



Inventorship and Ownership of Patents

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Ownership of Patents: What is a Patent?



- **Negative right**
 - Patent gives its owner the right to prevent others from using his invention **as claimed** in the patent.
 - However, **it does not by itself give its owner the right to make, use, sell, or offer to sell the invention.**
 - If making the claimed invention would infringes someone else's patent, then the patent owner cannot make, use or sell his own invention without the permission of the other of the other patent.
- **Territorial**
 - Must obtain patent protection in every country where protection is desired.
 - Different laws may apply in each country.
- **Personal property**
 - Can be bought, sold, licensed, bequeathed, etc.

Ownership of Patents

- Default rule: **Inventor** is owner of the patent.
- Transfer of ownership: **assignment**.
- Circumstances where employer may own patent.
 - Employment agreement may prospectively assign inventions to employer.
 - Local law may make employer owner of invention made by employee during the course of employment.
- Collaboration/consulting agreements should address ownership of resulting patents.
- Prospective assignment versus agreement to assign.

Abbott Point of Care v. Epocal (Fed. Cir. 2012)

- *Abbott Point of Care v. Epocal*, 666 F.3d 1229 (Fed. Cir. 2012)
- Abbott sued Epocal claiming ownership and alleging infringement of two patents invented by Lauks who worked for Abbott predecessor (i-STAT) until 1999, then was retained as a consultant from 1999-2001.
- Applications were filed by Lauks in 2001 directed to inventions made while Lauks was a consultant, and subsequently assigned to Epocal, a company founded by Lauks.
- In his **employment agreement** Lauks agreed to disclose and assign inventions he “may make or conceive during [his] employment of which relate to any present or prospective activities of [his employer]” but his **consulting agreement** did not contain any such obligation and allowed Lauks to pursue other non-conflicting interests.
- **Held: Abbott did not own the patents** because the consulting agreement did not continue the disclosure and assignment covenant of the employment agreement.

Inventorship Basics

- An inventor is someone who conceives of the subject matter claimed in the patent.
 - Depends on what is **claimed** in the issued patent.
 - Inventorship may change between filing and issuance if application is amended.
- Criteria are not the same as criteria for authorship.
- Joint inventors
 - Amount of inventive contribution irrelevant.
 - Only need to contribute to one claim to be an inventor.
- Liabilities of inventorship - legal duties.

Joint Ownership

- Each inventor is equal owner of patent, regardless of the relative contribution of each inventor.
- Only owners can sue to enforce a U.S. patent.
 - All owners must join patent infringement lawsuit.
 - Non-owner lacks standing to enforce a patent.
- One joint owner of a U.S. patent can license the patent (i.e. give another permission to make/sell/use the claimed invention) without the consent of the other owners.

Incorrect Inventorship

- Omitted inventors (non-joinder) or naming non-inventors (mis-joinder).
- America Invents Act 2011 removed former provision (§ 102(f)) that rendered patent invalid due to incorrect inventorship but U.S. Constitution and § 101 (defining patentable subject matter) may still include an inventorship requirement.
- Patent could still potentially be held unenforceable where non-joinder or mis-joinder is done with deceptive intent.
- Incorrect inventorship can be corrected before or after issuance by USPTO or a Court (35 U.S.C. §§ 116 and 256).
 - No longer requires lack of deceptive intention on part of non-joined or mis-joined inventor to correct inventorship (AIA).
- Ownership.
- Could result in lack of standing to enforce patent.

Conception of the Invention

- Inventor: one who conceives of the subject matter claimed in the patent.
- **Conception is the touchstone of inventorship.** *Burroughs Wellcome v. Barr Labs* 40 F.3d 1223, 1227-1228 (Fed. Cir. 1994)
- It is "the **formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention ...**" *Id.* at 1228.
- Conception is **complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice**, without extensive research or experimentation. *Id.* at 1228.
- Test for conception is whether the inventor had **an idea that was definite and permanent** enough that one skilled in the art could understand the invention; the **inventor must prove his conception by corroborating evidence**, preferably by showing a contemporaneous disclosure.
- An **idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan** he hopes to pursue.

Joint Inventorship

- “When an invention is made by two or more persons jointly, they shall apply for patent jointly ... Inventors may apply for a patent jointly even though
 - (1) they did not physically work together or at the same time,
 - (2) each did not make the same type or amount of contribution, or
 - (3) each did not make a contribution to the subject matter of every claim of the patent.”

35 U.S.C. § 116

Joint Inventorship: Requires Collaboration

- A joint invention is the product of **collaboration of the inventive endeavors** of two or more persons working toward the same end and producing an invention by their aggregate efforts. *Vanderbilt Univ. v. ICOS*, 601 F.3d 1297 (Fed. Cir. 2010).
- There must be **some element of joint behavior**, such as collaboration or working under common direction, one inventor seeing a relevant report and building upon it or hearing another's suggestions at a meeting. *Id.*
- Each contributor **need not have their own contemporaneous picture of the final claimed invention**.
- The qualitative contribution of each collaborator is the key - **each inventor must contribute to the joint arrival at a definite and permanent idea of the invention** as it will be used in practice.

