Inventorship in the University

Context



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Inventorship Generally

- "A person shall be entitled to a patent unless...he did not himself invent the subject matter sought to be patented." 35 U.S.C. 102
- US patents go to "first to invent"
- In the US, patents must be filed in the name(s) of the true inventor(s)
- Most foreign countries:
 - Applicant is the patent owner

First to file

HECKER LUP



Inventorship vs. Ownership

- Patents are property
- Rights are assigned
 - Written instruments
 - "Hired to invent"

"Inventor"

- Person who CONCEIVED of the invention
 - "Reduction to Practice" is not Conception
- Conceived of the CLAIMED subject matter
 - Inventorship may change as claims are added, deleted, or amended

"Conception"

"Formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice"

Coleman v. Dines, 754 F.2d 353 (1985)

Conception

- Two basic components
 - Recognition of a problem or goal
 - Development of a way to reach the goal or solve the problem

Joint Invention:

- Occurs when more than one person contributes to the CONCEPTION of the invention
- The COLLABORATION of two or more people working together to solve the problem addressed
- An individual must make a contribution to the conception of the claimed invention that is NOT INSIGNIFICANT in quality when measured against the dimension of the full invention to be a joint inventor
- There is NO explicit LOWER LIMIT on the quantum or quality of inventive contribution required

Joint Inventorship:

- "Some quantum of collaboration or connection"
- Joint inventors do NOT have to
 - physically work together or work at the same time
 - make the same type or amount of contribution
 - contribute to the subject matter of each claim of the patent

Who is NOT a Joint Inventor?

- Suggesting a desired end or result without suggesting means is not collaboration
- Merely following the instructions of another is not collaboration
- Providing publicly available information or general knowledge is not collaboration

Say what?

"The line between actual contributions to conception and the remaining, more prosaic contributions to the inventive process that do not render the contributor a co-inventor is sometimes a difficult one to draw."

Eli Lilly & Co. v. Aradigm Corp., 376 F.3d 1352 (Fed. Cir. 2004)

Consequences:

- If inventorship is incorrect (misjoinder and nonjoinder) the patent is INVALID
- Inventors have equal undivided interests in the patent
 - Failure to obtain an assignment from an unnamed inventor can result in loss of control over the patent
- Publications by the true inventors can prevent a patent from being obtained if the patent application does not list the same inventors

How Hard is it to Attack Inventorship?

- An issued patent's inventorship is PRESUMED VALID
- Anyone alleging invalidity due to incorrect inventorship bears the burden of proving misjoinder or nonjoinder by a clear and convincing standard of evidence (HIGH BURDEN)
- Testimony relating to incorrect inventorship must be CORROBORATION to be able to be considered as evidence
- If testimony is corroborated the court will evaluate the evidence under a RULE OF REASON standard and determine credibility

Correction of Inventorship

- Inventorship can be corrected if the error occurred without deceptive intent
- Inventorship should be amended during patent prosecution if claims are amended
- Venue
 - Patent Office
 - Petition to Correct under 35 U.S.C. 116
 - Interferences under 35 U.S.C. 135
 - Courts 35 USC 256

University Inventorship Issues

- Co-authors
- Supervisors
- Implementors
- Experts



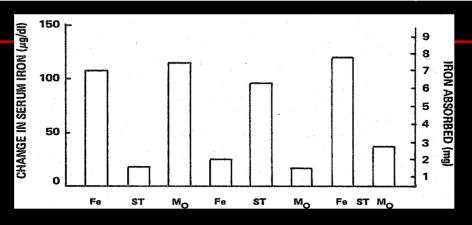
Legal Duties of Inventors

- Disclosure of prior art to Patent Office
 - Prior publications
 - Prior sales
- Disclosure of "Best Mode" of the invention

Inventorship in the University Context: Cases



University of CO Foundation v. American Cyanamid, 342 F.3d 1298 (Fed. Cir. 2003)





- Dr. Ellenbogen (Cyanamid) asked Doctors at CU to conduct an iron absorption study on Fe absorption on two prenatal multivitamin formulation
- The Doctors discovered a reformulation that increased absorption and conducted an Fe absorption study on the new formulation

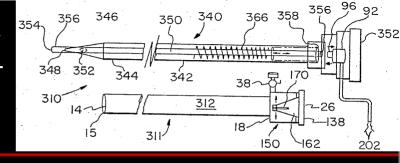
University of CO Foundation, Inc. v. American Cyanamid Co.

