



HOFFMANN EITLE

Criteria for reliance upon a technical effect and the
relevance of post-published evidence

Did G2/21 change the game?

Dr. Joachim Renken

Outline

Introduction

Referring decision T116/18

G 2/21

Criteria for relying on a technical effect for inventive step

Apixaban

Discussion



The problem-solution approach

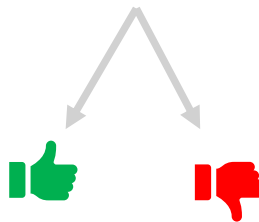
- (a) identifying the “closest prior art”;
- (b) comparing the subject-matter of the claim at issue with the disclosure of the closest prior art and identifying the difference(s) between both;
- (c) determining the technical effect(s) or result(s) achieved by and linked to these difference(s);
- (d) defining the technical problem to be solved as the object of the invention to achieve these effect(s) or result(s); and
- (e) examining whether or not a skilled person, having regard to the state of the art within the meaning of Article 54(2) EPC, would have suggested the claimed technical features in order to obtain the results achieved by the claimed invention



EPO uses '*problem-solution approach*' to assess inventive step...

...which **relies on the technical effect** *vis-à-vis* the closest prior art for formulating the '*objective technical problem*'.

→ The question of whether a technical effect, and post-filed evidence supporting it, can be relied upon can be **decisive for inventive step**.



Is Applicant free to choose the technical effect?

The answer prior to G2/21:

As a matter of principle any effect provided by the invention may be used as a basis for the reformulation of the technical problem, as long as said effect is **derivable from the application as filed** (see T 386/89).

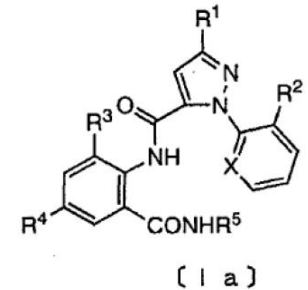
It is also possible to rely on new effects submitted subsequently during the proceedings by the applicant, provided that **the skilled person would recognise these effects as implied by or related to the technical problem initially suggested** (see G-VII, 11 and T 184/82).



- **Claim 1:** Insecticide composition comprising thiamethoxam and a compound of formula I.
- **Specification:** combination of thiamethoxam and formula I compound achieves synergy (over-additive insecticidal activity).
- **Prior art (D4):** thiamethoxam and formula I compounds disclosed individually
- **Problem:** Provide insecticide composition in which the insecticides act synergistically against insect species (*Chilo suppressalis*)



Referring decision T 116/18



Application: synergistic insecticide activity against pests A, B, C **mentioned**
Includes two examples showing this effect with pests A and B

- **Post-published data** filed by Opponent shows that this effect is not achieved for another example falling under scope of claims A and B
- **Post-published data** filed by Patentee shows that synergy obtained with claimed combination exemplified in patent against pest C

- **D21 (post-published document filed by patentee)** = **Sole evidence** to prove synergy against a certain insect species (*Chilo suppressalis*)
- Can **D21** be taken into account?
- if **yes**: patent **maintained**
- if **not**: patent to be **revoked**

Diverging Case Law identified by Referring Board

– “***ab initio plausibility***”: Post-published evidence can be relied upon only if the purported technical effect is made **at least plausible** in the application as filed

- Requires **a reason to assume** that effect is achieved, e.g., data or scientific explanation



– “***ab initio implausibility***”: Post-published evidence can be relied upon if the purported technical effect was **not implausible** from the application as filed (**no reasons to doubt** it).

– “***no plausibility***”: The concept of ‘plausibility’ is rejected altogether

Why Plausibility?