Rubin v. General Hospital Corp. (Fed. Cir. 2013)

- *Rubin v. General Hosp. Corp.*, 523 Fed. Appx. 719 (Fed. Cir. 2013).
- Rubin and Anderson identified a gene mutation causing familial dysautonomia.
- Rubin sent article to American Journal of Human Genetics who sent an abstract to Gusella for peer review (contrary to Rubin's request). Gusella declined to review the paper.
- Gusella's team had been working on the same problem and identified the same mutations and filed a patent application claiming the mutations and their diagnostic use.
- **Held:** Rubin and Anderson were not joint inventors of the Gusella patent because there was **no collaboration** between the teams of scientists.

Joint Inventorship: Quantity/Quality of Contribution

- No lower limit on the quantum or quality of inventive contribution required for a person to qualify as a joint inventor. *Fina Oil and Chemical Co. v. Ewen*, 123 F.3d 1466, 1473 (Fed. Cir. 1997)
- One need not conceive of the entire invention alone but joint inventor **must contribute in some significant manner to the conception.**
- Each of the inventors work on the same subject matter and **make some contribution to the inventive thought and to the final result.**
Burroughs Wellcome
- **Conception is complete** only when the idea is so clearly defined in the inventor's mind that **only ordinary skill** would be necessary to reduce the invention to practice, without extensive research or experimentation. *Burroughs Wellcome* at 1228

Joint Inventorship: Quantity/Quality of Contribution

- The basic **exercise of the normal skill** expected of one skilled in the art, without an inventive act, also does **not** make one a joint inventor.
- Therefore, a person will not be a co-inventor if he or she does no more than **explain to the real inventors concepts that are well known** in the current state of the art.
- [T]o be a joint inventor, an individual must make a **contribution to the conception of the claimed invention that is not insignificant in quality**, when that contribution is measured against the dimension of the full invention.
Fina Oil at 1473.

So Who Qualifies as a Joint Inventor?

- Did the person make a contribution to at least one **claim**?
- Was the person in a **collaboration** working on the subject matter of the claims?
- Did the person make some contribution to the **conception** of the claimed subject matter?
- Was the person's contribution sufficiently **significant**, amounting to more than what is already well known in the state of the art and amounting to more than a general restatement of the problem or goal at hand?

Records Documenting Inventorship

- Evidence of invention must be independently corroborated.
 - A contribution to conception is a mental act which cannot be accurately verified without corroboration. *Fina Oil*, 123 F.3d at 1474.
 - Distrust of inventor's own testimony.
 - Testimony of co-workers.
- Documentary evidence of inventorship, *e.g.*:
 - Laboratory notebooks.
 - Compound registration records.
 - Invention disclosure forms.
 - Meeting minutes.
- First to invent vs. First to file.
 - Records still important to establish proper inventorship / ownership and possibly provide evidence of derivation.

Burroughs Wellcome v. Barr Labs. (Fed. Cir. 1994)

- *Burroughs Wellcome v. Barr Labs.* 40 F.3d 1223 (Fed. Cir. 1994)
- Burroughs Wellcome (BW) had a series of patents covering the use of AZT in the treatment of HIV infection
- Inventors from BW tested AZT in laboratory mouse screens and found it had an effect on retroviruses
- Draft patent applications were prepared for filing in the UK based covering treatment of people infected with HIV using AZT.
- Around the same time, BW sent AZT under code to NIH for testing in a proprietary cell line, a better, more predictive assay for HIV treatment, and NIH workers found compound active.
- FDA approved AZT for treatment of HIV infection in 1987.

AZT Case (cont'd)

- Barr Labs filed an ANDA (application for approval of generic drug) for treatment of HIV using AZT.
- BW sued Barr for patent infringement
- Barr admitted their generic product would infringe BW's patents, argued they had a license from the government.
- Barr argued the government had rights in the invention because the NIH researchers were co-inventors.
- Barr argued that NIH researchers were inventors because BW could not have known AZT was effective against HIV without the results of testing in the NIH cell line.

AZT Case (cont'd)

- Did the NIH researchers contribute to the conception of the invention by carrying out the testing of AZT?
 - Remember: Conception requires a definite and permanent idea of the invention
- Held: NIH researchers were NOT inventors.
- BW inventors had a definite and permanent idea of the invention even before they knew the results of the NIH testing as corroborated by the patent application drafts of Feb 1985 which describe use of AZT for treatment of HIV.
- Didn't matter that BW didn't know for certain that AZT would work, conception is about whether they had a definite and permanent idea of the invention, as opposed to a general goal.

Falana v. Kent State University (Fed. Cir. 2012)

- *Falana v. Kent State University*, 669 F.3d 1349 (Fed. Cir. 2012).
- Postdoc and Professor worked on project to make temperature independent, high helical twisting power chiral additive for LCDs.
- Postdoc developed synthesis to make naphthyl-substituted TADDOLs and made an SS enantiomer with improved temperature independence.
- After Postdoc resigned, Professor used same synthesis to make RR enantiomer with even better temperature independence.
- Patent claimed chiral naphthyl-substituted TADDOLs but not methods of making them – and did not name Postdoc as an inventor.