- Dr. Ellenbogen filed for a patent as sole inventor of the new formulation
 - Claim 1: Method of enhancing aborption of iron in multimineral, iron-supplement preparations comprising the use of limited quanitites of oxides and carbonates of Ca and Mg administered in said preparations do not more than 300 and 75 mg respectively.....
- Dr. Ellenbogen was not an inventor
 - The Doctors exclusively conceived of the complete idea of the invention

Lesson:

• A person who does not contribute to the conception of the invention is not an inventor, even if the people who conceive of the invention are generally working at his/her direction

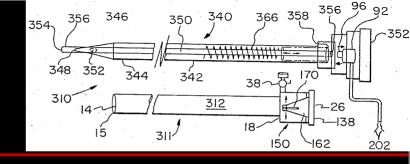
Ethicon, Inc. v. U.S. Surgical, 135 F.3d 1456 (Fed. Cir. 1998)



- Safety trocar tool for endoscopic surgery
- Dr. Yoon conceived generally of a safety trocar to prevent injury during trocar incisions
- Choi was an electronics technician who worked with Dr. Yoon on a safety trocar project
- Dr. Yoon patented safety trocar as sole inventor



Ethicon, Inc. v. U.S. Surgical

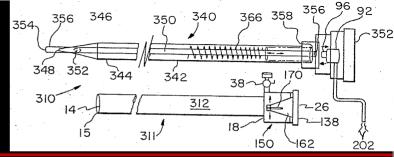


- Dr. Yoon granted exclusive license to Ethicon, who sued U.S. Surgical for infringement
- Court:
 - Out of the 55 claims in the patent, Choi contributed only to Claims 33 and 47
 - Choi was a joint inventor and granted a license to the whole patent U.S. Surgical
- Ethicon's infringement suit against U.S. Surgical was dismissed!

Ethicon, Inc. v. US Surgical

- Choi's license to Ethicon was not retroactive
 - Ethicon technically liable for past damages
- But:
 - Co-owners of patent must consent to file suit
 - Because Choi did not consent, the case was dismissed

Claim 33 (Choi's contribution in red)



• 33. A surgical instrument for providing communication through an anatomical organ structure, comprising:

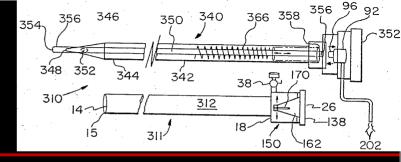
means having an abutment member and shaft longitudinally accommodatable within an outer sleeve, longitudinal movement of said shaft inside said sleeve being limited by contact of said abutment member with said sleeve, said shaft having a distal end with a distal blade surface tapering into a sharp distal point, said distal blade surface being perforated along one side by an aperture, for puncturing an anatomical organ structure when subjected to force along the longitudinal axis of said shaft;

means having a blunt distal bearing surface, slidably extending through said aperture, for reciprocating through said aperture while said abutment member is in stationary contact with said sleeve;

means positionable between said puncturing means and said reciprocating means for biasing a distal section of said reciprocating means to protrude beyond said aperture and permitting said distal section of said reciprocating means to recede into said aperture when said bearing surface is subjected to force along its longitudinal axis, whereby when said distal section of said reciprocating means is protruding beyond said distal point of said blade surface, said bearing surface obstructs anatomical members from making inadvertent contact with said distal point of said blade surface; and

STINSON Morrison Hecker LLP means connectible to the proximal end of said puncturing means for responding to longitudinal movement of said reciprocating means relative to said puncturing means and creating a sensible signal having one state upon recision of said distal section of said reciprocating means into said aperture and another state upon protrusion of said distal section of said reciprocating means from said aperture.

Claim 47 (Choi's contribution in red)



• 47. A surgical instrument for providing communication through an anatomical organ structure, comprising:

means having an elongate shaft exhibiting a longitudinal axis and terminating in a sharp, distal end, for puncturing the cavity wall of an anatomical organ structure;

means borne by said puncturing means distal end for converting counterforce exerted by said cavity wall against said distal end into transmissible energy;

means connected to said converting means for conveying said transmissible energy toward the proximal end of said puncturing means;

means having an interior bore coaxially aligned with the longitudinal axis of said shaft for receiving said puncturing means proximal end;

means for biasing said puncturing means proximal end to withdraw into said interior bore;

means interposed between said puncturing means proximal end and said interior bore assuming a normally protruding position for determining said puncturing means proximal end extended from said interior cavity in opposition to said biasing means.

