ASPI – Oct 6, 2020

Patent-eligibility (section 101): laws of nature

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Diagnostic inventions

- Courts
  - Supreme Court (Mayo v. Prometheus, 2012)
  - Fed. Cir. (Ariosa v. Sequenom, 2015)
    - Cert denied, S. Ct. 2016
- USPTO
  - Vanda memo on “methods of treatment” (2018)
    - Specifically distinguishes diagnostic inventions
  - Guidance examples on diagnostic inventions (2016)
    - Explicitly disregarded in Cleveland Clinic v. True Health (Fed. Cir. 2019) (non precedential)

Patent-eligibility analysis (Courts)

- Preliminary: Is the claimed invention directed to one of the four statutory patent-eligible subject matter categories: process, machine, manufacture, or composition of matter?
- Mayo/Alice step 1: Does the claim recite or involve one or more judicial exceptions?
- Mayo/Alice step 2: Does the claim as a whole recite something "significantly more" than the judicial exception(s)?

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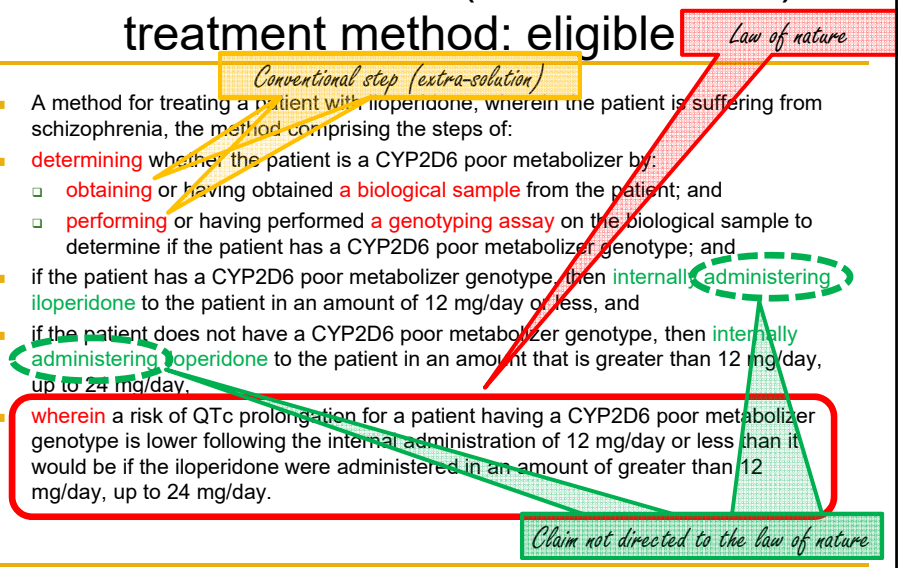
Mayo v. Prometheus (S. Ct. 2012) diagnostic method: ineligible

Conventional step (extra-solution)

Law of nature

- 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.

Vanda v. West-Ward (Fed. Cir. 2018) treatment method: eligible

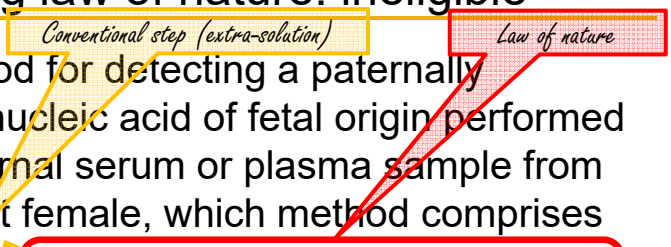


- A method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia, the method comprising the steps of:
- determining whether the patient is a CYP2D6 poor metabolizer by:
  - obtaining or having obtained a biological sample from the patient; and
  - performing or 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.

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
- Distinguished from diagnostic methods

Ariosa v. Sequenom (Fed. Cir. 2015) applying law of nature: ineligible



- 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.

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Rapid v CellzDirect (Fed. Cir. 2016): applying law of nature: eligible

- 1. A method of producing a desired preparation of multi-cryopreserved hepatocytes... comprising:
- (A) subjecting hepatocytes that have been frozen and thawed to density gradient fractionation to separate viable hepatocytes from nonviable hepatocytes,
- (B) recovering the separated viable hepatocytes, and
- (C) cryopreserving the recovered viable hepatocytes to thereby form said desired preparation without requiring a density gradient step after thawing the hepatocytes for the second time...

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Illumina v. Ariosa (Fed. Cir. March 17, 2020)

- 1. A method for preparing a deoxyribonucleic acid (DNA) fraction from a pregnant human female useful for analyzing a genetic locus involved in a fetal chromosomal aberration, comprising:
- (a) extracting DNA from a substantially cell-free sample of blood plasma or blood serum of a pregnant human female to obtain extracellular circulatory fetal and maternal DNA fragments;

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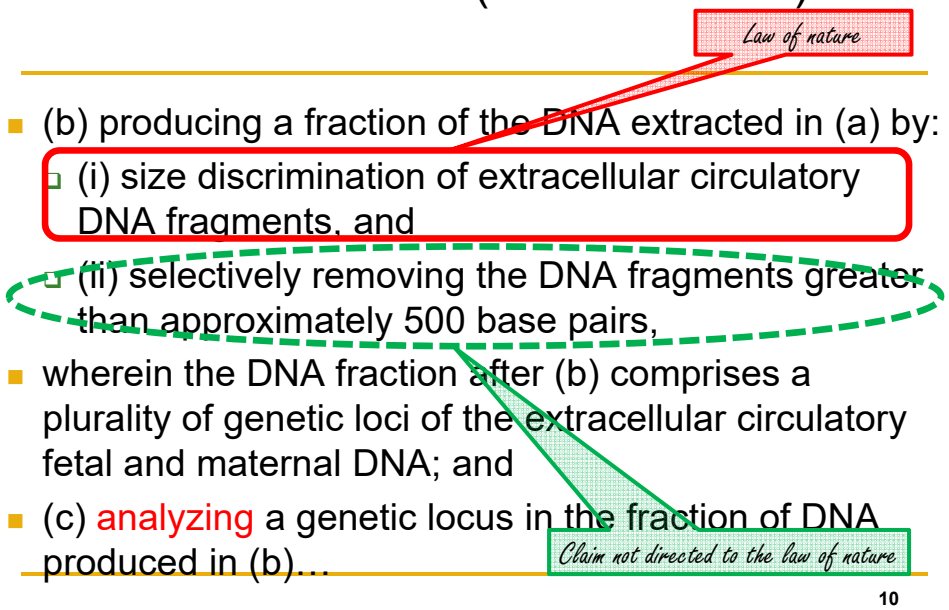
Illumina v. Ariosa (Fed. Cir. 2020):



