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European Biotech Case Law

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Agenda

- T 1540/21 (Abbott Laboratories) - Disclosure of publically available product
- G1/23 and T 0438/19 (Mitsui Chemicals, Inc) - Disclosure of publically available product
- G 2/21 - Is plausibility still relevant at the EPO?

A link to download these slides and a recording of this webinar will be emailed to you on Wednesday 06 September 2023.

Disclosure of publically available products
T 1540/21 (Abbott Laboratories)

T 1540/21 - Background

1. A ready-to-feed liquid infant formula comprising fat, protein, carbohydrate, vitamins, minerals, **at least 50 µg/liter of lutein**, and from 72 to 360 mg/liter docosahexaenoic acid, wherein the weight ratio of lutein (µg) to docosahexaenoic acid (mg) is from 1:2 to 10:1 and the formula is free of egg phospholipids.

T 1540/21 - Background

- D1 was a research article published Dec 2003:
  - D1 discloses SMA LBW infant formula comprising 100 µg/liter of lutein
  - D1 does **not** expliciety disclose that SMA LBW infant formula was free of egg phospholipids
  - D1 does **not** disclose that SMA LBW infant formula comprised 72 to 360 mg/liter DHA

T 1540/21 – Evidence

- Opponent filed further documents relating to SMA LBW infant formula:
  - D18 - Research article disclosing amount of DHA and source of lipids dated Feb 1999
  - D17 - Master formulation of SMA LBW dated Feb 1998
  - D3 - Master formulation of SMA LBW dated June 2003
  - D21 and D22 - SMA LBW bottle labels
  - D16 - Declaration from manufacturer

T 1540/21 – Opposition

- OD upheld the patent.
- Applied the “up to the hilt” standard of proof as some documents were entirely in the sphere of the opponent – not publically available.
- Evidence provided by the multiple documents was not considered to meet this standard.

T 1540/21 – Standard of proof

Opponent appealed OD decision

- The standard of proof which generally applies to a question of fact is the balance of probability.
- Exceptions may apply only where the relevant evidence lies entirely within the sphere of a specific party alleging the fact in dispute – often the case in prior use attack
- **However, where relevant evidence is in part in the public domain and in part not, there is no reason to depart from balance of probability.**

T 1540/21 – Appeal

- SMA Free of egg phospholipid
  - D1 disclosed that SMA LBW did not contain zeaxanthin
  - D1 further discloses:
  - "information on sources of fat in the milks was obtained from the manufacturers, and those milks with high concentrations of lutein and zeaxanthin, were found to contain egg lipid as a major fat source. **Egg lipid is a rich source of lutein and to a lesser extent zeaxanthin**, and therefore is the most likely source of these carotenoids in formula milks.

T 1540/21 – Appeal

- Additional document D29 – text book providing evidence that egg yolk contains high amounts of zeaxanthin
- Opponent filed further documents D30 and D31 teaching that vegetables are an alternative lutein source which can also lack zeaxanthin.
- D18 examines several nutritional products suitable for infants - discloses that SMA LBW contains single-cell oils as the raw material for adding the polyunsaturated fatty acids. Although about half of the products examined include egg lipids as the source of these fatty acids, SMA LBW does not.

T 1540/21 – BoA's decision

- As an intermediate conclusion, based on the evidence publicly available in printed documents on the date of priority of the patent, there is no reason to assume that SMA LBW comprises egg phospholipids. On the contrary, the opposite is more likely.
- Publically available information assessed on **balance of probability** by BoA.
- D1 and D18 together confirm that SMA LBW infant formula does not contain egg phospholipids and contain DHA

T 1540/21 – BoA’s decision

Additional evidence including ‘Internal’ documents are considered to be within the sphere of the opponent.

