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Patent Ownership and the Impact of Interactions with Others

Risks to Ownership, Managing Agreements With Other Parties, Patent Prosecution Strategies

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Who Owns That Patent? Do Your Interactions with Others Jeopardize Your Patent Ownership?

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March 5, 2020

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Intellectual Property Law

Disclaimer

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Outline

- Refresher on US inventorship standard
- Recent inventorship caselaw
- Troublesome factual scenarios
- Managing agreements with other parties
- Drafting and prosecution strategies
- Evaluating others' patents and detecting inventorship/ownership problems

Who is an Inventor?

- Inventor(s) "conceived the subject matter … recited in a claim"
  - Sewall v. Walters, 21 F.3d 411, 415 (Fed. Cir. 1994)
  - Conception: formation of "a definite and permanent idea of the complete and operative invention"
    - Townsend v. Smith, 36 F.2d 292, 295 (CCPA 1929)
- NOT enough to:
  - Merely suggest a result to be achieved
  - Explain the state of the art
  - Reduce a conceived invention to practice

Joint Inventors

- "Joint inventorship … can only arise when collaboration or concerted effort occurs—that is, when the inventors have some open line of communication during or in temporal proximity to their inventive efforts."
  - *Eli Lilly and Co. v. Aradigm Corp.*, 376 F.3d 1352, 1359 (2004).
  - Joint inventors must show some collaboration/concerted effort

How do Outside Interactions Impact Inventorship and Ownership?

- Cannot rely on a contract solution to all outside inventorship problems
  - Do you have a contract with every potential co-inventor or co-owner?

☑ Formal collaborations with academic groups or other companies

? Pre-agreement discussions that do not lead to agreement

☒ Prior employer of inventors who join your organization

☒ At a meeting, someone suggests an idea for a new product

? ☒ Stakeholder feedback on existing product

Establishing When Conception Occurs

Dawson v. Dawson, 710 F.3d 1347 (Fed. Cir. 2013)

- Appeal from interferences
  - Two interference counts: treating eye infection with topical azalide antibiotic (most commonly azithromycin) at specific dosage or in amount effective to treat infection
- Dawson changed affiliations from UCSF to InSite
  - Same individual on both sides of the "v."
  - Issue: when was conception complete relative to change of employment?

Dawson v. Dawson

- While at UCSF, Dawson proposed topically treating eye infection with the antibiotic
  - Generated WHO meeting presentation, outline, and report
    - Conception?
      - No product available, but listed vehicles including Durasite
      - Suggests ointment like 0.5% erythromycin ointment (was this dose suggestion?)
      - Some preliminary AE testing conducted on mineral oil / petrolatum carrier and 0.5% azithromycin
    - Not conception?
      - Report states efficacy and dosing schedule would need to be determined
      - Report describes need to assess PK and toxicity
      - Challenges of ointments identified
        - » Difficult to apply and poorly tolerated
      - Do these statements admit incomplete conception?

Dawson v. Dawson

- Dawson moved to InSite and worked with co-inventor Bowman to use InSite Durasite vehicle and establish dosages
  - Durasite = delivery depot made of acrylic acid polymers

- Dawson and Bowman filed patent application
  - Named InSite as assignee
  - Signed declaration of joint invention
  - Two patents issued

- UCSF filed its own patent application naming Dawson as sole inventor to provoke an interference
  - copied spec/claims from both patents
  - UCSF as junior party had burden of proof

Dawson v. Dawson

- Two interferences declared / two counts

  '719 count: A process for treating an eye, which comprises:

  topically applying an aqueous polymeric suspension of an azalide antibiotic, wherein said suspension comprises water,

  0.01% to 1.0% of an azalide antibiotic, and

  0.1 to 10% of a polymeric suspending agent which is a water-swellable water-insoluble cross-linked carboxyvinyl polymer which comprises at least 90% acrylic acid monomers and 0.1% to 5% cross-linking agent.

  '729 count: A process for treating an eye, comprising:

  topically applying an azalide antibiotic to an eye in an amount effective to treat infection in a tissue of the eye, wherein said topically applying comprises supplying a depot of a composition containing said azalide antibiotic on the eye.

