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MÜNCHEN LONDON

# Reach Through Claims in Europe

Dr. Thorsten Bausch

# Trilateral Project B3B 2001 (EPO, JPO, USPTO)

A patent application describes

- A novel and inventive receptor of SEQ ID No. 1,
- The expression of the receptor in an animal cell and the usefulness of the receptor for the treatment of obesity.
- The pharmacological mechanism involved in the treatment of obesity by the activation of this receptor
- Methods of screening for compounds that activate this receptor.
- Three working examples of receptor agonists X, Y, Z that were identified using the disclosed screening procedure.
- Antibodies that recognize the receptor were not actually produced.

Are the following claims allowable?

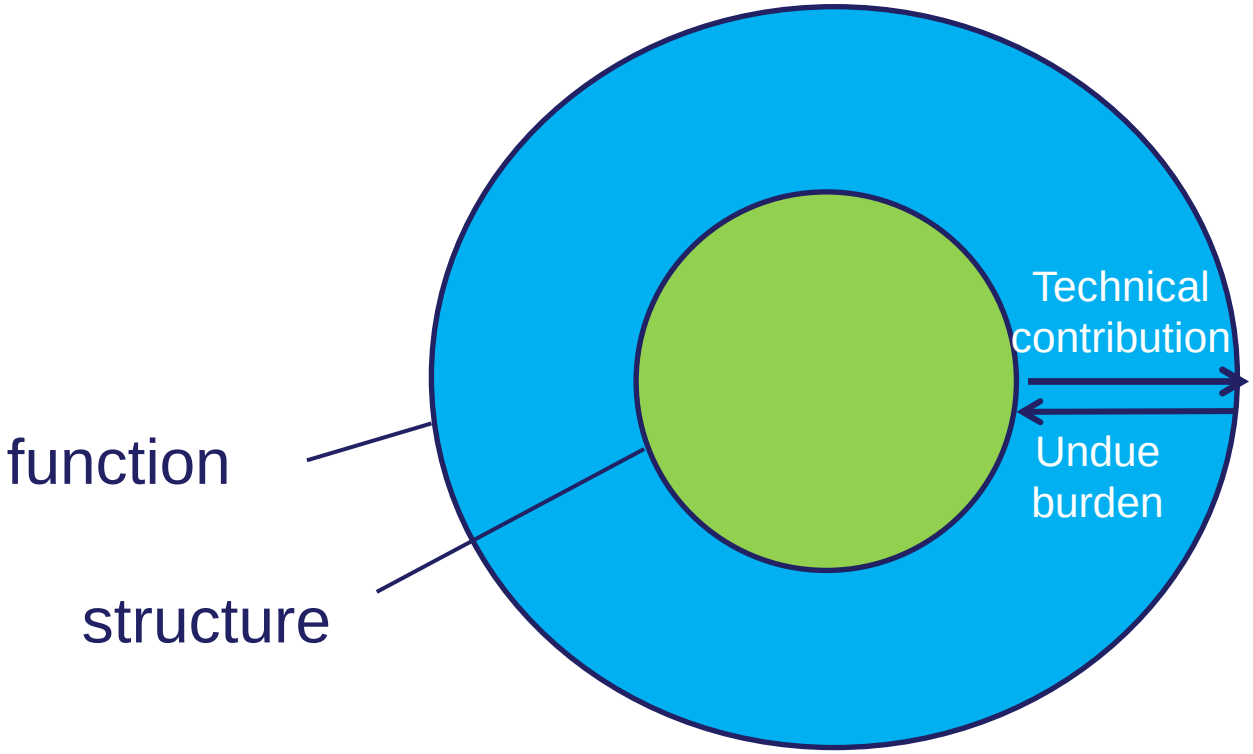
1. Receptor agonist, identified by the following screening method (...), for use in the treatment of obesity.
2. A monoclonal antibody that recognizes the receptor of SEQ ID No. 1.

