Contra Costa County Bar Association
Intellectual Property Law Section
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Review of Sections 101, 112, and Obviousness-Type Double Patenting

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The information presented is intended for educational purposes only, and should not be relied upon as legal advice.

If you have a legal question, please consult a competent attorney.

35 U.S.C. §101

Patent Eligible Subject Matter

"**A Diagnostic On Ramp to Highway 101**"

Cardionet v. InfoBionic

955 F.3d 1350 (Fed. Cir. 2020)

Two patents were subject of the decisions

The Invention

Cardionet obtained two patents directed toward differential diagnosis of atrial fibrillation and atrial flutter.

Background

Electrical activity leading to a heart beat in a normal condition is initiated by depolarization of a group of cardiac cells ("pacemakers" in the sinoatrial node or "SA" node).

Electrical depolarization is conducted to another group of cells ("AV node"). The AV node transmits the electrical signal simultaneously to the ventricular muscle, causing the ventricles to contract in a coordinated fashion.

The Invention

Atrial fibrillation and atrial flutter are characterized by increased rates of depolarization in the AV node and atrial muscle, thereby producing rapid contractions of the atria (atrial flutter). In atrial fibrillation, the rates of depolarization are increased further, so the atria do not contract in a coordinated fashion.

If the AV nodes do not properly transmit signals, a ventricular pacemaker may take over, and if that pacemaker is not part of the regular ventricular conductors, the ventricles may not contract in a coordinated fashion, leading to ventricular fibrillation, a potentially fatal condition.

The ‘207 Patent

Cardionet I

The district court found that the claims of U.S. Patent No. 7,941,207 (the ‘207 patent), to be ineligible for patenting under 35 U.S.C. §101, being drawn to a natural phenomenon.

On appeal to the Fed. Cir., Judge Stoll noted that the claims included detecting atrial fibrillation and atrial flutter, using ***non-linear statistical approaches***.

The ‘207 Patent

In Alice step one, we look to whether the claims ‘focus on a ***specific means or method that improves the relevant technology*** … We hold that the asserted claims of the ‘207 patent are directed to patent-eligible subject matter.

“The device more accurately detects the occurrence of atrial fibrillation and atrial flutter--as distinct from V-TACH or other arrhythmias—and ***allows for more reliable and immediate treatment*** of these two medical conditions.’

Generalizing the asserted claims as being directed to collecting, analyzing, and reporting data is inconsistent with our instruction ‘be careful to avoid oversimplifying the claims’ by looking at them generally and failing to account for the specific requirements of the claims.

The ‘850 Patent

Cardionet II

In contrast with the ‘207 patent, No. 7,212,850 (the ‘850 patent) do not claim patent eligible subject matter. Claim 31 is representative:

31. A system for reporting information related to arrhythmia events comprising:

a monitoring system ***configured to*** process and report physiological data, … and configured to identify arrhythmia events from the physiological data;

a monitoring station for receiving the physiological data from the monitoring system;

a processing system ***configured to*** receive arrhythmia information from the monitoring system and ***configured to*** receive ***human-assessed*** arrhythmia information from the monitoring station.

The ‘850 Patent

Judge Lourie found: “At step one, we conclude that the claims are ***directed to collecting, analyzing, and displaying data***, which we have repeatedly held to be ***abstract concepts***.”

Comments:

In Cardionet I, the claims were held eligible because of the use of “non-linear processes,” whereas in Cardionet II, no such limitations were present.

Unfortunately, the specification did not specify which non-linear processes were used, representing a possible challenge under 112(a) for lack of written description.

Illumina v. Ariosa et al.

Slip. Op. 2019-1419 (Federal Circuit. 17 March 2020)

Background:

Cell-free fetal DNA (cffDNA) present in the mother's blood, and is useful for identifying fetal genetic abnormalities.

Prior to U.S. Patent No. 6,258,540 (the '540 patent") diagnosis of fetal genetic abnormalities required amniocentesis.

In *Ariosa v. Sequenom* ("Ariosa") the Federal Circuit held claims to cffDNA of the '540 patent were ineligible, drawn to a law of nature.

