

## CLINICAL INNOVATION: Fair & Effective Incentives for New Uses of Established Drugs

# Plausibility and Second Medical Use Patents

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CLINICAL INNOVATION - Fair and Effective  
Incentives for New Uses of Established Drugs

**The Concept of “Plausibility” at the EPO:  
How much Data is needed for a Second  
Medical Use Patent?**

Dr. Michael Eder, df-mp  
Washington D.C., February 9, 2018

## The Concept of “Plausibility”



## The Concept of “Plausibility” – Where does it come from?

### Overarching Consideration:

*The extent of a patent monopoly conferred by a (European) patent should correspond to the inventors' actual contribution to the art.*

(see, e.g., T 409/91, T 1486/08)

The concept of “plausibility” was developed to exclude speculative patents, based on mere assertions where there is no real reason to suppose that the assertion made in the patent is true.

## The Concept of “Plausibility” – Boards of Appeal Case Law

### Overview about Key EPO BoA Decisions regarding “Plausibility”

#### A. Plausibility in the Context of Inventive Step / Obviousness - I

##### T 939/92 – Agrevo:

*“1. If a claim concerns a group of chemical compounds per se, an objection of lack of support by the description pursuant to Article 84 EPC cannot properly be raised for the sole reason that the description does not contain sufficient information **in order to make it credible that an alleged technical effect is obtained by all the compounds claimed** (Reasons No. 2.2.2).  
2. The question as to whether or not such a **technical effect is achieved by all the chemical compounds covered by such a claim may properly arise under Article 56 EPC**, if this technical effect turns out to be the sole reason for the alleged inventiveness of these compounds (Reasons Nos. 2.4 to 2.6).”*  
(Headnotes)



## The Concept of “Plausibility” – Boards of Appeal Case Law

### EPO BoA Decisions regarding “Plausibility”

#### A. Plausibility in the Context of Inventive Step / Obviousness - II

##### T 1329/04 – Factor-9/JOHN HOPKINS:

*“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.**”* (Headnote)



## The Concept of “Plausibility” – Boards of Appeal Case Law

### EPO BoA Decisions regarding “Plausibility”

#### B. Plausibility in the Context of Sufficiency of Disclosure

##### T 1164/11 – Medical Apparatus

*“It is not the purpose of the patent system to grant a monopoly for **technical speculations that cannot be realised** at the time of filing.”*

##### T 609/02 – AP-1 Complex / SALT INSTITUTE:

*“If the description of a patent specification **provides no more than a vague indication of a possible medical use** for a chemical compound **yet to be identified**, later more detailed evidence cannot be used to remedy the fundamental insufficiency of disclosure of such subject-matter.”*



## The Concept of “Plausibility” – Boards of Appeal Case Law

### Some Conclusions to be taken from the Body of Case Law rendered by the EPO Boards of Appeal in Recent Years

- Claims to a new active compound *per se* may generally need less supporting data than second medical use claims. However, **if it is not plausible that the compound has the purported therapeutic activity**, the **objective technical problem** may have to be redefined in a **less ambitious way**, often leading to a finding of obviousness
- If the Patent/Application relates to a **(further) medical use of a known compound**, achieving the asserted therapeutic effect is a **functional feature of the claim** and must therefore be **sufficiently disclosed** (Art. 83 EPC, see T 609/02)



## The Concept of “Plausibility” – Boards of Appeal Case Law

### Some Conclusions to be taken from the Body of Case Law rendered by the EPO Boards of Appeal in Recent Years

- Data / Working Examples are, however, not a *sine qua non* for making it plausible that the claimed invention solves a technical problem (Art. 56 EPC) and/or satisfies the requirements of Sufficiency (Art. 83 EPC).
- However, simply alleging that Compound X is suitable for treating disease Y is not sufficient: At least *some information* must be provided for plausibility / credibility
- Applicant / Patentee may rely on Common General Knowledge or an analogy to prior art compounds known to in a similar manner as purported in the Patent



