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REUMERT

FIR Morgenmøde

23. Januar 2020

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Casper Struve


PLAUSIBLY
AN
INTRODUCTION
zacco
Casper Struve, 19 Jan 2020

PURPOSE

- Plausibility
- Inventive step
- When post-published evidence is allowed
- When post-published evidence is not allowed.

- Plausibility
- Sufficiency
- When post-published evidence is allowed
- When post-published evidence is not allowed.

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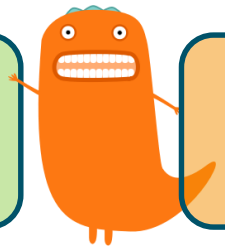
PROBLEM AND SOLUTION APPROACH

INVENTIVE STEP ACKNOWLEDGED

NON-OBVIOUSNESS OF THE SOLUTION

HAS THE PROBLEM BEEN SOLVED



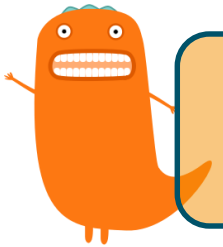
PLAUSIBILITY

TECHNICAL PROBLEM

Illustration source: https://openclipart.org/detail/175583/monster-orange-by-jsstrn *(CCO public domain)*

Illustration source: https://openclipart.org/detail/60109/award-by-sheikh_tuhin *(CCO public domain)*

PROBLEM AND SOLUTION APPROACH



PLAUSIBILITY

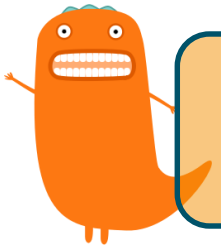
- Whether an application contains **enough data** to show that the problem has been **plausibly solved** over the **entire claim scope**.

- The EPC requires no experimental proof for patentability.
- Post-published evidence is not always required.
- This is in particular true in the absence of any formulated **substantiated doubt**.

r.13 of T 578/06

Case Law, 9th ed. I.D.4.6 Solving a technical problem – post-published documents

PLAUSIBILITY & CREDIBILITY



PLAUSIBILITY

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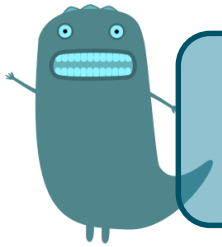

CREDIBILITY

- Whether an application contains **enough data** together with any **post-published evidence** to show that the problem has been **credibly solved** over the **entire claim scope**.

FIRST PLAUSIBILITY – THEN CREDIBILITY

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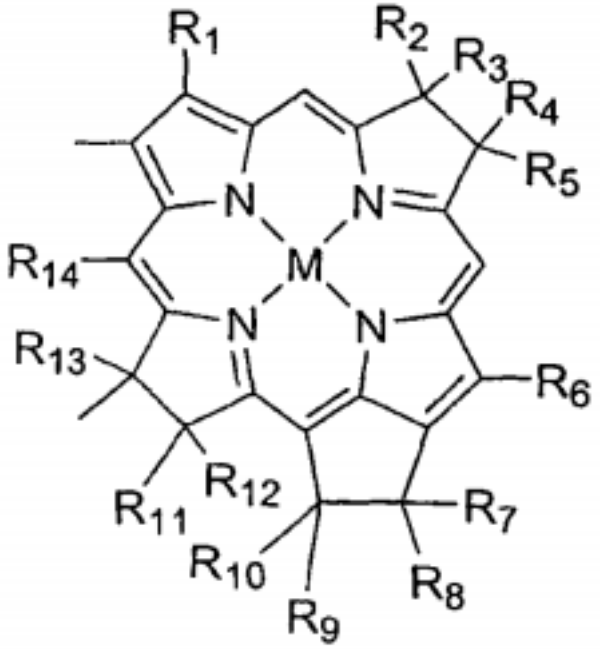
”JUST REWARD”

Bescheid/Protokoll (Anlage)	**Communication/Minutes** (Annex)	**Notification/Procès-verbal** (Annexe)
Datum Date Date 20.09.2007	Blatt Sheet Feuille 1	Anmelde-Nr.: Application No.: Demande n°:

The amendments carried out are acceptable under Article 123(2) EPC.

The subject-matter of claims 1-21 is both novel (Art. 54 EPC) and inventive (Art. 56 EPC).

The term "azo" employed in the definition of R_1-R_{14} designates a bivalent radical, namely -N=N-, whereas the R groups a monoradicals. Consequently the subject-matter of those claims, wherein "azo" is employed, does not fulfil the requirements of Art. 84 EPC.



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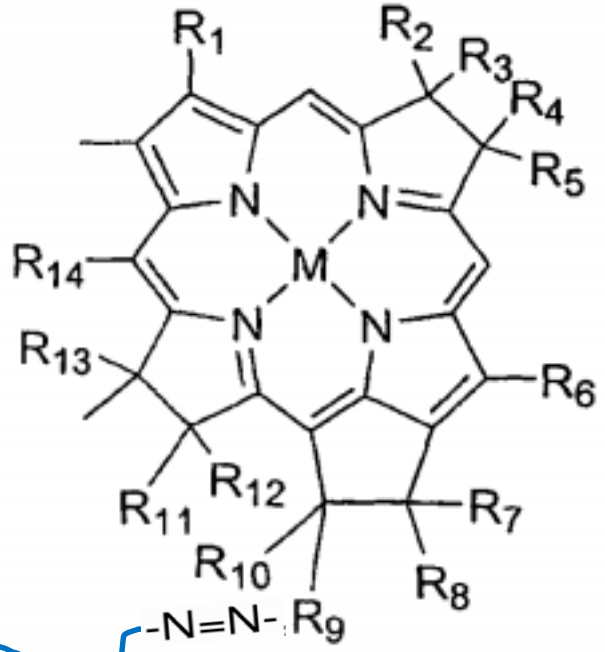

Anything in the world

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”JUST REWARD”

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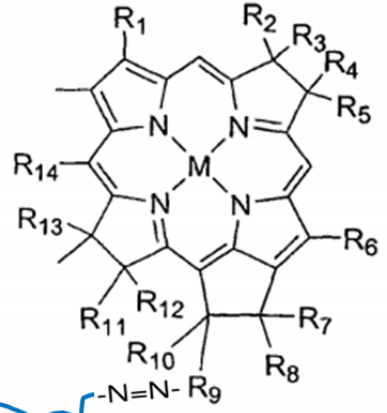
PATENTS - TRADEMARKS - DESIGNS



Anything in the world

European Patent Office
D-80298 München
Germany

By fax / confirmation by airmail

Date 28 January 2008

Our ref. P200400516 EP CAS/LPO/paw

We would like to point out that further restricting the claims (*e.g.* by introducing specific acids and azo substituents from the description) is seen as depriving the applicant of a just reward for the disclosure of his invention, especially because the substituents mentioned are readily understandable by the skilled person, and because the substituents are not the core of the invention but rather an obvious modification of the invention. This level of generalization is believed to be in line with Guidelines C-III 6.2.

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”JUST REWARD”

Datum Date Date	14.02.2008	Blatt Sheet Feuille	2	Anmelde-Nr.: Application No.: Demande n°:	

As it is not intended to deprive the applicant of a just reward for his disclosed invention, he is kindly invited to submit any further information (such as experimental data of other compounds synthesized) available in order to substantiate that all of the claimed compounds are an non-obvious solution to the problem underlying the application (i.e. that the above objected non-limiting definitions are indeed justified).

Plausible, but not credible over the whole scope

Post published evidence allowed, but not filed

Inventive step, claims limited

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GL F-IV, 6.2 (NOV 2019)

6.2 Extent of generalisation

Most claims are generalisations from one or more particular examples. The extent of generalisation permissible is a matter which the division must judge in each particular case in the light of the relevant prior art. Thus an invention which opens up a whole new field is entitled to more generality in the claims than one which is concerned with advances in a known technology. A fair statement of claim is one which is not so broad that it goes beyond the invention nor yet so narrow as to deprive the applicant of a just reward for the disclosure of his invention. The applicant is allowed to cover all obvious modifications of, equivalents to and uses of that which he has described. In particular, if it is reasonable to predict that all the variants covered by the claims have the properties or uses the applicant ascribes to them in the description, he is allowed to draw the claims accordingly. After the date of filing, however, the applicant is allowed to do so only if this does not contravene **Art. 123(2)**.

no substantiated doubt

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T 694/92 (MYCOGEN)

Headnote:

I. Where an invention relates to the actual realisation of a technical effect anticipated at a theoretical level in the prior art, a proper balance must be found between, on the one hand, the actual technical contribution to the state of the art by said invention, and, on the other hand, the terms in which it is claimed, so that, if patent protection is granted, its scope is fair and adequate (see point 3 of the Reasons).

II. In cases where the gist of the claimed invention consists in the achievement of a given technical effect by known techniques in different areas of application and serious doubts exist as to whether this effect can readily be obtained for the whole range of applications claimed, ample technical details and more than one example may be necessary in order to support claims of a broad scope. Accordingly, claims of broad scope are not allowable, if the skilled person, after reading the description, is not able to readily perform the invention over the whole area claimed without undue burden and without needing inventive skill (see points 5 and 19 of the Reasons).

GL F-IV, 6.2 (MYCOGEN)

3 5 19

7. For the purposes of Articles 56 and 83 EPC the same level of skill is required from the person skilled in the art (see T 60/89, OJ EPO 1992, 268) in two different technical situations: whereas for the purpose of evaluating inventive step the skilled person has knowledge of the prior art only, for the purpose of evaluating sufficiency of disclosure (and, hence, support) he or she has knowledge of the prior art and of the invention as disclosed.

