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U.S. and EPO Patent Prosecution Issues

July 19, 2023

Meet the Speakers

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Agenda

Background on Enablement

***Amgen v. Sanofi*: The Battle Over Enablement**

The EPO's plausibility case G 2/21

Enablement – Key Takeaways and Guidance for Moving Forwards

Plausibility – Key Takeaways and Guidance for Moving Forwards

Background on § 112(a), Enablement

- **35 U.S.C. 112(a)**

- **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention**

- **The written description requirement is separate and distinct from the enablement requirement**

- **This is not often an issue for electromechanical patents, but the recent US Supreme Court *Amgen v. Sanofi* decision relied heavily on its earlier decisions relating to electromechanical cases**

Background on § 112(a), The Legal Landscape

- **"Whether undue experimentation is needed is not a single, simple factual determination but rather is a conclusion reached by weighing many factual considerations." *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988)**

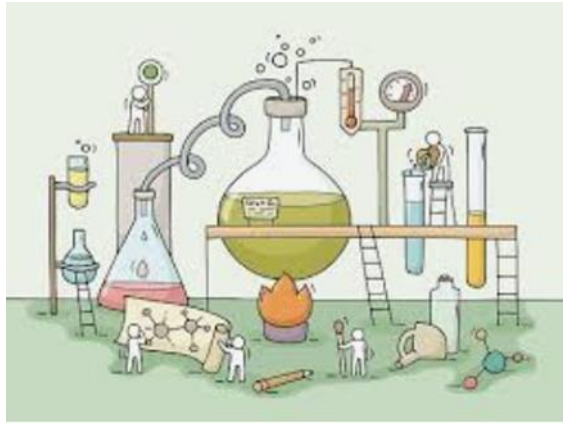
- **Disclosure must be "at least commensurate with the scope of the claims." *Crown Operations Ing'l v. Solutia Inc.*, 289 F.3d 1367, 1378-1379 (Fed. Cir. 2002) (citing *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys.*, 166 F.3d 1190, 1196 (Fed. Cir. 1999))**

- **"To prove that a claim is invalid for lack of enablement, a challenger must show by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without 'undue experimentation'." *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1188 (Fed. Cir. 2014)**

Background on § 112(a), The Legal Landscape

- ***Wands* Factors:**

1. Quantity of experimentation necessary
2. Amount of direction or guidance presented
3. Presence or absence of working examples
4. Nature of the invention
5. State of the prior art
6. Relative skill of those in the art
7. Predictability or unpredictability of the art
8. Breadth of the claims



- **Specification does not need to "describe how to make and use every possible variant of the claimed invention, when a range is claimed, there must be *reasonable enablement of the scope of the range*." *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1100 (Fed. Cir. 2020)**

Amgen v. Sanofi: The Battle Over Enablement

- ***Amgen Inc. v. Sanofi, Aventis LLC*, 987 F.3d 1080 (Fed. Cir. 2021)**
- **Drug: Repatha® – cholesterol-lowering monoclonal antibody therapy**
  - Also known as 21B12 and evolocumab
- **Patents: 8,829,165 and 8,859,741**
  - Title: Antigen Binding Proteins to Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9)
- **Both patents have the same text and figures with significant details and sequence information for 26 antibodies, and a general "treatise" on how to make other antibodies**
  - 384 pages, 575 sequences, 152 sheets of drawings, 42 Examples

US008829165B2

(12) **United States Patent**
Jackson et al.

(10) **Patent No.: US 8,829,165 B2**
(45) **Date of Patent: *Sep. 9, 2014**

(54) **ANTIGEN BINDING PROTEINS TO PROPROTEIN CONVERTASE SUBTILISIN KEXIN TYPE 9 (PCSK9)**

(71) Applicant: **Amgen Inc.**, Thousand Oaks, CA (US)

(72) Inventors: **Simon Mark Jackson**, San Carlos, CA (US); **Nigel Pelham Clinton Walker**, Burlingame, CA (US); **Derek Evan Piper**, Santa Clara, CA (US); **Wenyan Shen**, Palo Alto, CA (US); **Chadwick Terence King**, North Vancouver (CA); **Randal Robert Ketchem**, Snohomish, WA (US); **Christopher Mehlin**, Seattle, WA (US); **Teresa Arazas Carabeo**, New York, NY (US)

(73) Assignee: **Amgen, Inc.**, Thousand Oaks, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/866,016**

(22) Filed: **Apr. 18, 2013**

(65) **Prior Publication Data**

US 2013/0245235 A1 Sep. 19, 2013

Related U.S. Application Data

(63) Continuation of application No. 13/655,084, filed on Oct. 19, 2012, which is a continuation of application No. 12/474,176, filed on May 28, 2009, now Pat. No. 8,563,698, which is a continuation of application No. 12/197,693, filed on Aug. 22, 2008, now Pat. No. 8,000,457.

(60) Provisional application No. 60/957,608, filed on Aug. 23, 2007, provisional application No. 61/008,965, filed on Dec. 21, 2007, provisional application No. 61/010,630, filed on Jan. 9, 2008, provisional application No. 61/086,133, filed on Aug. 4, 2008.

(51) **Int. Cl.**
A61K 39/395 (2006.01)
C07K 16/40 (2006.01)

(52) **U.S. Cl.**
USPC **530/387.9**

(58) **Field of Classification Search**
None
See application file for complete search history.

