Recent Developments In Biomedical IP Law Part I: Patent Applications From Inventorship To Obviousness.

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About the Presenter

ADRIENNE B. NAUMANN

Adrienne B. Naumann established her own practice in 1996 which is exclusively intellectual property law. Ms. Naumann's practice includes individual entrepreneurs and start-up companies, as well as small and medium sized businesses. Her issued patents include a broad range of technologies including: a razor handle, board game, agricultural method, pneumatically driven trench shoring device, floral containers, electromechanical lock, laminar flow nozzle, portable exercise devices, mechanical bag holder and shelving. She has also filed successful patent application appeals in the Patent & Trademark Office on behalf of clients.

Ms. Naumann has obtained trademarks, copyrights and design patents on behalf of artists, writers and companies. In addition to obtaining intellectual property protection through government agencies, Ms. Naumann advises and drafts documents on matters of ownership, shop rights, work for hire, transfers of rights, licenses, permissions, rescission, consents, non-disclosure agreements, releases, trade secrets, proprietary information and web sites.

Ms. Naumann judges the Illinois Institute of Technology Interprofessional Projects Program in Chicago. Ms. Naumann also serves on the Board of the University of Chicago, Chicago Women's Alliance and on the e-Discovery committee for the Seventh Circuit Court of Appeals

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Course Description

Course Presentation

This course is an in-depth review of Biomedical Intellectual Property Law and review of cases from the Federal Circuit and Appellate Courts. The course reviews ongoing litigation between higher learning institutions. Intellectual Property law deals with laws to protect and enforce rights of the creators and owners of inventions, writing, music, designs and other works, known as the "intellectual property." The course examines intellectual property case law regarding Biomedical Devices, Pharmaceuticals and Genetic Engineering.

The course reviews Intellectual Property Law Inventorship; who is an inventor; who contributes to the claims of a patentable invention and employment and assignment agreements and required language. The course reviews Intellectual Property Law Trade Secrets; publicly reviewable and appropriation.

The course reviews Intellectual Property Law Anticipation: A claimed invention may be rejected under 35 U.S.C. 102 when the invention is anticipated or is "not novel" over a disclosure that is available as prior art and can be a disclosure of the claimed invention by the inventor for an invention sale, publication or an offer to sell prior to the inventors application for a patent.

The course reviews Intellectual Property Law Obviousness and the requirement that an invention be non-obvious. 35 § USC 103.

This course provides an intellectual foundation and introduces a set of learning skills essential for success in the legal profession and for life beyond. The course will provide opportunities for careful reading, for creative and critical thinking, for oral and written communication, and for engaging with others in a shared conversation about stimulating material.

Course Material

This material is intended to be a guide in general and is not legal advice. If you have any specific question regarding the state of the law in any particular jurisdiction, we recommend that you seek legal guidance relating to your particular fact situation.

The course materials will provide the attendee with the knowledge and tools necessary to identify the current legal trends with respect to these issues. The course materials are designed to provide the attendee with current law, impending issues and future trends that can be applied in practical situations.

Course Learning Objectives and Outcomes

This course is designed to provide the following goals, learning objectives and outcomes:

The ability to recognize and describe the definition of Intellectual Property law and how it deals with laws to protect and enforce rights of the creators and owners of inventions, writing, music, designs and other works, known as the "intellectual property."

The ability to recognize and describe the relevant federal law related to Biomedical Intellectual Property Law and cases from the Federal Circuit and Appellate Courts.

Participants will develop the ability to understand the relevant federal case law related to the status of ongoing litigation between higher learning institutions

Participants will develop an understanding of intellectual property case law regarding Biomedical Devices, Pharmaceuticals and Genetic Engineering.

Participants will develop an understanding of Intellectual Property Law Inventorship; who is an inventor; who contributes to the claims of a patentable invention and employment and assignment agreements and required language.

Participants will develop an understanding of Intellectual Property Law Trade Secrets; publicly reviewable and appropriation.