- (b) producing a fraction of the DNA extracted in (a) by:
  - (i) size discrimination of extracellular circulatory DNA fragments, and
  - (ii) selectively removing the DNA fragments greater than approximately 500 base pairs,
- wherein the DNA fraction after (b) comprises a plurality of genetic loci of the extracellular circulatory fetal and maternal DNA; and
- (c) analyzing a genetic locus in the fraction of DNA produced in (b)…

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Illumina v. Ariosa (Fed. Cir. 2020): dissent

- 500 base pairs limit is also a law of nature
- No improvement to detection technology
- Preemption of the natural phenomenon

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Conclusion: claim drafting?

- Draft longer claims?
- File a first application with broad claims, then a second with narrower claims? (lose one, win one?)
- Identify a broad characteristic as abstract idea, then claim a narrower characteristic?
- Claim a specific action not performed in all applications of the abstract idea? (to avoid preemption?)

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Conclusion: description drafting?

- Describe a broad characteristic as abstract idea, then describe the claimed characteristic as the inventors' contribution to the art?
  - The "surprising discovery" vs. the "improvement in the technology" (Mayo/Alice step 1)
- Differentiate the claimed characteristic from simple application of conventional technology?
  - To avoid "high level of generality" and "preemption" (Mayo/Alice step 2)

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Questions, comments?

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Claim interpretation: "configured to" v. "designed to" v. "adapted to" v. "capable of"…

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Nevro v. Boston (Fed. Cir. Apr 9, 2020): "configured to"

1. A spinal cord modulation system comprising:

a signal generator configured to generate a therapy signal having a frequency of 10 kHz, an amplitude up to 6 mA, and pluses having a pulse width between 30 microseconds and 35 microseconds; and

an implantable signal delivery device electrically coupleable to the signal generator and configured to be implanted within a patient's epidural space to deliver the therapy signal from the signal generator the patient's spinal cord.

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Nevro v. Boston: proposed interpretations

- Nevro (patentee): "configured to" = "designed to"
  - The description states that the system is "configured and programmed"
- Boston (accused infringer): "configured to" = "programmed to"
  - Does not need further configuration

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Nevro v. Boston: District Court's decision

- Indefinite
- Two equally possible interpretations:
  - Hardware and software have the capacity to generate the signals (but may require software programming)
  - The generator is programmed to generate the signals

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Nevro v. Boston: Fed. Cir. decision

- Not indefinite
  - Several "plausible constructions" do not exclude "reasonable certainty" under Nautilus v. Biosig (S.Ct. 2014)
- Meaning of "configured to" is "**programmed to** generate"
  - Claim language: recites a specific signal
    - Other method claims have a "step of configuring"
  - Description: focuses on setting the parameters
    - The system is "configured and programmed", not the signal generator
  - Prosecution history: applicant distinguished prior art that did not teach the programmed generator
    - "the specific combination of therapy signal parameters in the claimed ranges"

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Bonus issue (in other claims): "means to generate"

- Interpretation:
  - Corresponding structures in the description and their equivalents (35 U.S.C. 112(f))
- Not indefinite:
  - Corresponding structure is the "signal generator"
  - No requirement of an algorithm (only for general-purpose computer)
  - The description explains how to configure the parameters to obtain the desired signals

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Bonus case: Presidio v. AVX (Fed. Cir. Sep 23, 2020) (non-precedential): "adapted to"

- Claim: "*adapted to be positioned substantially parallel* to a major surface of a circuit board"
- Patentee: "adapted to" = "capable of being"
- Accused infringer: "adapted to" = "designed to be (= made to, designed to, or configured to)
- Fed. Cir. (non-precedential): "adapted to" means "**made, designed, configured**" if the description discloses structural features to make suitable for a claimed function

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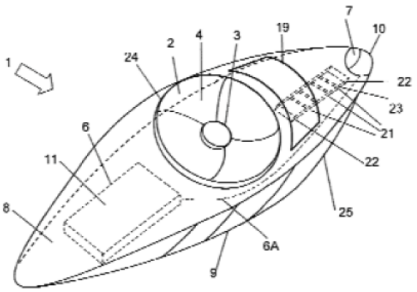
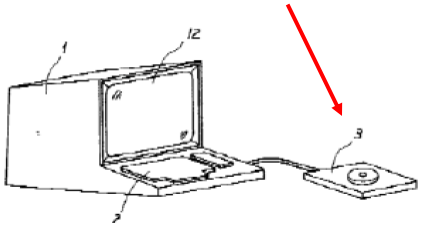
In re: Man Machine Interface Tech. (Fed .Cir. 2016) (cited in Presidio)

- Claim: remote control with body "adapted to be held by the human hand"



Cited art:



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Conclusion

- Choice of words in the claim are important
- Choice of embodiments in the description and drawings is important
- In the description, describe what is shown in the drawings
  - For example, as a non-limitative illustration, in some embodiments…

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PTAB post-grant proceedings: updates

