Teva and Art. 3 a)
A never ending Story?

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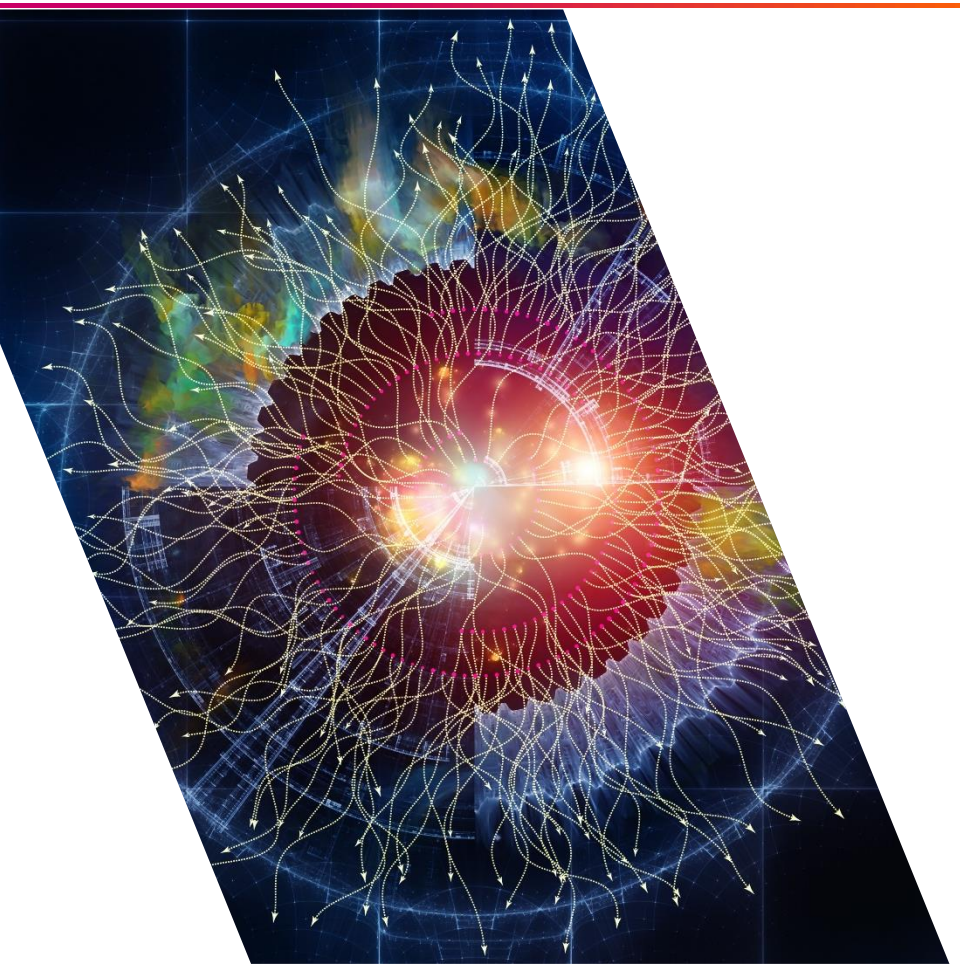
Once upon a time, there was Article 3 a)

Art. 3 a)



A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application: (a) **the product is protected by a basic patent in force**;