Participants will develop an understanding of Intellectual Property Law Anticipation: A claimed invention may be rejected under 35 U.S.C. 102 when the invention is anticipated or is "not novel" over a disclosure that is available as prior art and can be a disclosure of the claimed invention by the inventor for an invention sale, publication or an offer to sell prior to the inventors application for a patent.

Participants will develop an understanding of Intellectual Property Law Obviousness and the requirement that an invention be non-obvious. 35 § USC 103.

Upon completion of the course, participants should be able to apply the course material; improve their ability to research, plan, synthesize a variety of sources from authentic materials, draw conclusions; and demonstrate an understanding of the theme and concepts of the course by applying them in their professional lives.

Timed Agenda:

Presenter Name: Adrienne B. Naumann

CLE Course Title: Recent Developments In Biomedical IP Law Part I: Patent Applications From Inventorship To Obviousness.

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Recent Developments In Biomedical IP Law Part I: Patent Applications From Inventorship To Obviousness.

Course Material

Inventorship

I. Inventorship

A. Bio-Rad Laboratories, Inc. v. International Trade Commission, 10XGenomics, Inc., Intervenor, 996 F.3d 1302 (Fed. Cir. 2021) [hereinafter 'ITC,' '10X' and 'BioRad']

1. *Outcome*: The Federal Circuit affirmed the ITC's (i) finding of no patent ownership by BioRad and (ii) its limited exclusion order

2. *Background*

a. two researchers/employees investigated droplet genetic technology at a company which later became Bio-Rad

b. their BioRad employment agreements stated in relevant part that

(1) intellectual property including ideas, solely or jointly conceived, and during their term of employment, shall be assigned to Bio-Rad

b. the researchers later resigned and created 10X, and where they patented a gel bead technology

c. these researchers subsequently sued Bio-Rad for infringing their gel bead technology patents, and

(1) where these patents were obtained subsequent to the end of their Bio-Rad employment.

d. on appeal, Bio-Rad contended that it was a co-owner of the 10X gel bead patents based upon the researchers' assignments, and

(1) consequently, there could be no infringement

3. *Federal Circuit analysis*

a. ideas that could contribute to post-employment inventions, and where these ideas may rise to the level of co-inventorship post-employment,

(i) did not fall within Bio-Rad's assignment for intellectual property created during employment, and

(1) this assignment also does not reach inventions created after the term of the assignment, and

(2) even if post-employment innovation comprises an idea that occurred during employment

(3) this particular assignment is, by its own terms, governed by California law, and

(4) California law strongly encourages changes in employment without onerous post-employment obligations

(5) the assignment by its terms only includes intellectual property created during employment, and

(6) this relatively narrower scope distinguishes it from other assignments with different terms and time durations, and so

(7) whether an employment assignment reaches post-employment subject matter is governed in large part by the terms of the assignment

b. alternatively, the researchers/inventors did not conceive of the patented invention during their employment, because

(1) Bio-Rad's characterization of the researchers' alleged conception during employment was too general to support joint inventorship, and

(2) these same general ideas were previously existing and the subject of widespread endeavor in the industry

(3) there was no evidence that the researchers' conception date for a gel bead technology occurred prior to their employment departure date.

Trade Secrets

II. Trade Secrets

A. Life Spine, Inc. v. Aegis Spine, Inc., 8 F.4th (7th Cir. 2021) [hereinafter 'Life Spine' and 'Aegis Spine']

1. *Outcome:* Affirmed the district court's preliminary injunction order in a trade secret misappropriation case.