Illumina v. Ariosa et al.

U.S. Patent No. 9,580,751 (the '751 patent)

The '751 patent took a different approach to claiming cffDNA than invalidated patent ('540) in Ariosa.

According to the application, analysis of cell-free fetal DNA was uncertain because of the relatively small amount of fetal DNA in a sample of maternal blood.

Illumina v. Ariosa et al.

Claim 1 is illustrative

1. A ***method***, comprising:

(a) extracting DNA comprising maternal and fetal DNA fragments from a substantially cell-free sample of blood plasma or blood serum of a pregnant human female;

(b) ***producing a fraction of the DNA extracted*** in (a) by:

(i) size discrimination of extracellular circulatory fetal and maternal DNA fragments, and

(ii) ***selectively removing the DNA fragments greater than approximately 300 base pairs***, and

…

(c) analyzing DNA fragments in the fraction of DNA produced in (b).

Illumina v. Ariosa et al.

Federal Circuit

Judge Lourie noted:

Laws of nature and natural phenomena are not patentable, but applications and uses of such laws and phenomena may be patentable.

A claim to otherwise statutory subject matter does not become ineligible by its use of a law of nature or natural phenomenon [citing *Diamond v. Diehr*, 450 U.S. at 187].

Regarding the Mayo/Alice test, "we examine whether the claims are "***directed to***" a law of nature or natural phenomenon. Importantly, simply because a claim "recites" a judicial exception, that does not mean the claim is "directed to" the exception.

Illumina v. Ariosa et al.

"This is ***not a diagnostic case***. And it is ***not a method of treatment*** case. It is a ***method of preparation*** case."

Those process steps ***change the composition of the mixture***, resulting in a DNA fraction that is different from the naturally-occurring fraction in the mother's blood.

The focus of the dispute in this case is whether the claims of the '751 patent are "***directed to***" the natural phenomenon, i.e., whether they claim the discovered natural phenomenon itself versus ***eligible subject matter that exploits the discovery*** of the natural phenomenon.

We conclude that the claims are ***not*** directed to that natural phenomenon but rather to a patent-eligible method that utilizes it.

October 2019 Update USPTO 101 Guidance

Mere ***recitation of a judicial exception does not mean that the claim is "directed to***" that judicial exception under step 2A Prong Two.

Instead, under Prong Two, ***a claim that recites a judicial exception is not directed to that judicial exception, if the claim as a whole 'integrates the recited judicial exception into a practical application*** of that exception.'

Comment

Patent Examiners may consider claims ineligible if they simply "recite" a natural phenomenon. Illumina and the update guidance may provide an argument that the claims are not "directed to" and therefore are patent eligible.

Athena v. Mayo
Slip. Op 2-17-2509 (Fed. Cir. 2019)

Background

Athena is licensee of U.S. Patent No. 7,267,820 (the "'820 patent"), which claims methods for diagnosing neurological disorders by detecting antibodies to muscle-specific tyrosine kinase (MuSK).

A truncated version of Claim 9 is representative.

A ***method for diagnosing*** neurotransmission or developmental disorders in a mammal comprising ***detecting*** in a bodily fluid ***autoantibodies*** to an epitope of muscle specific tyrosine kinase (MuSK).

Athena v. Mayo

Court Decisions

The district court noted that the '820 patent's "specific concrete" steps were characterized generally as "routine, conventional steps" involving well-known enzyme-linked immunosorbent assays (ELISA).

The district court granted Mayo's motion holding that claims 6-9 were ***ineligible for reciting well-known, conventional steps***.

The Federal affirmed.

Athena v. Mayo

Dissent by Judge Newman

Claims 7-9 require specific steps. The panel majority ignores these steps, and instead holds that 'claims 7-9 are directed to a natural law because the claimed advance was only in the discovery of a natural law, and that the additional recited steps only apply conventional techniques.

Eligibility is determined for the claim, including all its elements and limitations. Claim limitations cannot be discarded when determining eligibility.

It is ***inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis*** (citing *Diamond v. Diehr*).

