



Brinkhof

ADVOCATEN

Young EPLAW conference, Brussels, 28 April 2014 Plausibility

Plausible and True: twin brothers?

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Themes

The plausibility requirement

Plausibility for broad claims

Inventive step or sufficiency?

EU harmonization?

Burden of proof?

Conor / Angiotech (taxol stent)

Claim 12 claimed a stent for preventing or treating recurrent stenosis.

Description: "stents may be placed in a wide array of blood vessels, both arteries and veins, to prevent recurrent stenosis".



No data, test etc.

Conor / Angiotech

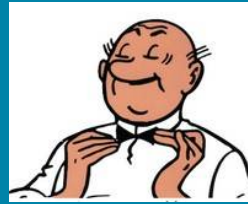
Sufficiently plausible?
T 1329/04 (John Hopkins)

Yes: no experimental data required

District Court The Hague, 17 January 2007 IEPT 20070117,
Court of Appeal 27 January 2009. Confirmed in
GSK/Pharmachemie (ondansetron) (Court of Appeal 2 November
2010, IEPT 20101102). Also: Eli Lilly/Ratiopharm (olanzapine),
Court of Appeal 27 September 2011, BIE 2011/13

Approvingly quoted in UK House of Lords
decision (see Andrew's presentation)

EU in line?



Not really!

Finasteride case (Merck/Mylan, District Court The Hague 24 April 2014, IEF 13782).

Patent for *androgenic alopecia* = baldness

Differs from French case (Teva/Merck, Tribunal de grande instance de Paris, 9 November 2010, see slides Dora).

NL: Example 5 makes invention plausible

Plausible

Conor / Angiotech & olanzapine:
'plausible' under inventive step.

Same reasoning in finasteride and ondansetron used for insufficiency.

Additional data important when plausibility effect is in doubt. Opponent must show "serious doubts, substantiated by verifiable facts" (e.g. T 19/90, T 890/02)

Does it work?

Second question: does it actually work?
(Finasteride, Mylan / Yeda, District Court The Hague 2
October 2013, IEF 13091)

Also here opponent must show “serious
doubts, substantiated by verifiable facts”

No improvement required, but important
for inventive step
(District Court The Hague, 2 October 2013,
IEPT20131002, Irbesartan).

Broad claims

A broad, functional claim. For example:
“antigen A that binds to receptor R”

Descriptions contains a few specific examples
of such antigens.

Plausible and working
over entire scope?



Broad claims

Does the specification make the effect plausible over the entire scope?

Concept fit for generalisation

T 435/91: a functional definition "is not sufficient if the patent discloses only isolated examples but fails to disclose (...) any technical concept fit for generalisation, which would enable the skilled person to achieve the envisaged result without undue difficulty (...)."

Insufficiency broad claims (1)

DSM / Novozymes (District Court The Hague 19 May 2010, IEPT20100519)

Patent invalid due to insufficient disclosure

Functional claim was considered a wish claim or a 'free beer' claim: something we all want!



More free beer!

Court: use claim for enzymes only contains functional features

Description does not disclose a technical concept fit for generalization

Skilled man is left in dark how to make the desired enzymes



Even more free beer!

Opponent not required to show non-working embodiments

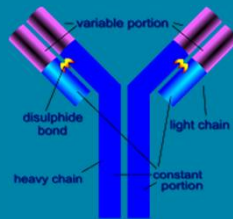
Court may have overlooked Slu/Lu ratio as concept for generalization?



Insufficiency broad claims (2)

Bayer/Abbott (adalimumab = Humira™)
District court of The Hague 20 October 2010;
IEPT20101020

Functional claim: antibodies that bind to TNF α
(a cell signaling protein) and capable of
achieving an inhibiting effect.



Bayer / Abbott (2)

Claim comprises high affinity monoclonal
antibodies that could not be made on priority
date without undue burden

Patent is insufficient

Court sees parallel with
T 1036/06 (Bayer) re
'reach through claims'.



Warns against functional claiming

Insufficient or not inventive?

Bayer patent contained technical effect in claim (binding to TNF α)

Non-working embodiments fall outside claim

No Agrevo (T 939/92) lack of inventive step?

Novozymes patent was a method claim without effect; Agrevo attack if embodiments do not work

Opponent must prove non-working embodiments

Concluding remarks

Patent must (1) make technical effect plausible and (2) deliver this effect.

Technical effect in claim > insufficient

Effect not in claim > Agrevo lack of inventive step

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beer!!**