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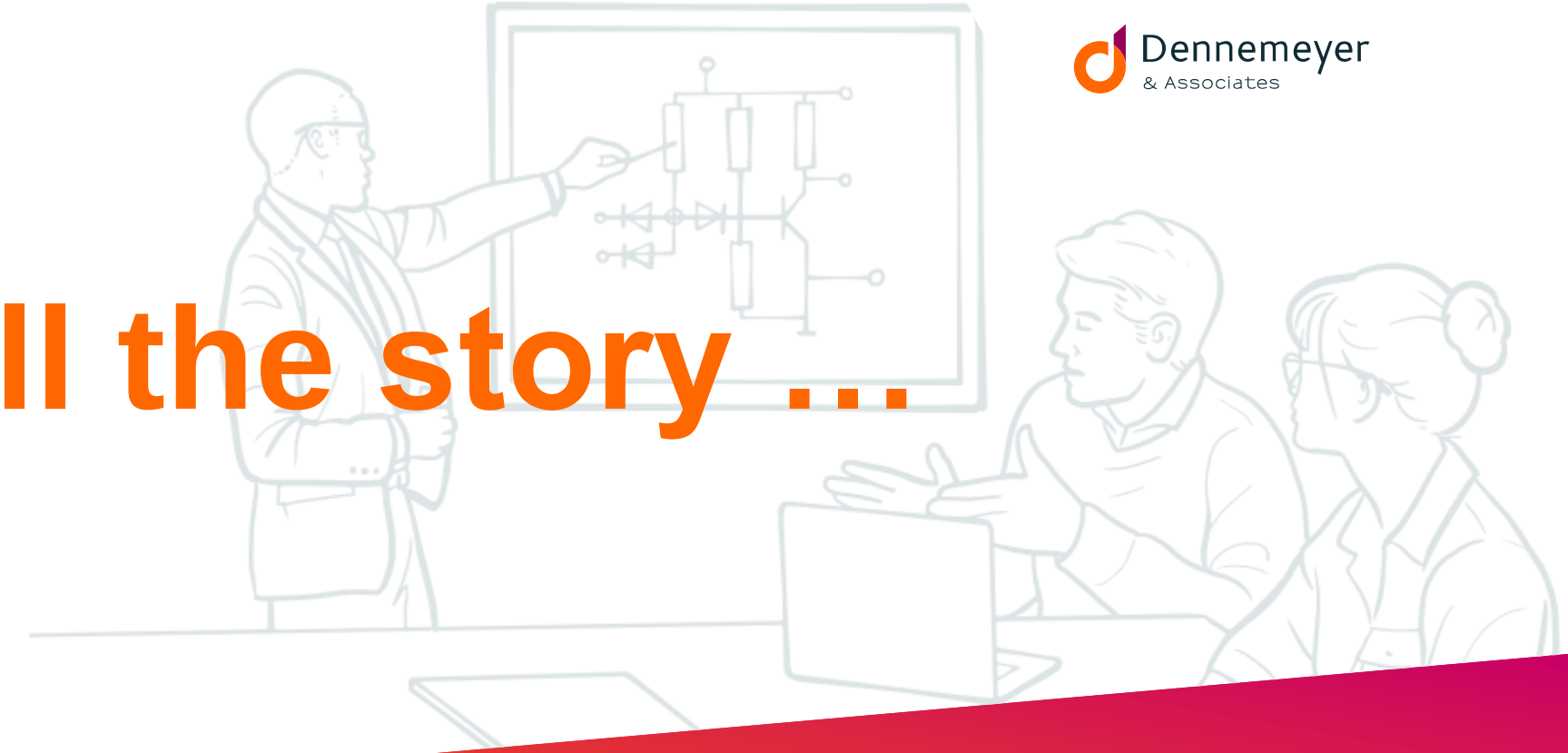
Let us tell the story …



- Medeva (C-322/10)
- Eli Lilly (C-493/12)
- Actavis I (C-443/12)
- Teva (C-121/17)

- QH (C-650/17) - pending
- Sandoz (C-114/18) - pending

Medeva (C-322/10)

- Pat.: A + B
- MA: A + B + C

- SPC: A + B + C?
- SPC: A + B?

Medeva (C-322/10)

Decision of the ECJ:

A competent industrial property office of a Member State is prohibited from granting an SPC relating to active ingredients which are **not specified** in the wording of the claims**.**

Article 3(b) does not preclude the competent industrial property office of a Member State from granting an SPC for a combination of two active ingredients, where the medicinal product for which the marketing authorisation is submitted in support of the application for an SPC contains not only that combination of the two active ingredients **but also other active ingredients.**

Medeva (C-322/10)

- Pat.: A + B
- MA: A + B + C

- SPC: A + B + C? No
- SPC: A + B? Yes

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What means „specified “?

Eli Lilly (C-493/12)

The patentee filed reach-through claims, claiming an antibody, binding to a full length Neutrokine-α polypeptide.

The competitor developed such an antibody, which realized the definition of the claims, and gained a marketing authorization for this antibody.

The patentee gained an SPC based on its own patent and the marketing authorisation of the competitor.

Eli Lilly (C-493/12)

Questions to the ECJ:

(1) What are the criteria for deciding whether “the product is protected by a basic patent in force” in Article 3(a) of Regulation [No 469/2009]?

(2) Are the criteria different where the product is not a combination product, and if so, what are the criteria?

(3) In the case of a claim to an antibody or a class of antibodies, is it sufficient that the antibody or antibodies are defined in terms of their binding characteristics to a target protein, or is it necessary to provide a structural definition for the antibody or antibodies, and if so, how much?’