Athena v. Mayo

These inventors are not claiming a newly described autoantibody; but a ***new multi-step diagnostic method*** a man-made reaction sequence ***employing new components in a new combination***.

Section 101 does not exclude new methods of diagnosis of human ailments.

The majority misconstrues the claim, in holding that claims 7-9 are directed to the 'concept' of 'the correlation between the presence of MuSK autoantibodies and MuSK-related neurological diseases like MG."

The claimed method determines whether this correlation is present, for diagnostic purposes, but ***the concept itself is not claimed***.

Diagnosing *Myasthenia Gravis* is not a law of nature, but a ***man-made chemical-biomedical procedure.***

Athena v. Mayo

Section 101 does not turn on whether any claim steps are '***standard techniques***.' The appropriate analysis of the rule of conventional processes steps in claims to a new method is under Sections 102 and 103, not Section 101."

Suggestions

Do not state that any methods are "standard."

Described all methods in detail.

Include "methods of treatment" steps like in *Vanda*.

Keep a continuing patent on file.

During prosecution, include court decisions and not only USPTO guidance.

"Section 101 Has Reached Detroit"
American Axle v. Neapco

American Axle & Manufacturing, Inc. v. Neapco Holdings LLC
Slip. Op. 2018-1763 (AAM #1; 3 October 2019 Fed. Cir.) and
American Axle & Manufacturing, Inc. v. Neapco Holdings LLC
Slip. Op. 2018-1763 (AAM #2; 31 July 2020 Fed. Cir.)
American Axle & Manufacturing, Inc. v. Neapco Holdings LLC
Slip. Op. 2018-1763 (AAM #3; 23 October 2020 Fed. Cir.)

These three cases illustrate some of the confusing and inconsistent decisions by courts applying section 101.

American Axle v. Neapco

Background

Driveshafts for cars and trucks ("propshafts") are integral to nearly all vehicles. Propshafts are generally hollow tubes, and can suffer from vibrations, which can produce noise, and can damage the propshafts and reduce their life span.

There are three types of vibration, "bending mode," shell mode," and "torsion mode."

Bending mode vibration involves energy transmitted longitudinally along the shaft and causes the shaft to bend. (Cls 1, 22 and 36).

Shell mode vibration involves a standing wave transmitted circumferentially about the shaft and causes the cross-section of the shaft to deflect or bend. (Cls 1, 22, & 36).

Torsion mode vibration involves energy transmitted tangentially through the shaft and ***causes the shaft to twist***. (Claim 36 only).

American Axle v. Neapco

American Axle ("AAM") addressed the problems by inserting "liners" into the hollow propshafts, which dampen the vibrations, and resulted in quieter, more long lasting vehicles, and was granted U.S. Patent No. 7,774,911 (the "911" patent).

Three independent claims and several dependent claims issued. The district court decided *sua sponte*, to consider only two independent claims 1 and 22. A truncated version of Claim 22 is below.

22. A method for manufacturing a shaft assembly of a driveline system, comprising:

providing a hollow shaft member (drive shaft);

tuning a mass and a stiffness of at least one liner; and

inserting the liner into the shaft member;

wherein the liner is a tuned ***resistive absorber*** for attenuating ***shell mode*** vibrations and a tuned ***reactive absorber*** for attenuating ***bending mode*** vibrations.

American Axle v. Neapco

AAM sued Neapco, and Neapco filed a motion for summary judgment alleging that the claims were ineligible laws of nature, namely Hooke's law, **F=kx**, where **F** is the force a spring, **k** is the "spring constant," and "**x**" is the displaced distance. This is a simple linear relationship.

The district court held for Neapco.

American Axle v. Neapco

Neither the claims nor the specification describes how to achieve such tuning. ***The specification does not discuss the process by which that liner is tuned***.

The district court concluded: "the Asserted Claims as a whole are directed to laws of nature: ***Hooke's law and frictional damping***." … The district court held that the claims' direction to tune a liner to attenuate to different vibration modes amounted to merely "instructing" one to apply Hooke's law without "providing a particular means of how to craft the liner and propshaft in order to do so.

Judge Dyk, for Federal Circuit, affirmed.