- D17: Master formulation (#IRLBWB009), in use as of May 1997
- D3: Master formulation (#IRLBWB011), in use as of October 2002
- D21: Label for a 100 ml bottle of "SMA Low Birthweight", and an internal label form for SMA LBW RTF (#IRLBWB009)
- D22: Label for a 100 ml bottle of "SMA Low Birthweight", and an internal label form for SMA LBW (#IRLBWB011)
- D16: Declaration by Head of the Development Centre (R&D) at Wyeth Nutrition’s facility in Askeaton, Ireland

T 1540/21 – BoA's decision

- G 1/92 indicated state of the art of a chemical composition of a product depends on the skilled person's ability to **analyse** and **reproduce** the product.

  "*Where it is possible for the skilled person to **discover the composition or the internal structure of the product and to reproduce it without undue burden**, then both the product and its composition or internal structure become state of the art.*"

- Patentee argued the SMA LBW could not be analysed and reproduced according to the case law G 1/92

T 1540/21 – BoA's decision

- Board was not convinced, noted that it was possible at the time to quantify the levels of the claimed compounds (e.g. as was done in D1) in SMA LBW.

- Board considered T 952/92, where a strict interpretation of G 1/92 was considered to not have been intended, i.e. a **complete** analysis leading to **exact** reproduction of the product is not necessary to destroy novelty

  - *"To conclude, the board is convinced that SMA LBW as analysed in D1 comprised all of the features of claim 1, in particular the concentrations of lutein and docosahexaenoic acid, the weight ratio of these two substances and no egg phospholipids."*

T 1540/21 – Summary

- A successful prior use attack based on combining multiple documents - evidence sufficient across those documents
- Burden of proof was **balance of probability** – would have been higher (“to the hilt”) if not publicly available
- A strict interpretation of G 1/92 to require complete analysis and exact reproduction by the skilled person was not what was intended in that decision – following T 952/92

G 1/23 - Referral to Enlarged Board Public prior use

G 1/92

- G 1/92 indicated state of the art of a chemical composition of a product depends on the skilled person's ability to **analyse** and **reproduce** the product.
    - "*Where it is possible for the skilled person to **discover the composition or the internal structure of the product and to reproduce it without undue burden**, then both the product and its composition or internal structure become state of the art.*"

G1/23 and T 0438/19: Background

- A material suitable as an encapsulating material for solar cell, which comprises an ethylene/α-olefin copolymer which has
- (a1) a content of 80-90 mol% of structural units derived from ethylene and 10-20 mol% of structural units derived from C3-20-(α-olefin);
- (a2) a MFR of 10-50 g/10 minutes, measured according to ASTM Dl238 at 190°C and under a load of 2.16 kg;
- (a3) a density of 0.865-0.884 g/cm 3, measured according to ASTM D1505;
- (a4) a shore A hardness of 60-85, measured according to ASTM D2240; and
- (a6) a content of aluminum element of from 10 to 500 ppm."

G1/23 and T 0438/19: Background

- The commercially available ethylene copolymer (ENGAGE® 8400) was cited as closest prior art.
- According to the opponent, prior art literature disclosed that ENGAGE® 8400 satisfied all features of the claims, except for the aluminium content.
- None of the cited documents disclosed the manufacturing method, the exact composition or internal structure of ENGAGE® 8400.
- Patentee argued ENGAGE® 8400 not reproducible

Previous decision G1/92 and divergence

- Aspect (i): Interpretation of “available to the public”

What is to be considered excluded from the prior art?

- If the composition of a commercial product is not analysable, does this exclude the commercial product as a whole from the prior art, including any relevant technical information reported in other documents?
- If a composition is not analysable, can you still cite documents reporting on characteristics of the product that composition is in?
  - i.e. product leaflet describing qualities like “hardness” or “polymer weight”

Previous decision G1/92 and divergence

- Aspect (i): Interpretation of “available to the public”
  - Divergent decisions:
    - T 370/02, T 2045/09, T 1833/14 and T 23/11 where the ***product*** as a whole was excluded from the prior art; and
    - T 946/04 and T 1666/16 where only the ***chemical composition/internal structure*** was excluded from the prior art

Example application in T 0438/19

- Aspect (i): Interpretation of “available to the public”
- This difference may seem theoretical
- May have practical effects, e.g. in referring case:
  - If ***product*** excluded from prior art, then ENGAGE® 8400 cannot be used as a starting point for inventive step.
  - If only ***composition*** of ENGAGE® 8400 excluded from the prior art, then the product can be used as a starting point, if technical information about that product is available and makes it of particular interest to the skilled person.