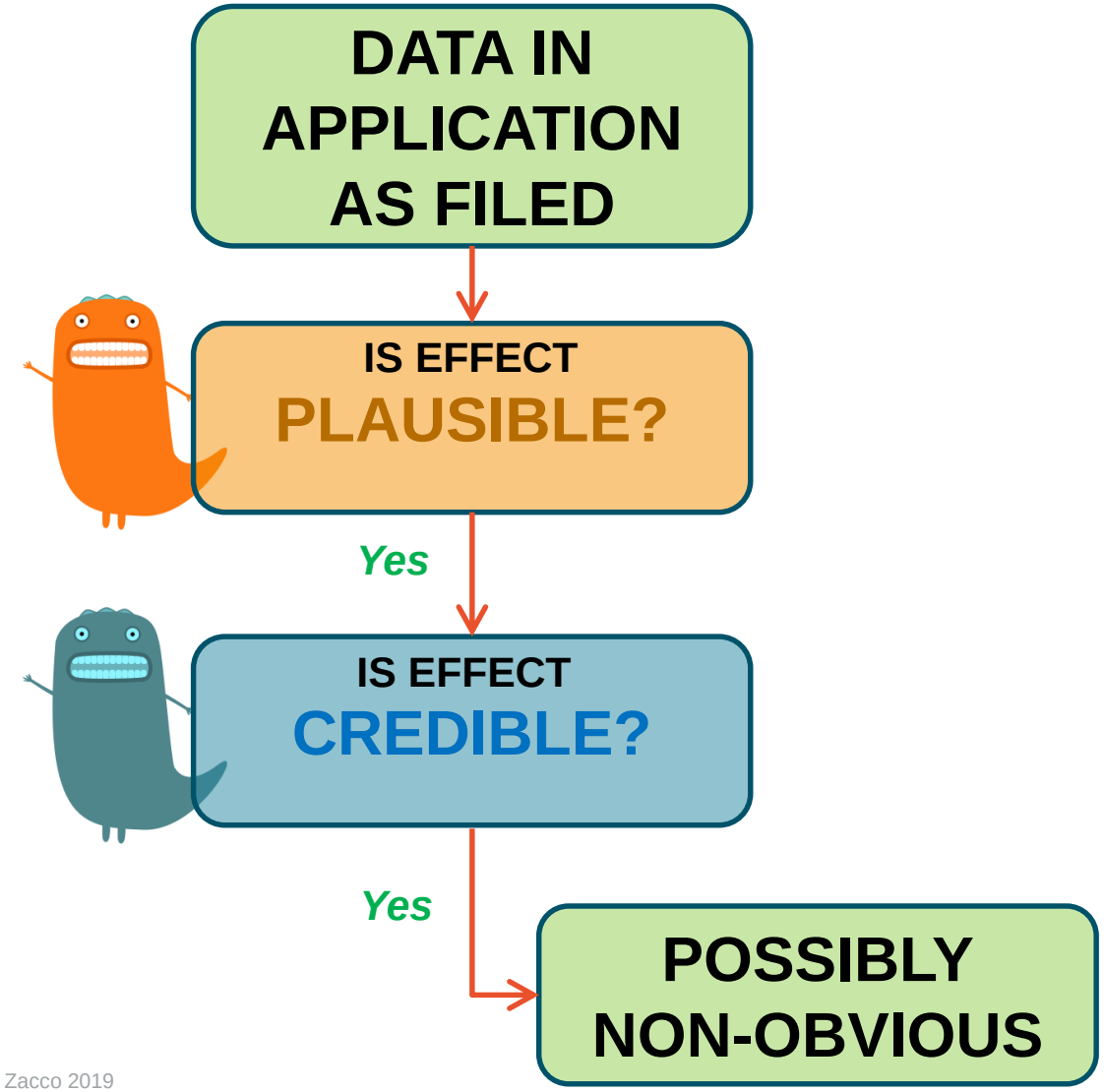
8. The above considerations show how closely interrelated and how critical the issues of support of the claims, sufficiency of disclosure and inventive step are in cases - such as the present one - where it is particularly difficult to find a proper balance between the breadth of the claims and the actual contribution to the state of the art by the disclosure of the patent in suit.

GL F-IV, 6.2 (MYCOGEN)

3 5 19

19. In view of the above considerations, the board has decided that the experimental evidence and technical details in the description of the patent in suit are not sufficient for the skilled person to reliably achieve without undue burden the technical effect of expression in any plant cell of any plant structural gene under the control of any plant promoter and that, consequently, they do not provide sufficient support for a claim, such as present claim 1, broadly directed to such a method.

PLAUSIBILITY & CREDIBILITY



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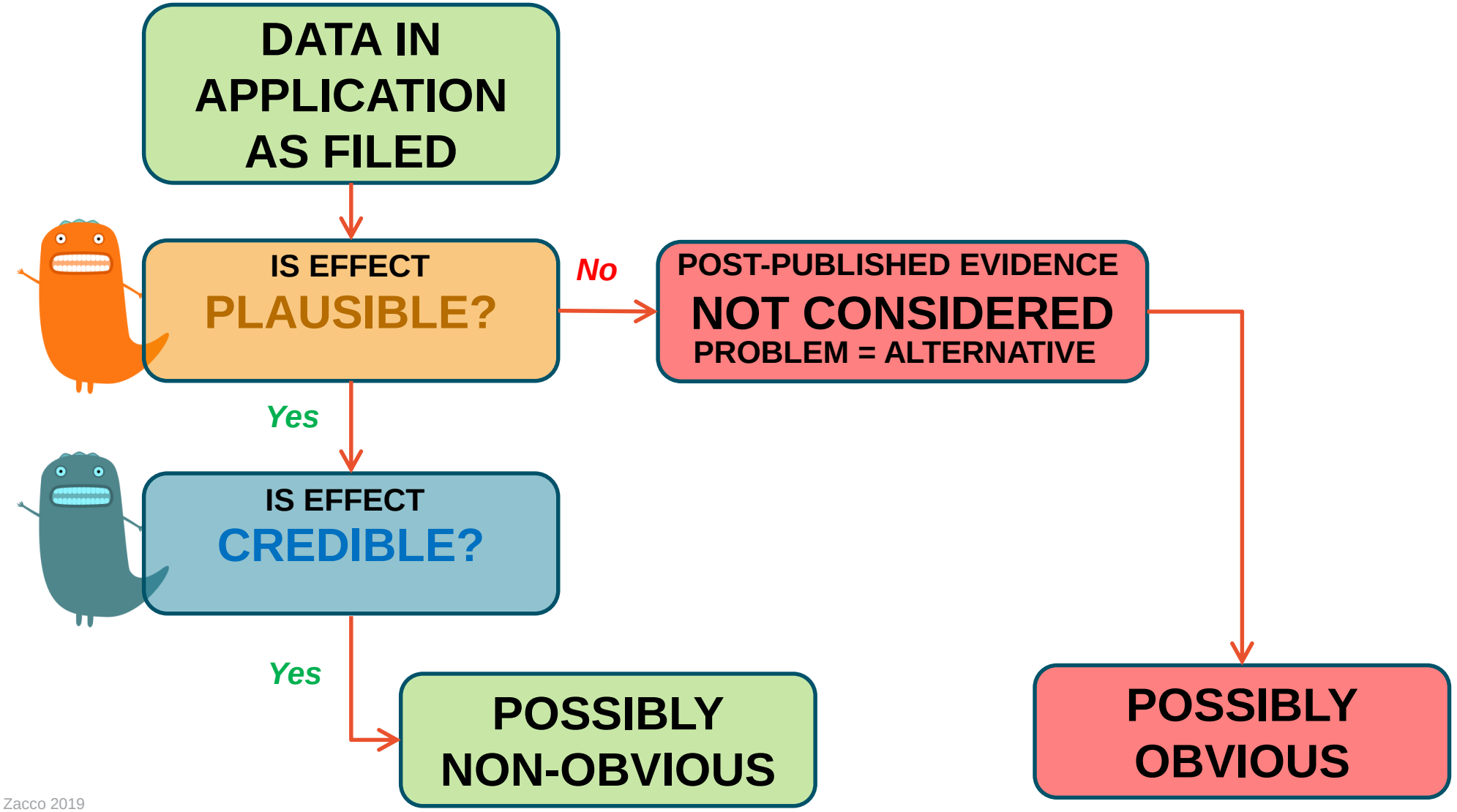
PLAUSIBILITY & CREDIBILITY



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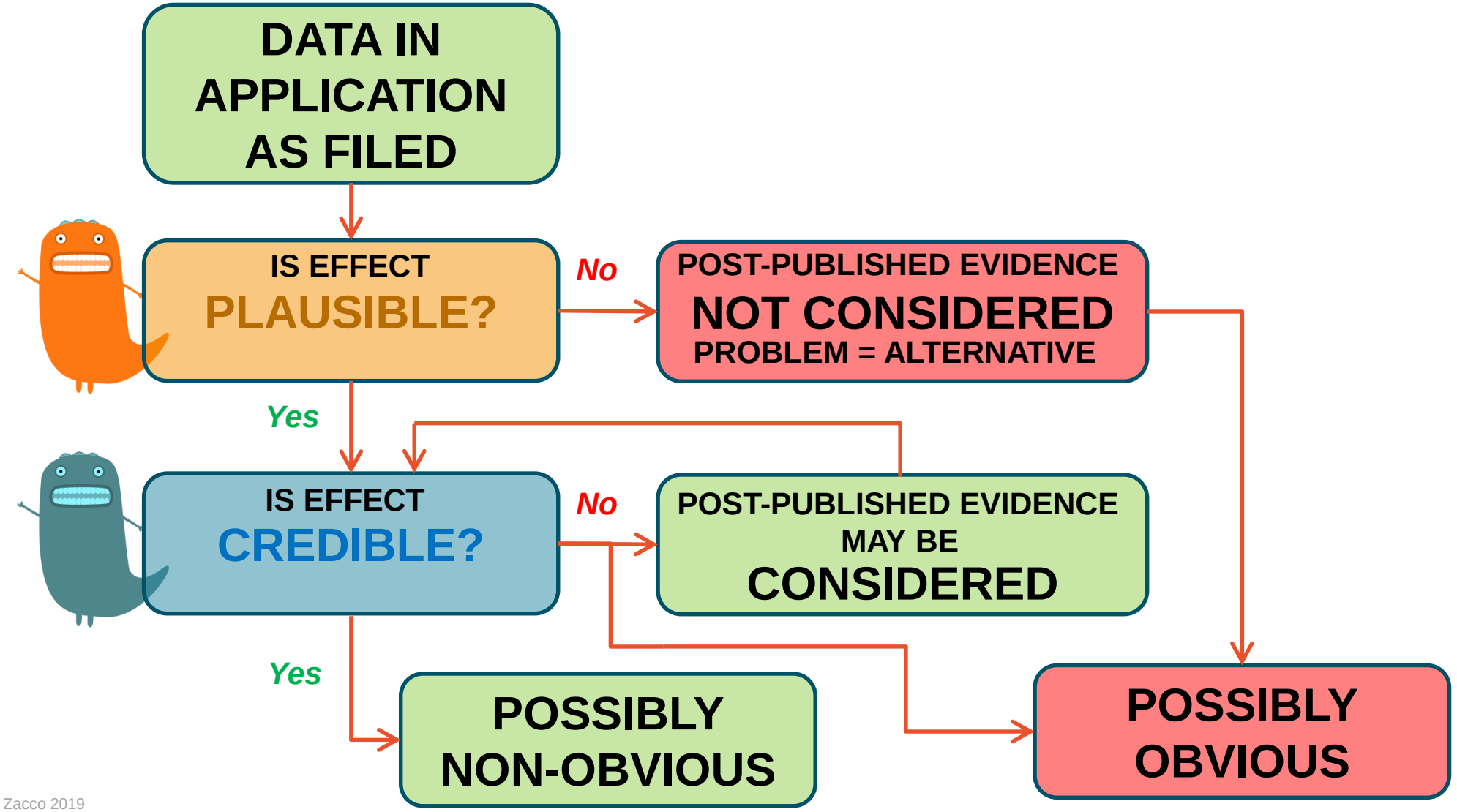
PLAUSIBILITY & CREDIBILITY



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T 939/92 – (AGREVO)

Herbicidal compounds (Triazoles)

<u>T 939/92 Keywords:</u>

- Alleged effect not credible for all claimed alternatives
- Solution to more general technical problem obvious

Illustration source: https://www.pxfuel.com/en/free-photo-eyfsv (CCO public domain)

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T 939/92 Headnote 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 2.4 to 2.6).

