of statutory revisions

- Make US patents great again?
- Correct imbalances of PGP, 101?
- Improve benefit/cost of US forum?
- Affaire à suivre…

Questions, comments?

Until Oct. 31, 2019:

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From Nov. 1, 2019:

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