Previous decision G1/92 and divergence

- Aspect **(ii)** : Degree of detail/completeness of **analysis** of product
- The Board of T 0438/19 considered this to require the use of subjective criteria, leading to legal uncertainty:
  - What level of detail of analysis is required?
  - For mechanical/electrical products with many components should only some structural elements require analysis?
  - Should this analysis extend to e.g. chemical composition of these components?
  - Should this be required even if some characteristics are irrelevant for the subject-matter under examination?
  - Relates to Q3 of referral G 1/23

Previous decision G1/92 and divergence

- Aspect **(iii)** : Degree of detail/completeness of **reproduction** of product
- The Board of 0438/19 considered there to be divergence for reproducibility too:
  - Exact reproduction of product required?
  - To what level of detail?
- Full, exact reproducibility? (T 977/93, T 1833/14)
- Only the relevant, e.g. claimed, features? (T 1452/16, TAKEDA UK LTD v F. HOFFMAN-LA ROCHE AG [2019] EWHC 1911)
- Not required or not addressed in detail? (T 510/10, **T 1540/21**, T 877/11)

Consideration of previous law

- The opponent of T 0438/19 responded with this hypothetical:
  - The recipe for Coca Cola is known to be secret.
  - In the hypothetical situation of a claim merely defining a caramel colour containing fizzy drink:
    - Could Coca Cola (which undoubtedly falls within such definition) not be seen to anticipate such subject-matter solely because it is not fully analysable/reproducible?
    - Could it be reasonable to conclude that it is not state of the art that Coca Cola contains water, carbon dioxide and caramel colour?

G 1/23: The Questions

1. Is a product put on the market before the date of filing of a European patent application to be excluded from the state of the art within the meaning of Article 54(2) EPC for the sole reason that its composition or internal structure could not be analysed and reproduced without undue burden by the skilled person before that date?
2. If the answer to question 1 is no, is technical information about said product which was made available to the public before the filing date (e.g. by publication of technical brochure, non-patent or patent literature) state of the art within the meaning of Article 54(2) EPC, irrespective of whether the composition or internal structure of the product could be analysed and reproduced without undue burden by the skilled person before that date?

G 1/23: The Questions

3. If the answer to question 1 is yes or the answer to question 2 is no, which criteria are to be applied in order to determine whether or not the composition or internal structure of the product could be analysed and reproduced without undue burden within the meaning of opinion G 1/92? In particular, is it required that the composition and internal structure of the product be fully analysable and identically reproducible?

G 2/21 - Is plausibility still relevant at the EPO?

Plausibility - concept

- Not essential for application to have experimental data or results, provided that nature of invention relies on a technical effect which is self-evident/predictable/based on conclusive theoretical concept, i.e. **plausible.**
- Originates in EPO case law as response to overly-broad claims and to prevent speculative claiming.
- Can arise in context of sufficiency and inventive step, particularly in life sciences.

“Plausibility” and post-filing data

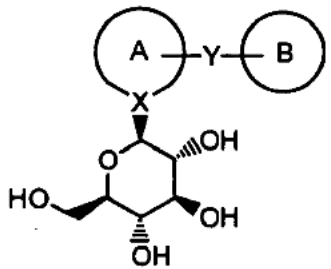
- **T 1329/04 (John Hopkins)** related to GDF-9, identified solely based on a structural analysis as a member of the TGF-β superfamily.
- No experimental data in the application as filed of functional activity of GDF-9.
- Board required that “it was at least plausible” based on the application as filed that the technical problem had been solved.
- Post-published evidence could only be used to support the original disclosure and not as the sole basis for inventive step.