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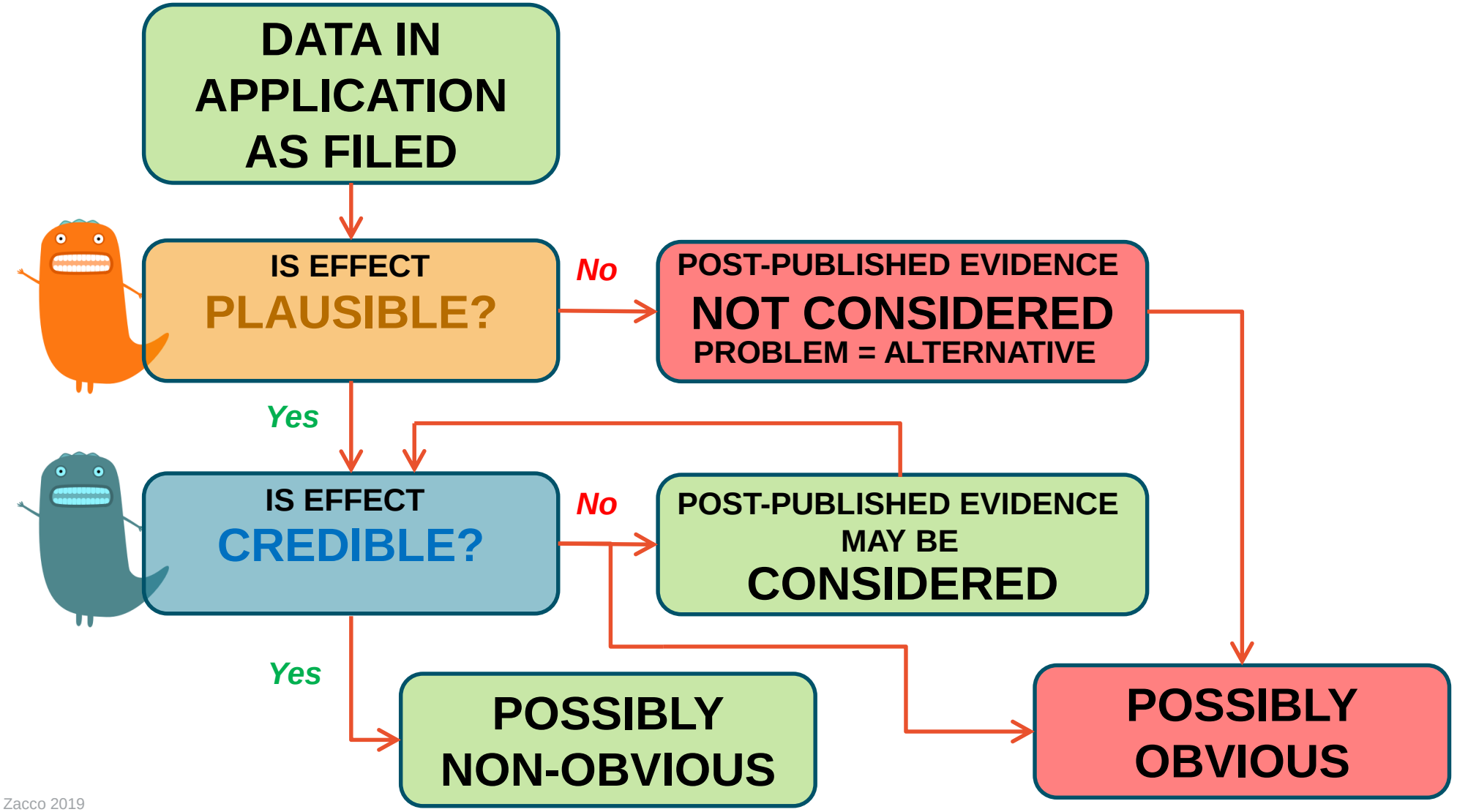
Plausible, but not credible over the whole scope

Post-published evidence allowed, but not filed.

Lack of inventive step, obvious alternative

Illustration source: https://www.pxfuel.com/en/free-photo-eyfsv (CCO public domain)

PLAUSIBILITY & CREDIBILITY



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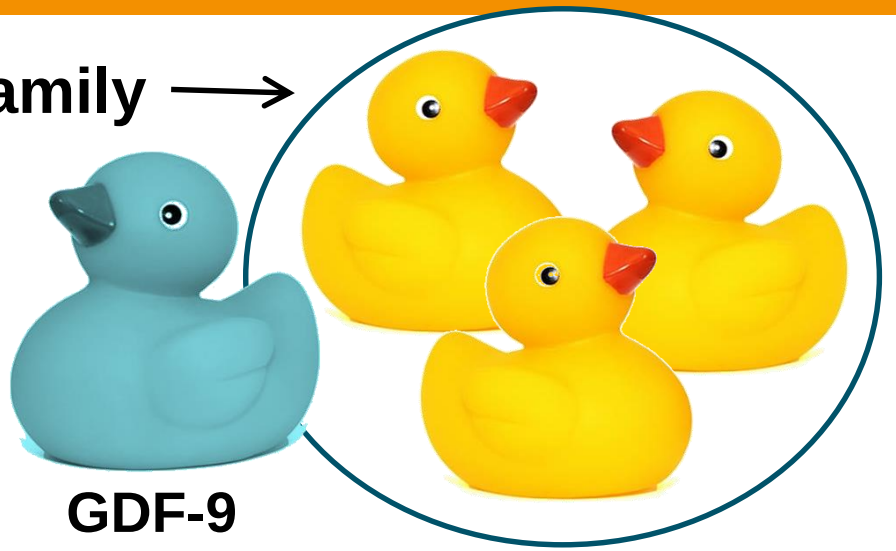
T 1329/04 – (JOHNS HOPKINS)

GDF-9

TGF-β super family →



GDF-9

<u>T 1329/04 Keywords (paraphrased):</u>

- An invention requires a contribution to the art.
  - Solving a problem and not putting forward one.
- Must at least be made plausible by the disclosure in the application that its teaching solves the problem.

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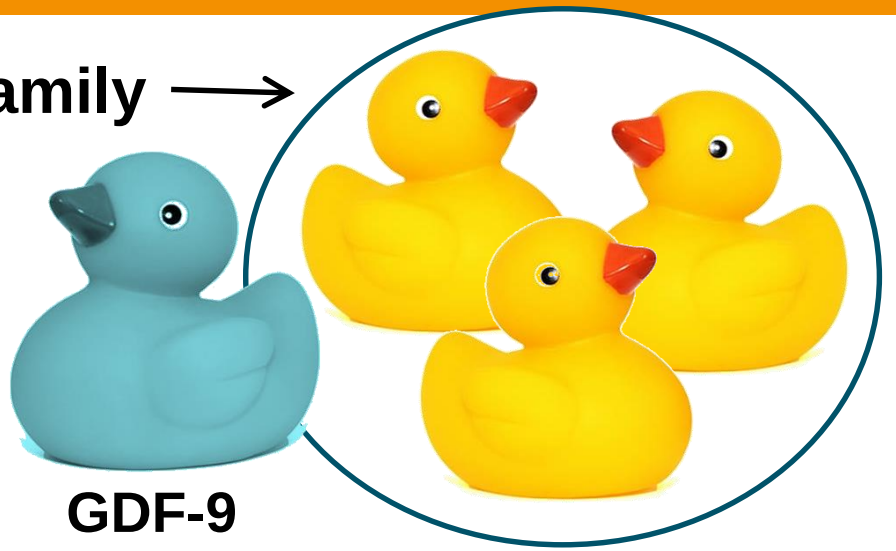

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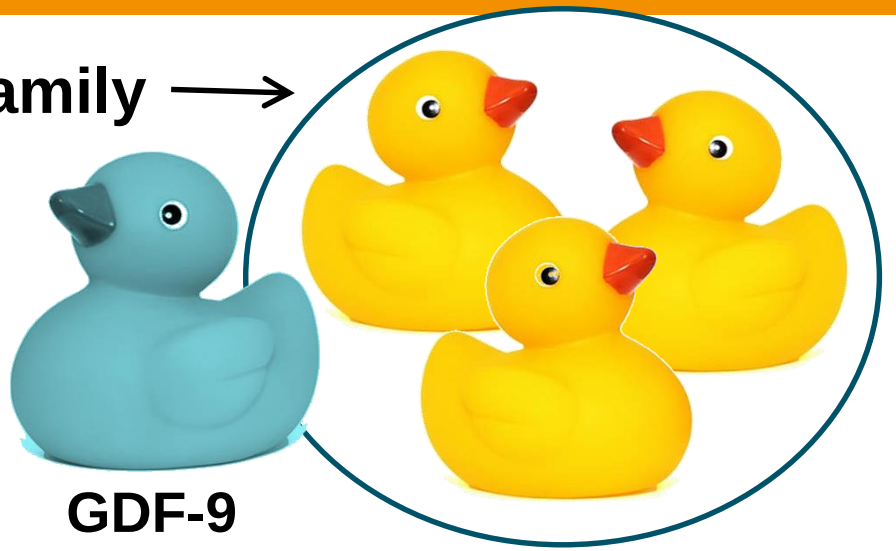