## The Concept of “Plausibility” – Boards of Appeal Case Law

### Some Conclusions to be taken from the Body of Case Law rendered by the EPO Boards of Appeal in Recent Years

- Data presented in the Patent do not necessarily need to relate to humans or even animal experiments – *in vitro* data are typically sufficient if the target affected by the compound is credibly associated with the claimed pathological condition / disease
- If *in vitro* (or even *in vivo*) data are not credibly related to the disease in question the requirement of sufficiency may not be met (cf. T 801/10, T284/12, T 2059/13)



## The Concept of “Plausibility” – Boards of Appeal Case Law

### How much Data is Needed For Pharmaceuticals at the EPO?

#### Lessons from the (ongoing) “Dasatinib” Saga

- Opposition Proceedings against two EP Patents directed to Dasatinib:  
**EP 1 169 038 B1 (“Product Patent”)**, relating to *inter alia* the compound “Dasatinib”; and  
**EP 1 610 780 B1 (“Medical Use Patent”)**, relating to the use of Dasatinib for preparing a medicament for the treatment of chronic myelogenic leukemia (CML)
- Both are under consideration by EPO Board of Appeal 3.3.01



## The Concept of “Plausibility” – Boards of Appeal Case Law

### The “Dasatinib” Saga - II

- Patent originally related to a large number of compounds said to be useful in the treatment of diseases/conditions benefitting from the inhibition of protein tyrosine kinases (PTKs), such as certain immunologic and oncologic disorders
- Although the original claims were in the form of broad Markush claims, the **compound Dasatinib was exemplified** (cf. Example 455 of EP’038) - but **not specifically mentioned in the original claims**



## The Concept of “Plausibility” – Boards of Appeal Case Law

### The “Dasatinib” Saga – Revocation of the Base Patent (EP’038)

#### EPO BoA 3.3.01 Decision T 488/16

- Patent listed a **possible inhibitory activity for a large number of different PTKs** generally known to be involved in immune and cancerous diseases.
- Possible PTK inhibition assays were described, but **no specific data was presented for any of the compounds** claimed in the application. Thus, it was **not clear which compound inhibited which PTK**.



## The Concept of “Plausibility” – Boards of Appeal Case Law

### The “Dasatinib” Saga – Revocation of the Base Patent (EP’038)

#### EPO BoA 3.3.01 Decision T 488/16

- BoA concluded that the claims, even when limited to Dasatinib only, were devoid of inventive step (Art. 56 EPC) – Patent revoked!

*“4.14 [...]. In the present case, there is also **no evidence** provided on the date of filing **that dasatinib is a suitably active PTK inhibitor, let alone an inhibitor for PTKs associated with the treatment of cancer, such as Src or Abl kinase**, the latter is not even mentioned in the application as filed. Structural similarity of small molecules does not necessarily imply similar function. Their activity is in general unpredictable and even minor structural changes can disrupt activity. **No established structure—activity relationship exists, which, in the complete absence of any verifiable data in the application, would make it plausible that dasatinib is a PTK inhibitor.**”*



## The Concept of “Plausibility” – Boards of Appeal Case Law

### The “Dasatinib” Saga – The Medical Use Patent (EP’780)

#### EPO BoA 3.3.01 Decision T 950/13

- Relevant claims of EP 1 610 780 B1 (EP’780) considered by BoA under sufficiency (Art. 83 EPC):

“1. Use of **dasatinib** in the manufacture of a medicament **for the treatment of chronic myelogenous leukemia (CML)**”

“2. Use of **dasatinib** in the manufacture of a medicament **for the treatment of chronic myelogenous leukemia (CML) resistant to imatinib.**”

- Application **text largely identical to base patent** (EP’038), cited as D1 in Opposition against use patent.
- But method involving dasatinib (Formula IV) for the treatment of specific cancers (including CML), optionally wherein these cancers are sensitive to inhibition of BCR-ABL kinase was set out in the original claims (cf. claims 3 and 4, respectively) and an additional para. bridging pages 46-47



## The Concept of “Plausibility” – Boards of Appeal Case Law

### The “Dasatinib” Saga – The Medical Use Patent (EP’780)

#### EPO BoA 3.3.01 Decision T 950/13

- Like base patent EP’780 did not include any experimental data
- PTK inhibition assays described were identical to those in the base patent – but **no mention of a BCR-ABL kinase assay!**
- Statement that “*compounds described in the examples had been tested in one or more of these assays, and have shown activity*” therefore cannot relate to BCR-ABL inhibition!
- BoA relied on a newly added paragraph (para. bridging pages 46-47 of the application) to conclude that **dasatinib, like imatinib, was an inhibitor of BCR-ABL kinase**  
(despite the fact that the cited passage continued with stating that the compounds are also useful in treating cancers that are sensitive and resistant to agents that target BCR-ABL, such as imatinib (Gleevec®).





