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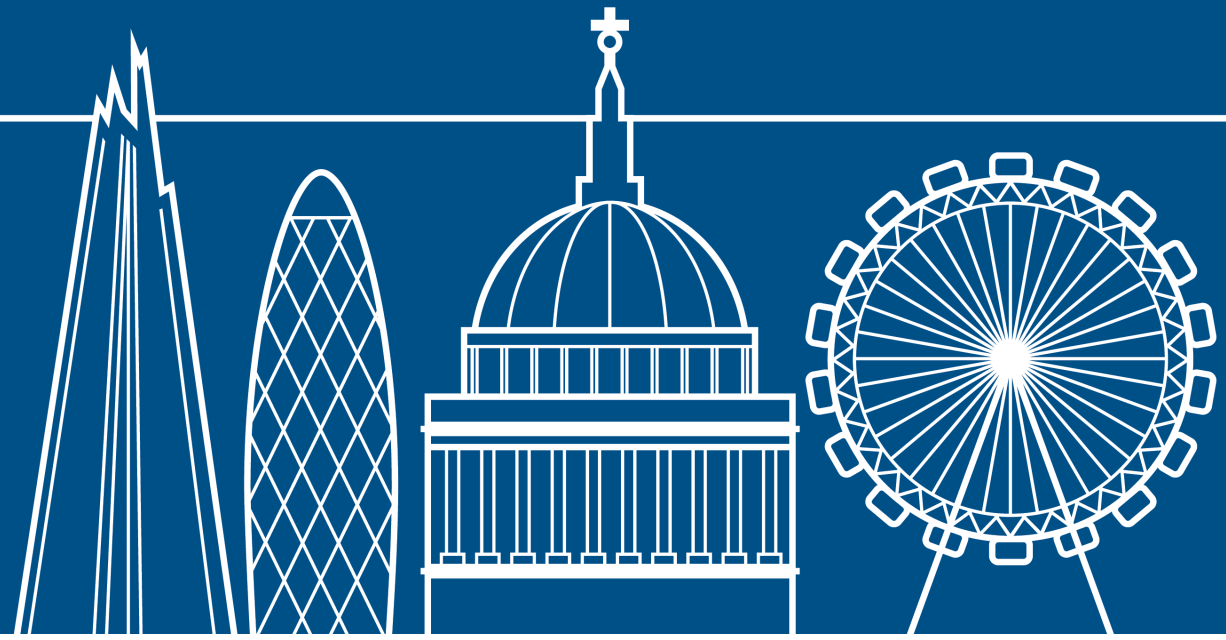
London, 1-7 October 2023



Post filing evidence in patents - assessment for inventive step and plausibility: Extrinsic evidence – holy grail for new forms of known substances

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21st Open Forum
London, England
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Introduction

Ms Archana Shanker
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Speakers

Ms Shanker Archana

Ms Alicia Alvarez Berkenwald

Dr Mary Anne Armstrong

Dr Emily Dodgson

Ms Micheline Gravelle

Talking Points

- Relevance of the “Plausibility” and post filing evidence for patentability
- Introduction to the Enlarged Board of Appeal Opinion in G02/2021
- Presentation by each panellist introducing the law in their country and the position on plausibility and post filing evidence in their jurisdiction
- Case study followed by a panel discussion on the said case study
- FICPI’s position on plausibility

Relevance of Post filing evidence

In view of the recent EBoA order G-2/21:

- The issue of whether an invention is plausible as on the priority date has arisen before several patent offices in some form or other
- The filing of expert affidavits including post published data is often allowed and used by Patent Offices/ Courts to overcome objections relating to patentability and invalidity related issues
- Including data or evidence at the time of filing of the application may have its own challenges- such as different prior arts cited by the Patent Office or challenger or the applicant
- How much of information or data will be required in the patent specification for post filing / published evidence to be acceptable
- Can this issue be adopted across technology. i.e. technology neutral

Position in UK and EP

Dr Emily
Dodgson

Plausibility at the EPO

- At the EPO, there is a higher level of underlying doubt with respect to certain types of invention (sufficiency) or the purported technical effects of certain types of invention (inventive step)