2. *Background*

a. Life Spine patented a medical device for insertion into a patient's spine, although

(1) this patent did not disclose interconnectivity or exact dimensions of all components

b. Life Spine contracted with Aegis to distribute its patented device to hospitals and surgeons, and

(1) Aegis signed a confidentiality agreement which included

(2) a prohibition against reverse engineering the device, as well as Aegis' obligations to protect Life Spine's confidential information

(3) however, Aegis's parent company used Life Spine's confidential information to produce a competing device

c. Life Spine then filed a trade secret misappropriation lawsuit against Aegis for selling this competing medical device

d. the district court entered an injunction prohibiting Aegis and its business partners from marketing the competing device

e Aegis appealed the injunction, in part contending

(1) that there was no trade secret because the alleged confidential information was publicly available,

(2) by the public viewing of the actual device at trade shows and the patent itself

3. *Appellate court analysis*

a. a company may maintain trade secret protection in undisclosed features even if it publicly discloses other features of the same product.

b. in this case, a third party could learn the precise measurements only with physical access to the device and sophisticated measurement technology, and

(1) most of these quantitative measurements were not disclosed in the patent

c. by selling exclusively to hospitals and surgeons, Life Spine did not disclose these dimensions, because

(1) Life Spine's representative was present during operations with the device, and

(2) hospitals and physicians signed confidentiality agreements

B. Oakwood Laboratories LLC v. Thanoo et al., 999 F.3d 892 (3d Cir. 2021)

1. *Outcome*: The appellate court vacated the district court's dismissal of the third amended complaint for trade secrets misappropriation, and
    a. remanded for further proceedings

2. *Background*
    a. Oakwood developed an injectable sustained release pharmaceutical within a microsphere delivery system, and
        (1) defendant Thanoo was the principal developer of this microsphere technology
        (2) thereafter Thanoo became employed by the defendant company Auromedics Pharma LLC
    b. Oakwood negotiated with Auromedics to jointly develop microsphere technology, and
        (1) provided a comprehensive document on the microsphere technology under a confidentiality agreement, but
        (2) after tis disclosure Auromedics ceased negotiations
    c. when Oakwood sued Thanoo and his new employer Auromedics for trade secret misappropriation, the district court dismissed the case, in large part based upon:
        (1) insufficient description of the trade secrets,
        and
        (2) insufficient allegations of the act of misappropriation

3. *Appellate court analysis*
    a. under the federal Defend Trade Secrets Act, an act of misappropriation includes use of the trade secret, and
        (1) 'use' is interpreted with a very broad scope
    b. a motion to dismiss a trade secret misappropriation lawsuit should not be granted unless there are no plausible allegations within the complaint
    c. Oakwood sufficiently identified its trade secrets, in part by
        (1) identification of variables affecting development of the microsphere technology such as test methods and results
            (i) as well as manufacturing processes, quality assurance, marketing strategies and regulatory compliance
        (2) also attached to the complaint were:
            (i) a memorandum provided under Auromedic's confidentiality agreement for negotiation, and

(ii) other documents containing secrets related to the microsphere project.

d. Thanoo began employment with Auromedics after the end of the negotiations relating to microsphere projects

e. Auromedics spent $6 million in development for four microsphere products, while

(1) Oakwood previously spent $130 million for it original microsphere development over almost twenty years

f. the above circumstantial evidence demonstrates that

(1) Auromedics and Thanoo plausibly used Oakwood's trade secrets, without permission, to create Oakwood's technology in record time

C. Mallet and Company, Inc. v. Lacayo et al., 16 F.4th 364 (3rd Cir. 2021)

1. *Outcome:* The preliminary injunction was vacated and remanded.

2. *Background*

a. Mallet and defendant company Synova compete in the release agent market for commercially distributed baking goods

b. the release agents generically comprise vegetable oils, mineral oils and lecithin as ingredients, but

(1) each formulation depends upon various parameters as well as implementation for release agent(s) and baking equipment

c. evidence indicated that Mallet's former employees, including Ms. Lacayo downloaded Mallet's release agent information, and

(1) thereafter was employed by the defendant company

d. the district court granted Mallet a preliminary injunction which prohibited defendants from using Mallet's trade secrets

(1) the injunction order included in relevant part:

[refrain from] "using Mallet's confidential, proprietary and/or trade secret information in any respect."