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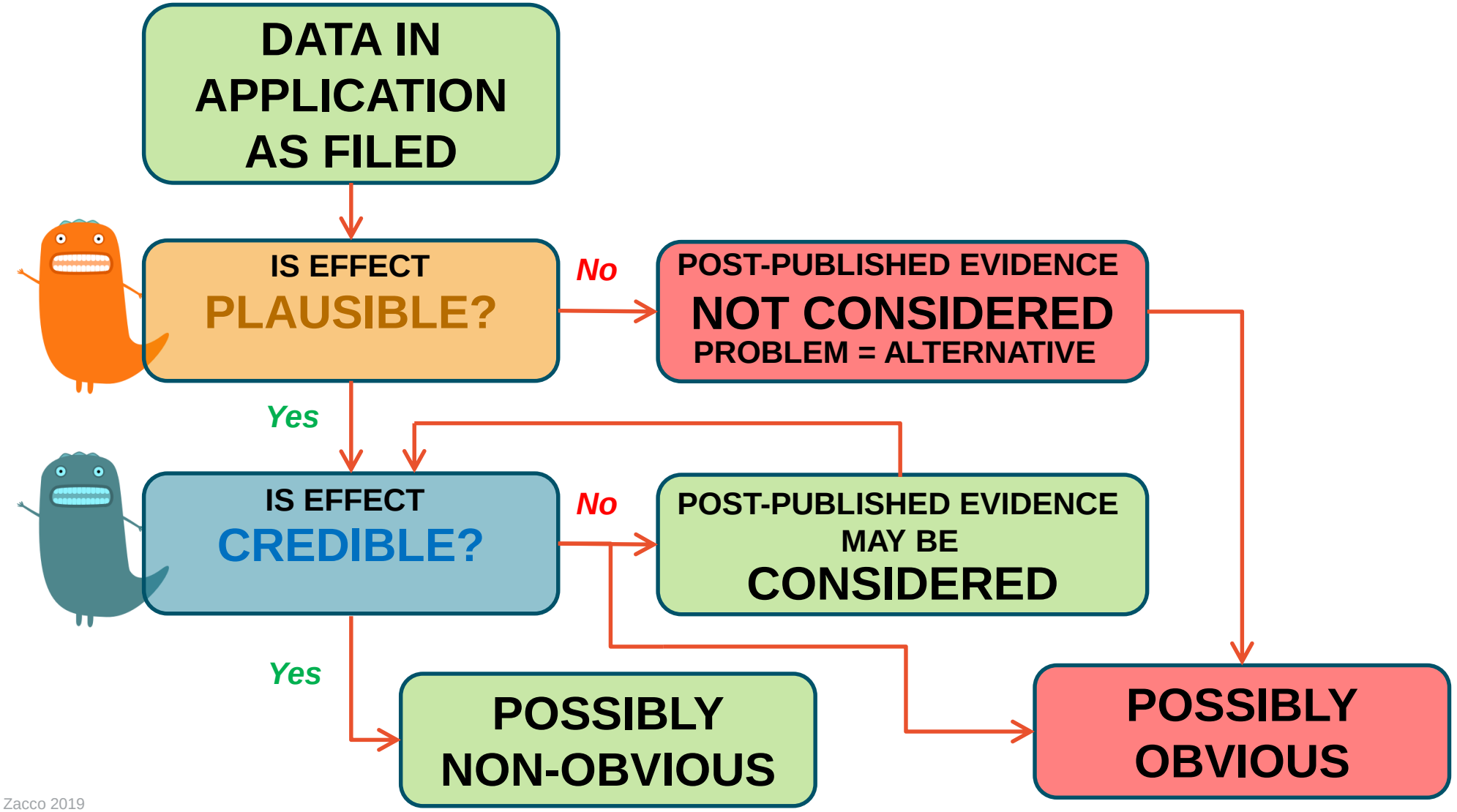
Not Plausible, and not credible

Post-published evidence not allowed, despite being filed.

Lack of inventive step, obvious alternative

Illustration source: https://www.pxfuel.com/en/free-photo-eyfsv (CCO public domain)

PLAUSIBILITY & CREDIBILITY



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T 433/05 – (CONJUCHEM)

Fusion Peptide Inhibitors

T 433/05:

- r.11 *"… When evaluating the quality of evidence provided in the patent in suit …, the Board notices that it* ***contains thirty examples concerned with the preparation of modified peptides according to the invention.*** *…"*

Illustration source: https://www.pxfuel.com/en/free-photo-errbq *(CCO public domain)*

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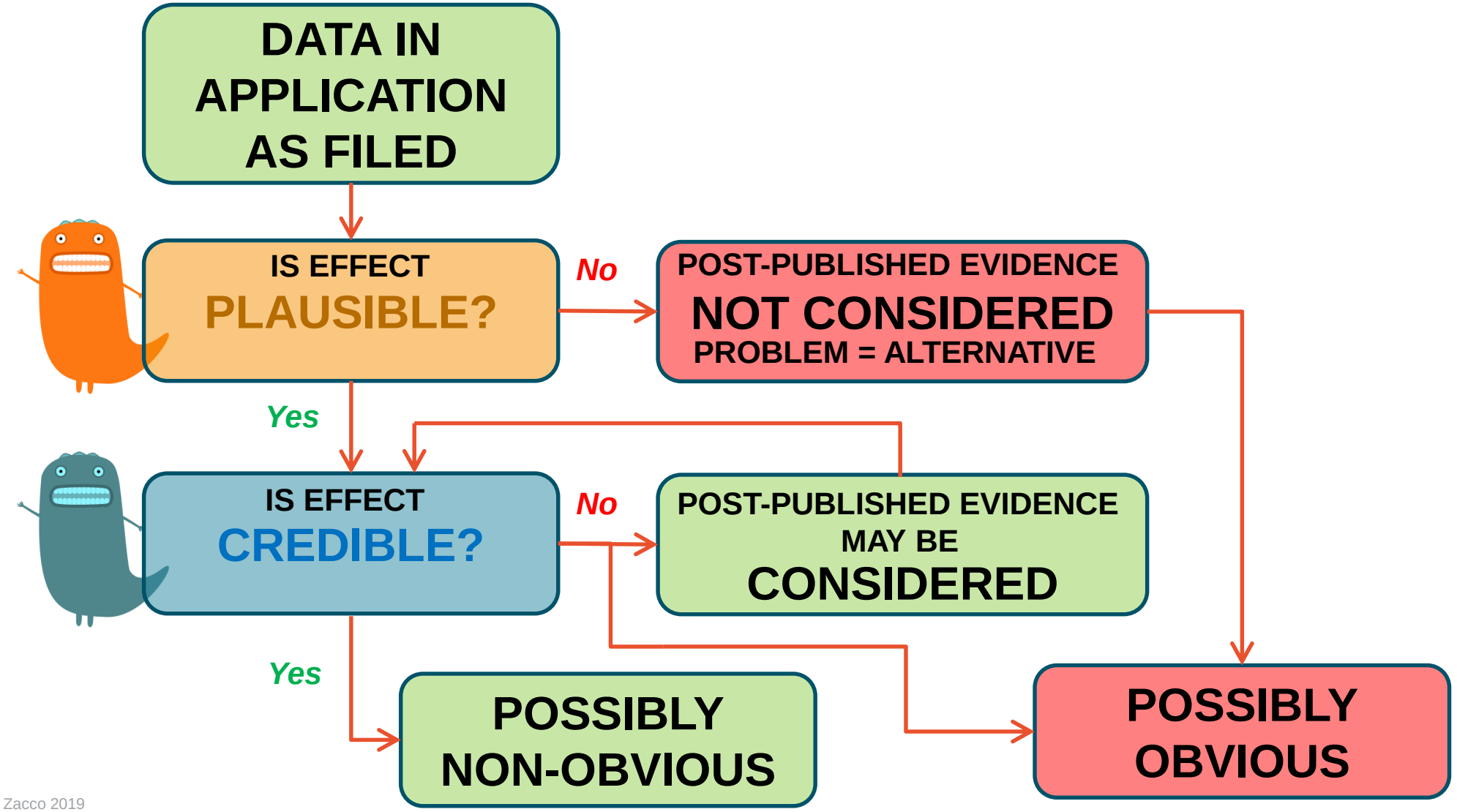
Plausible, but not credible

Post-published evidence allowed, and filed.

Inventive step acknowledged.

Illustration source: https://www.pxfuel.com/en/free-photo-errbq (CCO public domain)

PLAUSIBILITY & CREDIBILITY



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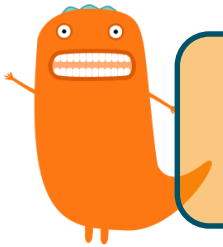
INVENTIVE STEP VS SUFFICIENCY



PLAUSIBILITY

- Whether an application contains **enough data** to show that the problem has been **plausibly solved** over the **entire claim scope**.

- Under which article (Art.83 vs. Art.56) should plausibility be evaluated?

SUFFICIENCY *vs.* **INVENTIVE STEP**

- **Sufficiency** is at stake, when the effect is described in the claim (**G1/03**).

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INVENTIVE STEP VS SUFFICIENCY

SUFFICIENCY *vs.* **INVENTIVE STEP**

- r.2.5.2 of G1/03:

  Lack of reproducibility of the claimed invention may become relevant under the requirements of **inventive step or sufficiency of disclosure**.

  If an effect is expressed in a claim, there is lack of sufficient disclosure. Otherwise, i.e. if the effect is not expressed in a claim but is part of the problem to be solved, there is a problem of inventive step (T 939/92, OJ EPO 1996, 309).

INVENTIVE STEP VS SUFFICIENCY

SUFFICIENCY *vs.* **INVENTIVE STEP**

- Typically 2nd medical use claims (**Art.54(5) EPC**) have the technical effect described in the claim:
  - **Composition X** for use in the **treatment of malaria**.

T 609/02 – (SALK INSTITUTE)

AP-1 complex

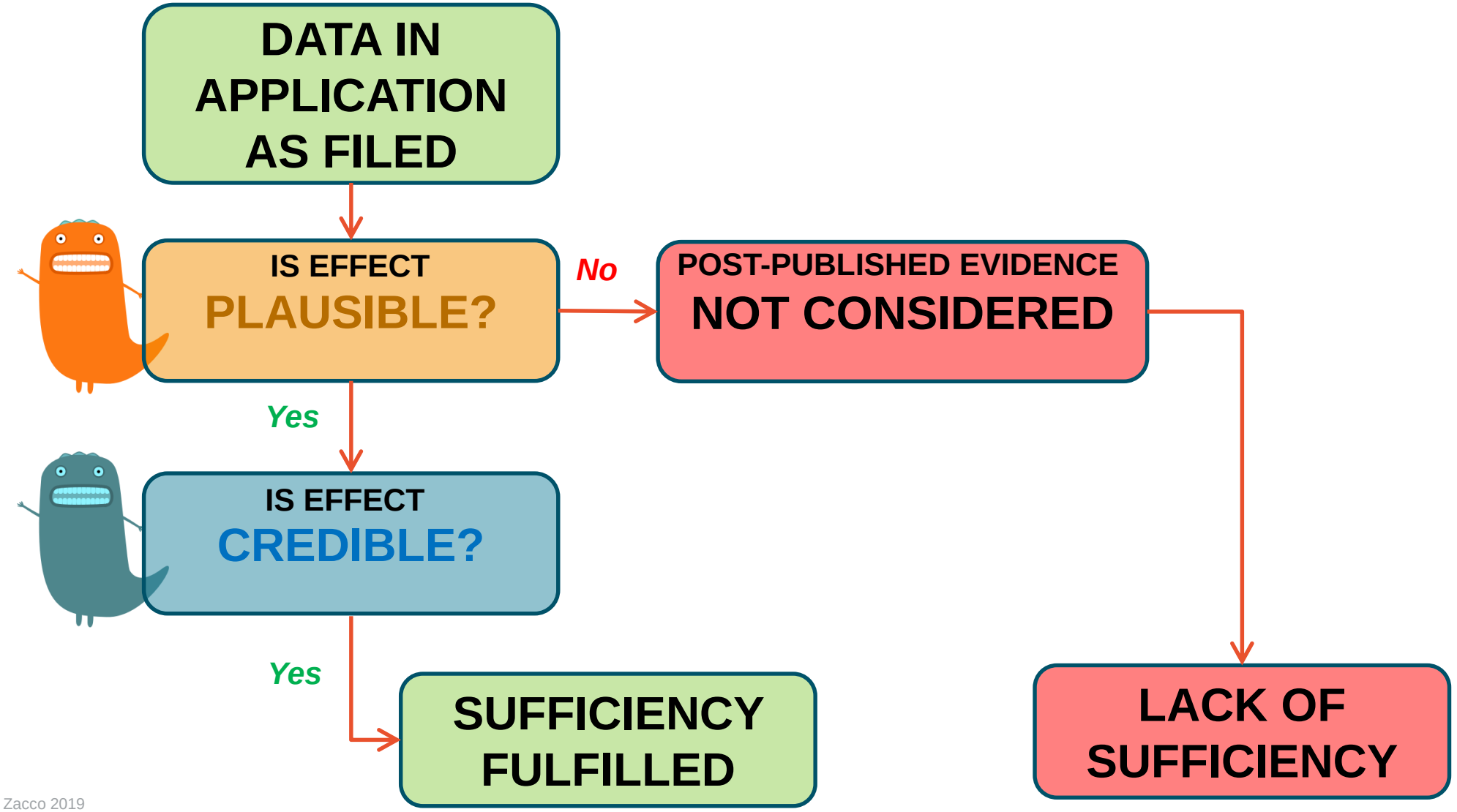
T 609/02:

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

Not plausible, and not credible
Post-published evidence not allowed.
Lack of sufficiency

Illustration source: https://www.pxfuel.com/en/free-photo-errbq (CCO public domain)

PLAUSIBILITY & CREDIBILITY



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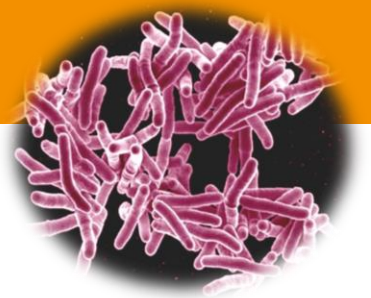
T 1599/06 – (UNIV CALIFORNIA)

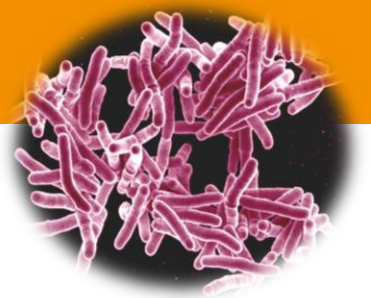


Mycobacterium vaccinating agent (Tuberculosis)

- Appeal is from a decision of the examining division
- **2nd medical use claim 1:** *"A vaccinating agent for use in promoting a protective immune response, in a mammalian host, against the infectious pathogen Mycobacterium, ..."*
- The description discloses that all the isolated proteins, including the **30 kDa** and **32A kDa** proteins, are to be used as vaccinating agents for promoting a protective immune response.
- The examining division considered that it was not plausible to claim that the **32A kDa** protein was able to promote protective immunity.
- The application discloses that guinea pigs immunised with the **30 kDa** protein are protected against challenge with Mycobacterium tuberculosis. No such data are reported for the **32A kDa** protein.

  Cropped photo from: https://en.m.wikipedia.org/wiki/File:Mycobacterium_tuberculosis_Bacteria,_the_Cause_of_TB_(5149398656).jpg *(CC BY 2.8)*

T 1599/06 – (UNIV CALIFORNIA)



Mycobacterium vaccinating agent (Tuberculosis)

- The examining division supported that the **32A kDa** protein was not a plausible vaccinating agent with reference to D1 indicating that the **30 kDa** protein provokes a strong reaction, while the **32A kDa** protein does not induce any skin reaction.
- the authors of document D1 see a possible reason for this difference.
- In the board's view, the results in document D1 pointed to by the examining division are not conclusive evidence of a difference in the immunological reactivities.
- The board sees no other evidence on file which would justify calling the immunoprotective properties of the **32A kDa** protein into question.

Cropped photo from: https://en.m.wikipedia.org/wiki/File:Mycobacterium_tuberculosis_Bacteria,_the_Cause_of_TB_(5149398656).jpg *(CC BY 2.8)*

T 1599/06 – (UNIV CALIFORNIA)

Mycobacterium vaccinating agent (Tuberculosis)

- Seeing the data for the **30 kDa** protein in the application, the skilled person would therefore consider it technically plausible to use the **32A kDa** protein, too, to promote protective immunity.
- The data in the application, in combination with the common general knowledge, provide an indication of the immunoprotective properties of the **32A kDa** protein.
- In addition, there is technical evidence on file corroborating the board's conclusion. Documents D7 and D8, both filed during the appeal proceedings, confirm that the **32A kDa** protein induces a protective immune response in animal models of Mycobacterium infection.

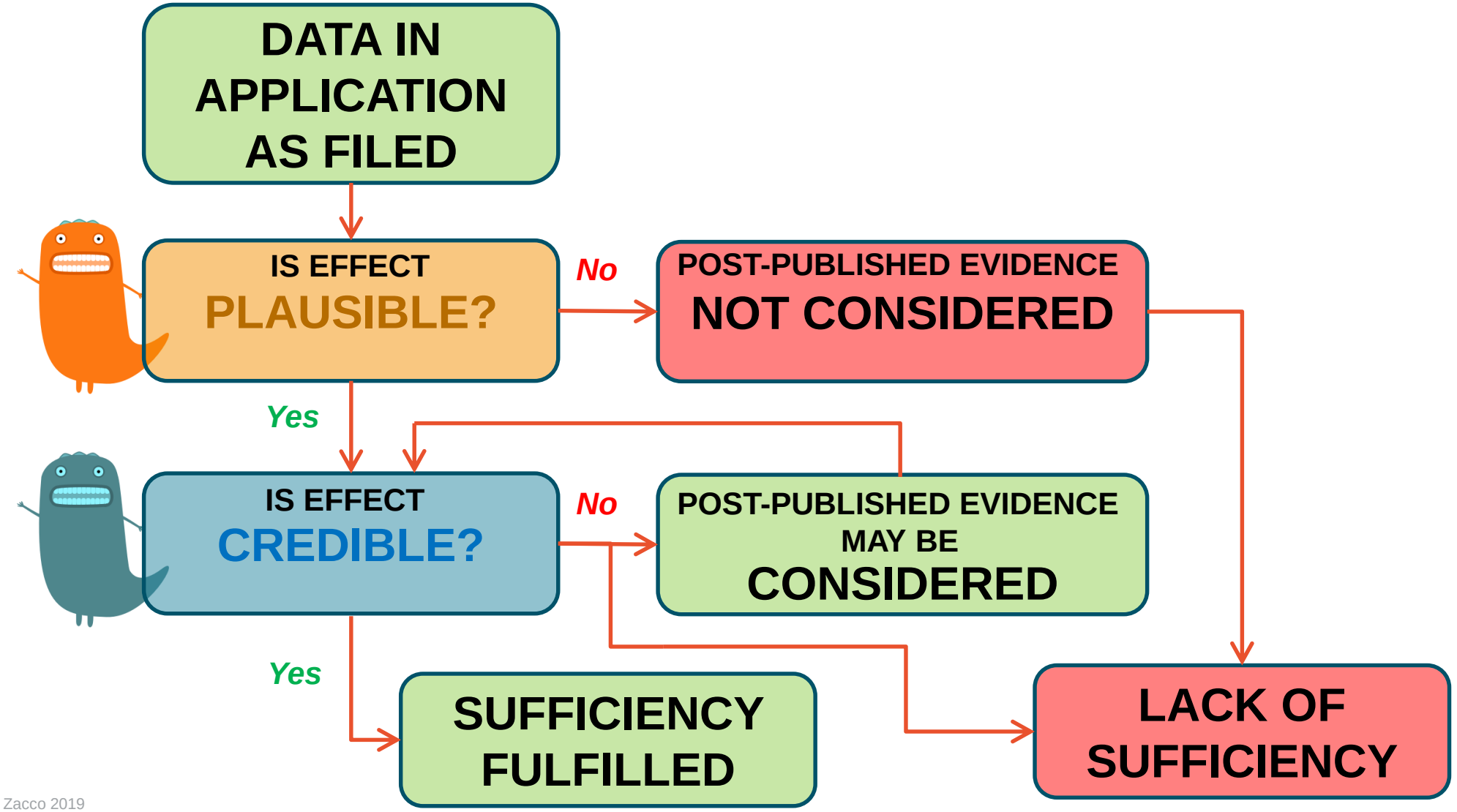
Plausible

Post-published evidence allowed, and filed.

Sufficiency acknowledged.

  Cropped photo from: https://en.m.wikipedia.org/wiki/File:Mycobacterium_tuberculosis_Bacteria,_the_Cause_of_TB_(5149398656).jpg *(CC BY 2.8)*

PLAUSIBILITY & CREDIBILITY



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THE END

OF THE INTRODUCTION

Casper Struve, 19 Jan 2020

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Ed Farrington

Plausibility at the EPO: Selected Recent Case Law

Ed Farrington

PhD, European Patent Attorney, partner

Inspicos PS

23rd January 2020

Selected Recent Case Law

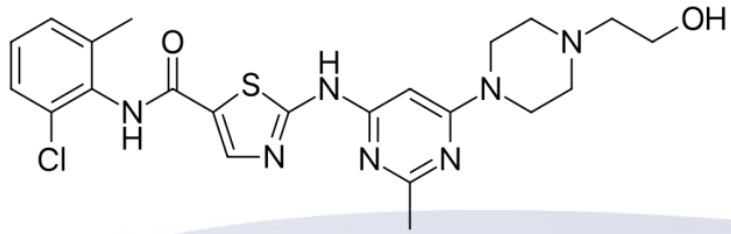
- Cases in which T1329/04 is (typically) cited.

  * = cited in the Case Law Book

- Generally:
  - Biotech/pharma cases
  - Little or no supporting data in the application as filed (supporting data may be filed at a later stage)
  - Little or no support from common general knowledge

T 488/16* (Dasatinib/BRISTOL-MYERS SQUIBB)

- 580 compounds including dasatinib originally covered
- Claim 1 as granted restricted to dasatinib



- No evidence for the purported technical effect (PTK inhibitor) in the application as filed, in particular not with respect to dasatinib

T 488/16* (Dasatinib/BRISTOL-MYERS SQUIBB)

- The purported effect was not supported by common general knowledge
- Post-published evidence was disregarded
- Problem reformulated as “provision of a further chemical compound”
- No inventive step

T 488/16 (Dasatinib/BRISTOL-MYERS SQUIBB)

- Extensive references by the appellant to EPO Case Law, national decisions from EPC contracting states and US case law.

- Referral to Enlarged Board denied:
  - No diverging Case Law
  - The question of whether a problem is plausibly solved is a technical question to be addressed by the technical Board of Appeal

T 488/16 (Dasatinib/BRISTOL-MYERS SQUIBB)

- Post-published **evidence in support that the claimed subject-matter** solves the technical problem the patent in suit purports to solve **may be taken into consideration, if it is already plausible from the disclosure of the patent that the problem is indeed solved**

- In the board's judgement, **it is not acceptable to draw up a generic formula, which covers millions of compounds, vaguely indicate an "activity" against PTKs and leave it to the imagination of the skilled reader** or to future investigations to establish which compound inhibits which kinase and is therefore suitable to treat the respective diseases associated therewith.