# Trilateral Project B3B 2001 (EPO, JPO, USPTO)

*The three Offices concluded that except for compounds X, Y and Z, the general scope of claim 1 does not comply with enablement, support and/or written description requirement… In the absence of such a relationship the skilled artisan would not know how to make and use compounds that lack a structural definition. The fact that one could have assayed a compound of interest using the claimed assays does not overcome this defect since one would have no knowledge beforehand as to whether or not any given compound would fall within the scope of what is claimed. It would require undue experimentation (be an undue burden) to randomly screen undefined compounds for a claimed activity.*

*Claim 2 complies with enablement and/or support requirements since the person skilled in the art could obtain a monoclonal antibody specific to a given protein, using routine and well known methods, and use the antibodies in diagnostic methods.*

# T 68/85




Functional definition is permissible only if (i) no more precise definition of the invention is possible and (ii) feature can be reduced to practice without undue burden.

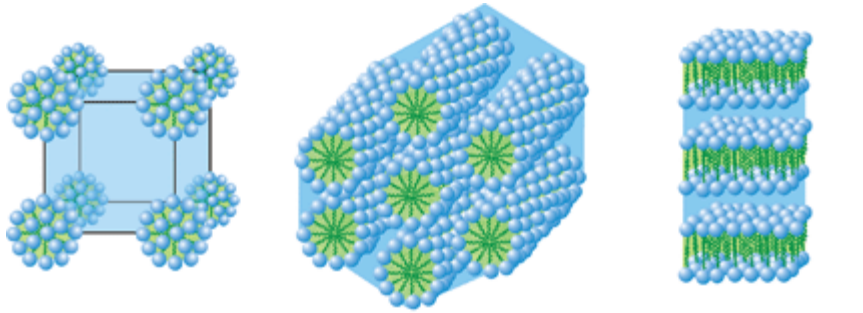
# T 435/91 - Detergents/Unilever

Claim

Detergent composition with an additive that is capable of forcing the surfactant system into the hexagonal phase

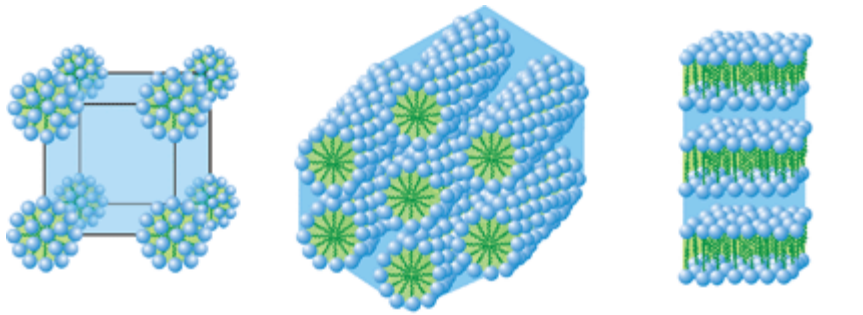
- It was possible to determine whether the surfactant is present in hexagonal phase.
- Specific examples were disclosed.
- However, the specification did not teach how to find other additives that fulfil this function.

➢ No sufficient disclosure



# T 435/91 - Detergents/Unilever - Headnote

The disclosure of an invention relating to a composition of matter, a component of which is defined by its function (in the present case an additive which forces a detergent composition into the hexagonal liquid crystal phase), is not sufficient if the patent discloses only isolated examples, but fails to disclose, taking into account, if necessary, the relevant common general knowledge, any technical concept fit for generalisation, which would enable the skilled person to achieve the envisaged result without undue difficulty within the whole ambit of the claim containing the "functional" definition



cubic phase $I_1$ hexagonal phase $H_1$ lamellar phase $L_\alpha$

# T 1063/06 (2009) - Reach-through claim/Bayer Schering

Claim

Use of compounds, which are capable of stimulating the soluble guanylate cyclase also independently of the heme group in the enzyme, to manufacture medicaments for the treatment of cardiovascular disorders.

- Novel (!) screening method disclosed.
- Specific examples disclosed.

➢ Sufficient disclosure?