## The Concept of “Plausibility” – Boards of Appeal Case Law

### The “Dasatinib” Saga – The Medical Use Patent (EP’780)

#### EPO BoA 3.3.01 Decision T 950/13

- BoA decided that **claim 1** (use of Dasatinib for the treatment of CML) **was sufficiently disclosed in view of functional analogy to the known CML drug and BCR-ABL inhibitor imatinib** (thus rendering it plausible that Dasatinib also works in a similar manner, see Reasons 3.3 to 3.6)
- In contrast, BoA concluded that **claim 2 (use of Dasatinib for the treatment of imatinib-resistant CML) was held insufficient** in the absence of experimental data or CGK supporting a biological activity different from that of imatinib
- BoA confirmed previous case law that **concrete experimental data** (or even *in vivo* data) **are not always necessary** to overcome the plausibility threshold (confirming T 578/06, No. 13)



## The Concept of “Plausibility” – Boards of Appeal Case Law

### The “Dasatinib” Saga – The Medical Use Patent (EP’780)

#### EPO BoA 3.3.01 Decision T 950/13

- BoA's summary of the rationale applied for the subject matter of claim 1:  
*“3.10.4 Concerning the **lack of explicit data**, the board reemphasises that in cases where the application **discloses a technical concept which is plausible in the light of the common general knowledge** at the relevant date, **but lacks concrete or tangible proof** that the claimed concept can be put into practice, **post-published documents may be used as evidence** that the invention was indeed reproducible without undue burden at the relevant filing date of the application (see T 1262/04, Reasons No. 5; T 157/03, Reasons No. 9).”*
- Re its finding that claim 2 was insufficient, BoA explained that:  
*“3.13.2 [...]. The **functional analogy to imatinib as BCR-ABL kinase inhibitor** is not helpful in this context and **cannot explain why dasatinib should be active, when imatinib is, or has become, inactive.**”*



## The Concept of “Plausibility” – Boards of Appeal Case Law

### The “Dasatinib” Saga – Conclusions

- Lack of concrete data in application does not need to be detrimental: If a functional analogy to a known drug exists and is alluded to in the patent, chances are high that plausibility threshold is met
- Chances to overcome plausibility hurdle increased for specific compounds and for specific (or limited number of) medical indication
- However, the latter may not be sufficient if there is no functional analogy to an agent known to be effective in the claimed treatment (cf. EP’780 claim 2)
- Caution: Relying on a functional analogy to known agent may open up a possible attack under inventive step (although the concepts of plausibility and obviousness are clearly different from each other, cf. T 950/13, Reasons No. 3.8)



## The Concept of “Plausibility” – Conclusions

### The EPO’s approach to Plausibility – Take Home Message

- **Remedy of Art. 56 (Obviousness) & Art. 83 (Sufficiency) EPC deficiencies by post-published evidence: similar standard!**
  - *If post-published data cannot be used in support of sufficiency, they can not be used to support inventive step either*
- **Experimental Data in the original application not always required in particular if**
  - the application discloses a plausible technical concept and
  - there are no substantiated doubts (CGK, prior art) that the claimed concept can be put into practice





Thank you for your attention!