T 1322/17 (Ibandronate/ATNAHS)

- Claim 1: “A medicament comprising 150 mg of ibandronic acid [...] for use in the prevention or treatment of osteoporosis by administration as a single dose.”

- Proprietor invokes the effect of reduced incidence rate of bone fractures and relies on post-published evidence

T 1322/17 (Ibandronate/ATNAHS)

- The application referred to the "ibandronate clinical development program". This program is not identified further.

- The results of this program were not included in the application and not made publicly available at or before the filing date.

- **Results only known to the inventors** derived from studies of unknown set-up **cannot be considered when assessing the plausibility** of certain effects.

T 1322/17 (Ibandronate/ATNAHS)

- It is noted that experimental evidence is not limited to clinical data.

- It is also noted that experimental evidence is not always necessary to render a certain effect plausible.

- A **mechanistic explanation** and/or common general knowledge may be sufficient in certain instances.

T 1322/17 (Ibandronate/ATNAHS)

- However, in this case, there were no supporting circumstances
  - Post-published evidence disregarded
  - Arbitrary choice
  - Not inventive

T 108/09* (Fulvestrant/ASTRA ZENECA AB)

1. Use of fulvestrant in the preparation of a medicament for the treatment of a patient with breast cancer who previously has been treated with an aromatase inhibitor and tamoxifen and has failed with such previous treatment.

- The sole example of the patent was a protocol for a clinical trial (not the clinical trial itself).

- Post-filed document 10 showed the results of the trial.

T 108/09 (Fulvestrant/ASTRA ZENECA AB)

- The board notes that the present case is different from the situation described in decision T 1329/04.

- In the present case, it was already known that fulvestrant was effective as a second-line agent in the treatment of breast cancer.

T 108/09 (Fulvestrant/ASTRA ZENECA AB)

- Document (10) is not the only source of information regarding the question whether fulvestrant is useful as a third-line agent

- The data contained in document (10) may be used in the evaluation of whether or not the problem underlying the present invention has been plausibly solved.

- Inventive

T 0536/07 (Co-expression soluble PACE/GENETICS INSTITUTE)

1. A mammalian host cell comprising

a recombinant DNA sequence encoding the mammalian paired basic amino acid converting enzyme PACE lacking a transmembrane domain, operably linked to a heterologous expression control sequence permitting expression of said PACE; and

a polynucleotide encoding a precursor polypeptide, wherein the precursor polypeptide is a substrate for the encoded PACE which is operably linked to a heterologous expression control sequence permitting expression of the protein product of the precursor polynucleotide by the host cell.“

T 0536/07 (Co-expression soluble PACE/GENETICS INSTITUTE)

- No working examples for the claimed subject-matter

- The objective technical problem was formulated as the provision of an **alternative system** to those disclosed in documents D5 and D9

- Post-published evidence D21, D22 demonstrated the feasibility of the proposed solution.

T 0536/07 (Co-expression soluble PACE/GENETICS INSTITUTE)

- Board: *"the present situation differs from that underlying decision T 1329/04"*

- In that case, relevant structural differences between the claimed product and related products described in the art **did not allow the former to be identified as a bona fide member of a family defined by the latter**…

T 0536/07 (Co-expression soluble PACE/GENETICS INSTITUTE)

- In the present case, there is **no indication whatsoever of a possible prejudice** in the art **or of foreseen difficulties** in carrying out the proposed solution.

- …no further information is found in the post-published evidence **that was not already made available to the skilled person by the contested patent**

- Inventive

“Reversing” the plausibility argument

- T1760/11* – no a priori reasons for the skilled person to regard the information in the application as filed as **implausible**

- T863/12* – no indication in the common general knowledge of a lack of plausibility

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How far does plausibility stretch?

T2371/13* (Association de deux colorants cationiques/L'OREAL)

1. **Use as direct dyes** in, or for the manufacture of, direct dyeing compositions for…**in particular the hair** …of **a combination comprising**

   (i) at least one cationic dye chosen from (I) Basic Brown 17, Basic Brown 16, Basic Red 76, Basic Red 118, (II) Basic Yellow 57, (III) Basic Blue 99 and

   (ii) at least one cationic dye of the following formulas (IV) or (VI)…

T2371/13* (Association de deux colorants cationiques/L'OREAL)

- The application as filed contained 4 “virtual examples”.

- Tests filed by the respondent during the examination procedure on September 29, 2004 and May 23, 2006 showed that the combination of cationic direct dyes as claimed **actually resulted in a improved selectivity**.

T2371/13* (Association de deux colorants cationiques/L'OREAL)

- Opponent: referred to Case Law around plausibility…

The results of all experimental tests filed by the respondent **after the date of filing** of the patent in suit **should be excluded from the discussion of inventive step** and therefore not be taken into account for the demonstration of the effect obtained on the uniformity of coloring.

T2371/13* (Association de deux colorants cationiques/L'OREAL)

- Board: It is customary to assert under inventive step a technical effect which is not explicitly mentioned in the application as filed.

- …in the present case, **disregarding tests** intended to demonstrate an improvement in the uniformity of the colors **would be incompatible with the problem / solution approach** which requires defining a document as the state of the art, which is not necessarily that cited in the patent application

T2371/13* (Association de deux colorants cationiques/L'OREAL)

- The question of whether the invention had been plausibly made at the time of filing was a question of **sufficiency**.
- But **this ground had not been raised** by the opponent…
- Opponent had themselves filed examples, to challenge those filed by the patentee
- Board: the problem is not credibly solved across the entire scope = lack of inventive step.

Summary

- Plausibility is to be assessed on a case-by-case basis
- Try to link the invention to the common general knowledge in other ways, e.g. mechanistic explanation
- It may be possible to ”reverse” the burden of proof with respect to the common general knowledge.
- So far, plausibility is (probably) limited to biotech and pharma cases.

Questions/Discussion?

KROMANN
REUMERT

Timo Minssen

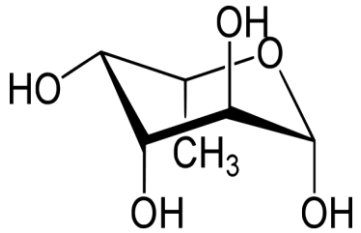
Recent case law developments in the UK & Denmark:

Plausibility – et plausibelt koncept inden for patentretten?
Torsdag den 23. januar 2020,
Kl. 09:00-10:30
Kromann Reumert, Sundkrogsgade 5, 2100 København Ø

Prof. Jur. Dr. Timo Minssen. LL.M., M.I.C.L.
Director, Centre for Advanced Studies in Biomedical Innovation Law
University of Copenhagen

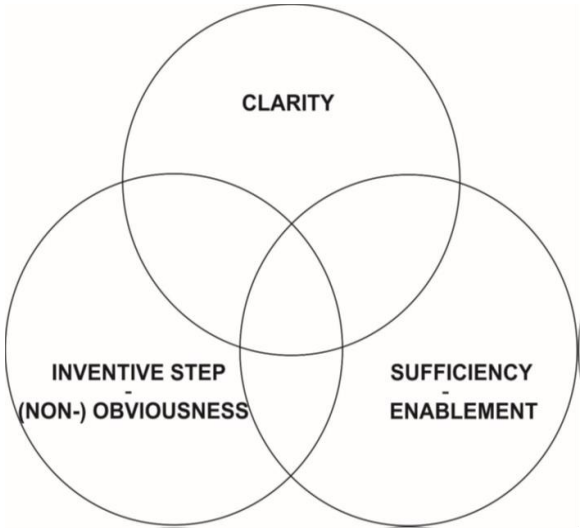
UNIVERSITY OF COPENHAGEN

CeBIL



Intro Point of Departure & Focus

- **Many EPO case law developments on "plausibility"**
- **Interesting parallel developments in national jurisdictions often heavily influenced and based on EPO decisions**
- **Yet, also some divergence and conflicting opinions/decisions can be identified.**
- **An area that is difficult to navigate for all stakeholders.**



- **Plausibility and credibility has also become more significant around the globe with interesting developments in e.g. UK, Germany, Canada & China**
- **But 20 minutes!** → **here focus on UK & Denmark**

1. UK

Is plausibility really an issue on the national arenas?: YES IT IS

- For the 1st time since the first edition in 1884, the 18th edition of ***Terrell on the Law of Patents*** **(2016)** included a reference to "plausibility"

- **Foreword by Birss J:**

- *"The emergence of that concept [plausibility] (or rather arguments about an alleged lack of it) in relation to each of inventive step, sufficiency and industrial applicability* ***represents a significant recent legal development in the life sciences****."*

- *"Chapter 13 of the last edition ("Invalidity Due to Insufficiency") contained no reference to the objection of want of plausibility ⋯* ***most cases of invalidity before the Patents Court now contain an allegation that the teaching of the patent is not plausible.*** *This represents a significant change in law and practice."*

Why plausibility? – Selected core cases of higher UK courts

- **EPO seen as gate keeper. Rationales considered by UK courts:**
- **To prevent speculative claiming:**
  - **Prendergast's Applications [2000]:** *"…[otherwise] it would be possible to make valid Swiss-type applications in relation to **all sorts of speculative uses** for established drugs and other chemicals **without a shred of evidence as to whether they would work, let alone as to whether they do work**. That seems to me to be potentially embarrassing in terms of overwork for the Patents Office … It appears to me to risk giving an uncovenanted benefit to a substantial or rich organisation which might seek to register a remarkable number **of wholly speculative patents**…"*
- **A check on overbreadth:**
  - **Regeneron v Genentech [2013] EWCA Civ 93**, which **referred to the TBA's decision in T609/02 Salk,in** in para. 100 and 101 that it must be possible for the skilled person to make a reasonable prediction that the invention will work with substantially everything falling within the scope of the claim, which the Court specifically equated with the requirement that ***"the assertion that the invention will work across the scope of the claim must be plausible or credible ".*** The Court of Appeal went on to state that if such a prediction could not be made then the scope of the patent monopoly would exceed the patentee's technical contribution to the art, thus rendering the claim insufficient.

Objective is to distinguish those applications which solve a technical problem from those which merely pose a further problem for the skilled person.

Where can it become relevant under the Patents Act 1977?

- Invention must be **new** (s2 Patents Act 1977 (Novelty));
- involve an **inventive step** (s3 Patents Act 1977 (Obviousness)); and
- be capable of **industrial application** (s4 Patents Act 1977 (Industrial Application)).:
- the specification of an application for a patent must disclose the invention in a manner which is clear enough and complete enough for it to be performed by a person skilled in the art (s14(3) Patents Act 1977 (**insufficiency**)); and
- the claim or claims of an application for a patent must be supported by the description (s14(5)(c) Patents Act 1977 (**lack of support**).