- Seeks to distinguish a **credible technical disclosure** from pure **speculation**
 - Currently mainly relevant for **biotech** and **pharma** inventions.
 - Increasing relevance for black box-like inventions involving **AI tools**?
- Invites applicants to **disclose** their data in the application
- Plausibility may be applied to technical effects relevant for
 - **Inventive step**
 - **Sufficiency of disclosure**
- But: **No explicit basis** in the EPC
- A “**court-invented pre-condition to validity**” (UK Supreme Court in *Warner-Lambert*)



Questions referred (simplified):

- 1) Can post-published evidence be disregarded on the ground that the proof of the effect rests **exclusively** on the post-published evidence?
- 2) If the answer to 1) is yes, can the post-published evidence be taken into consideration if the skilled person would have considered the effect plausible (ab initio plausibility)?
- 3) If the answer to 1) is yes, can the post-published evidence be taken into consideration if the skilled person would have seen no reason to consider the effect implausible (ab initio implausibility)?

Wide-ranging decision which makes several points about:

- a) Whether evidence can be disregarded;
- b) the burden of proof for technical effects;
- c) the concept of plausibility;
- d) post-published evidence in the context of sufficiency;
and
- e) post-published evidence in the context of inventive step.



a) Can evidence be disregarded (1)?

...the principle of free evaluation of evidence qualifies as a universally applicable principle in assessing any means of evidence by a board of appeal.

*Hence, 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.*

- So post-published data shouldn't be simply ignored
- Could have finished here, but the Enlarged Board had a lot more to say!



a) Can evidence be disregarded (2)?

*the only decisive factor is whether the judge is **personally convinced** of the truth of the factual allegation, i.e. how credible the judge classifies a piece of evidence.*

- What does this mean for “balance of probabilities”?



b) Burden of proof for technical effects

According to the established case law... it rests with the patent applicant or proprietor to properly demonstrate that the purported advantages of the claimed invention have successfully been achieved”.

*“plausibility”... is something that a patent applicant or proprietor **must demonstrate** in order to validly rely on an asserted but contested technical effect”*

- Compare e.g. with T 1797/09 “technical problem... in a patent is... credibly solved if there exist no reasons to assume the contrary... it is normally the Opponent's burden to prove the opposite or at least provide evidence casting doubt on the alleged solution of the problem.*



c) The concept of plausibility

*The Enlarged Board considers the conceptional notion inherent in the term “plausibility”, which is often used as a generic catchword, **as not being a distinct condition of patentability and patent validity, but a criterion for the reliance on a purported technical effect. In this sense, it is not a specific exception to the principle of free evaluation of evidence but rather an assertion of fact and something that a patent applicant or proprietor must demonstrate in order to validly rely on an asserted but contested technical effect”***

- This will likely have a significant impact on at least UK law
- As “catchword” Enlarged Board didn’t adopt the ab initio (im)plausibility/no plausibility analysis of referring Board



d) Post-published evidence in the context of sufficiency

Generally, evidence is relevant for:

- **Sufficiency** when effect is in the claim (i.e. second medical use claims); and
- **Inventive step** when effect is not in the claim but achieved over the prior art.



d) Post-published evidence in the context of sufficiency

*it is **necessary** that the patent at the date of its filing renders it **credible** that the known therapeutic agent, i.e. the product, is suitable for the claimed therapeutic application...*

***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. A lack in this respect **cannot be remedied by post-published evidence**.*

- Seems *ab initio* plausibility required for sufficiency – applicant has burden!



e) Post-published evidence in the context of inventive step (Headnote 2)

*A patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and 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**".*

- General uncertainty about what this key test actually means!



Criteria for relying on a technical effect

G 2/21 – Headnote 2

*A patent applicant or proprietor may **rely upon a technical effect for inventive step** if the skilled person, having the common general knowledge in mind, and 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**.*

- **No mention of plausibility**

- EBoA does not seem to support a “*distinctive legal concept*” of plausibility (reason 92)

- EBoA apparently introduces a **two-step test**.

- EBoA gives no explanation and admits “*abstractness*” of the criteria (reason 95).
- → What does “*derive ... as being encompassed by the technical teaching and embodied by the same originally disclosed invention*” mean?