**df-mp**

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# ALLEN & OVERY



## *Plausibility of medical use claims European perspective*

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9 February 2018

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## Plausibility: The Netherlands

### I

#### Sufficiency

District Court, 23 April 2014 (*Merck / Mylan*): Swiss type claim

Court of Appeal 27 January 2015 (*Novartis / Sun*): Swiss type claim (priority context)

“The claimed invention needs to be disclosed in an enabling manner in the priority document, in the sense that it needs to be credible that the claimed invention works, or to put it differently: solves the problem”

Court of Appeal 26 April 2016 (*Ajinomoto / GBT*): “not immediately implausible” that the patent actually works

#### Novelty

District Court 29 June 2016 (*MSD / Ono*)

- Start of plausibility with respect to novelty / prior art in Dutch decisions
- In medical use claims, prior art is novelty destroying when effect is made plausible (reference to EPO decisions)

Similar ruling about medical use claims in District Court 27 July 2016 (*AstraZeneca / Sandoz*)

## Plausibility: The Netherlands

### II

#### Inventive step

Court of Appeal 25 October 2016 (*Teva / Synthon*)

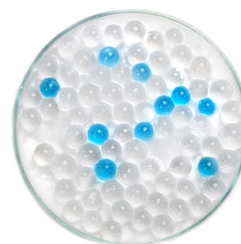
- Patent is inventive if the patent makes sufficiently plausible that the technical effect contributes to solving the formulated problem (PSA)
- Low threshold test

District Court 7 September 2016 (*Teva / Boehringer*)

- Technical effect must be plausible (≠ “not immediately implausible”)

#### Industrial applicability

No Dutch case law



## Plausibility: UK

### Plausibility in general is 'a threshold test' – but what is the threshold?

*"It must therefore be possible to make a **reasonable prediction the invention will work** with substantially everything falling within the scope of the claim or, put another way, the assertion that the invention will work across the scope of the claim **must be plausible or credible**. The products and methods within the claim are then tied together by a unifying characteristic or a common principle. If it is possible to make such a prediction then it cannot be said the claim is insufficient simply because the patentee has not demonstrated the invention works in every case."*

*(Regeneron / Bayer [2013])*

### With regard to obviousness the requirement of plausibility is different then a reasonable expectation of success

*"A test designed to prevent speculative claiming need go no further than requiring the patentee to show that the claim is **not speculative**: the specification does not need to provide the reader with any greater degree of confidence in the patentee's prediction"*

*(Warner-Lambert / Generics [2016])*

*"Plausibility is to exclude speculative patents, based on mere assertion, where there is no real reason to suppose that the assertion is true"*

*(Actavis / Eli Lilly [2015])*

## Plausibility: Germany

Speculative patents are generally rendered invalid for lack of inventive step.

FPC, 11 November 2008 (*Cetirizin*): insufficiency if the patent is **pure speculation** to the skilled person in light of the CGK.

### "Plausibility" in medical use claims:

In FCJ, 11 September 2013 (*dipeptidyl-peptidase inhibitor*) the FCJ held that based on the scientific reasoning, the generalization in the patent was still *credible*, although the claims were not enabled across their breadth.

Not all compounds encompassed by the claims lowered the blood sugar.



## Plausibility: France

With regard to sufficiency of medical use claims, the Supreme Court held (SC, 6 December 2017, (MSD / Teva)) that:

*“Whereas, first, when a claim relates to a further medical use of a substance or a composition, obtaining the therapeutic effect is a functional technical feature of the claim, so that if, to satisfy the requirement of sufficiency, it is not necessary for this therapeutic effect to have been demonstrated clinically, the patent must however, directly and unambiguously reflect the claimed therapeutic application, so that the skilled person understands, on the basis of generally accepted models, that the results reflect this therapeutic application.”*

No specific reference to ‘plausibility’, but an analysis of EPO case law included.

## Questions?

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## Second Medical Use Patents, Section 112 And The U.S. Courts

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## Written Description, Enablement & Utility: The Standards

- **Written Description:** Specification must reasonably convey to a POSA that the inventor had possession of the invention.
- **Enablement:** Specification must enable a POSA to practice the invention without undue experimentation.
- **Utility:** Claimed subject matter must be useful and operative.

*Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988); *In re '318 Patent Infringement Litig.*, 583 F.3d 1317, 1323 (Fed. Cir. 2009).

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PAGE 30

## Patents Are Not Awarded For Academic Theories

- **Written Description:** “Research hypotheses do not qualify for patent protection.”
- **Enablement:** A “starting point, a direction for further research” is not enabling.
- **Utility:** “The utility requirement prevents mere ideas from being patented.”