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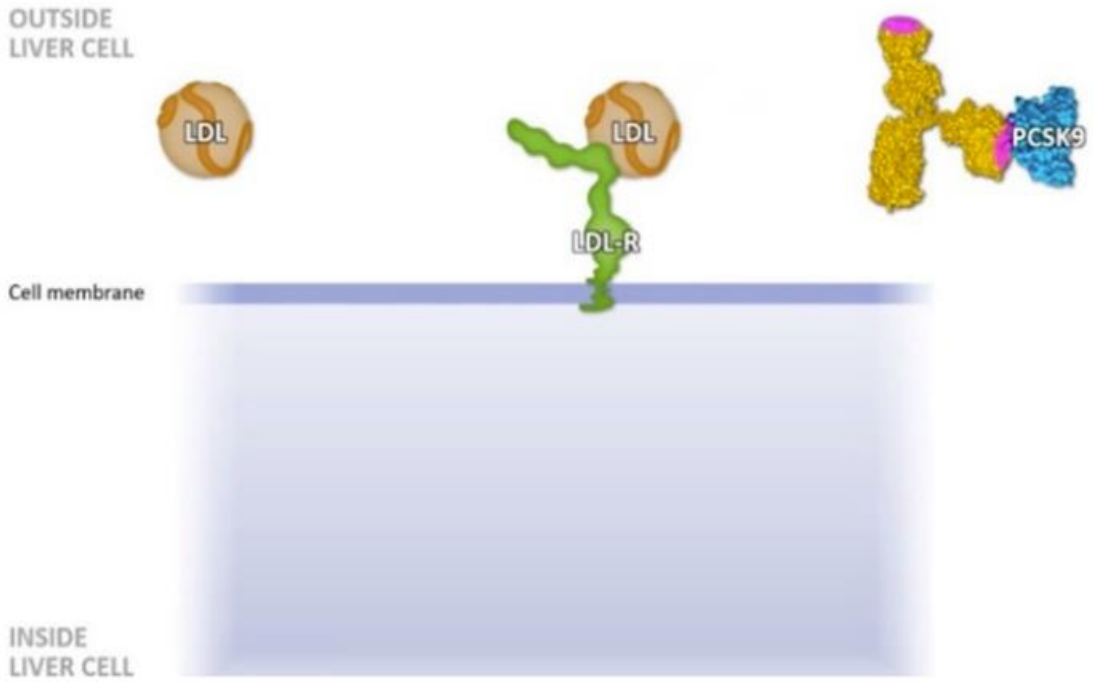
(57) **ABSTRACT**

Antigen binding proteins that interact with Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) are described. Methods of treating hypercholesterolemia and other disorders by administering a pharmaceutically effective amount of an antigen binding protein to PCSK9 are described. Methods of detecting the presence of PCSK9 in a sample using an antigen binding protein to PCSK9 are described.

29 Claims, 152 Drawing Sheets

Amgen v. Sanofi: The Battle Over Enablement

- **Patent claims directed to a *genus* of monoclonal antibodies that bind and block an enzyme (PCSK9)**
  - Low-density lipoprotein (LDL) cholesterol contributes to heart disease
  - Human body regulates LDL levels through receptors on our cells
  - PCSK9 binds LDL receptors, causing them to degrade, leading to increase in circulating LDL
  - By blocking PCSK9, the antibodies prevent the LDL receptors from being degraded – thus allowing for regulation of LDL in the bloodstrear



Amgen v. Sanofi: Functional Claims at Issue

- **Exemplary Claims: ’165 Claims 1 and 19**

> **1**. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID NO:3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR.
>
> **19**. The isolated monoclonal antibody of claim **1** wherein the isolated monoclonal antibody binds to at least two of the following residues S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of PCSK9 listed in SEQ ID NO:3.

- **Claims at issue: ’165 claims 19, 29; ’741 claim 7**

Amgen v. Sanofi: Case Background - Timeline

2011: Amgen receives a patent for a PCSK9-inhibiting antibody employed in drug Repatha

2011: Sanofi receives a patent for a PCSK9-inhibiting antibody employed in drug Praluent

2014: Amgen receives two patents ('165 and '741) claiming the entire genus of antibodies inhibiting PCSK9

2014: Amgen sues Sanofi for infringing its '165 and '741 patents with Sanofi's drug Praluent

2017: A jury finds Amgen's '165 and '741 patents **not to be invalid** and Sanofi stipulates to infringement

2017: Federal Circuit **reverses and remands** for trial court's error in excluding Sanofi's written description and enablement evidence, and improperly instructing the jury on the written description requirement

2019: District Court grants Sanofi's JMOL motion **for lack of enablement**

2021: Federal Circuit **affirms** finding no reasonable factfinder could conclude that the '165 and '741 patents provided adequate guidance to make and use the claimed antibodies beyond the examples provided