“Plausibility” and post-filing data

- **T 609/02 (Salk 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.
- **T 578/06 (Ipsen)**
  - Disclosure of experimental results in the application is not always required… if the application discloses a plausible technical concept and there are **no substantiated doubts** that the claimed concept can be put into practice.

T 0184/16 - background

- Claim 1: Compound of formula (I)….



(I)

- Claim 12: Compound… for use in treating or delaying progression or onset of diabetes mellitus [or related diseases].

- Pharmacodynamic target: SGLT (sodium-dependent glucose transporter), particularly SGLT2, involved in diabetes and diabetes-related diseases.

- Claimed compounds: no data to show inhibition of SGLT2 in application.

T 0184/16 – Board's Decision - Sufficiency

- Application does not contain any experimental evidence as regards plausibility of claimed compounds being SGLT2 inhibitors.
- **Need to determine whether plausibility can be acknowledged in view of CGK and prior art.**
- No indication there is *prima facie* any serious doubt, nor has the appellant argued that there exists any such doubt.
- No *a priori* reason or any indication in the CGK that the claimed therapeutic effect cannot be obtained.

T 0184/16 – Board’s Decision - Sufficiency

- Application cites D7 which refers to aryl C-glucosides – compounds with same core structure as compounds referred to in claim 12.
- D7 considers these aryl C-glucosides to be SGLT2 inhibitors and cites a number of other documents supporting effect for further compounds.
- Plausible that the therapeutic effect defined in claim 12 is obtained.
- D4 (proprietor's post filing data) can be taken into consideration to support disclosure in the patent application.
- D4 thus supports the view that compounds of formula (I) exhibit SGLT2 inhibition.
- The invention underlying claims is sufficiently disclosed.

T 0184/16 – Board's Decision – Inventive Step

- Board considers it plausible that claimed compounds inhibit SGLT2 …
- meaning post-published evidence D4 can be taken into account.
- Post published evidence (D4) compares activity of compounds according to D2 (prior art) and compounds of formula (I).
  - Shows that compounds of formula (I) exhibit an improved inhibitory activity compared to example 26 of D2.
- Therefore, objective technical problem is provision of **improved** SGLT2 inhibition.

T 0184/16 – Board's Decision – Inventive Step

- Claims held **inventive.**
- Criteria for plausibility and obviousness are different.
- For plausibility of a claimed effect to be acknowledged:
  - enough if no *prima facie* serious doubts that effect can be obtained
  - and conversely no *a priori* reason and indication in the common general knowledge that the effect cannot be obtained
- Obviousness is decided using the problem-solution approach.
  - an important consideration is whether the claimed solution is suggested and thus made obvious by the prior art

T 116/18 – G 2/21 Referral

- EP2484209 - Granted claim 1 relates to an insecticide composition comprising a combination of two (or more) compounds, namely thiamethoxam and at least one compound represented by a genus.
- Inventive step - patentee argued that this combination of compounds provides a ***surprising synergistic effect***.
- Application - contains data showing that ***two specific compounds*** from the genus, in combination with thiamethoxam, ***provide a synergistic effect***.

G 2/21 - 3 diverging lines of case law

1. "*Ab initio* plausibility" - post-filing data only admitted if effect plausible from application as filed
   - onus on applicant / patentee to show this is the case
2. "*Ab initio* implausibility"– post-filing data only admitted if no reason effect implausible from application as filed
   - onus on Examiner / opponent to show this is the case
3. "No plausibility" – all post-filing data should be admitted

G 2/21 - questions referred to EBA

If applicant relies on post-filing data for technical effect for inventive step:

1. Must the post-filing data be disregarded on the ground that proof of technical effect rests **exclusively** on the post-filing data?

2. If answer to question 1 is yes: can post-filing data be taken into consideration if, based on application as filed, skilled person at the relevant date would have considered the effect plausible (*ab initio* plausibility)?

3. If answer to question 1 is yes: can post-filing data be taken into consideration if, based on application as filed, skilled person at the relevant date would have seen no reason to consider the effect implausible (*ab initio* implausibility)?