Criteria for relying on a technical effect

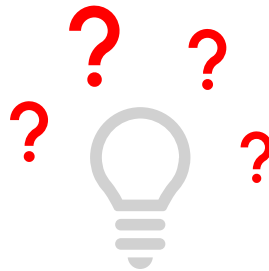
G 2/21 – Headnote 2

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- Some hints in the decision
 - EBoA: Test would **not have changed the outcome of** the previous **divergent case law** (reasons 71-72)
 - EBoA emphasizes “*pertinent **circumstances of each case***” (reasons 95).
 - → A flexible test which reconciles (seemingly) diverging case law?
 - Criteria for effects for **inventive step** are more lenient than for **sufficiency** (reason 77)



Clarification by the referring Board 3.3.02?



Criteria for relying on a technical effect

Preliminary Opinion of Referring Board (June 14, 2023)

Points 4-4.1:

*The parties should reflect on its meaning and impact on the present case. In the preliminary view of the board, **at least the following two interpretations are possible.***

*According to **a first possible interpretation**, [...] post-published evidence cannot be disregarded solely on the ground that it was not published before the filing date of the patent and was filed after that date (answer to question 1). However, the effect which this evidence addresses cannot be relied upon in the formulation of a technical problem if it was not plausible/credible or not implausible [...]. [...] it may be argued that **the Enlarged Board has endorsed at least the ab initio plausibility and ab initio implausibility lines of case law by formulating the same criterion for both lines and stating that this criterion would have led to the same result as (im-) plausibility considerations in the respective cases [...]. Therefore, a first possible interpretation appears to be that a patent proprietor can rely upon a technical effect and that postpublished evidence filed as proof thereof [...] can be taken into account provided that the effect is credible/plausible/not implausible [...].***




Criteria for relying on a technical effect

Preliminary Opinion of Referring Board (June 14, 2023)

Points 4-4.2:

The parties should reflect on its meaning and impact on the present case. In the preliminary view of the board, at least the following two interpretations are possible.

*According to a **first possible interpretation**, [...] post-published evidence cannot be disregarded solely on the ground that it was not published before the filing date of the patent and was filed after*

- Interpretation focuses on **(im)plausibility**.
- This creates **tension**...
 - ...with the **G 2/21 headnote**, which does not mention (im)plausibility at all, and
 - ...with the EBoA's view that plausibility is not a “*distinctive legal concept*” (reason 92)
- The interpretation provides **no actual explanation of the G 2/21 test**. 
 - How to **choose between the standards** (plausibility vs. implausibility)?

Criteria for relying on a technical effect

Preliminary Opinion of Referring Board (June 14, 2023)

Point 4.2:

A **second possible interpretation** may be that a patent proprietor can rely upon a technical effect and that **post-published evidence filed as proof thereof can be taken into account provided that this effect is derivable from the application as filed and (thus) does not change the nature of the claimed invention**. This would be the criterion that has been applied in decisions which focused only on whether the effect was disclosed in the application as filed, irrespective whether the effect was plausible/not implausible/credible at the filing date [...]. Therefore, under this approach, it would be neither necessary nor relevant to ask whether the effect relied upon was plausible/not implausible/credible to the skilled person at the filing date. Contrary to the above, **this approach would mean that the case law on plausibility would no longer be applicable**. This would be true for both standards identified by the board (type I and type II) in the referring decision (points 13.4 and 13.5 of T 116/18)."



Criteria for relying on a technical effect

Preliminary Opinion of Referring Board (June 14, 2023)

Point 4.2:

A **second possible interpretation** may be that a patent proprietor can rely upon a technical effect and

- **Consistent** with the **lack of reference to “(im)plausibility”** in the G 2/21 headnote
- However, the Board still provides **no explanation** of the actual test:
 - If the test does not apply any plausibility hurdle,...
 - How could it produce the **same outcome** as the **(strict) case law on plausibility** (reasons 71-72)?