- If the technical effect is in the claim the evidence for this will need to be considered under the heading of sufficiency

- If the technical effect is not in the claim but contributes to solution of the technical problem, the evidence will need to be considered under the heading of inventive step

G2/21_Some facts

- Claim 1 relates to an insecticide composition comprising thiamethoxam and compound(s) represented by the formula Ia
- In the application as filed the claimed compound is said to have a synergistic effect (not defined in claim), and evidence is provided to show this against two moth species
- **The Opponent** files (post-filed) data showing compound not effective against one of those two species. Argues synergistic effect not present over breadth of claim
- **The Proprietor** files (post-filed) data showing synergistic effect against a third species. The application mentioned the third species, but did not provide any efficacy data against the third species for compounds within the scope of the claims
- **The Opponent** argued this post-filing data should not be considered because the synergistic effect had not been made plausible in the application as filed ("ab-initio plausibility")
- Without the Proprietor's post-filed data, BoA considered it was not plausible that the claimed compound solved the technical problem of providing a synergistic effect

Questions to the EBoA

1. Must post-published evidence be disregarded if the proof of the effect rests **exclusively** on the post-published evidence?

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

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

G2/21 – EBoA Decision

Order:

I. 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.

II. 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**.

Also:

"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." [058]

G2/21 – EBA Decision - 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." [074]

- "…the scope of reliance on post published evidence is **much narrower** under sufficiency of disclosure compared to the situation under inventive step. In order to meet the requirement that the disclosure of the invention be sufficiently clear and complete for it to be carried out by the person skilled in the art, 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." [077]

Position in UK – Warner-Lambert

- **Warner-Lambert v Actavis [2018] UKSC 56** concerned a second medical use claim
- "the specification must disclose some **reason** for supposing that the implied assertion of efficacy in the claim is true"
- Not made plausible by bare assertion is not enough, needs to disclose reasonable scientific grounds
- Definitive proof not required, but a **reason** to believe, i.e. a **direct effect** on a mechanism specifically involved in the disease, demonstrated by experimental data or a priori reasoning **in the patent application**

Position in UK - Sandoz

- **Sandoz v BMS [2023] EWCA Civ 472** concerned a product claim to apixaban defined by its chemical formula
- The application as filed described a large number of compounds including apixaban and included generic statements that these compounds are inhibitors of factor Xa
- There was no data in the application as filed specifically showing that apixaban was a factor Xa inhibitor
- It was uncontentious that the claimed product, apixaban, was a factor Xa inhibitor
- Found invalid for lack of sufficiency and inventive step on the basis that efficacy of apixaban was not plausible based on the application as filed

Position in UK - Sandoz

"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. Equally, when considering insufficiency it is necessary to consider whether the specification **sufficiently discloses the claimed invention**. If it is not **plausible that the invention solves any technical problem then the patentee has made no technical contribution and the specification does not disclose any invention**. 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**." [92]

"..the standard of plausibility which should be applied….corresponds to the **"ab initio plausibility"** [94]

"subsequent data cannot be a substitute for sufficient disclosure in the specification" [95]

Position in the US

Dr Mary Anne Armstrong

Position in the US

1. Is PFE allowable in your jurisdiction to prove –

- **Inventive step** – by showing unexpected results, commercial success, long-felt but unsolved needs, failure of others, skepticism of experts etc

- **Sufficiency** –

Enablement: Applicant may submit factual affidavits under 37 CFR 1.132 or cite references to show what one skilled in the art knew at the time of filing the application (MPEP 2164.05) to support that the specification would enable one of ordinary skill in the art to make and use the claimed invention without resorting to undue experimentation

Written description: Much more difficult to rely on PFE because the written description requirement is based on what is disclosed in the specification

- **Utility –** Can rely on PFE to demonstrate that the invention has the asserted utility. However, utility rejections are fairly rare. "The bar for utility is not high." *Grunenthal GmbH v. Alkem Labs. Ltd.,* 919 F.3d 1333 (Fed. Cir. 2019)

Position in the US

2. Any landmark judgement/ case laws to support the above

37 C.F. R. § 1.132 Affidavits or declarations traversing rejections or objections.When any claim of an application or a patent under reexamination is rejected or objected to, any evidence submitted to traverse the rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under this section.