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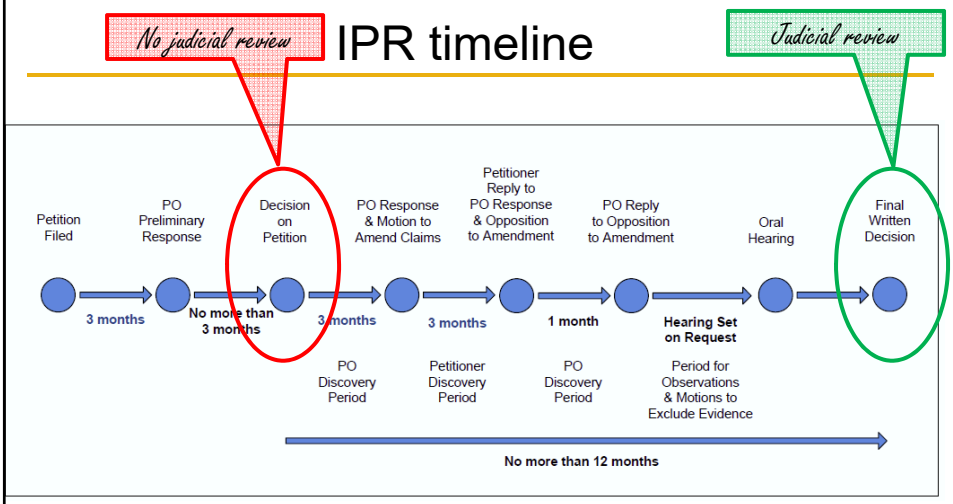
PGP (Post-Grant Proceedings) updates

- No judicial review of PTAB's decision to institute
  - Thryv v. Click-To-Call (S. Ct. Apr 22, 2020)
- No discretion to join new claims by the same petitioner to an already-instituted IPR
  - Facebook v. Windy City (Fed. Cir. Mar 18, 2020, modified Sep. 4, 2020)
- IPR amendments subjected to full patentability analysis, including eligibility and definiteness
  - Uniloc v. Hulu (Fed. Cir. Jul 22, 2020)

IPR timeline



Previous decision: Cuozzo v. Lee (S.Ct. 2016)

- 35 USC 314(d): PTAB institution decision is "final and nonappealable"
- S.Ct. (2016): prohibition of judicial review limited to issues "**closely tied to the application and interpretation of statutes** related to [the institution decision]"
  - Example: reasonable likelihood of unpatentability of a claim in view of the petition
  - Counter-example: constitutional issue

This year's decision: Thryv v. Click-To-Call

- 35 USC 315(b): IPR petition must be filed **within one year of service** of an infringement lawsuit
- 2001: Thryv sued on the patent, but **lawsuit is voluntarily dismissed without prejudice**
- 2012: Thryv sued by Click-To-Call on the same patent, petitions for PTAB institutes IPR,
- Trial instituted: PTAB considers that a voluntarily dismissed suit does not trigger the one-year time bar
- PTAB final decision: cancels some claims
- Click-To-Call appeals to Fed. Cir.
- Fed. Cir. reverses: section 315(b) has no exception

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Thryv v. Click-To-Call (S.Ct. Apr 22, 2020)

- Fed. Cir. Reversed
  - Reinstates the PTAB decision to institute the IPR
- Institution decision by PTO is not appealable
  - IPR prioritizes patentability review over timeliness ((314(d) > 315(b))
  - Even if the PTO's view was wrong (as admitted by the PTO in S.Ct. briefing)

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Facebook v. Windy City
one-year time bar / forum shopping

Starts one-year time bar to file IPR

- Jun 2, 2015: Windy City sues Facebook for patent infringement in WD North Carolina
- Jun 3, 2015: complaint served to Facebook
- Jul 24, 2015: Facebook files motion to dismiss and motion to transfer to ND Cal.
- Mar 16, 2016: motion to transfer granted
- Apr 6, 2016: scheduling order, scheduling conference set Jul 7, 2016

Facebook v. Windy City
one-year time bar / forum shopping

One-year time bar to file IPR ends

- Jun 3, 2016: Facebook files IPR listing some claims of the patents
- Oct 19, 2016: Windy City files its infringement contentions identifying specific claims
  - Some listed in the IPR, others not listed in the IPR
- ? Jan 2017: Facebook files another IPR listing more claims of the patents, requesting joinder to the prior IPR

Facebook v. Windy City
one-year time bar / forum shopping

- 35 USC 315(c): PTAB is allowed to join "any person" to an instituted IPR
- PTAB: joinder accepted
- Fed. Cir. Mar 18, 2020: reversed
  - "any person" cannot be the same petitioner

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Facebook v. Windy City
one-year time bar / forum shopping

- Thryv v. Click-to-Call (S.Ct. Apr 22, 2020):
  - PTO's wrong interpretation of dismissal without prejudice is not appealable
  - Prioritize patentability review over timeliness?
- Fed. Cir. Sep 4, 2020: modified opinion in Facebook v. Windy City
  - S.Ct. decision in Thryv about non-appealability of PTAB institution decision does not affect this case
  - PTAB has discretion to join any new party, but no discretion to join new issues by the same party

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Uniloc v. Hulu (Fed. Cir. Jul 22, 2020) proposed amended claims in IPR

Concurrent District Court litigation and IPR

- District Court:
  - Uniloc's claims held invalid under 101
- Fed. Cir.: affirmed
- IPR final decision:
  - Uniloc's **proposed substitute claims** refused as being unpatentable under 101
- Appeal by Uniloc:
  - Proposed amended claims should only be subjected to anticipation and obviousness analysis

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Uniloc v. Hulu (Fed. Cir. Jul 22, 2020) proposed amended claims in IPR

- Fed. Cir.: PTAB affirmed
  - Proposed amended claims in IPR must be subjected to full patentability analysis including eligibility (101) and definiteness (112)
- Dissent: decision is correct, but not appropriate because the issue was moot after invalidation of all claims
  - Citation: the majority "declares that dead patents can walk, at least as far as needed to die again on the same § 101 sword that killed it two years ago"

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Bonus case: Arthrex v. Smith & Nephew (Fed. Cir. Oct 31, 2019)

- Arthrex lost IPR, appealed on the ground that appointment of PTAB judges is unconstitutional
- Fed. Cir.: PTAB judges are "principal officers" so they should be appointed by the President and confirmed by the Senate (Const. Art. 2 Cl. 2)
  - Main reason: cannot be removed without cause
- Reversed and remanded to the PTAB

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Arthrex v. Smith & Nephew (Fed. Cir. Oct 31, 2019)

- Fed. Cir. bonus 1: removing the prohibition of "removal without cause" makes PTAB judges "inferior officers"
  - For future decisions, PTAB judges are now correctly appointed by the Secretary of Commerce (supervisor of the PTO)
- Fed. Cir. bonus 2: new status applies only prospectively,
  - Many cases (more than 100) must be remanded and re-decided
- Bonus 3: Supreme Court challenge?
  - Certiorari petitions pending
  - The UPTO has stayed the cases remanded under Arthrex