Preliminary Opinion of Referring Board (June 14, 2023)

Summary by the Board (Point 5.1):

*At this stage, this board is **not in a position to conclude** which of the two interpretations set out above is the one that most likely reflects the intended meaning of the expression "as being encompassed by the technical teaching and embodied by the same originally disclosed invention". **It is possible that the parties themselves will support further interpretations of G 2/21.***

- The Referring Board has not (yet) formed a clear view on G 2/21
- Its current interpretations of the G 2/21 test seem incomplete and/or create tension with G 2/21

Criteria for relying on a technical effect

Preliminary Opinion of Referring Board (June 14, 2023)

Summary by the Board (Point 5.1):

*At this stage, this board is not in a position to conclude which of the two interpretations set out above is the one that most likely reflects the intended meaning of the expression "as being encompassed by the technical teaching and embodied by the same originally disclosed invention". **It is possible that the parties themselves will support further interpretations of G 2/21.***

- The Referring Board had not formed a clear view on G 2/21 in its preliminary opinion
- The presented interpretations of the G 2/21 test seem incomplete and/or create tension with G 2/21
- Board seems amendable to **“further interpretations”** of G 2/21



Criteria for relying on a technical effect

Decision of Referring Board (July 28, 2023)

According to the minutes, the Board concluded that Patentee could rely on effect of synergism on *Chilo suppressalis* shown in D21.

Written decision is not yet available.



Criteria for relying on a technical effect

T 873/21 of June 20, 2023

- Asserted effect: improved insulin sensitivity, in particular a synergistic interaction of compound (A) and compound (B) as demonstrated by the supplemental experimental data D16.
- Therapeutic synergistic effect substantiated in D16 was derivable from the original application (improved effect in terms of insulin sensitivity when monotherapy with one or more dopamine receptor agonist is insufficient was generally described in the original application). Accordingly, the Board considered that the synergistic effect relied upon by the appellant was encompassed by the technical teaching of the original application.
- Therapeutic synergistic effect substantiated in D16 was embodied by the present combination since it was clearly the preferred combination in the original application (see page 22 line 25, claim 5 and all the examples).
- D16 was thus taken into account when assessing the inventiveness of the claimed subjectmatter.



Criteria for relying on a technical effect

Where does this leave us?

Core issue: What did the skilled person, with the common general knowledge in mind, understand at the filing date from the application as originally filed as the technical teaching of the claimed invention (Reason 71).

Two step test:

*Criterion 1: Would the skilled person **derive** said effect as being **encompassed by the technical teaching**?*

*Criterion 2: Would the skilled person **derive** said effect as being **embodied by the same originally disclosed invention**?*

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.



Criteria for relying on a technical effect

| Case | Effect relied upon | Effect generally mentioned in description | Evidence in application | Evidence taken into account to prove effect? |
|-----------|--|---|---------------------------------------|--|
| T 1329/04 | Further member of TGF- β superfamily | Yes | None | No |
| T 184/16 | Improved SGLT2 inhibition | Yes | None | Yes |
| T 31/18 | Improved tablet properties | Yes | None | Yes |
| T 488/16 | Improved PK activity /cancer | Yes | None (unclear data) | No |
| T116/18 | Synergism on <i>Chilo suppressalis</i> | Yes | Yes, but not with claimed combination | Yes |
| T873/21 | Synergism on insulin sensitivity | Yes | No | Yes |



Criteria for relying on a technical effect

T116/18

Asserted effect: synergy against *Chilo suppressalis*

Criterion 1: encompassed by technical teaching?

Technical teaching: Thiamethoxam in combination with another compound for controlling insect pests

Chilo suppressalis is a specific insect pest.

Criterion 1 thus satisfied.



Criteria for relying on a technical effect

T116/18

Criterion 2: embodied by the originally disclosed invention?

O argued that this requirement is not fulfilled because examples showing effect against *Chilo suppressalis* do not contain Thiamethoxam.