MPEP e.g. § 716.01(a) Objective Evidence of Nonobviousness

MPEP e.g. § 2164.05 Determination of Enablement Based on Evidence as a Whole

Position in the US

3. Your views on the three questions raised in EBA

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? – **No: In some circumstances the proof of the effect may rest exclusively on PFE**

2. If the answer is yes (the post-published evidence must be disregarded if the proof of the effect rests exclusively on this evidence), can the post-published evidence be taken into consideration if, based on the information in the patent application in suit or the common general knowledge, the skilled person at the filing date of the patent application in suit would have considered the effect plausible (**ab initio plausibility)? Yes**

3. If the answer to the first question is yes (the post-published evidence must be disregarded if the proof of the effect rests exclusively on this evidence), can the post-published evidence be taken into consideration if, based on the information in the patent application in suit or the common general knowledge, 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**)? **Yes**

Position in Canada

Ms Micheline Gravelle

Position in Canada

Utility

- Utility must be shown as of the filing date, either **demonstrated** (e.g. in the examples) or by **sound prediction** (*Apotex Inc. v. Wellcome Foundation Ltd*., 2002 SCC)
- Sound Prediction- based on the application as filed and CGK, a POSITA would predict that invention would have claimed utility
- Make sure application supports prediction of utility, include scientific rational
- Post-filing evidence PFE) rejected where utility not supported in application as filed
- PFE may be considered to show lack of utility or to refute such an allegation
- Promise of the Patent Doctrine thankfully abolished in 2017 (Astra Zeneca v Apotex, 2017 SCC 36)
- Applicants would be required to show utility for “promises” made in application
- Utility evidence higher for new uses of old compounds, new compounds- “scintilla of utility” will do

Position in Canada

Inventive Step- PFE

- Can not be used to show advantages not known at filing date (*Jansenn-Ortho v Novopharm,* 2006 FC 1234)
- Can be used to establish state of art e.g. literature review (*Eli Lilly and Company et al v Apotex Inc* (2009 FC 991)
- Can be used to show secondary considerations, e.g awards, commercial success (*Jansenn-Ortho v Novopharm,* 2006 FC 1234, *Bayer v Apotex* 2003 FC 1199)
- Can generally be used as comparative evidence with closest art

Enablement-PFE

- PAB decision- PFE may be considered to support enablement (*Re: Immunex Corp.*, CD 1302, 2010)

Position in India

Ms Shanker
Archana

Position in India - Inventive step & Sufficiency

- Under section 2(1)(ja) of the Act, inventive step objection is addressed by establishing a technical advancement of the present invention over the prior art
- Section 10(4) states that the complete specification must contain enough details to enable a PHOSITA to perform/ make the invention disclosed, and should at least show the best mode of working of the invention

La Renon Healthcare v Kibow Biotech (ORA/28/PT/2011/MUM)	Ajantha Pharma v Allergan (ORA/21/2011/PT/KOL)	Astrazeneca v Intas Pharma (MANU/DE/1939/2020)
• The Intellectual Property Appellate Board (IPAB) held that there must be explicit support for a claimed invention in the specification.	• Technical advancement must be present in the specification at the time of filing. • The IPAB held that data, especially comparative examples, were absolutely essential at the time of filing to support any advantages and claims. **Any additional technical advancement discovered after the filing date ordinarily may not be admissible.**	The Delhi High Court points to when post-filing data cannot be taken on record: "post priority date evidence …. to show technical advance **can only be taken into account to confirm the existence of technical effect which is found embedded in the specification** and is capable of being understood by PHOSITA and not to rely upon the same to establish its effect for the first time.

Does IPO accept Post-filing evidence?