(2) however, the injunction order did not elaborate upon which information comprised trade secrets

3. *Appellate court analysis*

a. the injunction lacked sufficient specificity for a meaningful appellate review, because

b. the injunction comprised thirteen broad categories which included

(1) publicly known information, including Mallet's own patent disclosures, and

(2) generally known information within the industry.

c. the injunction also did not differentiate or define

(1) know how acquired during employment, from

(2) actual trade secrets

d. the trade secret owner is responsible for demonstrating that its claimed trade secrets are protectable, and

(1) do not merely comprise general industry knowledge

e. takeaway: in licensing agreements and confidentiality agreements, be sure to carefully define and distinguish

(1) industry and employment 'know how' from

(2) information which could qualify as a trade secret

D. Masimo Corp. et al. v. True Wearables, Inc. et al., 2022 U.S. App. Lexis 1923 (Fed. Cir. Jan. 24, 2022) [non-precedential]

1. *Outcome:* Affirmed the preliminary junction granted to Masimo on its trade secret claims.

2. *Background*

a. Masimo had developed a proprietary algorithm for implementation within blood content detectors

b. Masimo learned that True Wearables had obtained the U. S. patent office's allowance for a patent application

(1) which included a version of Masimo's proprietary algorithm without Masimo's permission, and where

(2) a True Wearables employee had previously been employed by Masimo to develop versions of this particular algorithm.

c. Masimo moved for a preliminary injunction against True Wearables to prevent publication of the patent, because

(1) this algorithm would become public knowledge and no longer be a trade secret, after

(2) the application became a patent

(3) True Wearables contended that the algorithm was already publicly disclosed within the statistics industry and engineering community,

(i) so, it no longer possessed trade secret status

3. *Federal Circuit analysis*

a. publication does not necessarily result in loss of trade secret status if the published information is not generally known to people who could obtain economic value from it

b. in this case, publication occurred exclusively in the statistics community and electrical engineering industry, and

c. these industries are sufficiently far removed from the healthcare community to conclude that the algorithm

(1) was not generally known to people

(2) who could obtain economic value from it for developing blood content detectors

Anticipation

III. Anticipation, 35 U.S.C. section102

A. Junker v. Medical Components, Inc. et al., 25 F.4th 1027(Fed. Cir. 2022)

1. *Outcome:* The Federal Circuit reversed the summary judgement of no patent invalidity

2. *Background*

a. Mr. Junker owned a design patent for the ornamental design of a removable catheter sheath

b. Mr. Junker's associate sent a letter to a potential purchaser with specific information about items such as price and delivery

c. Mr. Junker commenced a lawsuit for infringement of his design patent by Medical Components

d. Medical Components contended that the letter was an offer for sale under 35 U.S.C. section 102

(1) the application for this catheter was submitted to the U.S. patent office more than one year after the letter's date, and

(2) so, the resulting patent was invalid.

e. however, the district court concluded that there was no on sale bar based upon the letter's standard commercial terms which generally appear within a firm business offer

3. *Federal Circuit analysis*

a. this letter qualified as a specific offer for sale, and not an initial negotiation, because in large part

(1) the letter was directed solely to a single company in response to a quotation request from this company, and

(2) there were several standard terms typical for a final commercial offer such as: delivery conditions, allocation of risks and liability, payment terms and purchase options

(3) the product described in the letter embodied the claimed design.

B. In re SurgiSil,14 F.4th 1380 (Fed. Cir. 2021)

1. *Outcome:* Reversal of the Patent Trial and Appeal Board's [P.T.A.B.'s] decision affirming the examiner's anticipation final rejection.