STINSON Morrison Hecker Lep

Lesson:

- An inventor who contributed to only ONE CLAIM can still have an undivided half interest in the whole patent
- If an assignment was not obtained from the omitted inventor, he/she can make patent "owner"

Stern v. Trustees of Columbia University (S.D. N.Y. 2005)

- Periodic application of prostaglandins to reduce intraocular pressure
 - Claim 1: A method for treating hypertension or glaucoma in a primate subject's eye comprising <u>periodically</u> contacting the surface of the eye with an amount of an eicosanoid or an eicosanoid derivative effective to reduce intraocular pressure in the eye without any substantial initial increase in said pressure and <u>to maintain reduced intraocular pressure</u>.
- Dr. Bito published data on PG to rabbit and owl monkey eyes
 - Problem: Tachyphylaxis
- Stern (student) carried out experiments for Dr. Bito as part of research elective in medical school
 - Stern applied single dose to rhesus rhesus monkeys & cats
 - Stern left and the problem of tachyphylaxis remained
- Both sets of experiments in Patent No. 4,599,353 as "examples"

Stern v. Trustees of Columbia University

- Dr. Bito discovered in later experiments periodic applications did not cause tachyphylaxis (also in example of patent)
- Court construed claims as prevention of tachyphylaxis through periodic administration
- Stern was found to be merely a medical student carrying out experiments under Dr. Bito's direction not an inventor
- Stern did not contribute to the patented periodic application

Lesson:

- Claim interpretation is important for determining inventorship
- A person merely carrying out the instructions of another is not an inventor

Huang v. CA Institute of Technology (C.D. Cal. 2004)

LOWER BUFFER RESERVOIR

10

POLVACRYLAMIDE GEL
COLUMN

14

LOWER BUFFER RESERVOIR

- Automatic DNA sequencer
- Photometer to detect fragments tagged with florescent dies run on a single electrophoresis gel track
- Dr. Huang's claimed his idea

Huang v. CA Institute of Technology

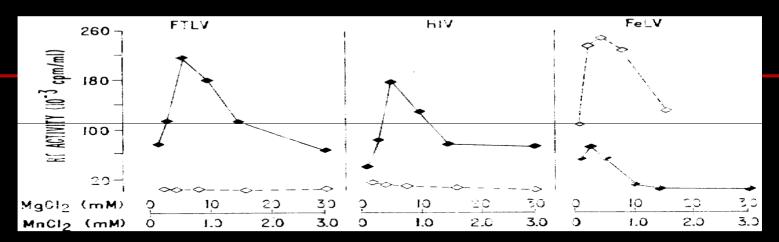
LOMPUTER DETECTOR OF LOWER BUFFER RESERVOIR

- Evidence: Lab notebooks
- Ct: Suit brought 20 years after creation
 - Now that invention received "international acclaim and tremendous financial success"
- Ct: Not sufficient corroboration if not witnessed or reliably dated

Lesson:

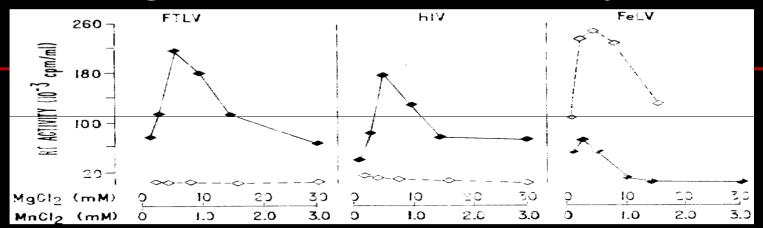
• An omitted inventor has the burden of proving by CLEAR and CONVINCING evidence that he/she contributed to the conception of one of the claims of the patent

Brown v. Regents of the University of CA (N.D. Cal. 1994)



- Brown maintained an animal shelter and noticed cats exhibiting immunodeficiency symptoms
- Brown turned over the cats and her extensive observations to U.C. Davis suspecting something similar to human AIDS
- University doctors performed extensive lab work and isolated FIV and developed detection and vaccination methods