American Axle v. Neapco

The asserted claims as a whole are directed to laws of nature: Hooke's law and frictional damping.

However, the majority offered several "natural laws"

1) "Hooke's Law and ***frictional damping***"
2) "Hooke's Law and ***possibly other natural laws***"
3) "Hooke's Law and ***nothing more***"

In essence, AAM's argument is that the system of the invention (a driveline propshaft and its liner) is too complex to be described by mere application of Hooke's law, which itself is a simple ***approximation of a single-degree-of-freedom spring-mass system***.

American Axle v. Neapco

The assertion that the system involved in the '911 patent is more complex than just a bare application of Hooke's law, does not render the subject matter patent eligible.

What is ***missing is any physical structure*** or steps for achieving the claimed result of damping two different types of vibrations."

Dissent: Judge Moore argued:

The majority's parrots the *Alice/Mayo* two-part test, but reduces it to a single inquiry: If the claims are directed to a law of nature (even if the court cannot articulate the precise law of nature) then the claims are ineligible and ***all evidence of non-conventionality will be disregarded*** or just plain ignored.

American Axle v. Neapco

Section 101 is monstrous enough, ***you need not even identify the precise natural law***. The claims "are directed to some ***unarticulated number*** of possible natural laws apparently smushed together and thus ineligible under §101.

The conclusion that claims 1 and 22 are representative is not correct. The parties did not agree, and the courts did not hear arguments of limitations of dependent claims.

It is ***inappropriate in light of these facts for the majority to sua sponte declare the claims representative*** and ignore the expressly argued dependent claims and limitations, and ignored Claim 36.

The majority concludes that the inventive concepts make no difference. Section 101 should not subsume section 112.

"The majority worries about result-oriented claiming; I am worried about ***result-oriented judicial action***."

American Axle v. Neapco

A request for rehearing *en banc* was denied 6 to 6. The court held Claim 22 to be ineligible under the invalidated claim 8 of *O'Reilly v. Morse*." Several dissents were lodged but only a few points are mentioned:

The majority announces that a claim is patent ineligible if it "clearly ***invokes*** a natural law, and nothing more, to accomplish a desired result." (the so-called "***nothing more test***").

This case does not represent an application of *O'Reilly*. It is, an expansion that would likely render ineligible ***claims found patent eligible by the O'Reilly court*** itself.

Despite this, the ***majority forges on, adopting a test that was proposed by no one***.

American Axle v. Neapco

Petition for Certiorari

On 28 December 2020, AAM filed a Petition for Certiorari. According to AAM,

"American Axle invented a new process for making a new, useful, and tangible thing. It is the type of invention that has long been eligible for patenting" (*Diamond v. Diehr*).

Truncated Questions Presented:

1. What is the appropriate standard for determining whether a patent claim is "directed to" a patent-ineligible concept under step 1 of Mayo/Alice?

2. Is patent eligibility a **question of law** for the court based on the scope of the claims or a **question of fact** for the jury?

American Axle v. Neapco

Amici filed briefs in this early sage. Most agree with AAM that the Supreme Court should grant Cert. Among the amici are the NYIP Law Association ("NYIPLA"), the Director of the USPTO, and the US Solicitor General.

NYIPLA: ***the statute*** is clear and ***does not include any "judicial exceptions***." There are no other statutory obligations in Section 101 beyond "utility."

Comments

Section 101 is based on the US Constitution, and the statute reflects Constitutional language, including "discoveries." The definition of "discoveries" in 1789, and still does, mean "to uncover," or "reveal."

The Supreme Court has not overturned Section 101 but declared its own "judicial exceptions" as part of 101, and not considering 112.

American Axle v. Neapco

Hooke's law is an approximation of a linear relationship, **F=kx**. However, hollow tubes being rotated are not approximated by Hooke's law.

Rather, the torsional stiffness of a shaft **kt** is defined by a higher-order (4^{th} power) relationship:

$$\mathbf{kt} = (\pi\, G\, \{\mathbf{D_o}^4 - \mathbf{D_i}^4\})/(32\, l),$$

where **G** is the **Modulus of Elasticity** in Shear (lb/inch);

l is the length (inches),

$\mathbf{D_o}$ is the outer diameter (inches), and

$\mathbf{D_1}$ is the inner diameter (inches).