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~~Conclusion~~ Obituary: CBM petitions

- Covered Business Method (CBM) reviews
  - Financial inventions except if technological
  - Full patentability review: 101, 112, 102, 103
    - Like post-grant reviews (PGR)
  - No 9-month time limit from grant
    - Like inter partes reviews (IPR)
- Petitions had to be filed by Sep 15, 2020

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Avoiding double patenting: Contractual refinements

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Reminder: statutory double patenting

- Statutory double patenting: prohibition against two patents by the same inventor claiming the same invention
  - 35 U.S.C. 101: Whoever invents or discovers any new and useful process… may obtain a patent therefor…
- If different inventive entities and different owners:
  - First-to-invent system: interference
  - First-to-file system: earliest effective filing date

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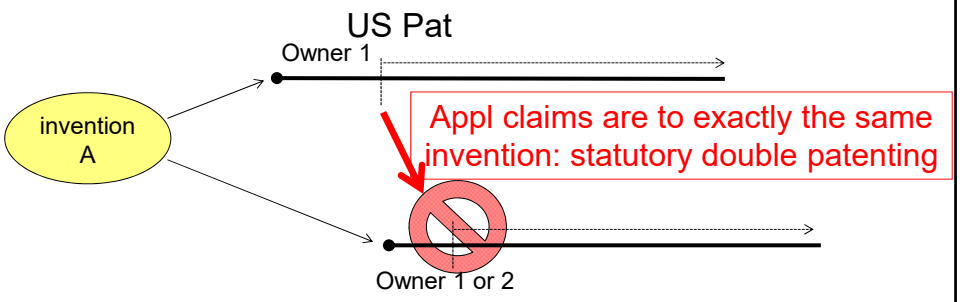
Statutory double patenting



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Reminder: judicially-created double patenting

- Judicially-created double patenting: prohibition against two patents by the same inventor or the same owner claiming inventions that are obvious one over the other
- Reasons:
  1) Potential extension of the right to exclude
  2) Potential right to exclude owned by two different parties (if one of the patents is assigned to another party)
- Resolution: Terminal Disclaimer

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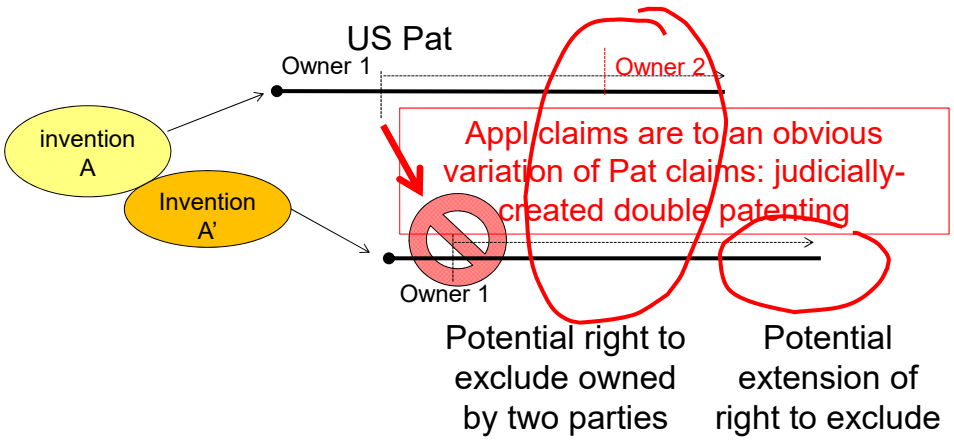
Judicially-created double patenting



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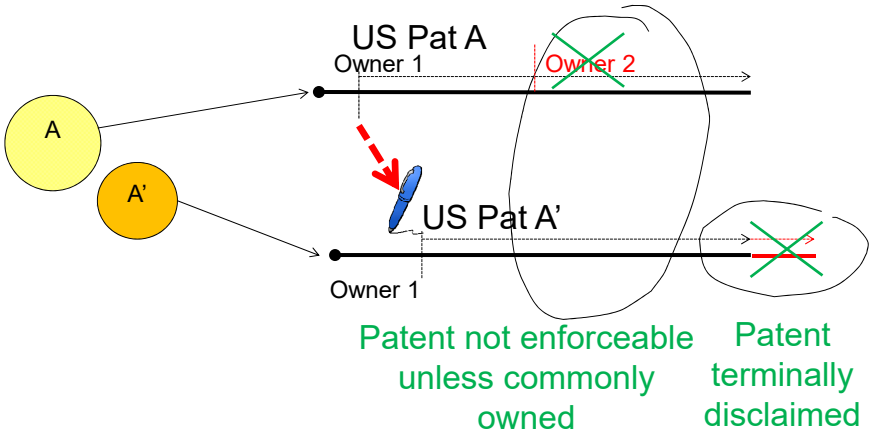
Terminal Disclaimer



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Terminal Disclaimer (USPTO form)

TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT

Docket Number (Optional)

In re Application of:

Application No.:

Filed:

For:

The owner*, _____, of _____ percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term **prior patent** No. _____ as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said **prior patent** is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

expires for failure to pay a maintenance fee;
is held unenforceable;
is found invalid by a court of competent jurisdiction;
is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
has all claims canceled by a reexamination certificate;
is reissued; or
is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

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Immunex v. Sandoz

- 1989: first Immunex patent application covering etanercept
- 1990: first Roche patent application
- **8 June 1995: US shifts to 20-year-from-filing patent term**
- 1997: first Immunex patent issues
- 1998: FDA approval of Enbrel® to Immunex
- 1999: Immunex takes Roche license
- **2004: Immunex-Roche "Accord & Satisfaction"**
  - **Immunex takes over prosecution of Roche applications**
- 2009: last Immunex patent issues
- 2012: last Roche patent issue
- 2016: Immunex and Roche sue Sandoz for patent infringement
  - Sandoz defense: **double patenting** because Immunex controlled prosecution of the Roche applications

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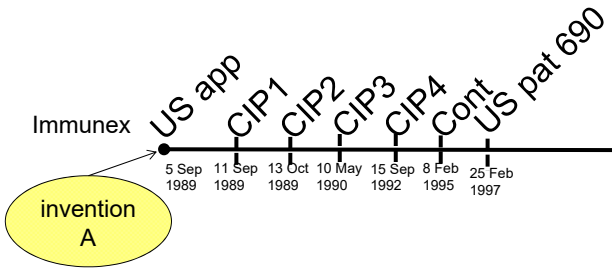
Immunex: 690 patent



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United States Patent [19]

Jacobs et al.