2. *Background*

a. SurgiSil's design patent application addressed an ornamental design for a manufactured lip implant

b. the examiner rejected the lip implant design application based upon anticipation by an earlier art tool design, and

(1) the P.T.A.B. affirmed, because

(2) in its view prior art for a claimed design is not limited to the manufactured article identified in the application claim

3. *Federal Circuit analysis*

a. prior art to a design claim is limited to the manufactured article identified in the claim, and

(1) here the claim is limited to lip implants

b. therefore, the lip implant design is not anticipated by a design for earlier non-lip implant devices, and

(1) where non-lip implant devices include art tools

Obviousness

IV. Obviousness, 35 U.S.C. section 103

A. Eli Lilly& Co. v. Teva Pharmaceuticals International GmBH, 8 F.4th 133 (Fed. Cir. 2021)

1. *Outcome:* Affirmed P.T.A.B.'s inter partes review final decision that method of treatment claims were valid.

2. *Background*

a. the disputed claims of three patents were directed to methods for treating migraines and other vasomotor ailments

b. the treatment includes administering a specific bioengineered antibody that targets a vasodilator associated with migraines

c. One representative independent claim reads in relevant part: A method for treating headache in an individual…. administering to the individual an effective amount of a humanized antibody…. [emphasis added]

d. Lily contended in its petition for inter partes review that

(1) the P.T.A.B. had improperly construed the claim preamble stating the intended purpose, that is, treating headache, as a claim limitation, and

(2) the claims were obvious over three references, because

(i) there was a reasonable expectation of success by skilled artisans in the industry when combining these references

3. *Federal Circuit analysis*

a. claim construction

(1) a statement of intended purpose in a method of treatment claim preamble generally is properly characterized as a claim limitation

(2) here migraine or headache treatment is paramount throughout the patent's disclosure, and

(3) these claims would not necessarily be operable for the same treatment of other medical conditions

(4) the preambles also provide antecedent basis for at least one subsequent claim limitation, i.e., administering to the individual, and

(5) without an individual experiencing vasomotor symptoms, there would be no claimed 'effective amount' of the antibody

b. Whether an ordinary skilled artisan would have a reasonable expectation of success

(1) a motivation to combine references is not the same inquiry as

(2) whether a skilled artisan in the same industry would have a reasonable expectation of success based upon the references, and

(i) if there is such a reasonable expectation then their obviousness finding becomes more probable

(3) both inquiries are necessary in an obviousness evaluation

c. here there was no reasonable expectation of success, because

(1) one reference was interpreted in a conflicting manner by experts, and

(2) another reference disclosed significant differences between the claimed large antibodies and the reference's smaller molecules

(3) in sum, there was substantial evidence of no reasonable expectation of success, and therefore no obviousness on this basis

B. Teva Pharmaceuticals International GmbH v. Eli Lilly & Co. et al., 8 F.4th 1349 (Fed. Cir. 2021)

1. *Outcome:* Affirmed the P.TA.B.'s conclusion of obviousness of Teva's claimed antibodies.

2. *Background*

a. Eli Lilly filed an inter partes review petition alleging that claims to Teva's bioengineered antibodies for treating migraines were obvious

b. the P.T.A.B. concluded that Teva's evidence of its patented product's commercial success, including licensing, was insufficient to overcome obviousness

3. *Federal Circuit analysis*

a. there is a rebuttable presumption of nexus [that is, a cause-effect relationship] between

(1) commercial success and a product as disclosed and claimed, and

(2) if the product is co-extensive with these claims

b. Teva's commercial success contention was based in part upon its distributed products, and

(1) which comprise antibodies of the challenged claims.

c. however, because Teva's claims were functional, and not structural, in limitations

(1) a claim encompassing a quantitively large group of antibodies does not qualify as nexus to any particular antibody.

d. furthermore, there was a separate Teva patent claiming features which were, however, unclaimed in the disputed patent in this appeal

(1) there was sufficient evidence that these unclaimed features were critical, and

(2) may have significantly contributed to commercial success,

(3) so there was no direct cause-effective relationship

e. any nexus between a Teva licensing agreement and the claimed invention was tenuous, because