The courts did not address Claim 36 or this issue.

In Re Leland Stanford University

Slip Op. 2020-1012 (Fed. Cir. 11 March 2021)

Background

Stanford University filed U.S. Application No. 13/445,925 (2012) directed to ***methods and computing systems*** for determining haplotype phase, an indication of the identity of the parent from whom a gene has been inherited.

In Re Leland Stanford University

A truncated version of Claim 1 is:

1. A method for resolving haplotype phase, comprising:

receiving and storing allele data on a computer;

receiving and storing pedigree data on a computer;

determining an inheritance state for the allele information using a Hidden Markov Model, …

wherein the inheritance states are maternal identical, paternal identical, identical, and non-identical;

receiving transition probability for inheritance states using a computer [UC];

receiving population linkage disequilibrium data UC;

determining a haplotype phase UC;

storing the haplotype phase UC; and

[displaying] the stored haplotype phase UC.

In Re Leland Stanford University

Decisions

The PTAB found that all steps of Claim 1 were directed to either (1) mental steps or (2) mathematical concepts, and were patent ineligible.

The human mind could process the information, and the mathematical models (*per se*) are abstract ideas. All of the algorithms and computer were well-known, routine, and conventional.

The PTAB held that dependent claims recited "providing the drug for treatment" were too general to provide the needed "inventive concept."

The Federal Circuit AFFIRMED.

101 Summary and Comments

Section 101 is enmeshed with other statutory provisions (especially 112).

Avoid general language. Recite "special purpose computers" (see *Bilski*).

Avoid functional claiming. Section 112(f) is a trap if claims are intended to be very broad.

Do not state that any methods are "well-known."

Rejections under Section 101 now includes claims similar to those of *Diamond v. Diehr*. (see *AAM v. Neapco*).

Perhaps one reason for the holding in AAM, is that in *Diehr*, the computer acted to perform one of the manufacturing steps.

Recite case law, not only the MPEP in preparation for Appeal.

Avoid "file first, invent later."

The Future of Section 101

The National Security Commission on Artificial Intelligence (NSCAI, created in 2019) has submitted a report to the President and Congress urging legislative reform of section 101.

"***The judicial undermining of patent eligibility, in defiance of the clear language in Section 101*** of the Patent Act, ***poses a clear and present danger*** to the pace of American innovation."

NSCAI's Final Report includes a chapter underscoring the importance of a strong intellectual property law system to U.S. ***national security interests*** tied to technological advancement.

According to Adam Mossoff, "The Supreme Court is now closing off the patent system to the innovations that it has long recognized as worthy of securing with patent protection. This has had a tremendously negative impact on the inventors and the companies working in the innovation industries that invest millions of dollars in creating the new products and services that drive economic growth, job creation, and higher standards of living. ***The Supreme Court is undermining America's long-standing comparative advantage*** among world economies in securing reliable and effective patent rights for all innovators.

The Future of Section 101

Patent Eligibility:

The ***Secretary of Commerce should assess and articulate*** the impact of current ***patent eligibility*** laws on innovation in ***AI and emerging technologies*** from an economic, trade, and national security policy perspective to better inform the legislative and agency efforts on ***patent eligibility reform.***

America's IP regime has spurred American ingenuity since the late 18th century. By protecting "***any new and useful process, machine, manufacture, or composition of matter***" through stable legal institutions governed by the rule of law, inventors and investors have relied on America's IP system to provide the certainty necessary to justify large and risky R&D investments, which are critical for technologies.

A strong and robust patent system is equally critical to incentivizing American innovation in AI and emerging technologies that affect national security. Unfortunately, ***recent patent eligibility court rulings have narrowed the scope of inventions that are eligible for patent protection. This has resulted in a broad swath of innovation that is now ineligible for patent protection*** in both ***digital technologies and biopharma,*** among others. The legal uncertainty for U.S. innovators and companies as to whether their inventions will be eligible for patent protection or susceptible to invalidation once granted is pervasive.