Counter-argument: O's interpretation would mean that experimental evidence is always needed; this was denied in G2/21.

Chilo suppressalis mentioned as possible insect pest in description; claimed combination described in description.

Criterion 2 satisfied.



T 31/18

Claim: *Tablet comprising imatinib with specific excipients*

- For inventive step, P relied on **post-published data** for claimed tablets showing improved abrasion resistance, hardness, and disintegration time
- No evidence in application as filed,
- General statement about the effects



Criteria for relying on a technical effect

T 31/18

Board:

- Said technical effect or problem must either be **explicitly mentioned** in the application as filed or **at least be derivable therefrom**, but **not necessarily originally supported by experimental evidence**.
- It can indeed not be expected from a patent applicant to include an extensive number of experimental evidences corresponding to all technical features which can possibly be claimed in the application as filed and which can possibly constitute a future distinguishing feature over the closest prior art, since said closest prior art and its technical disclosure may not be known to the applicant at the filing date of the application.

Post-published data can be relied upon – but not enough to establish inventive step



Criteria for relying on a technical effect

T31/18

Asserted effect: improved hardness, disintegration time

Criterion 1: encompassed by technical teaching?

Technical teaching: provision of imatinib tablets improving patients compliance, wherein the tablets have acceptable properties, as regards hardness, and a disintegration time of 20 minutes or less, by using specific excipients.

Criterion 1 thus satisfied.

Criterion 2: embodied by originally disclosed invention?

Technical effects relating to abrasion resistance, hardness, friability and disintegration time are explicitly mentioned in the application as filed.

Criterion 2 thus satisfied.



Criteria for relying on a technical effect

T1329/04

- The application concerned Polynucleotide encoding “Growth Differentiation Factor-9” (GDF-9), allegedly a new member of the TGF- β -superfamily
- GDF-9 exhibits major structural differences to the known members of this family
- The application did not contain any evidence that GDF-9 has the effects expected for a member of this family
- Such evidence was firstly provided in the form of post-published experimental data (effect on ovary maturation/survival)



Criteria for relying on a technical effect

T1329/04

- Problem to be solved: *Provision of a new member of the TGF- β -superfamily.*
- Solution according to the application: GDF-9, but...
 - No respective data or evidence in the application
 - Because of the large structural differences, it is not plausible that GDF-9 is a member of the TGF- β -superfamily
 - Post-published documents are the only evidence going beyond speculation; this was considered to be insufficient for acknowledging inventive step
- Problem not plausibly solved: Inventive Step denied!



Criteria for relying on a technical effect

T 1329/04 – Headnote

“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.”



Criteria for relying on a technical effect

T1329/04

Asserted effect: effect on ovary survival

Criterion 1: encompassed by technical teaching?

Technical teaching: An instruction addressed to a skilled person as to **how to solve a particular technical problem** using particular technical means (G1/19, Reason 24)

Criterion 1 not fulfilled because there is no technical teaching?

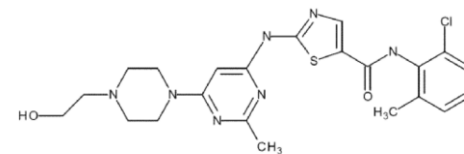
Criterion 2: embodied by originally disclosed invention?

No. Effect on ovary survival not disclosed in application.



Criteria for relying on a technical effect

T 488/16



Claim: *Dasatinib*

For inventive step, P relied on [post-published data](#) for Dasatinib showing specific PTK inhibition profile, which identifies Dasatinib as an inhibitor with potent anti-tumour activity

Disclosure in application as filed:

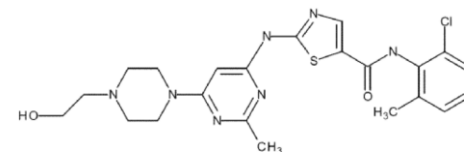
- Markush formula (I) covering > 1 million of compounds:
- 580 specific examples, example 455 = *Dasatinib*
- “Compounds described in the following Examples have been tested in one or more of these (PTK inhibitor) assays and have shown activity.”