[11] **Patent Number: 5,605,690**

[45] **Date of Patent: Feb. 25, 1997**

+17yrs= Feb. 25, 2014

[54] **METHODS OF LOWERING ACTIVE TNF-α LEVELS IN MAMMALS USING TUMOR NECROSIS FACTOR RECEPTOR**

[75] Inventors: **Cindy A. Jacobs**; **Craig A. Smith**, both of Seattle, Wash.

[73] Assignee: **Immunex Corporation**, Seattle, Wash.

[21] Appl. No.: **385,229**

[22] Filed: **Feb. 8, 1995** (before June 8, 1995)

Related U.S. Application Data

[63] Continuation of Ser. No. 946,236, Sep. 15, 1992, abandoned, which is a continuation-in-part of Ser. No. 523,635, May 10, 1990, Pat. No. 5,395,760, which is a continuation-in-part of Ser. No. 421,417, Oct. 13, 1989, abandoned, which is a continuation-in-part of Ser. No. 405,370, Sep. 11, 1989, abandoned, which is a continuation-in-part of Ser. No. 403,241, Sep. 5, 1989, abandoned.

Smith et al, Science, 248: 1019–1023, 1990 "A Receptor for TNF defines an Unusual Family of Cellular & Viral Proteins".

Bloom, J. Clin. Invest., 91: 1265–1266 (1993) "The Power of Negative Thinking".

Pennica et al., "Human tumour necrosis factor: precursor structure, expression and homology to lymphotoxin," *Nature* 312: 724 (1984).

Gray et al., "Cloning and expression of cDNA for human lymphotoxin, a lymphokine with tumour necrosis activity," *Nature* 312: 721 (1984).

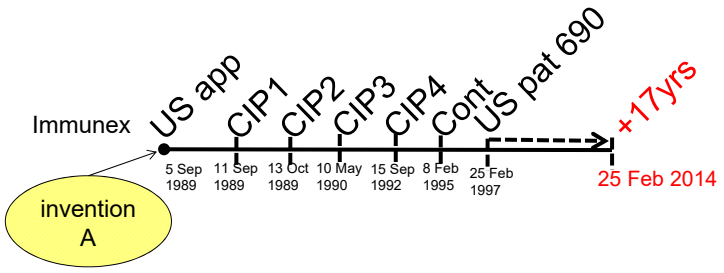
Baglioni et al., "Binding of Human Tumor Necrosis Factor to High Affinity Receptors on HeLa and Lymphoblastoid Cells Sensitive to Growth Inhibition," *J. Biol. Chem.* 260:13395 (1985).

Aggarwall et al., "Characterization of receptors for human tumour necrosis factor and their regulation by γ-interferon," *Nature* 318:665 (1985).

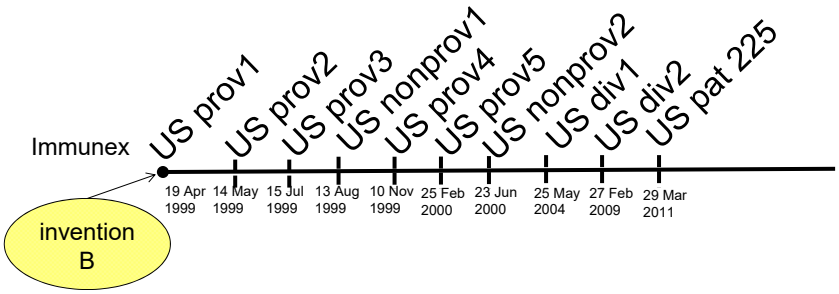
Yoshie et al., "Binding and Crosslinking of ^{125}I–Labeled Recombinant Human Tumor Necrosis Factor to Cell Surface Receptors," *J. Biochem.* 100:531 (1986).

50

Immunex: 690 patent



Immunex: 225 patent



US007915225B2

(12) **United States Patent**
Finck

(10) **Patent No.: US 7,915,225 B2**
(45) **Date of Patent: *Mar. 29, 2011**

(54) **SOLUBLE TUMOR NECROSIS FACTOR RECEPTOR TREATMENT OF MEDICAL DISORDERS**

(75) Inventor: **Barbara K Finck**, Mercer Island, WA (US)

(73) Assignee: **Immunex Corporation**, Thousand Oaks, 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.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **12/394,962**

(22) Filed: **Feb. 27, 2009**

(65) **Prior Publication Data**

US 2009/0163424 A1 Jun. 25, 2009

Related U.S. Application Data

(60) Division of application No. 10/853,479, filed on May 25, 2004, now abandoned, which is a division of application No. 09/602,351, filed on Jun. 23, 2000, now abandoned, and a continuation-in-part of application No. 09/373,828, filed on Aug. 13, 1999, now abandoned.

(60) Provisional application No. 60/164,676, filed on Nov. 10, 1999, provisional application No. 60/184,864, filed on Feb. 25, 2000, provisional application No. 60/130,074, filed on Apr. 19, 1999, provisional application No. 60/134,320, filed on May 14, 1999, provisional application No. 60/143,959, filed on Jul. 15, 1999, provisional application No. 60/148,234, filed on Aug. 11, 1999.