Section 112

Some interesting recent cases address specifics of 112(a), (b), and (f).

112(b) "Consisting Essentially Of"

NZNP Meds. LLC v. Actavis Labs, UT, Inc.
940 F.3d 680 (Fed. Cir., 10 October 2019), and
HZNP Finance Limited, Horizon Therapeutics USA, Inc. v. Actavis Laboratories UT, Inc.
Slip. Op. 2017-2149 et al., (Fed. Cir., 25 February 2020)

Background:

The patent in these cases are related to methods and formulations for treating osteoarthritis.

"Consisting Essentially Of"

Claim 49 is illustrative.

A topical formulation ***consisting essentially of***:

1-2% w/w diclofenac sodium;

40-50% w/w DMSO;

23-29% w/w ethanol;

12-12% w/w propylene glycol;

hydroxylpropyl cellulose; and

water to make 100% w/w, wherein the topical formulation has a viscosity of 500-5000 centipoise.

"Consisting Essentially Of"

Court Decisions

The district court found the term "consisting essentially of" to be indefinite.

"because the ***basic and novel properties of an invention are part of the construction of a claim*** containing the phrase "consisting essentially of," the Nautilus standard applies.

The Fed. Cir. affirmed. The terms (1) better drying time; (2) higher viscosity; (3) increased transdermal flux; (4) greater pharmacokinetic absorption; and (5) favorable stability were indefinite for failing to provide tests for these terms.

"Consisting essentially of" ***permit[s] inclusion of components not listed in the claim***, provided that they do not materially affect the basic and novel properties of the invention.

"Consisting Essentially Of"

Dissent

Judge Newman: The majority states: "Having used the phrase "consisting essentially of," and thereby incorporated unlisted ingredients or steps that do not materially affect the basic and novel properties of the invention, a drafter cannot later escape the definiteness requirement by arguing that the basic and novel properties of the invention are in the specification, not the claims.

This statement is contrary to long-standing law and practice as summarized in *Nautilus*."

In *Conoco Inv. v. Energy & Envtl. Int'l, L.C.* 460 F.3d 1349 (Fed. Cir 2006): the court recognized the difference between "***consisting of***" and "***consisting essentially of***," stating that "while '***consisting of' limits the claimed invention***, ***it does not limit aspects unrelated to the invention***.

However, no precedent has held that "consisting essentially of" composition claims are invalid unless they include the properties of the composition in the claims.

Patent Claims "Consisting Essentially Of"

Comments

Be careful about use of "consisting essentially of." Use of this phrase could be the basis of challenge. A better approach would be to use "***comprises***," because the question of non-enumerated components rendering the composition unfit for its intended purpose is less relevant.

See later comment on "***comprises … consisting of***"

If an Examiner suggests amending "comprises" to "consists essentially of," or "consists of," consider other alternatives. An Expert Declaration could address the matters of fact regarding the roles of non-enumerated components.

Another approach can be to include in the claims, some of the methods by which characteristics of the non-enumerated components can be analyzed.

"Wherein the Money"
Limiting, Inherent, or Aspirational

Allergan et al. v. Sandoz et al.,
Slip Op. 2018-2207 (Fed. Cir., 29 August 2019)

Background

Patent claims are often drafted with claims including the word "wherein" or "whereby." Some Examiners request such words to be removed. A truncated version of claim 1 of U.S. Patent 9,770,435 (the "453 patent" owned by Allergan is reproduced below.

1. A method of treating a patient with glaucoma or ophthalmic hypertension comprising administering (two drugs), ***wherein*** the method is as effective as the administration of 0.2% w/v brimonidine tartrate monotherapy three times per day and ***wherein*** the method reduces the incidence of one or more adverse events … when compared to the administration of 0.2% w/v brimonidine tartrate monotherapy three times daily.

"Wherein the Money"

Court Decisions

The district court held that the ***"wherein" clauses were limiting because they are material to patentability and express the inventive aspect of the claimed invention***. Therefore the district court held the claims not invalid.