Each of these 5 requirements are relevant to the issue of **plausibility**.

- Further, plausibility has also been raised in the context of **priority** (s5 Patents Act 1977).

UK- case law developments

- First case: ***Prendergast's Applications*** (1999), [2000] RPC 446.

- Jurisprudence now extends to:
  - **Inventive step** (e.g. *Conor v Angiotech*, [2008] UKHL 49 & Mylan v. Yeda et al [2013] EWCA Civ 925.
  - **Industrial applicability** (e.g. *HGS Inc. v Eli Lilly & Co [2011] UKSC 51.*)
  - **Insufficiency** (e.g. *Regeneron v Genentech [2013] EWCA Civ 93*)
  - **Priority et al.** (e.g. Hospira v Genentech [2014] EWHC 1094 (Pat)
  - **Novelty et al.** (e.g. *Merck v Ono [2015] EWHC 2973 (Pat)*)

- UK generally tends to follow the EPO approach but not perfect alignment (e.g. T903/05 *Gemvax*)

- Plausibility threshold for many years "very low": held to be different from the "fair expectation of success" standard in the "was it obvious to try?" test (*Actavis v Eli Lilly [2015] EWHC 3294*)

- More recently the **UK Supreme Court took a stricter approach in Warner-Lambert v Mylan & Actavis [2018]** UKSC 56 (14 November 2018).

Warner-Lambert v Mylan & Actavis [2018] UKSC 56 (14.11.2018): Facts I

- **WL** patent claimed the use of **pregabalin (Lyrica)** in the manufacture of a medicament for use in treatment of pain, including neuropathic pain and various sub-categories of peripheral neuropathic pain.
- **Actavis & Mylan**: disclosure in the specification did not render the claims to the treatment of neuropathic pain conditions plausible
- Hence the claim to the treatment of pain are **not plausible across its scope** and patent should be revoked
- WL commenced infringement proceedings in relation to Actavis's "skinny label" pregabalin product (marketed as Lecaent)
- Lecaent was authorised and marketed only for the non-patented indications of epilepsy and generalised anxiety disorder.

Warner-Lambert v Mylan & Actavis [2018] UKSC 56 (14.11.2018): Facts II

High Court held that

- claims to the treatment of pain and neuropathic pain were invalid on the ground of **insufficiency** as they were not rendered plausible across their scope.
- Even had they been valid, Actavis's "skinny label" product would not have infringed the asserted claims.
- However, despite the patent containing no data from an animal model of neuropathic pain, the claims to sub-categories of peripheral neuropathic pain were plausible.
- The High Court also held that an attempt by Warner-Lambert to make a post-trial amendment to limit the neuropathic pain claim to peripheral neuropathic pain was an abuse of process.

.

Warner-Lambert v Mylan & Actavis [2018] UKSC 56 (14.11.2018): Facts II

Court of Appeal

- **upheld the High Court's decision on validity**.
- provided obiter guidance on the test for infringement (not at focus)
- rejected Warner-Lambert's application to amend the patent post-trial as an abuse of process.
- Decision was appealed to the Supreme Court, which heard the case in February 2018.
- By the time the case reached the Supreme Court, the issues left to be resolved were the test for **infringement of a second medical use claim** and the **test for insufficiency based on lack of plausibility,** in particular with regards to claim 3.

Warner-Lambert v Mylan & Actavis [2018] UKSC 56: On Plausibility

- **Majority on sufficiency in para: 35 (endorsing T 0609/02 Salk) :**

"the patentee cannot claim a monopoly of a new use for an existing compound unless he not only makes but discloses a contribution to the art… the disclosure in the patent must demonstrate in the light of the common general knowledge at the priority date that the claimed therapeutic effect is plausible".'

- **Majority on sufficieny in para 52:**

"everything is possible that is not impossible, but "not impossible" is very far from being an acceptable test for sufficiency. Plausibility may be easy to demonstrate, but it calls for more than that ."

- **Majority on plausibility of industrial application** (cf. HGS v Eli Lilly & Co [2011] UKSC 51), summarised in para 107 :

A merely *"speculative"* proposed use of a claimed substance will not suffice, so *" a vague and speculative indication of possible objectives that might or might not be achievable"* will not do.

- Same with **lack of support of the claims** due to absence of any experiments of test, cf. Prendergast's Applications [2000] RPC 446 (Neuberger J)

UKSC in Generics v Warner-Lambert (14.11.2018)- Lord Sumption

- Plausibility is inevitably influenced by the legal context and test is relatively undemanding. BUT it cannot be deprived from all meaning! Then he makes a number of points of guidance:

- **First**, the proposition that a product is efficacious for the treatment of a given condition must be plausible.

- **Second**, it is not made plausible by a bare assertion to that effect, and the disclosure of a mere possibility that it will work is no better than a bare assertion.

- But, **third**, the claimed therapeutic effect may well be rendered plausible by a specification showing that something was worth trying for a reason – i.e. reasonable scientific grounds are disclosed for expecting that it might well work.

UK Supreme Court in Generics v Warner-Lambert (14.11.2018)- Lord Sumption

- **Fourth**, although the patent needn't prove the assertion that the product works for the claimed purpose, there must be something that causes the skilled person to think there is a reasonable prospect that the assertion will prove to be true.

- **Fifth**, that reasonable prospect must be based on "a direct effect on a metabolic mechanism specifically involved in the disease, this mechanism being either known from the prior art or demonstrated in the patent per se."

- But, **sixth**, the effect on the disease process need not necessarily be demonstrated by experimental data. It can be demonstrated by a priori reasoning.

- **Finally**, sufficiency is a characteristic of the disclosure, although disclosure may be supplemented or explained by the common general knowledge of skilled person.

Inc. Eli Lilly And Company & Ors v Genentech, Inc [2019] EWHC 387 & 388 (Pat) (01 March 2019)

- **First case applying Lambert**
- Relates to Genentech's EP (UK) patent for an anti-IL-17 antibody and its use use in treatment of rheumatoid arthritis (RA) and psoriasis.
- Lilly had a product, ixekizumab, and sought revocation of the patent and a declaration of non-infringement. Genentech counterclaimed for infringement
- **Arnold J** found in Lilly's favour on all counts.
- In particular he found that Genentech were squeezed between obviousness and insufficiency as to the medical use claims (as either the claims were obvious to try or the Patent would be insufficient for lack of plausibility in such respects):

> *"In my judgment the PSA would **not** **regard it as plausible** that an anti-IL-17A/F antibody would have a discernible therapeutic effect on psoriasis for the reasons given by Prof Krueger. I would emphasise five points"*

.

Inc. Eli Lilly And Company & Ors v Genentech, Inc [2019] EWHC 387 & 388 (Pat) (01 March 2019), (first case applying Lambert)

- ***First**, the absence from the Patent of any experimental data concerning the role or effect of IL-17A/F, let alone an anti-IL-17A/F antibody, in psoriasis.*
- ***Secondly,** the absence of any discussion of the role or effect of IL-17A/F in psoriasis.*
- ***Thirdly**, the limited support for IL-17A/A (let alone IL-17A/F) having a pathogenic role in psoriasis provided by the papers cited in the Patent, particularly given the common general knowledge as to all the other cytokines which were implicated in psoriasis.*
- ***Fourthly**, the fact that the Patent shows that IL-17A/F is an order of magnitude less potent than IL-17A/A.*
- ***Fifthly,** the fact that the specification claims efficacy against a broad list of conditions **which it is wholly implausible** that an anti-IL-17A/F antibody (or any form of IL- 17A/F therapy) would be effective against.*
- ***Moreover**, there is no emphasis on psoriasis in the specification. Such emphasis as there is concerns RA, which the skilled dermatologist would appreciate raised different considerations to psoriasis. In short, the claim of efficacy against psoriasis is speculative.*

.

Takeda v Roche [2019] EWHC 1911)- July 2019

- Judge BIRSS applied the UKSC in Lambert in asking whether the patent plausibly demonstrated a technical contribution to the art see e.g.:

- ***para. 203:*** *"In relation to each disclosure there are five questions to answer: Is it disclosed in the patent? Is it plausible? Is it true? Is it a technical advance? Does it support claims of the breadth they are?'*

- ***para 212:*** *[T]he contribution is limited to CHO cells. That does not support claims of the width of the relevant claims in this case, because they are product claims not limited to products made in CHO cells and because fucosylation is well known to depend on cell type.*

- **para 225: "***Figure 1 makes plausible the idea that the antibody tested reduces ADCC [i.e. antibody dependent cell death]. It also makes plausible the idea that the antibody exhibits no ADCC at the concentration (presumably) tested.* ***However it does not make plausible a wider proposition about the effect at higher concentrations since it simply does not address it.***

-

Further UK cases on inventive step and sufficiency

- *Merck v Shionogi* [2016] EWHC 2989 **(sufficiency)** in which it was held in paragraph 185 that plausibility in the context of inventive step is not limited to compound claims, but can also be raised in relation to claims including a functional limitation;
- *GSK v Wyeth* [2016] EWHC 1045 (Ch) **(inventive step and sufficiency);**
- *Accord v Medac* [2016] EWHC 24 (Pat) **(sufficiency)** in which it was held in paragraph 129 that the identity of the patentee (in that case found to be a well-respected pharmaceutical company) was not a factor which could be taken into account when considering the
- plausibility of the alleged technical contribution disclosed in the patent;
- *Eli Lilly v Janssen* [2013] EWHC 1737 **(sufficiency)**; and
- *Sandvik v Kennametal* [2011] EWHC 3311 (Pat) **(inventive step).**

2. Denmark

Denmark, no codified plausibility criterion, but implied by DPA/EPO case law

- **description** shall be sufficiently clear to enable a person skilled in the art to carry out the invention (**Section 8(2) of the Danish Patents Act**)

- **invention** must have technical character and solve a technical problem (**Administrative Order on Patents, Section 16(1)(2+3)).**

- **description** must explain the invention so that the technical problem and its solution can be understood **(Administrative Order on Patents, Section 18(1)(3**)), and
-
- **description** must be illustrated by means of examples or embodiments, so that claims are sufficiently supported **((Administrative Order on Patents, Section 18(1)(4))**.

- **assessment of inventive step:** only effects appearing from application as filed are considered, unless the new effects are related to or suggested by the application as filed **(Guidelines for Patents before the Danish Patent and Trademark Office)**.

- Only one Danish decision touching on the subject of plausibility seems to exist so far (Teva v. Mylan, preliminary injunction order, BS-38788/2018-SHR of 15 March 2019)

- However, heavy reliance on EPO case law and no additional relevant guidance.

Teva v. Mylan, Danish Maritime & Commercial High Court, Case BS-38788/2018-SHR, 15 March 2019

- Concerns infringement of patents DK/EP 2 949 335, DK/EP 2 630 962 and DK/EP 3 199 172, owned by Yeda and licensed by Teva (the "Patents").

- Directed to dosage regimen for treatment of relapsing forms of multiple sclerosis, including by injection of 40 mg glatiramer acetate 3 times a week with at least one day between every injection.