(51) **Int. Cl.**

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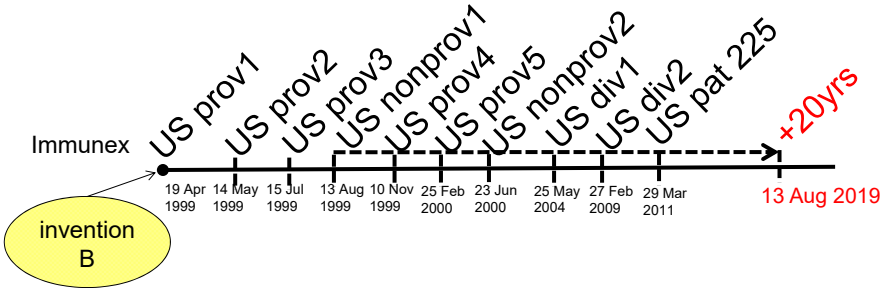
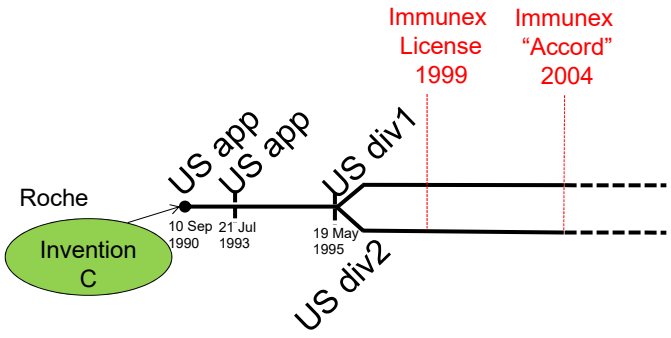
+20yrs = Aug. 13, 2019

Immunex: 225 patent



Meanwhile…
Roche patent applications



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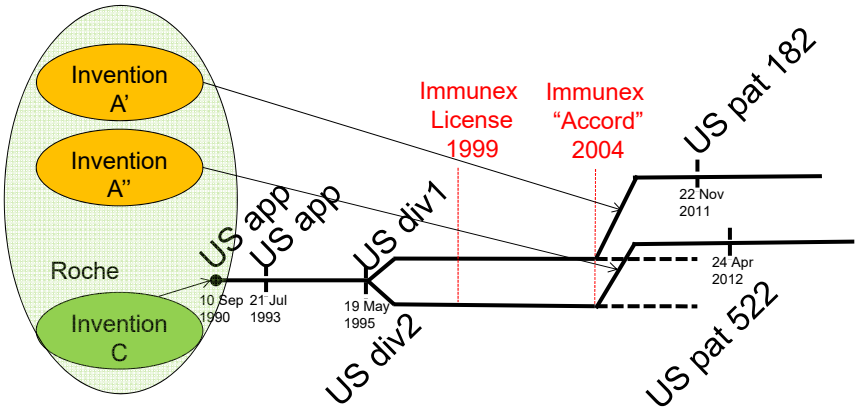
Roche patents
(Immunex prosecution after 2004)



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US008063182B1

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

(10) **Patent No.: US 8,063,182 B1**
(45) **Date of Patent: Nov. 22, 2011**

+17yrs= Nov 22, 2028

(54) **HUMAN TNF RECEPTOR FUSION PROTEIN**

(75) Inventors: **Manfred Brockhaus**, Bettingen (CH); **Reiner Gentz**, Rheinfelden (DE); **Dembic Zlatko**, Basel (CH); **Werner Lesslauer**, Basel (CH); **Hansruedi Lotscher**, Mohlin (CH); **Ernst-Jurgen Schlaeger**, Efringen-Kirchen (DE)

(73) Assignee: **Hoffman-LaRoche Inc.**, Nutley, NJ (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.: **08/444,790**

(before June 8, 1995)

(22) Filed: **May 19, 1995**

Related U.S. Application Data

(60) Division of application No. 08/095,640, filed on Jul. 21, 1993, now Pat. No. 5,610,279, which is a continuation of application No. 07/580,013, filed on Sep. 10, 1990, now abandoned.

5,118,500	A		6/1992	Hanel et al.
5,136,021	A		8/1992	Dembinski et al.
5,155,027	A		10/1992	Sledziewski et al.
5,211,945	A		5/1993	Wallach et al.
5,223,395	A		6/1993	Gero
5,225,538	A		7/1993	Capon et al.
5,258,498	A		11/1993	Huston et al.
5,264,416	A		11/1993	Park et al.
5,270,038	A		12/1993	Klimpel et al.
5,336,603	A		8/1994	Capon et al.
5,344,915	A	*	9/1994	LeMaire et al. 530/350
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5,447,851	A		9/1995	Beutler et al.
5,455,165	A		10/1995	Capon et al.
5,478,925	A		12/1995	Wallach et al.
5,512,544	A		4/1996	Wallach et al.
5,514,582	A		5/1996	Capon et al.
5,599,905	A		2/1997	Mosley et al.
5,605,690	A		2/1997	Jacobs et al.
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AU 58976 1/1991

(Continued)

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US008163522B1

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

(10) **Patent No.: US 8,163,522 B1**
(45) **Date of Patent: Apr. 24, 2012**

+17yrs= Apr 24, 2029

(54) **HUMAN TNF RECEPTOR**

(75) Inventors: **Manfred Brockhaus**, Bettingen (CH); **Reiner Gentz**, Rheinfelden (DE); **Dembic Zlatko**, Basel (CH); **Werner Lesslauer**, Basel (CH); **Hansruedi Lotscher**, Mohlin (CH); **Ernst-Jurgen Schlaeger**, Efringen-Kirchen (DE)

(73) Assignee: **Hoffman-LaRoche Inc.**, Nutley, NJ (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.: **08/444,791**

(before June 8, 1995)

(22) Filed: **May 19, 1995**

Related U.S. Application Data

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5,136,021	A		8/1992	Dembinski et al.
5,155,027	A		10/1992	Sledziewski et al.
5,211,945	A		5/1993	Wallach et al.
5,223,395	A		6/1993	Gero
5,225,538	A		7/1993	Capon et al.
5,258,498	A		11/1993	Huston et al.
5,264,416	A		11/1993	Park et al.
5,270,038	A		12/1993	Klimpel et al.
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5,599,905	A		2/1997	Mosley et al.
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AU 58976 1/1991