Criteria for relying on a technical effect

T 488/16

Findings of Board (I)

- **Inherently unlikely** for any skilled person that **all** of the compounds of the invention or at least a substantial amount of them will exhibit the alleged PTK inhibitory activity
- **Mere verbal statement does not render activity credible**
- **No common general knowledge** which, even in the absence of data, made it **plausible** that the compounds of the invention, in particular *dasatinib*, could be expected to show PTK inhibition.
 - i.e. burden on patentee!
- Effect of improved PK activity cannot be relied upon
- **Dasatinib obvious as simply alternative compound**



Criteria for relying on a technical effect

T488/16

Asserted effect: provision of specific PTK inhibition profile rendering compound suitable for treatment of cancer

Criterion 1: encompassed by technical teaching?

Technical teaching: provision of specific PTK inhibitors useful for the treatment of a variety of diseases

Criterion 1 thus satisfied? Is there a technical teaching?



Criteria for relying on a technical effect

T488/16

Criterion 2: embodied by originally disclosed invention?

Dasatinib provided as specific embodiment. But: specific PTK inhibition profile and suitability for treating cancer not disclosed in application.

Inventive effort required to find that dasatinib shows PTK inhibition profile to render it suitable for treating cancer?

G2/10: The term "embodiment" is commonly used to define a specific combination of features or a specific mode of carrying out the invention, by contrast to a more abstract definition of features which can be carried out in more than one way.

Criterion 2 thus NOT satisfied?



The Application

“Detailed description of preferred embodiments”

-15 numbered embodiments and a further 20 unnumbered embodiments of the invention.

-Embodiment 1 is a broad Markush formula, while the second “preferred” embodiment is another broad Markush formula. Embodiments 3-15 are all described as “preferred”.

Embodiment 8 is a novel compound selected from a list of 74 compounds, one of which is apixaban. Embodiment 15 is a novel compound selected from a list of another 124 compounds. There is no embodiment directed specifically to apixaban.

Compounds of the invention “are inhibitors of factor Xa and are useful as anticoagulants for the treatment or prevention of thromboembolic disorders in mammals (i.e., factor Xa-associated disorders)”. The effectiveness of the compounds as factor Xa inhibitors “was determined” by means of the same chromogenic assay as in WO 131.

Some compounds of the present invention were shown to be direct acting inhibitors of the serine protease thrombin” by the same thrombin inhibition assay as in WO 131. Using this methodology “some compounds of this invention were evaluated and found to exhibit a K_i of less than 10 μM , thereby confirming the utility of the compounds of the present invention as effective thrombin inhibitors”.



UK Court of Appeal [2022] EWHC 822 (Pat) of May 4, 2023

- On Warner-Lambert Co LLC v Generics (UK) Ltd:
 - The patent contained second medical use claims in Swiss form of a known pharmaceutical, pregabalin. Claim 1 claimed the use of pregabalin to treat pain. Claim 3 claimed the use of pregabalin to treat neuropathic pain, and there were subsidiary claims directed to specific types of neuropathic pain. There were also claims directed to inflammatory pain. The specification contained data from animal models supporting the claim to efficacy against inflammatory pain, but neither experimental data nor theoretical reasoning supporting the claim to efficacy against neuropathic pain. The Court held that the specification made it plausible that pregabalin was efficacious to treat peripheral neuropathic pain, but not central neuropathic pain. Since claim 3 covered both types of neuropathic pain and Warner-Lambert had not applied, even conditionally, to amend claim 3 down to peripheral neuropathic pain, it followed that claim 3 was invalid on the ground of insufficiency. The majority of the Supreme Court (Lord Reed, Lord Sumption and Lord Briggs) held, for the reasons given by Lord Sumption, that the disclosure in the specification did not make it plausible that pregabalin was efficacious to treat any kind of neuropathic pain. [Minority: Warner-Lambert's argument that cases such as Ipsen (T578/06) showed that a lower standard of plausibility was to be applied.]