Eli Lilly (C-493/12)

Decision of the ECJ

Article 3(a) … must be interpreted as meaning that, in order for an active ingredient to be regarded as ‘protected by a basic patent in force’ within the meaning of that provision, **it is not necessary** for the active ingredient to be identified in the claims of the patent **by a structural formula.**

Where the active ingredient is covered by a **functional formula** in the claims of a patent …, Article 3(a) of that regulation **does not, in principle, preclude the grant of an SPC** for that active ingredient, on condition that it is possible to reach the conclusion on the basis of those claims, interpreted inter alia in the light of the description of the invention, as required by Article 69 of the Convention on the Grant of European Patents and the Protocol on the interpretation of that provision**, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question,** which is a matter to be determined by the referring court**.**

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What means „Implicitly but Necessarily“?

Actavis I (C-443/12)

- Pat.: A, A + (B)
- MA: A ; MA: A + B

- SPC 1: A
- SPC 2: A + B ?

Actavis I (C-443/12)

Claims 1 to 7 of the basic patent are based on solely irbesartan or one of its salts.

Claim 20 of the patent relates to a pharmaceutical composition containing irbesartan in association with a diuretic.

However, no specific diuretic is named in claim 20 nor in the description of the basic patent.

Actavis I (C-443/12)

Questions to the ECJ:

(1) What are the criteria for deciding whether “the product is protected by a basic patent in force” in Article 3(a) of … Regulation No 469/2009?

(2) In a situation in which multiple products are protected by a basic patent in force, does Regulation [No 469/2009], and in particular Article 3(c), preclude the proprietor of the patent being issued a certificate for each of the products protected?’

Actavis I (C-443/12)

Decision of the ECJ:

I

n circumstances …, where, …, the holder of that patent has **already obtained an SPC for that active ingredient** entitling him to oppose the use of that active ingredient, either alone or in combination with other active ingredients, Article 3(c) … **must be interpreted as precluding** that patent holder from obtaining – on the basis of **that same patent but a subsequent marketing authorization** for a different medicinal product containing that active ingredient in conjunction with another active ingredient which is not protected as such by the patent – **a second SPC relating to that combination of active ingredients.**

Actavis I (C-443/12)

Reasoning of the ECJ:

The basic objective of Regulation No 469/2009 is to compensate for the delay to the marketing of what constitutes the **core inventive advance**, namely, in the main proceedings, **irbesartan**.

If it were accepted that all subsequent marketing of that active ingredient in conjunction with an unlimited number of other active ingredients **conferred entitlement to multiple SPCs**, that would be contrary to the requirement to balance the interests of the pharmaceutical industry and those of public health.

The second SPC would be admissible, if it concerned **a totally separate invention.**

Actavis I (C-443/12)

- Pat.: A, A + (B)
- MA: A
- MA: A + B

- SPC 1: A
- SPC 2: A + B ? No

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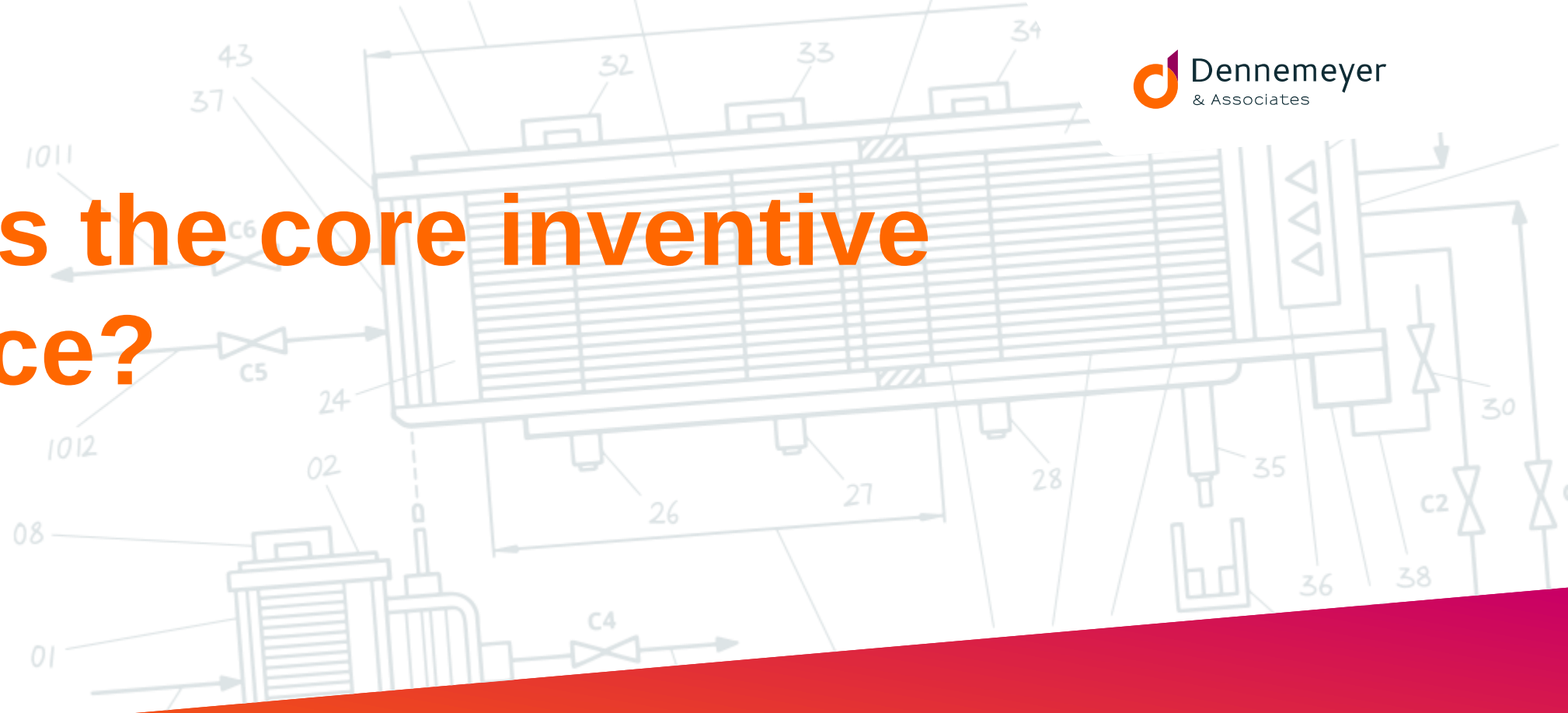
What is the core inventive advance?