2022: Supreme Court grants certiorari

2023: Supreme Court decision

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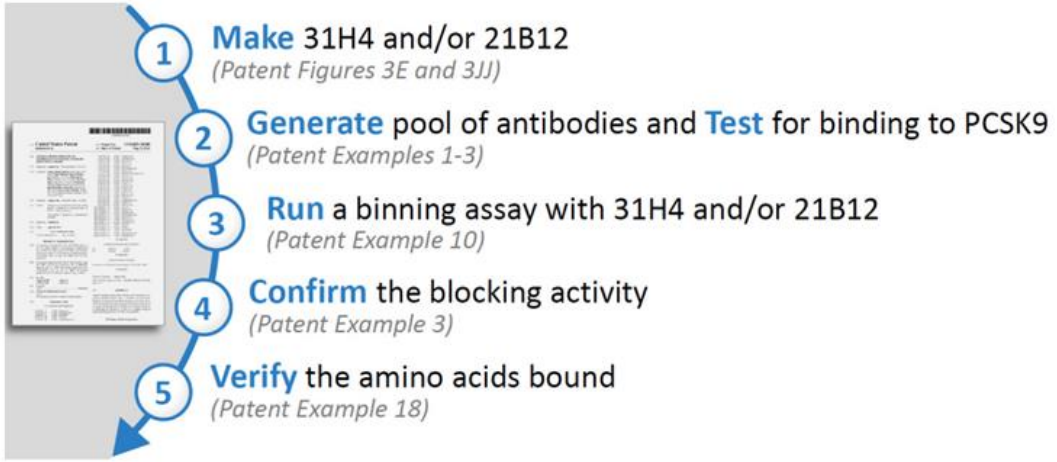
Amgen v. Sanofi: Amgen's CAFC Argument

- **Claims enabled – no undue experimentation:**
  - POSITA can make all antibodies within the scope of the claims by following a roadmap using anchor antibodies and well-known screening techniques as described in the specification, or
  - By making conservative amino acid substitutions in the 26 examples.
- **Specification includes:**
  - Amino acid sequence for 26 representative antibodies (including 21B12);
  - Crystal structures of two of those antibodies: 21B12 and 31H4;
  - Atomic structure of PCSK9's "sweet spot" for blocking binding of LDL receptors and PCSK9;
  - "Roadmap" for quickly and easily making claimed antibodies:



Amgen v. Sanofi: Sanofi's CAFC Argument

- **Claims require undue experimentation:**
  - **Millions of antibody candidates within the scope of the claims**
  - Disclosures do not provide significant and specific guidance
  - Antibody generation is **unpredictable**
  - Practicing the full scope of the claims requires **substantial trial and error**

- **Sanofi emphasized the breadth of the claims: While Amgen focused on the number of antibodies known to satisfy the claims, Sanofi argues that the court must look at the number of candidates that must be made and tested to determine whether they satisfy the claimed function.** ***Amgen Inc. v. Sanofi,*** **987 F.3d 1080, 1085 (Fed. Cir. 2021)**

Amgen v. Sanofi: CAFC Decision

- **"[T]he enablement inquiry for claims that include functional requirements can be particularly focused on the breadth of those requirements, especially where predictability and guidance fall short." Id. at 1086**
- **"Similar" cases considered by Federal Circuit:**
- ***Wyeth & Cordis Corp. v. Abbott Labs*., 720 F.3d 1380, 1385 86 (Fed. Cir. 2013):**
  - Claims covering method of preventing restenosis with rapamycin compounds having certain functionality are invalid for lack of enablement
  - ***Large number of possible candidates*** ("millions") within the scope of the claims
  - ***Specification lacked structural guidance and showed testing of only one compound***
  - Would have required ***undue experimentation*** to ***synthesize and screen each candidate*** to determine which compounds in the claimed class exhibited the claimed functionality
- ***Enzo Life Sciences, Inc. v. Roche Molecular Sys., Inc.,*928 F.3d 1340 (Fed. Cir. 2019)**
  - Claims required particular structure and functionality
  - Specification failed to teach whether the many embodiments of broad claims would exhibit required functionality
- ***Idenix Pharms. LLC v. Gilead Sciences Inc*., 941 F.3d 1149 (Fed. Cir. 2019)**
  - Undue experimentation would have been required to synthesize and screen billions of possible compounds, given lack of guidance across full scope
  - "[N]eedle in a haystack"

Amgen v. Sanofi: CAFC Decision

- **Wands Factors:**
  1. Quantity of experimentation necessary: "[S]ubstantial amount of time and effort" to through either trial and error (making changes to the disclosed antibodies and then screening them for desired binding/blocking properties, or by discovering antibodies *de novo* based on the randomization and screening roadmap)
  2. Amount of direction or guidance presented: Some guidance, but "not significant" guidance for the full scope of the claims
  3. Presence or absence of working examples: "Narrow scope" of working examples
  4. Nature of the invention;
  5. State of the prior art;
  6. Relative skill of those in the art;
  7. Predictability or unpredictability of the art: Unpredictable
  8. Breadth of the claims: Indisputably broad
- **Breadth of disclosure v. claims: While claims include antibodies that bind up to 16 residues, none of the examples binds more than 9; three claimed residues to which no disclosed example binds**
- **No enablement – undue experimentation is required to make and use the full scope of the claims**

Supreme Court: Amgen Argument

- **Proposed Questions Presented:**
  1. Is enablement a question of fact to be determined by the jury?
  2. Is enablement governed by the statutory requirement that the specification teach those skilled in the art to "make and use" the claimed invention, or whether it must instead enable those skilled in the art to reach the full scope of claimed embodiments without undue experimentation, i.e., to cumulatively identify and make all or nearly all embodiments of the invention without substantial time and effort?
- **No dispute that the genus claims are broad – focuses on sufficiency of the disclosure**
- **Argues patent challenger must provide a "'concrete identification of at least some embodiment' that cannot be made without undue experimentation. Amgen Petition at 28 (citing *McRO,* 959 F.3d at 1100 (Fed. Cir. 2020))**
- **"Devastating" effect on innovation**
  - Amici agree: GSK, Association of University Technology Managers, Group of IP Professors