UK Court of Appeal [2022] EWHC 822 (Pat) of May 4, 2023

- On G2/21: It is clear from these observations as well as the Enlarged Board's earlier reasoning that the fundamental consideration when a court or tribunal is considering whether a claimed invention involves an inventive step is whether the technical effect asserted by the patent applicant or proprietor is derivable by the skilled person from the application as filed read with the common general knowledge.
- As the Claimants point out, the present case is **strikingly similar to BMS/Dasatinib**. Moreover, BMS/Dasatinib does not stand on its own, because the claim in **Johns Hopkins**, which was another of the cases relied upon by Lord Sumption and reviewed by the Enlarged Board, was effectively a claim to a specific molecule. Furthermore, the underlying principles are applicable as much to claims to single chemical compounds as to claims to classes of compounds and second medical use claims.



UK Court of Appeal [2022] EWHC 822 (Pat) of May 4, 2023

- The fundamental principle is that the scope of the patent monopoly must be justified by the patentee's technical contribution to the art. This remains so whether the scope of the claim is broad or narrow. Thus when considering inventive step it is necessary to consider what technical problem the claimed invention solves. If it is not plausible that the invention solves any technical problem then the patentee has made no technical contribution and the invention does not involve an inventive step.
- It follows that, in order for a claim to a single chemical compound to be patentable, the application must make it plausible, when read in the light of the skilled person's common general knowledge, that **the compound has the utility asserted for it.** Moreover, **it makes no difference whether the claim incorporates the use of the compound as a technical feature or whether the claim is simply to the compound per se and the assertion of utility is only to be found in the specification.** This is because, as explained above, there is no invention in merely identifying a new chemical compound; invention can only lie in identifying its utility.



UK Court of Appeal [2022] EWHC 822 (Pat) of May 4, 2023

- On Ground 1: There is no requirement that the specification makes it plausible that the compound is useful. It is sufficient that the specification discloses the structure of the compound and a method of synthesis and contains an assertion of potential utility for the compound, provided that that assertion is not manifestly speculative or wrong.
- Court: Given that the present case cannot be distinguished from Warner-Lambert, it follows that the criterion of plausibility must be applied when determining whether the claimed invention involves an inventive step and is sufficiently disclosed. I therefore reject ground 1. I would add that **I do not understand how it is possible to determine whether a claimed invention is speculative other than by assessing whether it is plausible.** They are two sides of the same coin.



UK Court of Appeal [2022] EWHC 822 (Pat) of May 4, 2023

- On Ground 2: The judge erred in law because he applied the standard of plausibility laid down by the majority in Warner-Lambert when he should either have applied the standard advocated by the minority or applied the standard laid down by the majority less strictly.
- Court: The standard of plausibility which should be applied is the standard adopted by the majority in Warner-Lambert, not the standard espoused by the minority or some other “less strict” standard. **It is fair to say that the standard adopted by the majority corresponds to the “ab initio plausibility” test identified in Sumitomo, while the standard espoused by the minority corresponds to the “ab initio implausibility” test.** As discussed above, the Enlarged Board has taken the view in G 2/21 that the two approaches can be reconciled. **I am bound to say that it seems to me that the divergence of opinion in the Supreme Court shows that the two approaches do not necessarily produce the same outcome.** It also appears to me, however, that the harmonised approach adopted by the Enlarged Board, while eschewing the language of “ab initio plausibility” and “ab initio implausibility”, is as a matter of substance much closer to the former than to the latter. Be that as it may, as I have already noted, **it is not suggested by BMS that G 2/21 justifies this Court in departing from WarnerLambert.** I therefore reject ground 2.