# T 1063/06 (2009) - Reach-through claim/Bayer Schering

*The claim encompasses an indefinite and innumerable host of alternatives…In order to pick from that host the skilled person cannot draw on his common general knowledge to identify from the host of possible alternatives those suitable compounds which, along with the exemplified compounds, are also covered by the functional definition, because the application discloses that the invention is based on a „new mechanism of action". In selecting the compounds possessing the necessary capability, all he has to rely on is the information provided by the application. In the absence of any selection rule in the application, not even in the form of a structure-activity relationship on the basis of which he could identify from the outset suitable compound classes, the skilled person must resort to trial-and-error experimentation using the screening method. This represents undue burden.*

# T 1063/06 (2009) - Reach-through claim/Bayer Schering

The Board referred to 3 decisions:

- T 435/91 Detergents/Unilever
- T 216/96 PCR/Hoffmann La Roche
- T 1151/04 Dipeptidyl Peptidase IV Effectors/Prosidion

On T 216/96:

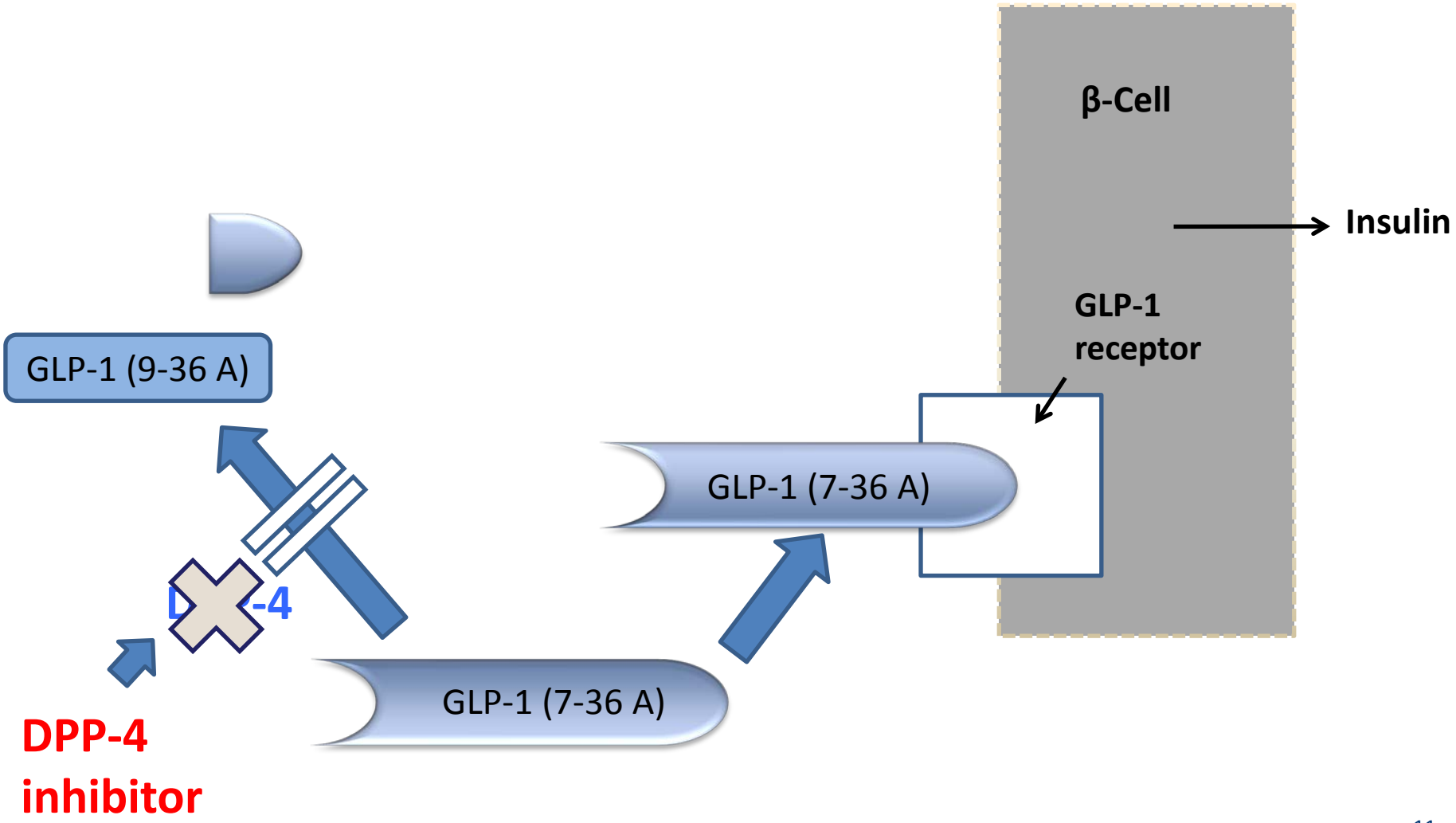
*The primers claimed in the cited decision do not constitute an innumerable host of alternatives from which the skilled person has to pick the suitable ones but rather a finite number, which have already been narrowed down to a single chemical family by reference to their function as primer, and are also defined by the nucleic acid sequence, which is to be determined, as being its complementary sequence in accordance with the lock-and-key principle. That is why the basis for the decision in T 216/96 is different…*