Supreme Court: Sanofi Argument

- **Proposed Questions Presented:**
  1. Is enablement, an issue of patent validity, a question of law based on underlying findings of fact?
  2. Did the lower court err in determining that no reasonable jury could conclude that the patents are enabled?
- **Genus claims cover "'a vast scope of possible antibodies,' reaching 'millions' if not 'an astronomically large number' of antibodies"**
  - Even Amgen witnesses could not estimate the number of antibodies within the claims' scope
  - Amgen's experts agree that knowing the amino acid sequence of an antibody doesn't tell you about its binding properties. You have to test them to determine whether generated antibodies actually "bind and block"
  - Even changing a single amino acid may change the antibody's function
- **Amgen did not dispute that enablement requires making and using the "full scope" of the claimed invention in the jury instructions**

Supreme Court: Question Actually Presented

***Amgen, Inc. v. Sanofi*, 598 U.S. ____ (2023)**

- **Certiorari granted on Question 2 of Amgen's petition:**

  - Whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to "make and use" the claimed invention, 35 U.S.C. 112,
  - or whether it must instead enable those skilled in the art "to reach the full scope of claimed embodiments" without undue experimentation – *i.e.*, to cumulatively identify and make all or nearly all embodiments of the invention without substantial "time and effort."

Amgen v. Sanofi - Supreme Court Decision (May 18, 2023)

- **According to the Supreme Court, Amgen's patent specification discloses only two methods to make other antibodies that perform the two claimed functions (binding to particular targets on PCSK9 and blocking PCSK9 from binding to LDL receptors)**

- **Lengthy description was just a "roadmap"**
  - Generate antibodies in lab
  - Test to see if any binds to PCSK9, and if yes
  - Test to see if any binds to sweet spot, and if yes
  - Test to see if any block PCSK9 from binding to LDLR

- **Conservative substitution**
  - Start with antibody known to bind and block PCSK9
  - Substitute AAs with other AAs known to have similar properties
  - Test resulting antibody for binding/blocking LDLR

Amgen v. Sanofi - Supreme Court Decision

- **The claims cover "a vast number" (millions) of antibodies, but the patents provided details for only 26 antibodies**

- **Court compared the Amgen case to:**

  - **Morse telegraph** claim covering all means of telegraphic communication (1854)

  - **Incandescent lamp** claims to carbonized fibrous material filament (1895)

  - **A new glue** to replace animal-based glues (1928)

  - All held invalid as too broadly/functionally claimed vs. what patent taught ("claimed much but enabled little")

Amgen v. Sanofi - Supreme Court Decision

O'Reilly v. Morse (1854)

15 How. 62 (1854)

Claim 8 "too broad, and not warranted by law"

Claim 8 "covered all means of achieving telegraphic communication, yet Morse had not described how to make and use them all."

If Claim 8 allowed, there would be "no necessity for any specification" besides stating the discovery itself

Overly broad claim 8 was invalid

8. I do not propose to limit myself to the specific machinery or parts of machinery described in the foregoing specification and claims, the essence of my invention being the use of the motive power of the electric or galvanic current, which I call "electro-magnetism," however developed, for marking or printing intelligible characters, signs, or letters at any distances, being a new application of that power of which I claim to be the first inventor or discoverer.

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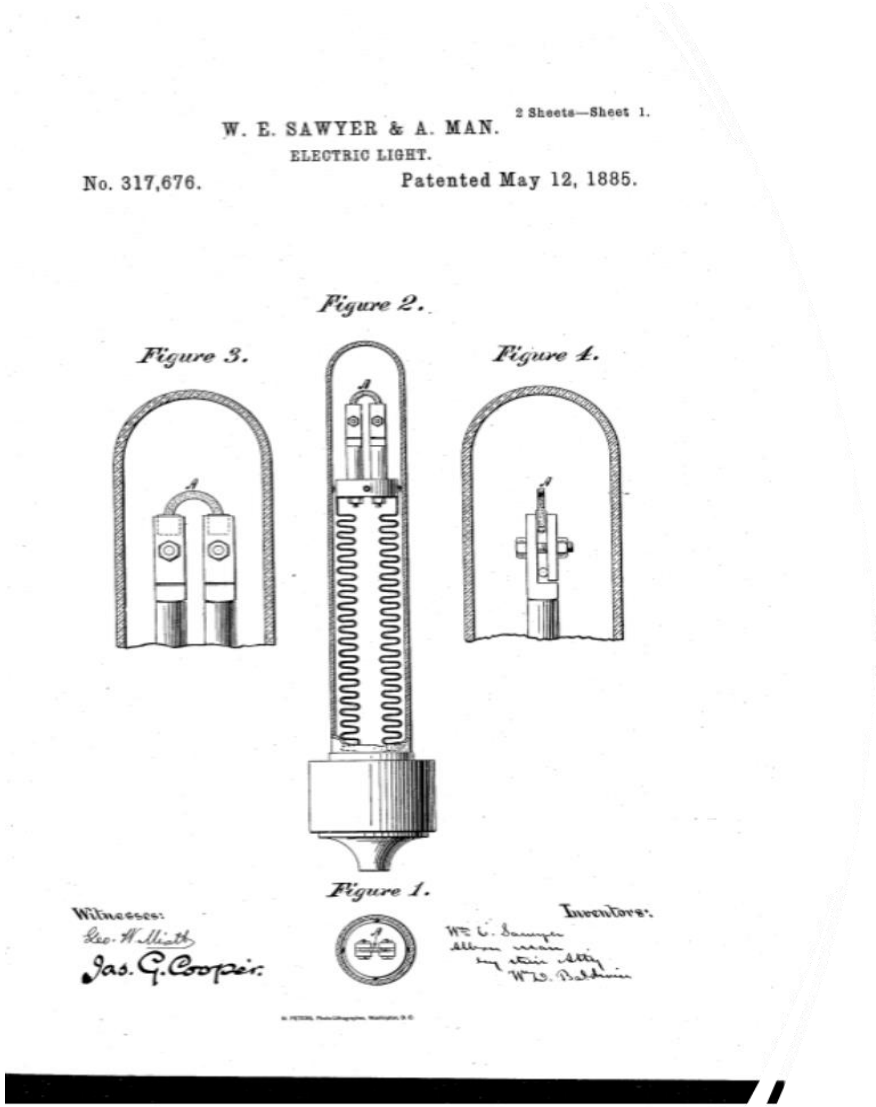
Amgen v. Sanofi - Supreme Court Decision