On appeal, Sandoz argued that (1) the "wherein" clauses "merely state the intended results, and (2) the recited results are not 'material to patentability.'"

The Fed. Cir. affirmed:

Example I formulation administered BID demonstrated a ***favorable safety profile*** that was comparable to timolol BID and ***better than*** brimonidine TID with regard to the incidence of adverse events.

"Wherein the Money"

Comment

Ensure that "wherein clauses" reflect not merely "aspirational" statements," "inherent results," or "intended uses," but are limiting.

Include prior art results in the claim comparing the results obtained by the inventors, thereby providing support that the plain meaning of a wherein clause supports patentability. Consider Jepson-type claims.

Inclusion of references to the specification and prosecution history can support a conclusion that "wherein" clauses are limiting, therefore material to patentability and not indefinite.

"Comprising ... Consisting of"

Amgen et al. v. Amneal et al.

Slip Op 2018-2414, 2019-1086

Fed. Cir., 7 January 2020

Background

Amgen is the owner of U.S. Patent No 9,375,405 (the '405 patent). Claims are drawn to pharmaceutical compositions ***comprising*** a calcium receptor-active compound, and Markush groups identifying enumerated excipients ***consisting of,*** enumerated binders selected from the group ***consisting of***, and enumerated disintegrants selected from the group ***consisting of.*** ...

Amgen sued Amneal for infringement, and Amneal argued that the inclusion of both "comprises" in the preamble and "consisting of" in the Markush groups rendered the claim invalid as indefinite.

“Comprising ... Consisting of”

Patent Examiners have rejected such claims, and may request that the word “comprises” in the preamble should be replaced by “consisting of.” in line with a presumption that Markush groups and the preamble should be closed to un-recited elements.

Court Decisions

In a Markman hearing, the district court held that Amgen did not overcome the “very strong” presumption that the Markush groups for the binder and disintegrant elements are closed to un-recited binders and disintegrants.

Amgen appealed the claim construction.

“Comprising ... Consisting of”

The Fed. Cir. reversed.

The ‘comprising’ term In the preamble renders the claim open-ended, even when other language restricts the scope of particular claim elements, and the ‘***consisting of’ term here only applies to the (Markush groups***) …”

Without more, such language is satisfied when and accused product contains a component that is from the Markush group. It does not forbid infringement of the claim if an additional component is present functionally similar to the component identified in the Markush group.

USPTO Guidance on Functional Claiming Under 112(f)

The current standard for analysis under Section 112(f) during examination is based on *Williamson v. Citrix,* 792 F.3d 1339, 1349 (Fed. Cir. 2015) (*en banc*).

Prior to *Williamson*, (a) if a claim used "means for" or "step for," there is a strong presumption that the claim should be analyzed under section 112(f). (b) If ***"means for" is not present, there was a strong presumption that the claim did not fall under 112 (f).***

Under *Williamson*, the presumption in (b) was discarded. If the claim contained so-called "nonce" words (not having any structural meaning), it would be limited to the disclosure in the specification and their equivalents.

Examples of nonce terms include "module for," "device for," "unit for," "component for," "element for," "member for," "apparatus for," "machine for," "configured to," or "system for."

USPTO Guidance on Functional Claiming Under 112(f) and Indefiniteness

Claims for computer-implemented inventions are often drafted in "means plus function" format: claiming the results without reciting the steps needed.

This has been based on the idea that a savvy computer programmer could draft code based on the desired results.

Prior to *Williamson*, the courts applied the standard of *In re Packard*, 751 F.3d 1307 (Fed. Cir. 2014, where "a claim would not be considered to fall under 112(f) if the claim were "amenable to construction," or "not insolubly ambiguous."

The *Williamson* standard has been incorporated into the 2019 USPTO Guidance, where the use of "means for" invokes 112(f).

112(b): Indefiniteness

According to the 2019 Guidance, "For a computer-implemented 35 U.S.C. § 112(f) claim limitation, the specification must disclose an ***algorithm***, or else the claim is indefinite…"

In In re Aoyama, 656 F.3d 1293, (Fed. Cir. 2011) the Fed. Cir. stated: "when the disclosed structure is a computer programmed to carry out an ***algorithm***, 'the disclosed structure is a special purpose computer. (see *In re Bilski*).