Brown v. Regents of the University of CA

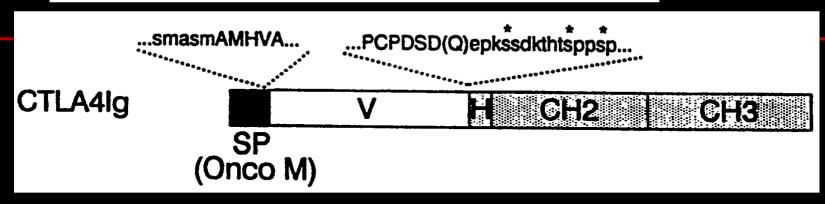


- Brown may have played a role in discovery of FIV but was not found to be an inventor
- Patents covered the (1) isolated FIV and (2) detection methods
- Brown did not contribute to the conception of isolated FIV or the detection methods

Lesson:

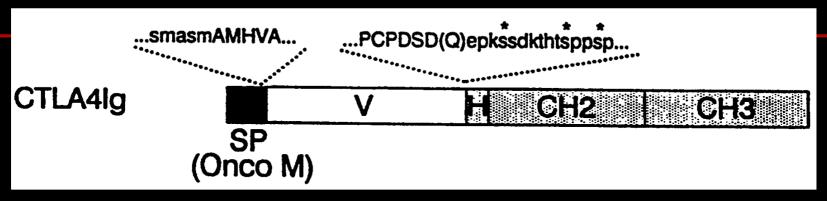
• A person must make a contribution to the conception of one of the claims of a patent to be an inventor, not merely make contributions that aid the inventors in their conception

Regents of the University of MI v. Bristol-Meyers Squibb Co.



- Various patents related to soluble CTLA4 proteins
 - Ptns bind to B7 on B-cells to prevent B7/CD28 immune response.
- 5/89: Dr. Thompson, a UMI professor, informed BMS scientists that CD28 and CTLA4 were probably functionally/structurally related (in prior art)
- 12/89: BMS discovered B7/CD28 activation pathway
- 1990: Dr. Thompson suggested CTLA4 would bind B7
 - Uncorroborated testimony of 1989
 - By this time, BMS were already making CLTA4-Ig

Regents of the University of MI v. Bristol-Meyers Squibb Co.



- Thompson was not found to be an inventor
- Thompson did not prove by clear and convincing evidence that he contributed anything to the claimed invention other than publicly available information

What can we take away from <u>Regents of the</u> <u>University of MI v. Bristol-Meyers Squibb Co.</u>?

 Merely providing publicly available information, encouragement, or suggesting a desired result or possible course of action without suggesting a method does not make a person an inventor

IDEC Pharmaceuticals v. Corixa Corp. (S.D. Cal. 2003)

- Method of treating B-cell lymphoma using radioimmunotherapy with Ab for maligiant cells
 - Possible MB1 (anti-CD37) and B1 (anti-CD20)
 - RIT must be lower than that which would require BM transplant
- Dr. Miller assembled teams of doctors from several universities to develop and perform the MB1 protocol
- Two of the doctors, Kaminski and Wahl, developed the B1 protocol from the MB1 protocol
 - B1 protocol included pre-dosing step
- The B1 protocol led to the patent

IDEC Pharmaceuticals v. Corixa Corp.

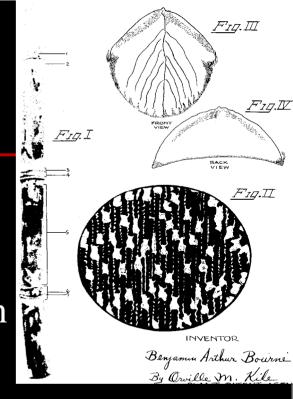
- The court refused to find Miller with inventor on motion for summary
 - Claim included the non-myeloablative dose,
 and Miller contributed to that
 - B1 and pre-dosing were suggested by B1
- So Miller was an integral part of the MB1 protocol which was the basis of the B1 protocol and even suggested important elements of the B1 protocol

What can we take away from <u>IDEC</u> Pharmaceuticals v. Corixa Corp.?