The Incandescent Lamp Patent
159 U.S. 465 (1895)

- William Sawyer and Albon Man made a claim for "every fibrous or textile material"
  - Claim 1. An incandescing conductor for an electric lamp, of carbonized fibrous or textile material, and of an arch or horseshoe shape, substantially as hereinbefore set forth.
- Potentially enabled if inventors disclose "a quality common" to fibrous and textile substances that made them "peculiarly" adapted to incandescent light, so that others would know how to "select among such materials"
- Sawyer and Man's lamp proved defective and quickly fell out of use because most fibrous and textile materials failed to work


W. E. SAWYER & A. MAN. 2 Sheets—Sheet 1.
ELECTRIC LIGHT.
No. 317,676. Patented May 12, 1885.
Figure 2.
Figure 3.
Figure 4.
Figure 1.
Witnesses:
Jas. G. Cooper.
Inventors:

Amgen v. Sanofi - Supreme Court Decision

The Incandescent Lamp Patent - *159 U.S. 465 (1895)*

- Thomas Edison invented incandescent lighting employing bamboo produced in Japan as a source of carbon filaments
- Sawyer and Man sued Edison for infringement
- Supreme Court **held that only through "painstaking experimentation" did Edison discover that a special bamboo "answered the required purpose"**
- Supreme Court held that Sawyer and Man **"claimed much but enabled little"**
- The fact that paper happens to belong to the fibrous kingdom did not invest Sawyer and Man with sovereignty over this "entire kingdom"
- **Broad patent claims held invalid for lack of enablement**

Amgen v. Sanofi - Supreme Court Decision

Holland Furniture Co. v. Perkins Glue Co. (1928)

277 U.S. 245 (1928)

- Perkins invented new starch glue similar to animal glue
- Specification described the key input—the "starch ingredient"—in terms of its "use or function" instead of the "physical characteristics or chemical properties" of the key ingredients
- Required gluemakers to engage in "elaborate experimentation"

28. A glue comprising cassava carbohydrate rendered semi-fluid by digestion and having substantially the properties of animal glue.

Amgen v. Sanofi - Supreme Court Decision

Holland Furniture Co. v. Perkins Glue Co., 277 U. S. 245 (1928)

- Supreme Court held that Perkins was entitled to its patent on the specific starch glue it had invented, but could not claim all starch glues made from whatever starch happened to perform as well as animal glue
- To hold otherwise "would extend the monopoly beyond the invention"
- **The broad claim is invalid for lack of enablement**

Amgen v. Sanofi - Supreme Court Decision

The Supreme Court also described prior cases that met the enablement requirement

- ***Wood v. Underhill*, 5 How. 1 (1846)**
  - The patent claimed a process for making bricks by mixing coal dust into clay
  - The patent included "a general rule" about the proportion of dust and clay to use and offered two alternative proportions "where the clay has some peculiarity"
  - The Court upheld the claim, recognizing that "some small difference in the proportions must occasionally be required" given the varieties of clay

- ***Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261 (1916)**
  - The patent claimed a process for separating metal from mineral ores
  - "[P]reliminary tests" were required to adapt the process to any particular ore
  - The Court upheld the claim, explaining that "the certainty which the law requires in patents is not greater than [what] is reasonable"

Amgen v. Sanofi - Supreme Court Decision

- A specification may call for a reasonable amount of experimentation to make and use a patented invention, but the specification must enable the full scope of the invention as defined by its claims
- **The more one claims, the more one must enable**
- What is reasonable in any case will depend on the nature of the invention and the underlying art
- Specification need not always describe with particularity how to make and use every single embodiment within a claimed class
- For instance, it may suffice to give an example (or a few examples) if the specification also discloses "some general quality . . . running through" the class that gives it "a peculiar fitness for the particular purpose."
- But in allowing that much tolerance, courts cannot detract from the basic statutory requirement that a patent's specification describes the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art" to "make and use" the invention

Amgen v. Sanofi - Supreme Court Decision

- Amgen's two approaches to make other antibodies (road map and conservative substitution) amount to little more than two research assignments
- The road map approach merely describes step-by-step Amgen's own trial-and-error method for finding functional antibodies
- Conservative substitution is not much different, as it requires scientists to make substitutions to the amino acid sequences of antibodies known to work and then test the resulting antibodies to see if they do too - an uncertain prospect given the state of the art
- **They leave a scientist about where Sawyer and Man left Edison: forced to engage in "painstaking experimentation" to see what works - that is not enablement, but "a hunting license"**
-
- **This is not an enabling disclosure, even allowing for reasonable experimentation**