# T 1063/06 (2009) - Reach-through claim/Bayer Schering

***Intermediate conclusion**:*

- *Functional definition of compounds by means of its binding to a receptor lacks a sufficient disclosure if identification of further compounds requires undue experimentation.*
- *No undue experimentation if compounds can be prepared with routine methods (e.g. antibodies) or if there is a „selection rule" for these compounds.*
- *A selection rule can possibly be*
  - *a structure-activity relationship on the basis of which he could identify from the outset suitable compound classes, or*
  - *the indication of a specific compound class (e.g. nucleic acids) in combination with the functional definition.*

# T 1151/04 – Dipeptidyl Peptidase IV Effectors/Prosidion



# T 1151/04 – Dipeptidyl Peptidase IV Effectors/Prosidion

Claim

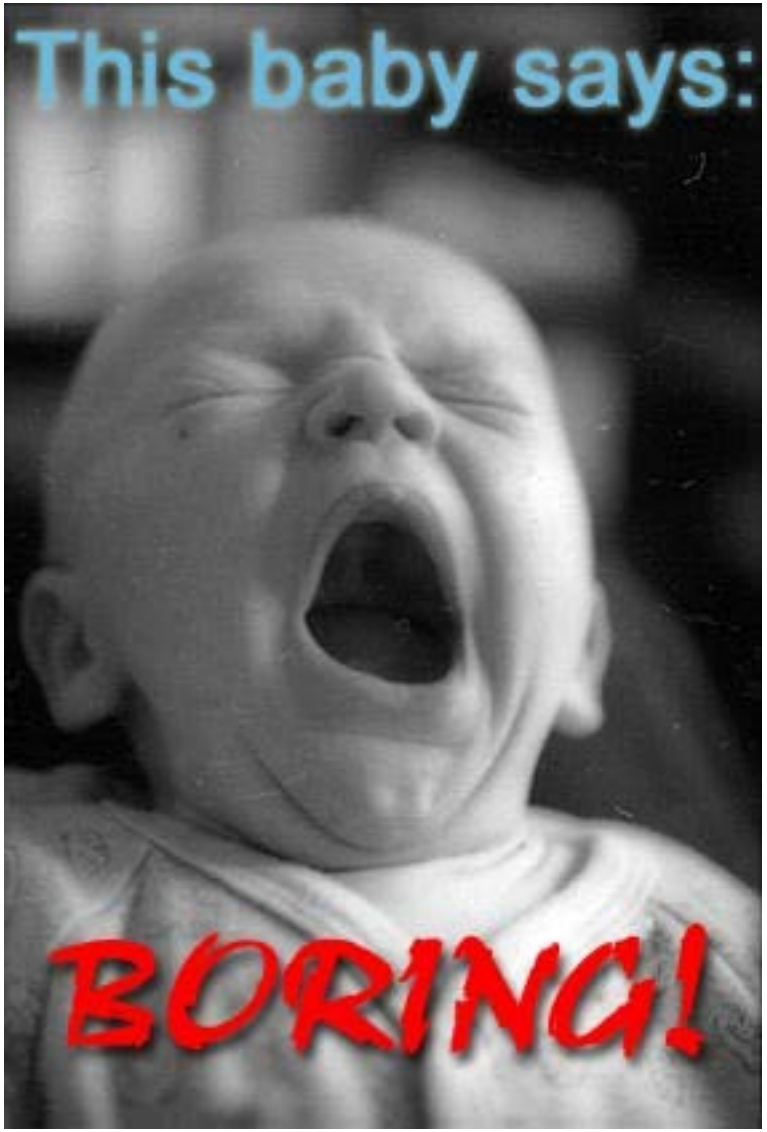
*Use of inhibitors of Dipeptidyl Peptidase IV enzyme activity for the manufacture of compounds for lowering the blood sugar level (simplified).*