(1) the licensed products were apparently not co-extensive with any particular claim, and

(2) the license included more than 150 additional antibodies

C. University of Strathclyde v. Clear-Vu Lighting, LLC, 17 F.4th 155 (Fed. Cir. 2021).

1. *Outcome*: Reversed the P.T.A.B.'s inter partes review finding of obviousness, because it was not supported by substantial evidence

2. *Background*

a. Strathclyde's patented invention is directed to killing antibiotic resistant bacteria exclusively with blue light of specific wavelengths, and

(1) without a photo sensitizing agent

b. Clear-Vu relied upon one reference that described a successful method for inactivation of bacteria, but this method required a photosensitizer

(1) the secondary references disclosed experiments, but no inactivation without a photosensitizer

(2) although one secondary reference disclosed quantified parameters to modify if a photosensitizer was present

3. *Federal Circuit analysis*

a. motivation to combine references

(1) a skilled artisan would not be motivated to entirely omit a photosensitizer when combining these references,

(2) because they each disclosed success exclusively with a photosensitizer

b. there was no reasonable expectation of success

(1) none of the references disclosed successful inactivation without a photosensitizer

(2) others failed to inactivate these bacteria without a photosensitizer despite attempts with diverse light doses and blue light wavelengths

D. Almirall, LLC et al. v. Amneal Pharmaceuticals LLC et al., 28 F.4th 265 (Fed. Cir. 2022)

1. *Outcome*: Affirmed the P.T.A.B's inter partes review decision that claims were obvious over prior art references

2. *Background*

a. Almirall claimed methods for treatment of certain skin ailments with a formulation comprising in relevant part:

(1) a specific "viscosity builder," which comprised a co-polymer designated as an "A/SA agent"

(2) this claimed A/SA agent was disclosed by two of three references, and

(i) one of these references described A/SA agent as an excellent gelling and thickening agent (i.e., a viscosity builder)

(3) the remaining third reference disclosed viscosity builders other than A/SA agents, and in particular a substance known as a carbomer

b. the P.T.A.B. concluded that there was motivation for an ordinary skilled artisan

(1) to combine the disclosure of one reference with the A/SA agent disclosed by the two remaining references, because

(2) the two references disclosing A/SA agents, as well as expert testimony, evidenced that an ordinary skilled artisan would substitute A/SA agent for the carbomer thickening agent in the remaining reference, and

(3) thereby achieve the claimed invention with a reasonable expectation of success, in part because

(i) the A/SA gelling agent and the carbomer viscosity builder predictably functioned in the same manner as in their previous utilities, and

(4) the A/SA gelling agent and the carbomer were known to be functionally and chemically interchangeable for this skin topical utility, but

(5) it was well known the A/SA gelling agent was significantly superior for this purpose over the carbomer disclosed in the primary reference

b. moreover, the ranges of the claimed viscosity builder/gelling agent overlapped with the references' ranges of gelling agents

c. Almirall appealed, contending that the P.T.A.B. erred with this finding.

3. *Federal Circuit analysis*

a. substantial evidence confirmed that the claimed A/SA thickening agent was functionally interchangeable with the carbomer, and

(1) was otherwise compatible with the remaining claimed formulation components

b. there was no acceptable evidence that values within Almirall's claimed ranges provided unexpected results or significant improvements over prior formulations, and

c. here the claimed A/SA gelling agent was predictable, because it was a known substitute for a prior art thickening/gelling agent

d. one reference explicitly stated that these prior art materials were well known in the industry

e. based upon this predictability there was both a (i) motivation to combine, and (ii) a reasonable expectation of success for this claimed substitution.