Dawson v. Dawson

- Held: General idea or research plan lacking details ≠ conception.
  - Preliminary statement about potential with recommendations for continued work falls short of an inventive contribution.
- '719 interference count recited specific *dosage concentrations* that were not in original report.
  - Dosage concentrations of azithromycin not developed until inventor employed by InSite and coordinating with second inventor Bowman
- '729 interference count recited "amount effective to treat"—requires conception of what amount would be effective
  - WHO documents explicitly stated that "efficacy … will need to be determined"
- No UCSF ownership in either case

Dawson v. Dawson

- The type of proceeding matters!
  - Interference judgments are all or nothing: a party (here, Dawson before leaving UCSF) either conceived the count in its entirety, or didn't
  - What could UCSF do post-AIA (not interference, not derivation, perhaps only breach of contract re: assignment of invention)
- UCSF had no inventor testimony (Dawson was a hostile witness)
- Reyna dissent: "WHO presentation manifested inventive embryo which thereafter sought deliverance"

What Could UCSF Have Done Differently?

- On UCSF side
  - Did Dawson leave because his idea was not getting traction/support?
  - Importance of exit interviews
  - Capture and file on inventions before employee departs
    - Look for unfiled invention disclosures and undocumented inventions
- Need to consider incomplete conceptions
  - Tension between first-to-file and adequate conception
  - Will discuss incomplete conceptions further with *In re VerHoef*

What Could UCSF Have Done Differently?

- On UCSF side
  - Could UCSF have filed '729 count when Dawson left?
    - No specific vehicle
    - No specific dosage
    - What about mineral oil/petrolatum and 0.5% azithromycin

Compare '729 count: A process for treating an eye, comprising: topically applying an azalide antibiotic to an eye in an amount effective to treat infection in a tissue of the eye, wherein said topically applying comprises supplying a depot of a composition containing said azalide antibiotic on the eye.

What Could UCSF Have Done Differently?

- On UCSF side
  - WHO disclosures as prior art
    - Disclosures in 1997
    - InSite filed 1999 and UCSF filed 2007
    - Was real error not filing before WHO presentation? Needed more than WHO materials for patentability.
      - Can't contend prior art is what makes you inventor

Other Take Aways

- On InSite side
  - Claim features necessary to take it from an "idea" to an "invention"
  - For new employer, make sure to include claim limitations conceived *after* start date
    - Broader not always better!
    - Including dosages made their case stronger
      - Specific details may be stronger than general functional terms like effective amount
    - Make sure you have additional limitations in claims beyond research goal
    - Emphasize what new employer has that old employer did not
      - Method steps? Structural details? Dosages? Reagents? Reaction conditions?

Other Take Aways

- Narrowing claims can also change identity of inventors
- What would have happened if Dawson at UCSF collaborated with Bowman?
- Are these the same claim limitations necessary for enablement/written description?
  - Did research plan lack elements necessary for § 112 support?

Risks from Early Discussions

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

- Issue: Inventorship of claim to method of improving bioavailability of inhaled insulin
- Lilly and Aradigm discussed potential collaboration using Lilly's insulin compounds and Aradigm's expertise in aerosol drug delivery
  - 4 meetings
    - Presumably *pre-agreement* re: patent ownership/control
  - Lilly scientists suggested to use insulin lispro in aerosol devices
    - Lispro has reversal of two amino acids
    - Same bioactivity, but less self-association (disassociates quickly into rapidly-absorbed monomeric form after administration) and therefore more rapid action

Eli Lilly v. Aradigm

- Claim in patent listing Aradigm inventors required **2X increase in bioavailability** of **aerosolized, inhaled** insulin by using **lispro** instead of recombinant human insulin
  - Held: Lilly scientist did not contribute to an invention with that scope
    - No evidence Lilly disclosed 2X bioavailability
  - Lilly scientist testified to always talking about lispro, but could not prove anything about increased bioavailability after inhalation
    - Not a contribution to conception
    - Only suggestion for Aradigm to try lispro in its devices
    - Lilly's original lispro patent issued before Aradigm filed its application
    - Aradigm developed and only Aradigm scientists were inventors

Criticality of Claim Scope

- 2X bioavailability was in a dependent claim, and court focused on failure to prove contribution to conception of claim with this feature
- What if claim did not recite 2X bioavailability?
  - District court credited communication of suggestion to use lispro
  - Lilly may have won
  - Does it matter if 2X bioavailability had been used as evidence of unexpected results?
  - But independent claim only recited improved bioavailability in preamble and rapidly dissociating into monomeric form in the body of the claim

What Could We Do Differently?