The Hague Court of Appeal August 25, 2023

- According to Sandoz et al. the test formulated in G2/21 means that a claimed technical effect may only be relied upon in assessing inventive step if the average person skilled in the art already understands from the patent application that the claimed effect is actually achieved by the invention and the problem is actually solved, or at least that this is made plausible. That position is rejected.
- The court agrees with BMS that the only requirement set forth by G2/21 for being allowed to consider a technical effect - as determined by comparison of the invention disclosed in the patent with the closest prior art - when formulating the objective problem statement and assessing inventive step on that basis is, that **it is inferable ("derivable") to the average person skilled in the art using his general knowledge of the art on the priority date from the application that the claimed technical effect is encompassed by the technical teaching thereof and embodies the same invention disclosed therein.**



The Hague Court of Appeal August 25, 2023

- It follows from the GKB's considerations in G2/21 that, according to G2/21, the test does not mean that it is always required that the application already includes evidence that the alleged technical effect actually occurs or that this is made plausible in the application, as Sandoz et al. argue. In para. 74 of G2/21, the GKB pointed out that inventive step and sufficiency of disclosure should clearly be treated separately and on their own merits...In the preliminary view, it is incompatible with this consideration to interpret G2/21 in such a way that the assessment of inventive step requires the condition that the alleged effect has always already been made plausible in the application, as advocated by Sandoz et al.
- It also follows that 'technical teaching' is not to be understood as 'that which is taught to the average person skilled in the art by means of information contained in the application as to how the technical problem is actually solved by technical means' (as Sandoz et al. incorrectly argue, para. 63 pleading HB). As BMS correctly argues, **the technical teaching of a patent should be understood as "that which is taught to the average person skilled in the art about how the technical problem can be solved by technical means"**.



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- Contrary to Sandoz et al.'s argument, this interpretation of G2/21 by the court does not lead to a free pass for speculative patents. Indeed, the granting of protection on the basis of a purely speculative patent for an invention that is only subsequently made **is prevented by the requirement that the technical effect is already encompassed by the technical doctrine of the application and embodies the same invention revealed therein.** Moreover, it is undisputed that EP 415 does not involve a speculative patent. BMS has argued undisputedly that the inventors had already experimentally established the favorable affinity and selectivity of apixaban prior to filing the patent application.
- In this case, **what matters in assessing whether the criteria set forth by G2/21 are met is that the application expressly and specifically identifies the relevant effect as the primary objective of the patent. The technical effect achieved by the patent on which BMS relies is improved factor Xa inhibition.**
- The circumstances of the apixaban case imply that on the priority date the average person skilled in the art could derive from the application that apixaban has the most advantageous effect as an fXa inhibitor. Therefore, the criterion as described in G2/21 has been met.



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- This is confirmed by the outcome of ground cases abroad. ...In summary, both the **French** and **Norwegian** courts on the merits held that the average person skilled in the art, using his general knowledge of the art, could, on the priority date, infer from the application that the goal of finding a compound with - compared to already known factor Xa inhibitors - improved factor Xa inhibition, selectivity and pharmacological properties, could be achieved with apixaban and that this could then be, and is uncontested, proven by post-filed evidence.
- For the time being, the **test applied by the English court** - which is also defended by Sandoz et al. in these proceedings - **is a different test** from that applied by paragraph II of the Order in G2/21. The English test was developed by the English Supreme Court in a case involving sufficiency of disclosure rather than inventiveness.
- Note: Two out of the three CoA judges are also UPC appeal judges!



Let's discuss...

Is criterion 1 stricter than the old criterion that the skilled person would have to recognise the effects as implied by or related to the technical problem initially suggested? (see GL; specific activity/toxicity)

Does criterion 2 require that the asserted (specific) effect is mentioned/disclosed in original application documents?

Or does criterion 2 require that the means for achieving the effect is disclosed as an embodiment in the original application document?

How will highly speculative applications be rejected in the future?

Highly speculative

=

not clear how the purported problem is solved

=

no technical teaching?



Thank you!



Dr. Joachim Renken
jrenken@hoffmanneitle.com