G 2/21 – sufficiency – medical use claims

- EBA initially intended to limit scope of referral to inventive step – not sufficiency
- But EBA confirmed scope of reliance on post-filed data is much narrower under sufficiency compared with inventive step
- For sufficiency, EBA confirmed that proof of claimed therapeutic effect must be in application as filed
  - in particular if, in absence of experimental data in application as filed, not credible to skilled person that therapeutic effect is achieved
- Lack of sufficiency in this respect cannot be remedied by post-filed data – confirming existing case law

G 2/21 – inventive step – answer to Q1

- Evidence submitted by a patent applicant or proprietor to prove a purported 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
- Generally positive for applicants – but subject to new test

G2/21 – reliance on a technical effect

- The relevant standard for the reliance on a purported technical effect when assessing whether or not the claimed subject-matter involves an inventive step concerns the question of what the skilled person, with the common general knowledge in mind, would understand at the filing date from the application as originally filed as the technical teaching of the claimed invention.

G2/21 – inventive step – answer to Q2(&3)

- 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

G2/21 – what happened to plausibility?

- EBA stated “plausibility” **not** a distinctive legal concept or specific patent law requirement under EPC
  - just a catchword used in case law of Boards of Appeal, national courts and users of European patent system
- But does it live on in another guise?
- Still exists for sufficiency – “credible” = “plausible”
- What about inventive step?

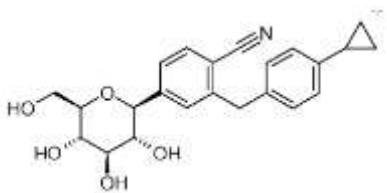
G 2/21 - the new test

1. **the technical teaching of the claimed invention**
2. technical effect relied upon, even at a later stage, **needs to be encompassed by that technical teaching**
3. **and embodied** by the same originally disclosed invention

T116/18 – application of G 2/21

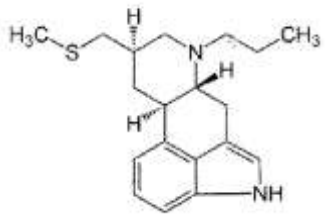
- Referring BoA – invitation for comments
- Effect can be relied upon if it is plausible/credible/not implausible from the application and common general knowledge; or
- Effect can be relied upon if it is derivable from the application and common general knowledge.

T 873/21 – application of G 2/21



SGLT2 inhibitor - **Velagliflozin**

+



Dopamine receptor agonist - **Pergolide**

For use in treating/preventing a Equine Metabolic Syndrome (EMS), Equine Pituitary Pars Intermedia Dysfunction (PPID), and laminitis

- Distinguishing feature over CPA – use of **Velagliflozin** + Pergolide
- Alleged technical effect – improved insulin sensitivity – synergistic interaction between A + B – **only shown in post-filed data.**

T 873/21 – application of G 2/21

- Both compounds were known at the priority date to be effective for treatment of metabolic disorders.

- An improved effect in terms of insulin sensitivity when monotherapy with one or more dopamine receptor agonist is insufficient was generally described

- Board considered that the therapeutic synergistic effect substantiated in post-filed data was derivable from the original application, and that the data of D16 **only provided a quantification** of the obtained improvement in insulin sensitivity described in the original application.

T 873/21 – application of G 2/21

- The synergistic effect relied upon by the appellant was encompassed by the technical teaching of the original application in light of the common general knowledge regarding the therapeutic effects of compound (A) and compound (B) and was **embodied** by the present combination **since it was clearly the preferred combination in the original application**.

- In line with G 2/21, the technical effect demonstrated by the post-published experimental data provided in D16 is thus to be taken into account when assessing the inventiveness of the claimed subject-matter.

Final thoughts

- ‘Plausibility’ no longer applied as a specific test?
- Sufficiency – ‘plausible’ v ‘credible’
- Inventive step – will the new test result in different outcomes?

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Any Questions…?

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