- Resolve IP ownership by agreement before substantive discussions?
  - Practical difficulties: bandwidth, lack of financial terms, alienation of potential partners at early stage
  - When to address patent ownership/control?
    - Any agreement involving the exchange of ideas?
    - Shrink-wrap agreements regarding product feedback?

What Could We Do Differently?

- Caution about sharing info before IP ownership is resolved?
  - Good idea in general, but lispro per se was fully disclosed
- Resort to non-patent protection (state law)?
  - Trade secret: arguably not applicable (would need to prove efforts to maintain secrecy and improper means to obtain/use)

What Could We Do Differently?

- Precautionary filing of own patent application?
  - Likely a prophetic filing
  - May not have been able to support express 2X bioavailability limitation
    - Lispro known to be absorbed faster than regular insulin even after subcutaneous administration
    - What about inherency?
  - Assuming sufficient information was known about the Aradigm platform, enablement seems OK
  - Devil may be in the details but this might have helped, at least in US
    - (Results may vary ex-US, especially where working examples are necessary)

Hypothetical Variations

- What if lispro hadn't been disclosed yet?
  - If Lilly scientist contributed nonpublic information necessary to reach a "definite and permanent idea of the complete and operative invention," it seems like a much stronger case for inventorship
    - The fact that lispro itself was already disclosed/patented seems critical to the outcome of the actual case
  - Also much stronger case for trade secret misappropriation/violation of CDA
    - Remedy unclear, but willful misappropriation can support strong equitable remedies

Precautions to Consider for Disclosing Party

- Even if CDA does not resolve IP ownership, could include license clause for any patent that includes information covered by the CDA
  - Protect your FTO in the event of inadvertent inclusion
- Follow up on termination provisions when a CDA does not result in a full collaboration
  - Confirm confidential information is returned/destroyed
  - Include clause about certification of compliance with return/destruction obligations

Precautions to Consider for Receiving Party

- Ensure technical/scientific personnel understand seriousness of improperly using outside information and inform patent counsel of any concerns
- If a potential issue does arise, it may be better to resolve it sooner rather than later
  - E.g., cost to obtain an assignment in the nature of a quit-claim deed could be much lower at an early stage

Merely Suggesting Can Rise to the Level of Inventorship

In re VerHoef, 888 F.3d 1362 (Fed. Cir. 2018)

- Vet treating VerHoef's dog for difficulty walking and dragging back paw ("knuckling")
  - Discussed commercial harness to support hind leg
    - Failed to fix knuckling
  - VerHoef constructed similar homemade harness, but had same results
  - VerHoef recognized that connecting harness to toe instead of ankle could work better
    - VerHoef: "There has to be a way to connect the cord to the toes."
    - Vet suggested attachment strategy (figure eight around toes and lower leg) as something to consider
    - VerHoef made harness implementing vet's figure eight idea

In re VerHoef

- VerHoef filed joint application naming himself and vet
  - Relationship soured
  - Abandoned joint application and refiled with VerHoef sole inventor
  - Vet filed her own application on the same day as VerHoef sole application
- VerHoef application rejected under § 102(f)
- Was vet a joint inventor?

In re VerHoef

- Inventorship requirements
  - contribute in some significant manner to the conception or reduction to practice of an invention
  - make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and
  - do more than merely explain to the real inventors well-known concepts and/or the current state of the art.

In re VerHoef

- Federal Circuit found both VerHoef and vet were inventors
  - Figure 8 loop essential feature of invention, recited in claims, and meaningfully distinguished prior art
  - Inventorship does not require equal contributions
    - Figure eight loop not insignificant, a well-known concept, or summary of prior art

Risks of Getting Advice

- Don't engage in brainstorming with other parties
  - Don't present problems for others to solve
- Expect valuable innovation will come from interactions with other parties and plan accordingly
- Limit interactions between an outside person with an idea and your R&D team
  - Stop the information flow
  - Don't use an outside person as a sounding board even when they start a discussion
  - Joint inventorship requires collaboration

Interpersonal Issues

- Importance of relationship issues
  - Chicken and egg problem
    - Does relationship go bad because of inventorship calls or do people change inventorship because of other interpersonal issues?
  - Decouple inventorship from ownership when possible
    - If both parties are happy with ownership/compensation, inventorship becomes less contentious

Incomplete Conceptions

- Compare *Dawson* to *VerHoef*
- Question of incomplete conception
  - Dawson's conception was incomplete before job change
  - VerHoef's conception was incomplete before vet suggested figure eight
  - No ownership for UCSF, but VerHoef is still an inventor
- Different results if same person moving jobs vs. different people?