E. Teva Pharmaceuticals USA, Inc. v. Corcept Therapeutics, Inc., 18 F.4th 1377 (Fed. Cir. 2021)

1. Outcome: Affirmed the P. T. A. B.'s final post-grant review decision finding non-obviousness

2. *Background*

a. Corcept claimed a 600 mg. dose of a specific pharmaceutical combined with a specific biochemical inhibitor for treating Cushing's disease (i.e., an ailment causing excess cortisol production)

b. the prior art taught that only less than and including 300 mg. of this specific pharmaceutical drug was considered clinically safe.

c. the P.T.A.B. concluded that the claimed 600 mg. dose

(1) combined with a specific biochemical inhibiter was not obvious

3. *Federal Circuit analysis*

a. there was no reasonable expectation of success for claimed treatment based upon the references, because

(1) the success is tied to the claimed daily dose of 600 mg. together with a specified inhibitor, and

(2) according to expert testimony, there was no expectation for any safe dose over 300 mg.,

b. here there was no range overlap, because the prior art range was capped at 300 mg. daily, and

c. an ordinary skilled artisan would not have expected this higher dose to behave similarly to a lower dose, and much less in an unexpected significantly improved manner

F. Adapt Pharmaceuticals et al. v. Teva Pharmaceuticals, Inc. et al., 25 F.4th 1354 (Fed. Cir. 2022)

1. *Outcome:* Affirmed the district court's determination of obviousness

2. *Background*

a. the challenged patents claimed

(1) methods of treating an opioid overdose by intranasal administration of a formulation (with naloxone as the active ingredient) as well as

(2) devices for intranasal administration thereof

b. previously only trained medical staff could administer the formulation intravenously, and

(1) the intranasal device required assembly prior to use and generally delivered excessive fluid

c. the FDA previously encouraged development of improved products to overcome these hurdles

d. Teva submitted an Abbreviated New Drug Application (ANDA)to the FDA requesting approval for

(1) a generic version of Adapt's patented device and formulation.

e. after Adapt brought a patent infringement lawsuit,

(1) Teva contended that the claimed formulation ranges were obvious over several references

f. the district court agreed that the asserted range claims would have been obvious in view of the references, and

(1) entered a final judgement of invalidity

g. Adapt appeals the obviousness and invalidity judgment

3. *Federal Circuit analysis*

a. obviousness requires a motivation to combine analysis

(1) separate and apart from a reasonable expectation of success analysis.

b. here the prior art intranasal device shortcomings were well known in this industry during the relevant time period

c. the FDA encouraged development of an improved intranasal treatment several years prior to the patent priority date

d. both the references and experts recognized drawbacks of earlier intranasal treatments

e. an ordinary skilled artisan previously knew that the claimed formulation ingredient sodium chloride is often present to prevent nasal irritation, and

(1) the references disclosed the concentration of sodium chloride within the claimed ranges

f. evidence indicated that in prior formulations, pH, i.e., hydrogen ion concentration, is routinely optimized between 3.5 and 7 to avoid nasal irritation

g. the claimed preservative is commonly used in intranasal formulations, and

(1) one reference disclosed a value within the claimed range

(2) the claimed preservative/filler prevents naloxone degradation, and

(i) is expressly taught in one reference

h. after a 2012 industry FDA meeting, an ordinary skilled artisan would have created the claimed device as requiring an improved one step treatment

i. a skilled artisan in this industry would have implemented the claimed 4 mg. dosage intranasally

(1) based upon the known bio equivalency with the corresponding intravenous dosage

j. the references provide examples comprising the active ingredient combined with claimed formulation ingredients