- Teva markets glatiramer acetate under the trademark Copaxone®.

- December 2017, Mylan obtained MA in DK for the follow-on medicinal product Copemyl 40mg/ml ("Copemyl"). Mylan registered a price for Copemyl in the Danish medicinal price register in February 2018, and subsequently won a public tender effective from 1 October 2018.

Mylan's arguments on the merits

- patents invalid due to lack of novelty, inventive step & for insufficiency.
- admitted that if the Patents were valid, sale etc. of Copemyl would infringe.
- primary argument for invalidity was that since **none of the Patents contain data** from clinical trials proving the technical effect of the invention, it was **not made plausible** at the priority date that technical problem was solved.
- Instead, PSA would in fact have **serious doubts** on the priority date about Teva's invention as a formerly suggested every-other-day-regimen had proven to cause greater side effects.
- Thus, Mylan argued that Teva could not make use of post-published evidence from after the priority date to show that the technical effect of the invention was indeed achieved.
- In addition, if PSA on the priority date would have found the inventions described in the Patent applications plausible, the Patents would be invalid for **lack of inventive step** because they did not contain any clinical data themselves.

TEVA' arguments

- There exists a legal **presumption of plausibility**.
- Patent applications contain well-outlined protocol for phase III-trial, which Teva had filed an FDA application for one day before priority date to prove the technical effect.
- Therefore, the PSA would **have found it plausible that the technical effect of the invention could work**. Hence, Teva **should be allowed to include post-published** evidence to document the technical effect of the invention.
- There is **no squeeze between plausibility for insufficiency and obviousness** since inventive step test must be carried out based on data available prior to priority date only, while the plausibility test also includes the information in patent application.

The decision- **15 March 2019**

- The Danish Maritime & Commercial High Court granted a preliminary injunction against the sale etc. of Copemyl in Denmark.

- **Court:** Since Patents were granted by the EPO, a presumption of validity exists, and no decisions from the EPO had weakened this presumption.

- Based on the extensive evidence produced during the proceedings, **including 5 deviating expert testimonies**, the Court concluded that there was not sufficient basis to overturn the presumption of validity and establish that the Patents were invalid.

- Accordingly, the Court concluded that Teva had rendered it probable that the Patents were valid and infringed by Mylan's sale etc. of Copemyl.

- **No interlocutory appeal** by Mylan of that particular decision, despite controversy.

- But a main action is pending, and the case has led to divergent decision in UK & Germany

Conclusions- Basic findings I

- **Unfortunately the Danish court did not elaborate further and simply relied on the EPO decision (the question is if that one was well founded on EPO Case Law)**

- **Results of the main action will be interesting to see in light of recent case developements at the EPO and in the UK**

- **BUT: Has the UKSC gone to far in the UK in heigtening the plausibility thresholds???**

- **After high water-mark a EPO in e.g. T 1329/04 – Factor-9/JOHN HOPKINS & T 870/04 – BDP1-Phosphatase/MAX-PLANCK EPO appeared to have reached a well balanced approach in e.g. T 898/05 – Hematopoeitic receptor/ZYMOGENETICS**

- **Performable sufficient if high quality and co-herent in silico evidence, but not performed required**

Conclusions- Basic findings

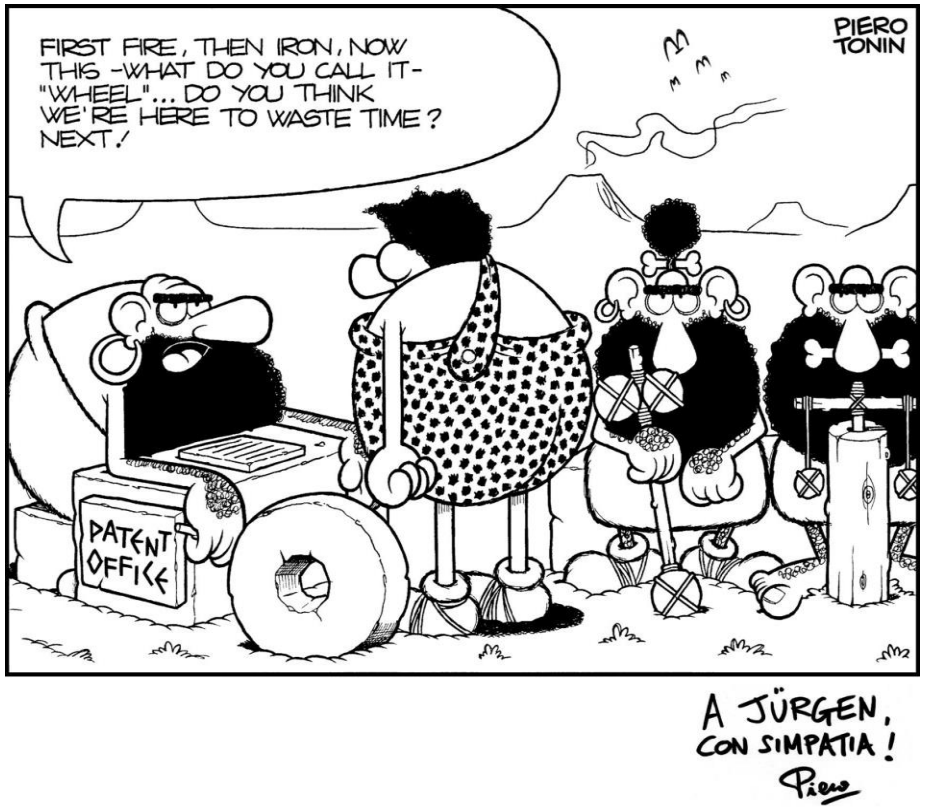
- **Problem is timing: How early and how broad should you file in the patent race?**
- **Breadth of the claims and the "sweet spot" of the supporting *in silico* or wet data must be considered very carefully**
- **The quality and availability of that data is improving rapidy so more problematic issue probably inventive step and old patents**
- **The problem is the uncertainty left by "case by case determinations", in particular for10-15 year old patents**
- **Squeeze between inventive step and sufficiency not clear**
- **Need of an Enlarged Board of Appeal decision? Article 112 criteria met?**

Robin Jacob (Former Lord Justice of Appeal of the Court of Appeal) at Fordham IP Conference 2019- Reported by IP Kat

'

"I am going to advance a proposition that the law has gone mad. An inventor tells you here is my invention, and he is right. He gives no details why it is going to work. Plausibility has got out of hand. Plausibility should only play a role when something is not plausible. We ought to be thinking very carefully about requiring clinical trials and evidence."

The 2019 AIPPI reports & resolution a much needed development to fuel and inform the debate



- Clear? Unambiguous?
- Credible? Plausible?
- Complete? Sufficient?

Retrieved from the presentation of Jürgen Meier, Vossius & Partner on Plausibility at the:

AIPPI 2017 Sydney World Congress
OCTOBER 13 - 17, 2017

Thank you! Questions or comments?

novo nordisk fonden

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REUMERT

Ulla Klinge

Plausibility – AIPPI Study Question and Resolution London 2019

Ulla Klinge
European Patent Attorney, partner, Inspicos P/S and PhD Fellow at KU

23rd January 2020

Agenda

- Study Question
- Summary Report
- Resolution AIPPI London September 2019

Study Question - Plausibility

- Basis for study
  - Lack of harmonisation
  - Significant economic impact, in particular in the life science/pharma sector
  - May create disincentive to early filing

Study Question – Previous work of AIPPI

- Q69 – sufficient description of the invention
- Q82 – Patent protection of biotechnological inventions
- Q142 – Breadth of claims, support by disclosure and scope of protection of patents
- Q150 – Patentability requirements and scope of protection of ESTs, SNPs and entire genomes
- Q180 – Content and relevance of industrial applicability and/or utility as requirements for patentability
- Q213 – The person skilled in the art in the context of the inventive step requirement in patent law

Study Question – position papers and panel sessions

- AIPPI 2017 Position Paper summarising the above resolutions
- Panel Session Sydney 2017 ”sufficiently plausible”
- Resolution Cancun 2018 – Use of post-filing data in support of inventive step/non-obviousness

Study Question - Scope

- A (further)patentability requirement?
  - General credibility of the invention
  - General prohibition of speculative filings
  - Specific restrictions re prophetic examples

NB: use of post-filing data not within scope of this Study Question

Summary Report

- 33 national reports
- Summary of policy considerations and proposals for improvement

Summary Report - highlights

- Availability of patent protection aims to incentivize early disclosure or of ”completed inventions”? – 65% BOTH
- Harmonisation of plausibility desirable? – 80% YES
- Should there be a plausibility requirement? – 45% YES, 55% NO

Summary Report - highlights

- Credibility depends on whether technical effect is claimed feature, e.g. second medical use
- Speculative filings – CN: experimental data to verify effect/use; NL: not full proof of effect at priority; UK: contribution commensurate with scope of patent

Summary Report - highlights

- Plausibility prohibition of prophetic examples? 70% NO – US: would create unnecessary barrier to timely filing; DK: patent not a hunting license – not sufficient to assert that technical problem is indeed solved
- Different plausibility tests for different types of claims? 70% NO

Resolution - background

- Plausibility a (further) patentability requirement?
  - Sufficient evidence/disclosure in the application that a technical effect can be achieved – as opposed to ”speculative applications”
  - Relevant in relation to sufficiency, clarity, utility, industrial applicability, use of post-filing data and novelty and inventive step
  - Relevant in chemical/pharmaceutical field, but also in relation to e.g. AI

Resolution

- No need for a stand-alone plausibility requirement
- If plausibility is to be examined (credibility of technical effect, prohibition of speculative patent, use of prophetic examples) one of many elements of already existing patentability and validity requirements

Resolution – credibility

- Low and narrowly understood threshold
  - Application contains (implicitly) explanation of why technical effect is obtained; or
  - Credible to PSA that effect may be obtained; or
  - PSA no serious doubt that effect works as described

  Effect claimed for patentability/validity must be credible

Resolution – speculative claims

- Patentability and validity requirements prohibit speculative claims
- Claim not speculative for mere reason that technical effect not explicitly mentioned

Plausibility – speculative claims

- Invention characterised by
  - structural features – technical effect/use not critical for plausibility
  - functional features – plausible that technical effect/use can be obtained

  Plausibility does not necessarily lead to lack of inventive step

Resolution – prophetic examples

- Plausibility considerations should not prohibit the presence of prophetic examples

Resolution – relevant date and burden of proof

- Plausibility should be evaluated as at the priority date
- If plausibility challenged wrt validity/patentability – burden of proof should be that of said requirement under consideration

Relevant links

- https://aippi.org/wp-content/uploads/2019/07/Study-Guidelines_Patents_Plausibility_22January20191.pdf
- https://aippi.org/wp-content/uploads/2019/08/SummaryReport_PATENTS_London2019_final_-160719.docx.pdf
- https://aippi.org/wp-content/uploads/2019/10/Resolution_Patents_Plausibility_English4.pdf

Questions/Discussion?

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