Amgen v. Sanofi - Supreme Court Decision

- **Court unanimously held Amgen's broad functional claims invalid for lack of enablement (decision written by Justice Gorsuch)**

- **Amgen seeks to monopolize an entire class of things defined by their function, i.e., Amgen seeks to claim "sovereignty over [an] entire kingdom" of antibodies**

- **"If a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class. In other words, the specification must enable the full scope of the invention as defined by its claims. The more [broader] one claims, the more one must enable."**

- **Thus, this decision applies to all types of inventions, not just antibodies**

The EPO's Plausibility Case G 2/21 - Admissibility of Post-Filing Data

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Agenda

The concept of plausibility before decision G 2/21

Questions referred to the Enlarged Board

The answers of the Enlarged Board

Agenda

The concept of plausibility before decision G 2/21

The Concept of Plausibility

- The words “plausibility” and “plausible” (or “implausible”) do not appear in the Articles of the EPC. So where does the requirement come from?

- The Enlarged Board decision G 1/03 states:
  - ”… If this is not the case and there is lack of reproducibility of the claimed invention, this may become relevant under the requirements of inventive step or sufficiency of disclosure. *If an* **effect is expressed in** *a claim*, there is lack of **sufficient disclosure**. Otherwise, i.e. *if the* **effect is not expressed** in a claim but is *part of the problem to be solved*, there is a problem of **inventive step**.”

- Typical example (in the life sciences at least) of a claim where “an effect is expressed in a claim”: a method of treatment claim
- Typical example of a claim where “an effect is not expressed in a claim”: a compound/composition of matter claim

Origin of the term “Plausibility” in the case law

- **T 1329/04**:
- “The definition of an invention as being a contribution to the art, i.e. as solving a technical problem and not merely putting forward one, requires that it is at least made **plausible** by the disclosure in the application that its teaching solves indeed the problem it purports to solve. Therefore, even if supplementary post-published evidence may in the proper circumstances also be taken into consideration, it may not serve as the sole basis to establish that the application solves indeed the problem it purports to solve.”

- → To have an invention, the applicants must at least make it **plausible** to conclude that a problem has been solved.

Plausibility and Post-Filing Data

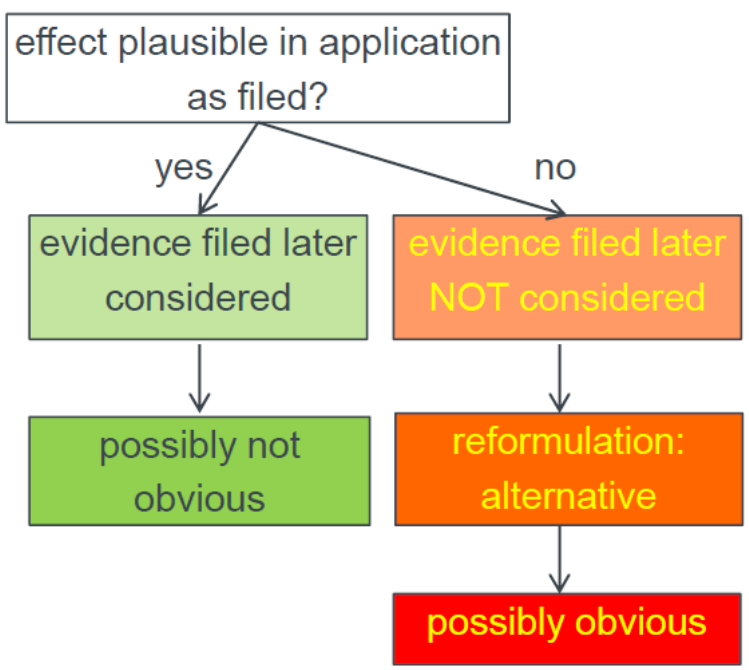
- Returning to G 1/03:
- *"… If an effect is expressed in a claim*, there is lack of sufficient disclosure… *if the effect is* not expressed in a claim but is *part of the problem to be solved*, there is a problem of inventive step…
- → Basis for "plausibility" may be either in Article 83 or in Article 56.

- Article 56: "An invention shall be considered as involving an inventive step if, having regard to the state of the art, *it is not obvious to a person skilled in the art*…". The US "counterpart" to Article 56 is 35 USC 103.
- Article 83: "The European patent application shall disclose the invention in a manner *sufficiently clear and complete* for it *to be carried out by a person skilled in the art*." The US "counterpart" to Article 83 is (arguably) 35 USC 112(a):