*Ariad*, 598 F.3d at 1353; *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1386 (Fed. Cir. 2013); *In re '318 Patent Infringement Litig.*, 583 F.3d at 1323-24.

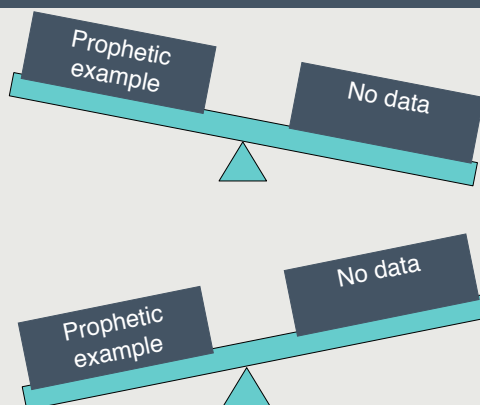
## Does Written Description Require Working Examples?

- **One the one hand:** Written description “does not demand either examples or an actual reduction to practice.”
  - “Prophetic examples . . . certainly can be sufficient to satisfy the written description requirement.”
- **On the other hand:** A “‘wish’ or ‘plan’ for obtaining” the invention or “mere mention of a desired outcome” is insufficient.

*Ariad*, 598 F.3d at 1352, 1357.



## How Have The Courts Treated Prophetic Examples?



**Insufficient Written Description:**  
*CreAgri, Inc. v. PinnacLife, Inc.*, No. 11-CV-6635-LHK, 2013 U.S. Dist. LEXIS 179253 (N.D. Cal. Dec. 18, 2013), *aff'd* 579 Fed. App'x 1003 (Fed. Cir. 2014).

**Sufficient Written Description:**  
*Bone Care Int'l, L.L.C. v. Roxane Labs., Inc.*, No. 09-cv-285 (GMS Consolidated), 2012 U.S. Dist. LEXIS 80450 (D. Del. Jun. 11, 2012).

## Can *CreAgri* And *Bone Care* Be Reconciled?

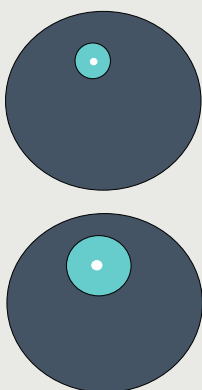
- ***CreAgri***, 2013 U.S. Dist. LEXIS 179253 at \*47:
  - Prophetic study did not “describe the full [claim] scope.”
  - Prophetic “study designs fail[ed] to disclose any results whatsoever, whether realized or predicted.”
- ***Bone Care***, 2012 U.S. Dist. LEXIS 80450 at \*121-25:
  - Prophetic example disclosed all claim elements: therapeutic agent, disease and therapeutic effect.

## Does Enablement Require Working Examples?

- **On the one hand:** A “patent does not need to provide actual working examples” to be enabled.
  - Considerable amount of experimentation is permissible if routine or guidance is provided in the specification.
- **On the other hand:** “[R]outine experimentation is ‘not without bounds.’”
  - An iterative trial-and-error process may be undue.

*Alcon Res. Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1189-90 (Fed. Cir. 2014); *Wyeth*, 720 F.3d at 1386.

## How Have The Courts Treated Routine Experimentation?



### **Not Enabled:** *Wyeth*, 720 F.3d at 1386.

- Claim: 10s of 1000s compounds.
- Specification: 1 species plus screening assays.
- Prior art: 4 species.

### **Enabled:** *Erfindergermeinschaft Uropep GbR v. Eli Lilly & Co.*, No. 2:15-CV-1202-WCB, 2016 U.S. Dist. LEXIS 137318 (E.D. Tex. Aug. 25, 2017).

- Claim: 10s of 1000s compounds.
- Specification: 4 species plus screening assay.
- Prior art: 100s species.

## Can *Wyeth* and *Uropep* Be Reconciled?

- **Wyeth**, 720 F.3d at 1385-86:
  - Specification silent on how to modify disclosed species.
  - Each assay took weeks and “until you test [the compounds], you really can’t tell whether they work or not.”
  - Specification disclosed “a starting point for further interactive research in an unpredictable and poorly understood field.”
- **Uropep**, 2017 U.S. Dist. LEXIS 137318 at \*59-68:
  - Field was “mature” and “well-developed”; assay was “routine.”
  - It “took a few weeks to screen half a million compounds.”