Drafting Tips

- Specification should explain challenges inventors overcame between "idea" and "conception"
  - If some embodiments do not work, may wish to present negative data
  - Show that original suggestions was not a complete conception
  - Here had not solved the "knuckling" problem until the vet suggested the figure eight construction
  - Drafting to emphasize insufficiency of invention before your client contributed a limitation strengthens inventorship claim

Claim Strategy

- Patent filings subsequent to exchange of information: consider claim scope carefully

- What if figure eight was not necessary to patentability?
  - Would conception have been completed without figure eight?
  - What if figure eight had been in a dependent claim
    - Can you disclaim a claim to exclude a joint inventor?
      - Reissue
      - Statutory disclaimer under 37 CFR § 1.321

Importance of documenting the inventive process

Vanderbilt Univ. v. ICOS Corp., 601 F.3d 1297 (Fed. Cir. 2010)

- Vanderbilt alleged its scientists were coinventors on a patent for tadalafil (Cialis drug substance)
- Issue: whether Vanderbilt scientists contributed to conception along with Glaxo scientists that came up with the final structure
  - ICOS is Glaxo's successor in interest
- Held: no clear and convincing proof of joint invention involving Vanderbilt scientists

Vanderbilt Univ. v. ICOS Corp.

- Vanderbilt scientists discovered the enzyme targeted by tadalafil, PDE5, which breaks down cGMP
- Initial agreement: Glaxo funded research into cGMP analogs by the Vanderbilt scientists; University would retain ownership, and Glaxo gets license
  - Glaxo encouraged focus on PDE5 inhibitors
  - Vanderbilt scientists started from readily available IBMX and synthesized a substituted version with 160X potency increase
  - Glaxo UK was informed of this through a proposal for a further research agreement, along with a number of other analogs containing the "Vanderbilt Structural Features" (VSF)
  - Vanderbilt proposed further research and variations, and listed male impotence as an area of interest

Vanderbilt Univ. v. ICOS Corp.

- About one month later, Glaxo France tested 26 PDE5 inhibitor candidates including GR35273x (a beta-carboline with certain similarities to tadalafil and its predecessor, GR30040x)
- Vanderbilt's proposal was forwarded to the head of chemistry at Glaxo France (Dr. Labaudiniere) about one month after that
- Two weeks later, Dr. Labaudiniere tested 29 more candidate inhibitors, including GR30040x, which he then identified as the lead compound
  - Vanderbilt argued that all of these included some of the VSF
  - Dr. Labaudiniere assigned further work to Dr. Daugan, who discovered tadalafil through testing further modifications to GR30040x

Vanderbilt Univ. v. ICOS Corp.

- Vanderbilt's arguments:
  - The VSF led to GR30040x; Dr. Labaudiniere couldn't have identified it without Vanderbilt's contribution
  - The key modification of GR30040x to reach tadalafil was based on Vanderbilt scientists' work
- ICOS's counter:
  - Dr. Labaudiniere independently discovered GR30040x starting from other related beta-carboline compounds including GR35273x
    - Evidence: minutes of research meetings showed recognition of GR35273x as a PDE5 inhibitor, commencement of testing of further analogs, and identification of GR30040x as a new inhibitor
    - Drs. Daugan and Labaudiniere both testified to not knowing of the Vanderbilt research until well after identifying GR30040x
- Court: affirmed that Vanderbilt failed to prove non-joinder of inventors by clear and convincing evidence
  - No clear error in district court's determination that theories were equally plausible

Vanderbilt Univ. v. ICOS Corp.

- Close case: burden of proof may have been dispositive
- Court noted that both parties lacked documentation to establish parts of their theories
  - Different result if Glaxo's research minutes had not been available?
  - Or if ICOS had been able to connect the dots from its scientists to Labaudiniere or Daugan?
- Time frame was early 1990s; this might be a different case today, given the ubiquity and persistence of email

Important to Document the Inventive Process

- Good recordkeeping practices to document inventive activity still matter, even under the AIA's first inventor to file regime
  - Key issue was how Labaudiniere got to the GR30040x structure
  - Both sides had suggestive evidence for their theories but neither had a smoking gun
  - Interferences are gradually receding into history, but proving an early date of conception can still defeat an inventorship challenge
    - Show conception before earliest alleged contribution from outside