Applicant may express that ***algorithm in any understandable terms including as a mathematical formula***, in prose, or as a flow chart, or "in any other manner that provides sufficient structure." *Finisar Corp. v. DirecTV Grp., Inc.,* 523 F.3d 1323, (Fed. Cir. 2008).

112(a): Written Description

In *LizardTech Inc. v. Earth Resource Mapping Inc*., 424 F.3d 1336, (Fed. Cir. 2005), the court found that a single example did not support a broad genus claim.

In Hynix Semiconductor Inc. v. Rambus Inc., 645 F.3d 1336, (Fed. Cir. 2011): "so long as disclosure of the species is sufficient to convey to one skilled in the art that the inventor possessed the subject matter of the genus, the genus will be supported by an adequate written description.").

2021 Guidance on Section 112(b)

The USPTO recently issued new guidance on Post-Grant Proceedings.

Prior to the 2021 Guidance, the PTAB used the Packard standard: "a claim is indefinite when it contains words or phrases whose meaning is unclear."

Claim construction will now be the same as the Supreme Court's decision in *Nautilus, Inc. v. Biosig Instruments, Inc*. 572 U.S. 898 (2014);

A claim is unpatentable for indefiniteness if the claim, read in light of the specification delineating the patent, and prosecution history, fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention."

2021 Guidance on Section 112(b)

Comments

According to the USPTO Guidance, to overcome problems with 112(f), specifications and claims should include the "algorithm."

Although the 2019 and 2021 Guidances favor the use of "algorithms," there may be a conflict with § 101 (but see *Bilski*).

One of the categories of patent ineligible subject matter for being abstract is "mathematical concepts." Mathematical concepts, mathematical relationships, mathematical formulations, and mathematical calculations may all be abstract ideas, and therefore not patent eligible.

Courts have not reconciled this conflict.

In addition to the "nonce" words, be careful about use of prepositions, e.g., "for," "to" and the like. Prepositions may lead to a finding that the claim is under 112(f).

"A preposition is not something to end a sentence with."

Obviousness Type Double Patenting (ODP)

ODP is a common ground for rejection. If the claims of one application are "obvious variants" of another application or patent having the same inventors, overcoming such a rejection can be by filing a Terminal Disclaimer (TD).

The requirement for filing a TD is that both application(s) or patent(s) be commonly owned.

Obviousness Type Double Patenting (ODP)

In *Immunex et al v. Sandoz et al,* Slip Op. 2020-1037 (Fed. Cir. 1 July 2020), the Federal Circuit analyzed the validity of a TD.

Immunex holds an exclusive license from Roche for the product "Enbrel," comprising the chemical etanercept. The claims of the '182 and '225 patents are directed to methods of manufacture of etanercept.

Sandoz applied an abbreviated Biologics License Application (aBLA), which is an act of infringement as is filing an ANDA.

ODP

The case turned meanings in the license and Accord and Satisfaction Agreements between Roche and Immunex.

Decision

Roche retained sufficient rights in the invention so ***the patents in issue were not commonly owned*** by Immunex.

Roche retained the right to use the patented product for internal, non-clinical research only, and was obligated to assist Immunex in any infringement litigation, and retained a ***secondary right to sue*** if Immunex failed to rectify infringement. If such a right were triggered, ***Roche's right to sue may, under its sole control, initiate suit and retain the entirety of any damage***.

The court held that ***Roche retained sufficient rights*** and Immunex was not the "owner" of both patents.

Therefore, the TD was defective, not enforceable, resulting in invalidation of the patent.

ODP

Comment

The ‘182 and ’225 patents were both Divisional applications, resulting from a Restriction Requirement.

Generally, if a Restriction Requirement is made the claims are distinct and TDs are not required. However, when interpretation of license agreements controls, the situation is less clear.

Properly drafted license agreements should ensure that ***substantive provisions are explicit, including what, if anything, is retained by the licensor***.

Ideally, any agreement should be an Assignment of all rights.

THANK YOU

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