## Does Utility Require Working Examples?

- **Written Description:** Written description “is not about whether the patentee has proven to the skilled reader that the invention works, or how to make it work, which is an enablement issue.”
- **Enablement:** A “patent does not need to guarantee that the invention works to be enabled.”
- **Utility:** If a patent claim fails to meet the utility requirement, then it also fails the how-to-use aspect of the enablement requirement.

*Alcon*, 745 F.3d at 1191; *id.* at 1189; *In re '318 Patent Infringement Litig.*, 583 F.3d at 1323-24.

## How Have The Courts Treated The Utility Requirement?

United States Patent [19]  
Davis [11] Patent Number: 4,663,318  
[45] Date of Patent: May 5, 1987

- No experimental data
- Inventor “wasn’t sure” it would work
- Post-filing date data confirmed utility but not submitted to PTO

**Insufficient Utility:** *In re ’318 Patent Infringement Litig.*, 583 F.3d at 1323-27.

**Sufficient Utility:** *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 Fed. Appx. 917, 923-26 (Fed. Cir. 2011).

## Can *In re ’318* And *Eli Lilly* Be Reconciled?

- ***In re ’318 Patent Infringement Litig.***, 583 F.3d at 1324, 1327:
  - No “reasonable correlation” between activity and therapeutic use.
  - Specification “does no more than state a hypothesis and propose testing to determine the accuracy of that hypothesis.”
  - Post-filing date data could not be used as not available until after issuance.
- ***Eli Lilly***, 435 Fed. App’x. at 924-26:
  - Mechanism of drug action known to be relevant to claimed use.
  - Utility was fully described in the specification; no allegation of falsity.
  - Post-filing date data was available before grant but Examiner did not consider the disclosed utility so incredible as to require additional data.

## Interplay Between § 112 And Obviousness

- ***Merck & Co., Inc. v. Teva Pharms. USA, Inc.***, 395 F.3d 1364, 1374 (Fed. Cir. 2005):
  - The patent set “forth no human or clinical or laboratory data showing the safety and tolerability of the [claimed] treatment methods.”
  - “[T]he claimed invention adds nothing beyond the teachings of [the prior art] articles.”
  - “Thus, the district court clearly erred in finding any difference between the claimed invention and [the prior art] on this point.”

## Interplay Between § 112 And Obviousness

- ***Alcon Res., Ltd. v. Apotex Inc.***, 687 F.3d 1362, 1366-70 (Fed. Cir. 2012):
  - Prior art did not disclose that the drug was safe in humans.
  - Patent at issue contained *in vitro* tests but no human data.
  - Just as a POSA would have been able to practice the claims “despite [the patent’s] lack of explicit instruction that [the compound] is safe for human [] use, the artisan would have a reasonable expectation of success for adapting [the prior art] for the same use” in humans.

## How Have The Courts Applied *Merck*?

- ***Novartis Pharms. Corp. v. West-Ward Pharms. Int'l, Ltd.***, No. 15-CV-474-RGA, 2017 U.S. Dist. LEXIS 205600, at \*25-26 (D. Del. Dec. 14, 2017):
  - *Merck* did not hold that patentee may never rely on the absence of prior art clinical data when the patent does not contain such data.
  - In *Merck* the prior art disclosed all claim elements, with only a minor difference in a dosage, and the patent provided no reason for the departure from the prior art dosage.
  - Where “[t]he prior art does not disclose all elements of the asserted claims, [] the holding in *Merck* does not apply.”