Teva (C-121/17)

Gilead markets an antiretroviral medicinal product indicated for the treatment of persons infected with HIV, comprising tenofovir disoproxil (‘TD’) and emtricitabine (‘EC). Gilead was granted a marketing authorization by the EMA.

Claim 27 of the basic patent claims: ‘A pharmaceutical composition comprising TD together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients.’

Gilead obtained an SPC for the combination of TD and EC.

Teva (C-121/17)

Questions to the ECJ:

What are the criteria for deciding whether “the product is protected by a basic patent in force” in Article 3(a) of Regulation No 469/2009?

Teva (C-121/17)

Decision of the ECJ:

Article 3(a) must be interpreted as meaning that a product composed of several active ingredients with a combined effect is ‘protected by a basic patent in force’ within the meaning of that provision where, even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, those claims relate necessarily and specifically to that combination.

For that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:

- the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and
- each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent.

Teva (C-121/17)

Reasoning of the ECJ:

A product is ‘protected by a basic patent in force’ in so far as, if that product is not expressly mentioned in the claims of the basic patent, one of those claims relates to it necessarily and specifically.

For that purpose, that product must, from the point of view of a person skilled in the art and in the light of the description and drawings of the basic patent, necessarily fall under the invention covered by that patent.

The person skilled in the art must be able to identify that product specifically in the light of all the information disclosed by that patent, on the basis of the prior art at the filing date or priority date of the patent concerned.

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This is not the End …

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The Story still continues …

QH (C-650/17) – pending

Is a product protected by a basic patent in force pursuant to Article 3(a) of Regulation (EC) No 469/2009 only if it forms part of the subject matter of protection defined by the claims and **is thus provided** to the expert as a **specific embodiment**?

Is it not therefore sufficient for the requirements of Article 3(a) of Regulation (EC) No 469/2009 if the product in question satisfies the general functional definition of a class of active ingredients in the claims, **but is not otherwise indicated in individualised form** as a specific embodiment of the method protected by the basic patent?

Is a product not protected by a basic patent in force under Article 3(a) of Regulation (EC) No 469/2009 if it is **covered by the functional definition** in the claims, but was **developed only after the filing date of the basic patent** as a result of an independent inventive step?

Sandoz (C-114/18) – pending

Where the sole active ingredient the subject of a supplementary protection certificate issued under [the SPC Regulation] is **a member of a class of compounds which fall within a Markush definition** in a claim of the patent, all of which class members embody the core inventive technical advance of the patent, is it sufficient for the purposes of Article 3(a) of the SPC Regulation that the compound would, upon examination of its structure, immediately be recognised as one which falls within the class (and therefore would be protected by the patent as a matter of national patent law) **or must the specific substituents necessary to form the active ingredient be amongst those which the skilled person could derive**, based on their common general knowledge, from a reading of the patent claims?

Questions? Please ask.

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