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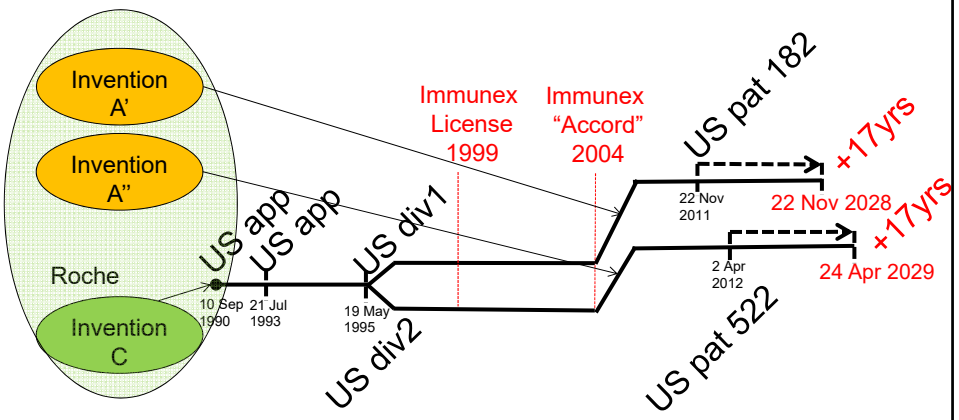
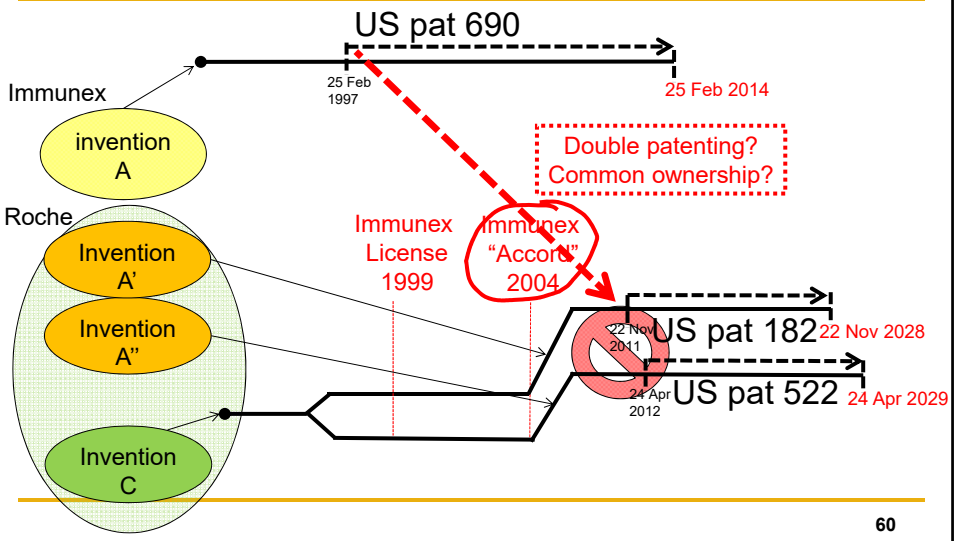
Roche patents
(Immunex prosecution)



Roche patents:
Sandoz double patenting defense



Immunex-Roche “Accord & Satisfaction”: rights to Immunex

- Paid-up, irrevocable, **exclusive license**
  - Exclusive right to make, have made, use, sell, offer for sale, import
  - Exclusive right to sublicense
  - Exclusive right to prosecute applications in the patent family
- First right to rectify suspected infringement at its sole expense, sole control (lawsuit, sublicense), and sole benefit (damages, royalties)
- **Right to purchase the patents from Roche for $50K**
- **Right to approve an assignment of the contract by Roche**

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Immunex-Roche “Accord & Satisfaction”: rights to Roche

- Right to conduct internal research (non-clinical)
- **Right to sue if Immunex does not, 180 days after written notification from Roche**, at its sole expense, sole control, sole benefit
- **Right to approve an assignment of the contract by Immunex**

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Immunex v. Sandoz (Fed. Cir. Jul 1, 2020)

- Double patenting is equitable:
  - Avoid gamesmanship in prosecution to extend patent term
  - But limited scope to avoid chilling effect on collaboration and licensing
- Common ownership of "all substantial rights" is "informative":
  - Enforcement (right to sue)
  - Alienation (right to license and assign)

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Immunex v. Sandoz (Fed. Cir. Jul 1, 2020)

- Accord & Satisfaction did not assign all substantial rights to Immunex
  - Right to sue: Roche's right to sue is conditional, but absolute after the 180-day notification time period (Immunex can no longer grant a sublicense)
    - In a previous case Speedplay v. Bebop (Fed. Cir. 2000), the patentee had transferred all substantial rights because the licensee could sublicense even after initiation of a lawsuit
  - Right to assign: Roche can veto an assignment of rights by Immunex to a third party

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Immunex v. Sandoz (Fed. Cir. Jul 1, 2020)

- Dissent: Roche's rights are "illusory"
  - Immunex can purchase or sublicense the patent upon notification by Roche
    - Price of purchase option is minimal ($50K compared to "tens of millions" for overall transaction
  - Roche offered to assign the patents, but Immunex refused
    - Shows the parties' intention

Conclusion

- Smart contract drafting
  - Full purchase/sublicense option, but expiration 180 days after notification
  - Avoids full transfer of a substantial ownership right
- Smart gamesmanship
  - Does not promote predictability of the double patenting doctrine

More generic conclusion on double patenting

- Think before signing (a Terminal Disclaimer)
- Options in prosecution:
  - Traversing the double patenting rejection on the merits
  - Adjusting claim scope to avoid obviousness over the claims of the other application/patent

Questions, comments?