## Second Medical Use Patents, Section 112 And The U.S. Courts

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## Navigating the Challenges of Repurposing an Old Compound

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## U.S. Prosecutor's Toolkit

- > 1. Change Method Indication
- > 2. Change Treatment Regimen
- > 3. Change Formulation
- > 4. Combination Therapy
  
- > Must balance patentability against enforceability
  
- > Maximize claim scope coverage to advance opportunities



## Patentability - U.S. Gatekeepers to prevent purely speculative patents

- Enablement (35 USC 112)
- Written Description (35 USC 112)
- Anticipation (35 USC 102)
- Obviousness (35 USC 103))



## Enablement & Written Description

- Written Description
  - The written description requirement serves “both to satisfy the inventor’s obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed.” *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005).
- Enablement
  - “The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.”. *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988)



## Anticipation

- A claim is anticipated only if each and every element as set forth in the claim is found, either **expressly or inherently** described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). (Emphasis added)
- The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. See *Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).)
  - However, the discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957).
  - However, when the claim recites using an old composition or structure and the “use” is directed to a result or property of that composition or structure, then the claim is anticipated. *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978)

## Obviousness

- > *Graham Factors for determining obviousness (Graham v. John Deere Co., 383 U.S. 1 (1966))*
- > *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) – Supreme Court invokes “common sense” and “Obvious to Try” as rationales for obviousness.
  - Common sense teaches us that familiar items may have obvious uses beyond their primary purpose, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.”
  - “When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has a good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.” (Emphasis Added)

## A Glimmer of Hope?

- > *Genzyme v. Dr. Reddy* (Fed. Cir. December 18, 2017) - When a USPTO Examiner relies on an article (e.g. a journal article) that includes an **“isolated sentence, without explanation,” and without supporting testing** to allege that the article is a teaching for obviousness purposes, *Genzyme* may be useful to counter that this teaching **does NOT provide a “reasonable expectation of success”** when **combined with evidence of unpredictability in the art.**

## Change Method Indication

- > Compound A is a known cancer therapeutic and you discover that it can be used to treat lupus
  - What's the evidence? Incorporate into Specification:
    - Need art accepted in vitro model of disease or animal model of human disease (enablement/plausibility)
    - Emphasize and develop evidence of surprising results
  - What's next? Know the Prior Art:
    - Think about potential overlap in patient populations
    - Understand doses used, modes of administration
    - Teaching away from your indication
  - Being overly inclusive can be problematic in future

## Draft Claims Based on Understanding

- > A method for treating a subject afflicted with lupus, the method comprising administering a therapeutically effective amount of Compound X to the subject.
- > A method for treating a subject afflicted with lupus, the method comprising administering a therapeutically effective amount of Compound X to the subject, wherein the subject is not known to be afflicted with cancer.
- > Common Obstacles: Anticipation (Inherency), obviousness.

## Change Treatment Regimen

- > Mode of administration: systemic v localized; oral, intravenous, subcutaneous, localized (via e.g., injection), topical (skin, lips), aerosolized, anal, vaginal, intrathecal
- > Timing /frequency/duration of administration
  - Example of Claim: A method for treating a subject afflicted with lupus, the method comprising administering a therapeutically effective amount of Compound X to the subject, wherein the Compound X is administered at less than 50 mg/kg at a frequency of twice per day.
  - Reasoning: Compound X is used at higher doses (e.g., > 75 mg/kg) and 3X per week) – cancer treatment requires higher dose and greater frequency (=higher toxicity)
- > Common Obstacles: Written description and enablement.

## Combination Therapy

- > Combination of Compound X and Compound Y known to be used in new indication (e.g., lupus)
  - Example of Claim - A method for treating a subject afflicted with lupus, the method comprising administering a therapeutically effective amount of Compound X and a therapeutically effective amount of Compound Y to the subject.
- > Synergistic activity optimal, but not required
- > Common Obstacles: Enablement, Written Description, Obviousness (Genzyme v. Dr. Reddy)

## Change Formulation

- > Change to slow release or delayed release (e.g., altered encapsulation or via mixed materials pill/capsule)
- > Change concentration of active agent
- > Change excipient
- > Derivatives, analogs (e.g., conjugates)
- > Multimeric conjugates

## Balancing patentability against enforceability

Claim Scope  
(Narrow to Broad)



Ease of Enforceability  
(Easiest to Hardest)



- > 1. Change Method Indication
- > 2. Change Treatment Regimen
- > 3. Change Formulation
- > 4. Combination Therapy

### Potential Targets for Enforcement (Direct/Inducing)

Physician

Medical Group (Practice)

Pharmacist

Hospital System

Drug Manufacturer

Party marketing the compound with label instructions that describe patent use

Patient using the drug

# QUESTIONS?