G. University of California et al. v. The Broad Institute et al., Interference No.106,048 (P.T.A.B. 2017)

1. *Outcome*: The P.T.A.B. dismissed the interference
2. *Background*

a. an interference determines which person was the first to invent the same single invention as that claimed by another person

b. the molecular assembly known as CRISPR-Cas9 alters genetic sequences, and

(1) naturally does so in bacteria for protection against viruses

c. more specifically, the CRISPR-Cas9 system comprises a combination of (i) protein and (ii) genetic material known as ribonucleic acid (RNA) and (iii)unique structural characteristics [hereinafter CRISPR-Cas9

d. Broad (including Massachusetts Institute of Technology and Harvard) and U.C. (including European colleagues) each asserted to be the first inventor(s) of a bacterial derived CRISPR-Cas9, with these same structural characteristics, operable in plant and animal cells [eukaryotes]

e. UC's patent applications exclusively claimed and described operable CRISPR-Cas9 in a cell-free environment, but

f. Broad's patents and applications all explicitly described and claimed CRISPR-Cas9 which cleaved genetic material successfully in eukaryotic cells

g. the P.T.A.B. concluded that there were two separate inventions:

(1) the CRISPR-Cas9 which operates in an in vitro cell free environment, and

(2) the CRISPR-Cas9 which operates in eukaryotic cells, and so it dismissed the interference, because

(3) there was no reasonable expectation of success that bacterial derived CRISPR-Cas9 would operate successfully in eukaryotic cells

3. *The Federal Circuit* affirmed the P.T.A.B. in University of California et al. v. The Broad Institute, Inc. et al., 903 F. 3d 1286 (Fed. Cir. 2018)

a. the test for patentably distinct inventions is whether each invention is non-obvious in view of the other, and

b. obviousness requires that there be a reasonable expectation of success

c. in this case, experts testified, or previously observed, that operability of bacterial components in eukaryotic cells was unpredictable, and

d. eukaryotic cells may degrade bacterial derived CRISPR-Cas9, or this CRISPR-Cas9 may not penetrate eukaryotic protein/DNA complexes,

(1) in addition to other potential hurdles such as temperature, ion concentration, and acid concentration

e. the inventors also stated as of 2012 that a successful CRISPR-Cas9 assembly in eukaryotes would be difficult to achieve

f. this substantial evidence demonstrated that there was no reasonable expectation of success in achieving CRISPR-Cas9 operable in eukaryotic cells, and

(1) therefore, there was no obviousness, and

(2) the two CRISPR-Cas9 assemblies (bacterial and eukaryotic) were patentably distinct

g. because there were two inventions and not one, the Board properly dismissed this interference

H. Auris Health Inc. v. Intuitive Surgical Operations, 32 F.4th 1154 (Fed. Cir. 2022)

1. *Outcome*: Vacated and remanded to P.T.A.B. based upon incorrect obviousness finding

2. *Background*

a. Intuitive's patent was directed to a robotic surgery system that

(1) remotely exchanges surgical tools using a combined controller and pulley system

b. all the claim limitations were individually present in the reference

c. Intuitive contended that was no motivation to combine claimed limitations disclosed in the references, because

(1) there was general skepticism within the industry regarding any kind of robotic surgery

d. upon appeal, Auris challenged the P.T.A.B.'s reliance upon general industry skepticism about robotic surgery to find no motivation to combine the references

3. *Federal Circuit analysis*

a. industry problems addressed in a patent may provide a reason to combine elements in the claimed manner

b. however, evidence of skepticism should be specific to the claimed invention and not generic to the industry.

c. no caselaw was provided which supports the contention that generic skepticism indicates no motivation to combine to arrive at a specific claimed invention

Resources

Resources Specific to this Course

In addition, please see the resources cited within the material.

Resources for the Legal Professional

ABA Center for Professional Responsibility - www.abanet.org/cpr

Chicago Bar Association - www.chicagobar.org

Commission on Professionalism - www.2civility.org

Judicial Inquiry Board - http://www.illinois.gov/jib

Illinois Board of Admissions to the Bar - www.ilbaradmissions.org

Illinois Department of Financial and Professional Regulation - www.idfpr.com/default.asp

Illinois Lawyers' Assistance Program, Inc - www.illinoislap.org

Illinois State Bar Association - www.isba.org

Illinois Supreme Court - www.state.il.us/court

Lawyers Trust Fund of Illinois - www.ltf.org

MCLE Program - www.mcleboard.org