Plausibility and Post-Filing Data

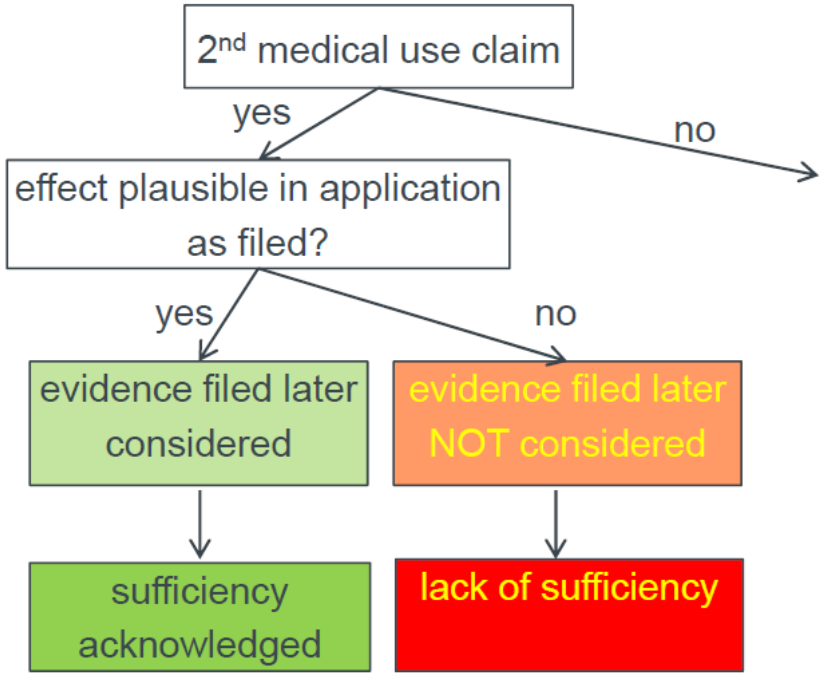
Art. 56 EPC

Inventive step



Art. 83 EPC

Sufficiency



Source: Haderlein - Plausibility (https://www.epo.org/news-events/events/conferences/2019/boa2019.html)

Plausibility and Post-Filing Data before G 2/21

- The concept of plausibility is relevant for inventive step and sufficiency (second medical use claims), enablement of prior art, and validity of priority claims

- If an effect is found to be not plausible in view of application as filed, this could sometimes not be remedied using post-filing evidence

- Three lines of case law with differing plausibility thresholds:

1) Low: Refusing the concept of plausibility, because it has no basis in the EPC

2) Medium: An invention is plausible, unless there is evidence to the contrary

3) High: An invention is **not** plausible, unless the application as filed makes it plausible

Plausibility and Post-Filing Data before G 2/21

- Best practice to make admissibility of post-filing evidence most likely in light of a divergent application of this not well-defined plausibility threshold:

-> Include all available data relevant for the invention in the application to be filed

-> Link the data to technical teachings

-> Strike the balance between securing an early filing date and taking the plausibility hurdle

Agenda

Questions referred to the Enlarged Board

The Referring Case T 116/18

- The main request would not be allowable if only the data in the patent in suit … could be taken into account.

- If the post-published data could also be taken into account, the main request would be allowable.

-> The allowability of the main request crucially depends on the question of whether the post-published … can be taken into account.

- … whether post-published evidence … can be taken into account is a fundamental question of law for which diverging lines of case law exist.

-> Guidance from the Enlarged Board is required.

The Questions

- 1. Should an exception to the principle of free evaluation of evidence …be accepted in that post-published evidence must be disregarded on the ground that the proof of the effect rests **exclusively** on the post-published evidence?

- 2. If the answer is yes…, can the post-published evidence be taken into consideration if the skilled person at the filing date of the patent application in suit would have considered the effect plausible (**ab initio plausibility**)?

- 3. If the answer is yes…, can the post-published evidence be taken into consideration if the skilled person at the filing date of the patent application in suit would have seen no reason to consider the effect implausible (**ab initio IMplausibility**)?

Low Threshold: No Plausibility

- A third line of case law rejects the concept of plausibility altogether. This third line of case law is referred to as applying the "**no plausibility**" standard.

- This standard could give rise to what is often referred to in the case law as **"speculative patenting"** or **"armchair inventions"** where a monopoly is conferred to a patent applicant for mere speculation rather than a true invention. [See T 116/18, Reasons 13.6-7]

Medium Threshold: Ab Initio Implausibility

- In a second line of case law, post-published evidence can only be **disregarded** if the skilled person would have had legitimate reasons to **doubt** that the purported technical effect would have been achieved on the filing date of the patent in suit.

- This standard reflects a **middle** ground in the case law. [See T 116/18, Reasons 13.5 and 7]

High Threshold: Ab Initio Plausibility

- “In a first line of case law, post-published evidence can be taken into account **only** if, given the application as filed and the common general knowledge at the filing date, the skilled person would have had reason to assume the purported technical effect to be achieved.

- By applying the ab initio plausibility standard strictly, the ultimate result would be that patent applicants receive a patent **only** for embodiments for which experimental data or other substantiation is contained in the application as filed that makes the effect invoked for inventive step plausible for these embodiments.

-> An extension of the claimed scope over what has been experimentally shown or otherwise substantiated in the application as filed would **lead to refusal** of the application. [T 116/18, Reasons 13.4]

Agenda

The answers of the Enlarged Board

Answer to Question 1: No!

- Evidence submitted by a patent applicant or proprietor to prove a technical effect relied upon for acknowledgement of inventive step of the claimed subject-matter may **not** be disregarded

- **solely** on the ground that such evidence, on which the effect rests, had not been public before the filing date of the patent in suit and was filed after that date. [G 2/21, Headnote I.]

-> The principle of free evaluation of evidence is confirmed in G 2/21.

Questions 2 and 3: Wrong Questions

- The term “plausibility” … relied upon by the referring board in questions 2 and 3 of the referral …, does **not** amount to a distinctive legal concept or a specific patent law requirement under the EPC.

- It rather describes a generic catchword seized in the jurisprudence of the boards of appeal, by some national courts and by users of the European patent system. [G 2/21, Reasons 92]

Questions 2 and 3: The Relevant Standard

- The relevant standard for the reliance on a purported technical effect … concerns the question of what the skilled person … would understand … from the application as originally filed as the technical teaching of the claimed invention.