- The answer is **YES**
- A recent decision by the Calcutta High Court in OYSTER POINT PHARMA INC. VS THE CONTROLLER OF PATENTS, the Court has observed that **there is no specific time provided in the Patents Act that prevents the filing of additional data, at a later stage** i.e. after the filing of the patent claim
- IPAB (OA/33/2015/PT/KOL): *"Filing of additional documents, data and evidence in support of the invention, to overcome the objection raised and to attack a specific objection is something which* **is allowed** *under the Patent Law of not only India but also other foreign jurisdictions".*
- The Delhi High Court in *Astrazeneca vs Intas Pharma* (MANU/DE/1939/2020): *"The plaintiffs' argument that post filing data relating to the invention is admissible is based on two grounds: (i) First and foremost, the applicant may not be fully aware of the advances and properties of the subject invention, in this case, the compound DAPA, on the priority date. In this behalf, it is stated that DAPA's properties for treatment of heart failure came to be known only subsequently. (ii) Second, there is no requirement in law that all properties, advantages, and* characteristics *should be stated on the filing date of the patent application".*

UPSHOT – INDIA

- While the Indian High Courts and Patent Offices are flexible in accepting the post-filing data, a **barometer should be set fair** to urge the applicants to provide enough support of the technical effect in the specification at the time of drafting the specification

- This will help in supporting the evidence that is filed after to find a complete support on the specification

Position in Argentina

Ms Alicia Alvarez Berkenwald

Position in Argentina

- **Post-filing evidence could be accepted if it is supported explicitly or implicitly in the application as filed**
  - Art 19 PL, Regulatory Decree, provides for the incorporation of complements and corrections within 30 days from the filing date; afterwards, complements and corrections as well as new examples could be added only as a reply to an office action and as a complement for better understanding the invention. No new matter allowed
  - According to the Guidelines for examination; Part C chapter IV, VI, Annex I: New examples or new effects subsequently presented, even if not allowed to be included in the specification, **may be** considered by the examiner as evidence of patentability, **e.g. inventive step**. Thus, an additional example **may be** accepted as evidence of an improvement to the state of the art based on the information given in the originally filed application

Position in Argentina

New forms of known products

- New forms of known products are not considered novel
- Polymorphs are found obvious. Polymorphism considered an intrinsic property of the solid state
- Methods for obtaining polymorphs are considered routine experimentation

Position in Argentina

- Use claims drafted as “product XXX for use in YYY” are allowed as long as the product is new.
- Use claims should be dependent on a preceding claim directed to the new product *per se*.
- PFE *holy grail* in Argentina?

Position in Argentina

Patent granted after PFE

- **Application AR 2014 01 03857**, counterpart to WO 2015055757, the application claimed the **use of pesticides** (I) optionally combined with known insecticide/fungicides (II).
- First OA: all claims rejected for being directed to uses. PFE provided compositions of synergistic effect, claims modified to compositions with a synergistic effect. Use claims drafted as “product for use” in dependent claims.
- Second OA requiring clarifications to the PFE.
- Patent granted after new PFE providing ratio between (I) and (II), a limited list of compositions claimed, indicating ratios between components, uses in dependent claims.

Position in Argentina

Application rejected after PFE

- **Application 2010 01 04448** claimed phytosanitary compositions, all components generally defined.
- First OA: clarity objections, each component must be defined in a quali-quantitative manner.
- PFE provided new examples, new claims indicating components/range except for “fatty alcohol ethoxylate”, that was not specified or exemplified.
- New OA rejected the claims for insufficency and lack of enablement.
- Second PFE restricted to a specific alcohol ethoxylate and argue common use in the art of said alcohol.
- Application was rejected based on insufficiency and lack of enablement (New matter? Lack of plausability?)

Case Study

Bibliographic Details - EP2484209

Protected countries

Granted: AU, CA, CH, CN, DE, EP, ES, FR, GB, GR, HU, IN, IT, JP, KR, MX, NL, TR, TW, US, ZA

Status in corresponding Jurisdiction:

Countries	Status
The US	Granted- US9408390B2 , US9018235 B2
India	Granted- IN268878B
EP	Granted - EP2910125B1, EP1719409B1, EP2474227B1
JP	Granted - JP5674891B2, JP5410476B2, JP5341925B2
CA	Granted - CA2556300C
BR	Abandoned - BR PI0507843, BR 12 2015 001539-1 A2, BR122015001535-9
MX	Granted - MX 316414, MX 333767, MX 381560

Case Study - US

Corresponding USP 9018235

- Claims were rejected as being obvious over Berger et al. US Pat. 7,696,232 ('232 patent)
- In response to the rejection, the Applicant submitted a Declaration under 37 C.F.R. 1.132 to demonstrated unexpected improved results with the invention compared to the prior art. The Declaration stated,

> It is clear from Table 1 that the Compound (I-7), when used as a mixture with clothianidin or dinotefuran, was found to produce a greater insecticidal effect than would be expected when individually used alone, and the synergistic effect due to the mixing was observed.