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ASPI – Oct 6, 2020

Antitrust and standard-essential patents (SEPs)

Nicolas Seckel

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SEP vocabulary

- Standard-related acronyms:
  - SSO (standard-setting organizations)
  - SEP (standard-essential patents)
  - FRAND licenses (fair, reasonable and non-discriminatory)
- Actors: SSO participants
  - SEP owners (practising, non-practising, patent assertion entities…)
  - Implementers (component manufacturers, OEMs = original equipment manufacturers…)

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Legal framework

- Contract law
- Patent law
- Unfair competition
- **Antitrust**

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SEP vocabulary (USA)

- Federal Courts
  - Supreme Court, Circuit Courts, District Courts
- ITC (International Trade Commission)
  - Unfair competition through importations
- DOJ (Department of Justice)
  - Antitrust
  - Also unfair competition
- **FTC (Federal Trade Commission)**
  - Unfair competition
  - Also antitrust

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US Courts: patent damages
35 USC 284

- Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a **reasonable royalty** for the use made of the invention by the infringer, together with interest and costs as fixed by the court.
- Problems: hold-up (by SEP owner), royalty stacking (by multiple SEP owners)…

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US Courts: patent injunctions
(Ebay v. MercExchange, S. Ct. 2006)

- Four equitable factors for injunctions
  1) Irreparable harm to patentee
  2) Inadequacy of monetary compensation
  3) Balancing parties' interests
  4) The public
- Problem: hold-out (by standard implementer)
  - Since a FRAND license is acceptable to the patentee, there is no irreparable harm

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US Courts: no systematic FRAND negotiation framework

- Compare with EU: Huawei v. ZTE (CJEU 2015)
  - Implementer states willingness to take license
  - SEP owner diligently proposes FRAND license
  - Implementer diligently responds

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Antitrust: typology

- Sherman Act:
  - Section 1: grouped discrimination (cartel)
  - Section 2: individual discrimination (abuse of monopoly)
- Problem: a monopoly is not per se anti-competitive
  - Patent monopoly is protected by the US Constitution

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Antitrust: examples

- Refusing to deal with competitor at short-term loss, for the long-term gain of an increased monopoly
  - Aspen Skiing v. Aspen Highland (S. Ct. 1985)
- Extracting SEP royalty for products whether or not they carry the patented technology
  - Caldera v. Microsoft (D. Utah 1999)
- Extracting discriminatory (= non-FRAND) SEP royalties for products sold by others than SEP owner
  - Broadcom v. Qualcomm (3rd Cir. 2007)

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Antitrust: one more example? FTC v. Qualcomm

- Qualcomm grants FRAND licenses to OEMs only, refuses to license ship supplier competitors
- Qualcomm grants covenants not to sue to competitors only if they promise to sell exclusively to OEM licensees
  - FTC v. Qualcomm (ND Cal. 2019)
  - Appealed to the 9th Circuit

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Qualcomm: SEP/chips business model

- 1) FRAND licenses: only to OEMs (customers: Apple, Samsung…)
  - "No license, no chip": licenses are supplier-neutral, but unless the OEM takes a license, Qualcomm refuses to sell chips (to avoid patent exhaustion)
  - High royalty based on commercial product price (smartphones)
- 2) Chip suppliers (competitors: Intel…): only covenants not to sue, and only if they promise not to supply unlicensed OEMs
  - No FRAND licenses to chip suppliers, and no covenant without the promise (to avoid patent exhaustion)
  - Qualcomm sells its own chips at competitive price (low)

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Qualcomm's "volume discount" to Apple

- 3) Apple: payback to Apple if Apple buys chips exclusively from Qualcomm

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Antitrust issues: abuses of monopoly?

- Qualcomm's low price on chips made it difficult for chip suppliers to compete
  - In practice, Qualcomm competitors could not produce enough chips, so OEMs could not shift entirely to non-Qualcomm chips?
- Qualcomm recouped the low chip price through high FRAND license royalties to OEMs
  - In practice, since OEMs had to pay the FRAND license anyway, they had less incentive to use non-Qualcomm chips?
- Qualcomm's "volume discount" to Apple was an abuse of monopoly power?
  - In practice, Apple continued buying all its chips from Qualcomm
  - Qualcomm's goal was to prevent or delay competition by Intel

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FTC v. Qualcomm (9th Cir., Aug 11, 2020)

- Threshold issue: relevant market is the chip market, not the smartphone market
  - Qualcomm's competitors are chip suppliers (e.g.: Intel)
  - OEMs are Qualcomm's customers (e.g.: Apple, Samsung)
- Threshold remark: novel business practices are not necessarily illegal
  - Qualcomm has a unique business position as both 1) owner of SEPs on smartphones and 2) chip supplier to smartphone manufacturers

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FTC v. Qualcomm (9th Cir., Aug 11, 2020): licenses to OEMs

- "No license, no chip" to OEMs is not discriminatory licensing under antitrust laws
  - Qualcomm does not compete against OEMs
  - Licenses to OEMs are chip-supplier neutral

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FTC v. Qualcomm (9th Cir., Aug 11, 2020): no licenses to chip suppliers

- "No license" to chip suppliers is not discriminatory licensing under antitrust laws
  - Not a "refusal to deal"
    - No history of licensing chip suppliers
    - No renunciation of short-term profits for long-term benefit
  - No need to investigate FRAND obligations
    - Covenants to suppliers are de-facto licenses, so no unreasonable harm to competition
    - No intentional deception to SSOs about FRAND licenses (like in Qualcomm's previous SEP licensing model)

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FTC v. Qualcomm (9th Cir., Aug 11, 2020): high SEP royalties, low chip prices

- SEP license royalties are not anticompetitive
  - High royalties (under "no license, no chip") are not anticompetitive per se
    - No duty to price the license at "reasonable royalty" under patent law (especially not the "smallest salable patent-practicing unit" rule)
    - Any antitrust harm is to customers (the OEMs), not to competitors (the chip suppliers)
  - Low chip prices ("margin squeeze") are not anticompetitive per se
    - No evidence of predatory pricing, e.g., below cost
    - A monopolist is allowed to lower its rates in response to a competitor's entry into the market

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FTC v. Qualcomm (9th Cir., Aug 11, 2020): Apple "volume discount"

- Apple "volume discount" did not have anticompetitive effects in practice, except possibly in 2014
  - Apple switched to Intel after 2014
  - No injunction is needed now

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Conclusion

- "Anti-competitive" vs. "hyper-competitive"
  - SEP license royalties higher than perceived "fair value" of patented technology are not anticompetitive per se
- Antitrust vs. contract, patent law
  - Disputes over FRAND licenses are best resolved under contract and patent laws: "arbitration claims, negotiations, threatening to move to different chip suppliers, and threatened or actual antitrust litigation (sic)…"
  - Fair and reasonable: reasonable royalty calculations and injunctive relief factors

Questions, comments?

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This presentation is not legal advice