• A person who collaborated with the inventor(s) on work that provides a basis for the invention can be an inventor

Bourne v. Jones (S.D. Fla. 1951)

- Plant patents on several varieties of sugar cane
- University of Florida investigation program to produce sugar cane better adapted to Florida
- Stevens was the agronomist and Bourne was the cane breeder
- Separate but inter-related parts of joint project
- Selection of canes was based on joint efforts and resulted from work of both men



Bourne v. Jones

- Bourne and Jones were found to be joint inventors
- Only from the work of

 both could there be a certain

 determination of the characteristics of

 a newly developed cane



What can we take away from Bourne v. Jones?

• People performing separate activities can be joint inventors if they combine those separate activities to create the invention

Iron Ore Co. v. Dow Chemical Co. (D. Utah 1972)

AN (prill)	60	70	80	90	60 10
Sodium nitrateAl (fine, explosive grade)	40	30	20	10	30
Part (a).—I" diameter, 20 gran	n press	sed tet	ryl boo	ster	·
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Part (b).—2" diameter, 160 gram	cast 50)/50 per	atolite	booste	r
Minimum water for detonation Maximum water for detonation Density at minimum water Density at maximum water	12	3 12	1 12	_{īō} -	<u></u> 9
	1.20	1.06	1.06		

- Explosive composition comprising ammonium nitrate and heat producing metal
- Dr. Cook heading up University of Utah project for the Navy
- Farnam head of Iron Ore Co.
- Farnam merely emphasized to Cook problem of handling water in boreholes and contributed encouragement and financial backing for adopting Cook's knowledge of the possibilities of An + Al + H2O mixtures

Iron Ore Co. v. Dow Chemical Co.

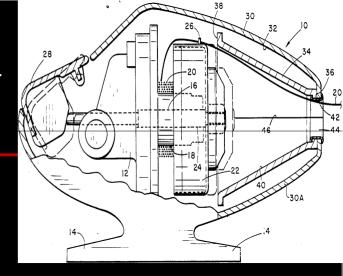
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- Farnam was found not to be an inventor because he made no actual or substantial contribution to the patent
- The court found Farnam and Cook knew Farnam had made no contribution and therefore there was deceptive intent in listing Farnam as inventor
- Because there was deceptive intent in listing
 Farnam as an inventor the patent was invalid

What can we take away from Iron Ore Co. v. Dow Chemical Co.?

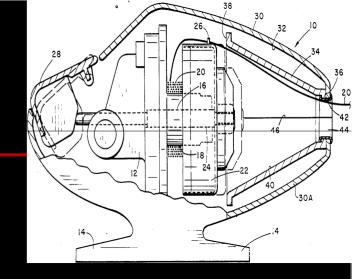
• Listing a person as an inventor who did not even arguably make an actual or substantial contribution to the patent can invalidate a patent and be found to be constitute deceptive intent, preventing correction

Swede Industries, Inc. v. Zebco Corp. (Fed. Cir. 1996)



- High performance ascetically pleasing closed face fishing reel
- Peterson filed as sole inventor but really was developed with co-inventor Kimbrough
- In an infringement action the infringer sought to invalidate the patent for incorrect inventorship and alleged the inventorship could not be corrected due to deceptive intent

Swede Industries, Inc. v. Zebco Corp.



- The court found that the infringer had not proven that there had been deceptive intent in the omission of Kimbrough
- Because there had not been deceptive intent the inventorship could be corrected, saving the patent from invalidity

What can we take away from <u>Swede</u> Industries, Inc. v. Zebco Corp.?

• A party alleging patent invalidity due to incorrect inventorship has the burden of proving deceptive intent, if it is not glaringly obvious from the circumstances, to prevent correction to save the patent

In re Katz

- Induction of Immunological Tolerance
- Claim 1. A therapeutic immunosuppressive agent capable of inducing specific immunological tolerance to an antigen by supression of antibody response, comprising a conjugate of D-glutamic acid:D-lysine copolymer and the antigen insulin.
- Katz's application rejected as anticipated by an article written less than 1 year before filing by Katz and several students
 - 102(g): article was a different inventive entity
- Katz established that the students were merely credited in the article because they did work under his direction and supervision by submitting a declaration
- The students were found not to be inventors and therefore the article could not anticipate the application because it was Katz's own work

Lesson of In re Katz?

• Publications by the inventor(s) discussing the invention that are published within a year prior to the date of application can make obtaining a patent more difficult if the author(s) of the publication are not all the same as the inventor(s) of the patent