Falana v. Kent State University (cont'd)

- Postdoc sued for correction of inventorship.
- Kent State argued the claims excluded the compound made by Postdoc.
- Court held that even if this was correct, Postdoc's contribution to synthesis method of naphthyl-substituted TADDOL's was sufficient for inventorship.
- Conception of a chemical compound requires knowledge of both the specific chemical structure of the compound and an operative method of making it, so a contribution to finding an operative synthesis method can qualify as a contribution to conception.

Inventorship Problem

- At Big Pharma Company (BPC), a team of scientists has discovered new Receptor A antagonists as part of its cancer drug discovery program
- The patent has been written and is ready to be filed – but who are the inventors.
- The characters (all employees of BPC) are:
 - Gus – project team leader
 - Curt – lab leader
 - Mike – lab associate 1
 - Charles – lab associate 2
 - Susan – lead biologist
 - Patent Attorney
- From Miller and Evans, *The Chemist's Companion Guide to Patent Law*, Wiley, 2010.

Inventorship Problem: Background

- Gus, Curt, Mike, and Charles are part of a chemistry team trying to design antagonists of Receptor A.
- At a team meeting, Curt proposes making a series of compounds.
- Gus vehemently opposes making the compounds, and there is a heated argument, but Gus gives in and ultimately states that he believes in the idea and that they should proceed.
- Curt proposes one synthetic route using known starting materials and straightforward chemistry.
- Mike proposes a second route using novel starting materials prepared by methods not known in the art.
- Curt approves Mike's second route because it may allow access to different members of the chemical series that can't be obtained by Curt's straightforward route.

Inventorship Problem: Background

- Charles easily prepares compounds of the series using Curt's straightforward route.
- Mike also successfully prepares compounds using his route.
- The compounds are tested in routine binding experiments and are found to have good potency.
- The compounds are then tested in standard rat models at Susan's direction and also show promising activity.
- Curt reports to Gus the exciting results and Gus proposes that they patent the compounds.
- Curt works with the patent attorney to prepare the patent application.
- It's almost time to file the application, but who are the inventors?
- Patent Attorney interviews each of the possible contributors.

Inventorship Problem

**PATENT ATTORNEY
INTERVIEWS
POTENTIAL INVENTORS**

Inventorship Problem

Analysis

- Assume Gus, Curt, Charles, Mike and Susan worked collaboratively
- Patent application contains the following types of claims:
 - Compounds of Formula I.
 - Pharmaceutical compositions comprising compounds of Formula I.
 - Methods of treating disease X by administering a compound of Formula I to a patient.

Inventorship Problem

Analysis

- Charles – Inventor or non-inventor?

NON-INVENTOR

- ❖ Charles did not contribute to the conception of the invention. He was merely a “pair of hands” executing instructions from Curt. The tweaking of reaction conditions by varying temperature is not a sufficiently significant inventive contribution because it was not more than what anyone of ordinary skill in the art would do.

Inventorship Problem

Analysis

- Mike – Inventor or non-inventor?

INVENTOR

- ❖ Unlike Charles, Mike probably did contribute to the conception of the invention. He was more than a “pair of hands” because he developed novel synthetic methods requiring more skill than what was already known in the art. The fact that the indole compounds could not be reached without using Mike’s novel process also indicates that the inventive contribution was sufficiently significant.
- ❖ It does not matter that Mike made fewer compounds than Charles. Joint inventors need not make equal contributions.

Inventorship Problem

Analysis

- Curt – Inventor or non-inventor?

INVENTOR

- ❖ Curt is clearly an inventor because he contributed to the conception of the invention by proposing the series of compounds **and** a synthetic route to those compounds. The fact that he did not make any of the compounds does not factor in. It's all about the idea and whether it was sufficiently **definite and permanent** such that not more than ordinary skill would be required to reduce it to practice.

Inventorship Problem

Analysis

- Gus – Inventor or non-inventor?

NON-INVENTOR

- ❖ While Gus made the development of the compounds possible by endorsing the research, he did not contribute to the conception of the invention because he had no role in coming up with the idea of the compounds or in developing them.
- ❖ Merely being the boss or sponsor of the research does not make one an inventor.

Inventorship Problem

Analysis

- Susan – Inventor or non-inventor?

NON-INVENTOR

- ❖ Susan used routine assays for testing the compounds which would not be sufficiently significant to qualify as an inventive contribution since it is not more than what any person of ordinary skill in the art would do. However, had Susan proposed new diseases for treatment based on her assay data, and these treatments were claimed in the application, she may very well be an inventor.

Inventorship Problem

Analysis

- ❖ Joint inventors are Curt and Mike
- ❖ What order should their names be in?
- ❖ What would happen if one or more of non-inventors Gus, Charles or Susan were also named as inventors?
- ❖ What would happen if Curt or Mike was not named?
- ❖ What happens if the scope of the claims change during examination?
- ❖ Who's going to care if the inventorship is right anyway?
- ❖ Who would be named on *J. Med. Chem.* paper describing discovery of the Receptor A antagonists?