Board

*For such (untested) compounds the skilled person is necessarily unaware of structural or other prerequisites regarding their characterization from his common general knowledge. Thus,* ***all conceivable*** *organic compounds and, as the case may be, e.g. as cofactors, even inorganic compounds can a priori exhibit the functional feature.*

**No sufficient disclosure because trial-and-error experimentation is necessary to find suitable inhibitors.**

# T 1151/04 – Dipeptidyl Peptidase IV Effectors/Prosidion



# But....

Patentee had not only an EP patent, but had still retained his German priority application!

This application also matured into a patent and was opposed.

Both the Patent Office (First Instance) and the Federal Patent Court (Second Instance) revoked the DE patent, essentially for the same reasons as the EPO Board of Appeal.

Patentee filed an appeal on a point of law with the Federal Court of Justice….


Patent Maintained

# Dipeptidyl Peptidase Inhibitors / Federal Court of Justice

## Federal Court of Justice (X ZB 8/12 – 11/9/2013)

*The facts underlying the appeal do not justify the assumption that the wording of the claim extends beyond what the skilled reader of the patent understand to be the most general form of the described technical teaching…*
*It is moreover to be assumed that a number of Dipeptidyl Peptidase inhibitors were already known at the filing date, even though these were exclusively used for other purposes. The way in which the skilled person could determine whether such an inhibitor is suitable for the proposed use is described in the patent. It can thus not be ascertained that the required experiments would amount to an undue burden.*

The Court thus disagreed with both the EPO‘s Board of Appeal and the Federal Patent Court!

# Dipeptidyl Peptidase Inhibitors / Federal Court of Justice

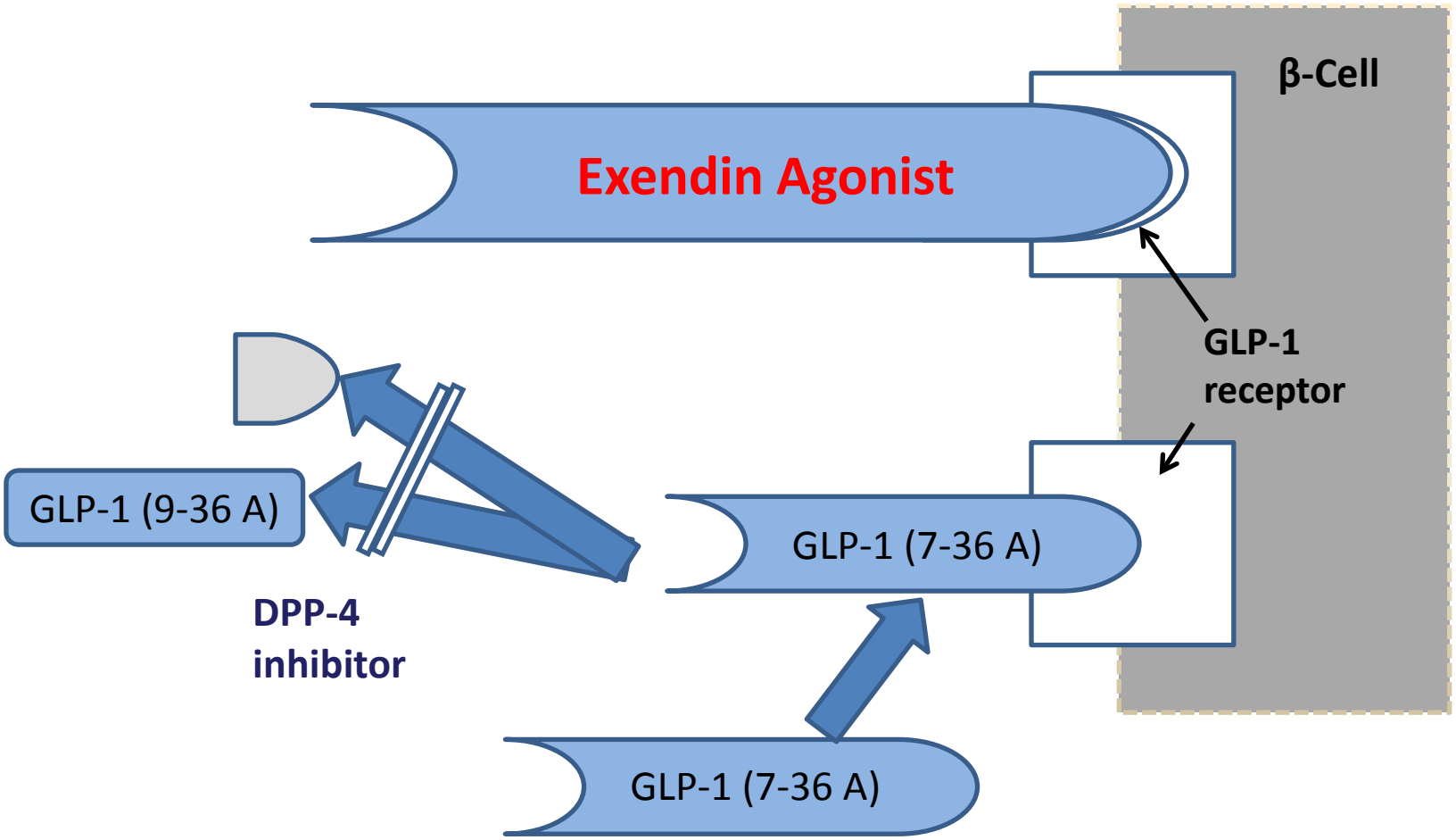
## Court Headnotes (X ZB 8/12)