- The technical effect relied upon, even at a later stage, needs to be encompassed by that technical teaching and to embody the same invention, because such an effect does not change the nature of the claimed invention. [G 2/21, Reasons 93]

Questions 2 and 3: The Answer of the Board

- A patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person ... based on the application as originally filed, would derive said effect as being encompassed by the **technical teaching** and embodied by the same originally disclosed invention. [G 2/21, Headnote II.]

Enablement –Takeaways and Guidance Moving Forward

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Enablement - Takeaways and Guidance

- **Focus on scope of claims**
  - **"**The specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable." *Id.* at 13.
- **More predictability in underlying art = more likely experimentation will be viewed to be "reasonable"**
  - "A specification may call for a reasonable amount of experimentation to make and use a patented invention. What is reasonable in any case will depend on the nature of the invention and the underlying art." *Id.* at 15.
- **Do not "monopolize" an entire genus**
  - "If a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class." *Id.* at 13.
  - "Amgen seeks to monopolize an entire class of things defined by their function…. The record reflects that this class of antibodies does not include just the 26 that Amgen has described by their amino acid sequences, but a 'vast' number of additional antibodies it has not." *Id.* at 16.
- **Guidance cannot amount to mere directions for trial and error**
  - Roadmap and conservative substitution "approaches amount to little more than two research assignments . . . [that] leave a scientist . . . Forced to engage in 'painstaking experimentation' to see what works." *Id.* at 16-17.
  - Make sure that the specification includes clear guidance on how to make and use the claimed invention

Enablement - Takeaways and Guidance

- **Enablement law has not changed, but the US Supreme Court decision provided clarification regarding how much disclosure is required**
- **Broad claims are not entirely banned, but claims in unpredictable arts will have to be more specific and tailored**
- **Consider reviewing issued patents for overly broad claims, as there is no time limit on requesting a narrowing reissue**
- **Consider cancelling broad claims and/or adding narrower claims in pending applications, e.g., prior to receiving a first action on the merits**
  - There may be more freedom to interpret narrow claims through DOE
  - Rejections of broad claims by USPTO can trigger prosecution history estoppel

Enablement - Takeaways and Guidance

- **Draft a “layered” specification and claims, i.e., include both broad and narrow disclosures and claims**
- **Draft claims to recite specific structural details**
- **Try to avoid having only functional language in claims**
  - Such claims are judged more harshly under enablement
- **Include as many working examples as possible for specific support of different species**
- **Include a “reasonable” number of species, and try to have diverse species, not all within one aspect of a genus**
- **Consider keeping certain functional features as a trade secret, rather than including them in a patent application**

The EPO’s plausibility case G 2/21
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Key Takeaways and Guidance Moving Forward

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The decision would not have changed an outcome

- According to the Enlarged Board, none of the earlier decisions would have come out differently in view of the new decision.

- “Applying this understanding to the aforementioned decisions, not in reviewing them but in an attempt to **test** the Enlarged Board’s understanding

- the Enlarged Board is satisfied that the outcome in each particular case would **not** have been different from the actual finding of the respective board of appeal. Irrespective of the use of the terminological notion of plausibility…” [G 2/21, Reasons 72]

“Abstractness” of the decision

- The Enlarged Board is aware of the abstractness of some of the aforementioned criteria. [G 2/92, Reasons 95]

-> “A patent applicant or proprietor may rely upon a technical effect … if the skilled person … would derive said effect as being encompassed by the **technical teaching** and embodied by the same originally disclosed invention.”

- What is a technical teaching?
- “…patent protection is reserved for inventions involving a **"technical teaching"**, i.e. an instruction addressed to a skilled person as to how to solve a particular technical problem using particular technical means.” [EPO Guidelines, G-II.2]

-> Include technical teachings in your application to facilitate admission of post-filing evidence and discussion of inventive step in general.

What about sufficiency (enablement)?

- The scope of reliance on post published evidence is **much narrower** under sufficiency of disclosure (Article 83 EPC) compared to the situation under inventive step (Article 56 EPC).

- The proof of a claimed therapeutic effect **has to be provided** in the application as filed, in particular if, in the absence of experimental data in the application as filed, it would not be credible to the skilled person that the therapeutic effect is achieved. [G 2/92, Reasons 77]

Plausibility and Post-Filing Data before G 2/21

- Best practice to make admissibility of post-filing evidence most likely in light of a divergent application of this not well-defined plausibility threshold.

  - Include all available data relevant for the invention in the application to be filed
  - Link the data to technical teachings
  - Strike the balance between securing an early filing date and taking the plausibility hurdle

Post-Filing Data after G 2/21

- Best practice to make admissibility of post-filing evidence most likely in light of decision G 2/21:
- Include all relevant wet lab data
- If there are any *in silico* data or predictions of relevance available, include that
- Include prophetic examples
- Discuss technical effects shown in the examples

- For the discussion of technical effects think broadly and derive technical teachings:

  -> Put data into context, provide technical explanations, discuss potential advantages, discuss how/why one can reasonably extrapolate/generalize particular examples to a broader **technical teaching** (“without wishing to be bound by theory”)

Questions?

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- Proud member of various professional organizations, such as the Institute of Professional Representatives before the European Patent Office and the German Chamber of Patent Attorneys.
- Vast industry knowledge, including but not limited to, energy & chemicals, life sciences, biotech & diagnostics, pharmaceuticals, and academic research & medical centers