- The Examiner agreed that Applicant demonstrated unexpected improved results, but the rejection was not overcome because the data was not commensurate in scope with claims.
- The claims were ultimately amended to be commensurate with the compounds tested to show unexpected results.

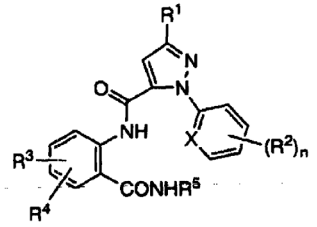
Case Study - Canada

- CA 2556300- corresponds to EP 2484209
- Only one office action, novelty raised
- No utility or inventive step objections, no PFE submitted
- Amended claims to remove composition claims
- Only “method for controlling insect pest” claims issued
- Formula Ia and specific neonicotinoid compounds

Case Study - India

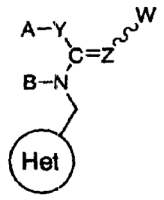
- IN 268878 - corresponds to EP 2484209
- Granted in 2015
- Inventive step objection
- Section 3 (e)- Test data was included in the specification

1. An insecticide composition which comprises one or not less than two kinds of compounds being selected from a compound represented by the formula [I]:



[I]

wherein R^1, R^2 ,R^3 and R^4 are the same or different, and each represent a hydrogen atom, a C_{1-6} alkyl group, a C_{1-6} haloalkyl group or a halogen atom; R^5 is a hydrogen atom or a C_{1-6} alkyl group; X is CH or N; n is 0 to 3, or a salt thereof, and a neonicotinoid compound represented by the formula [II]:

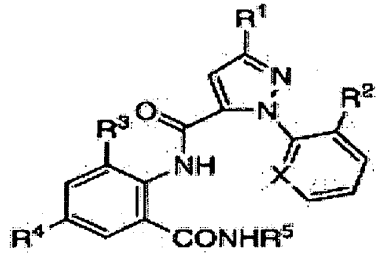


[I I]

Case Study - India

- Definitiveness
- Claims were limited
- Section 3 (e)
- Test data was included in the

1. An insecticide composition which comprises one or not less than two kinds of compounds being selected from a compound represented by the formula:



[I a]

wherein R^1 is a halogen atom or a C_{1-6} haloalkyl group, R^3 is a halogen atom, R^2 and R^5 each are a C_{1-6} alkyl group, R^4 is a hydrogen or halogen atom, and X is N, or a salt thereof,
and a neonicotinoid compound selected from clothianidin, thiamethoxam and dinotefuran,
and wherein the weight ratio of compound [Ia] or its salt and the neonicotinoid compound is 1 : 0.1 to 1 : 20.

Case Study – Latin America

- In Latin-America, counterparts to Sumitomo EP ´809 patent were filed only in Brazil and Mexico

- In Brazil, application BR PI0507843 and divisional applications BR 12 2015 001539-1 A2 and BR122015001535-9, were abandoned for not responding to the first office action

Case Study - Latin America

- The Mexican counterparts, i.e. MX 316414, MX 333767 and MX 381560 were all granted without dealing with PFE
- In the first two cases, a sort of PPH was applied. In the third case (MX'560), the application as originally filed was allowed without objections
- Post-granting oppositions are not available in MX. All three patents are valid, and annuities have been duly paid.

Closing Note

- FICPI's position- ***Test results submitted after the filing date***

Authorities to take into account during examination or evaluation of a patent application or patent any test results submitted after the filing date of the application to address any objections to allowability or validity, regardless of the date of completion of the testing, provided that those results relate to the invention as disclosed in the content of the application as originally filed.

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