a) The applicant is not obliged to limit the protective scope to explicitly described embodiments, but may make certain generalisations to cover the entire invention.

b) Whether a claim containing generalisations is enabled depends on whether the protective scope extends beyond that which the skilled person, considering the description and the working examples, would have viewed as the most general teaching solving the underlying problem.

c) Functionally describing a group of compounds is not precluded by the fact that such wording encompasses not only compounds already known in the art or disclosed in the specification, but also compounds that may be provided in the future; even if their provision requires inventive activity.

# Sanofi-Aventis vs. Amylin – DE and NL



# Sanofi-Aventis vs. Amylin – DE and NL

Claim:

*Use of a pharmaceutical composition which is a dosage unit form, adapted for peripheral injection suitable to deliver from 10 µg to 100 µg per day of an exendin or exendin agonist which is an exendin peptide compound in a single or divided doses comprising a pH buffering agent wherein the pH of the composition is from 3.5 to 5.0 for the manufacture of a medicament for the therapeutic reduction of body weight in a human or animal subject.*

Nullity plaintiff: Broad, functional definition, hence insufficient disclosure.

Yet both the German Federal Patent Court and the Dutch District Court of The Hague maintained the patent with this claim!

# Sanofi-Aventis vs. Amylin – DE and NL

## Federal Patent Court - 3 Ni 24/12 (EP)

*In connection with this substance group the patent in suit not only contains comprehensive explanations on the structural features of compounds comprised by this definition, but also a large number of examples for their preparation (p. 13, Ex. 5 to p. 82, Ex. 190). The skilled person is, based on these indications, put in a position to readily obtain exendin agonists that are exendin peptide compounds, and to check, using orientating experiments as described in the patent, to which extent the aimed activity can be achieved. (…) If an inter alia functionally defined group of substances – here: exendin agonist that is an exendin peptide compound – comprises, in addition to compounds that are known or described in the patent, also substances that first have to be prepared in the future, this does not stand in the way of enablement, nor that their provision may require inventive activity (FCJ Dipeptidyl-Peptidase-Inhibitors)*

*To the extent that plaintiff denies enablement under the aspect of an inappropriate claim breadth, this does not constitutes a nullity ground (FCJ Blasenfreie Gummibahn I X ZR 7/00).*

# The 3 Scenarios in EP / DE: Enablement?

| | EP | DE |
|---|---|---|
| Scenario 1<br>No inhibitors known or disclosed<br>No SAR | NO | Undecided |
| Scenario 2<br>Four inhibitors known / disclosed | NO | YES |
| Scenario 3<br>Inhibitors well known, but for different use | YES | YES |

# Consequences

So will we see a renaissance of national biotech patents in Europe?

**Future will tell....**

**tbausch@hoffmanneitle.com**