Handle Outside Proposals Carefully

- Joint inventorship differs from basic infringement and validity in that who knew what and how they learned it matters
  - Be careful about who gets access to outside proposals – need to know basis
    - Counterpoint: the likely inventors may be the scientists most well qualified to evaluate proposals
    - Can still make sure the inventors are diligent in documenting how they came to their ideas
    - Watch out for changes in direction subsequent to receiving outside information
  - The separation between Glaxo UK (where Vanderbilt proposal initially went) and Glaxo France helped ICOS's case
    - Vanderbilt couldn't clearly prove communication of its ideas to Labaudiniere

Be Aware of the Limits of Ownership Clauses

- The parties had an ownership clause in their *initial* research agreement, but it fell by the wayside and this dispute still happened
  - Alleged invention came *after* new proposal for *additional* research
  - Vanderbilt's new proposal - related to but evidently outside the scope of the initial agreement, which provided for ownership by Vanderbilt and license to Glaxo
    - Never matured into a new agreement! Ownership terms in initial agreement create false sense of security?
  - From Vanderbilt's perspective – new proposal arguably disclosed too much too soon
    - Disclosed "Vanderbilt Structural Features" without any protection beyond default law

Financial Repercussions of Inventorship Disputes

Dana-Farber Cancer Institute, Inc. v. Ono Pharm. Co., Ltd., 379 F. Supp.3d 53 (D. Mass. 2019)

- Scientists from Ono Pharmaceuticals (Dr. Honjo), Dana-Farber Cancer Institute (Dr. Freeman), and Genetics Institute (Dr. Wood) collaborated to characterize cancer and PD-1 / PD-L1 connection
  - Material transfer agreements
  - Collaboration agreements
- Relationship soured over patent application filings and naming inventors

Dana-Farber Cancer Institute v. Ono Pharm.

- Freeman and Wood file patent application to *modulating the immune response by activating or blocking the PD-1/PD-L1 pathway*
- All three write several journal articles
- Honjo finds out about patent application
  - Asked to be an inventor, but was not added
- Honjo files application to *treating cancer by blocking the PD-1/PD-L1 pathway*
  - Does not name Freeman and Wood

Dana-Farber Cancer Institute v. Ono Pharm.

- Patents issued naming Dr. Honjo and not Drs. Wood/Freeman
  - Licensed by Medarex, which was acquired by BMS
  - Supported marketing of anti-PD-1 monoclonal antibodies for treatment of cancer (checkpoint inhibitor)
    - Opdivo™ (nivolumab)
    - 2017 sales $4.9 billion; 2018 sales $6.7 billion
  - BMS sued Merck, Regeneron, Novartis, Tesaro, Roche Genentech, and AstraZeneca
    - Pfizer (successor to GI) settled; Dana-Farber has rights (and a policy not to grant exclusive licenses)

Due Diligence

- When licensing/acquiring patents, make sure to evaluate inventorship
  - Search for companion publication to application
    - Some of the Freeman, Wood, Honjo articles predated Honjo's filing
      - Should prior articles and Freeman/Wood application suggest investigation?
    - Are we searching for later-dated publications?
      - Are individuals from other organizations less likely to operate as a pair of hands only reducing to practice?

Due Diligence

- Ask the parties whether they engaged in any collaborations
- Look for any evidence that would suggest another party or motivate further investigation
- Potential inventors come out of the woodwork with potential product and $$

Hypotheticals and Q&A

Feedback on Approved Drug

- PharmaCorp makes antibiotic for treating tuberculosis (TBatx)
- Clinical trials show improved efficacy over current antibiotics, but some resistance remaining
  - FDA approves drug
- Doctor who participated in clinical trials sees PharmaCorp CSO at conference and suggests combination therapy of TBatx with previously-approved TBprime, which has a different mechanism of action
  - Scenario A: PharmaCorp's first attempt succeeds
  - Scenario B: PharmaCorp's first attempt fails, requires modification to administration protocols, timing, or dosage, and then works
    - Scenario B1: Interacts with doctor
    - Scenario B2: Does not interact with doctor

Intercompany Testing

- LittleCo has developed an antimicrobial coating
- Before collaboration agreement, BigCo wants to test coating
- LittleCo sends to BigCo for testing in medical products along with technical information on the formula for the coating
  - BigCo scientists propose formula change
  - BigCo could not have done the testing without LittleCo's materials and formula
    - Option A: parties do not enter into collaboration agreement because of poor test results
    - Option B: after collaboration ends, BigCo continues to work with coating and makes new invention

Thank you!

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