de Rechtspraak

Rechtbank
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Aftermath of Medeva

Rian Kalden

Senior Judge

District Court
The Hague

Medeva test on art 3(a) ‘protected by a basic patent’

- **Infringement test rejected**
- **What does ‘*specified / identified in the wording of the claim*’ mean?**

UK
Novartis v MedImmune 10-2-12

- **Test is unclear, save in its rejection of the infringement test**
  - **Is it sufficient to fall within scope of the claim?**
  - **Is it sufficient if it is covered by Markush formula?**
  - **Is it sufficient if it is defined in functional terms?**
- **Inevitable that there will be further references**
- **Active ingredient within broad class claimed but nothing to *identify specifically* this active ingredient as the product of the process in question**

UK
CoA Medeva 3-5-12

- **"specified" can mean anything between expressly naming, actually describing, effectively implying something, or being the result of a reasonable construction of the claims.**

- **The infringement test having been rejected, Medeva's SPC applications could not be granted wherever the line should be drawn.**

NL
CoA Lundbeck v Generics 24-1-12

- **Claim mentioned non-toxic acid addition salts of escitalopram**
- **Active ingredient escitalopram oxalate was not explicitly mentioned in the claims, but was held to be "obviously part of the subject matter of the patent" as the skilled person would -on the basis of the description in which this active ingredient was mentioned- understand it was meant to be covered by the claim**
- **Claim language provided sufficient "specification" to support an SPC**

NL
DC TH Sanofi v Teva 14-9-12

- SPC for irbesartan (expired) based on claim 1
- SPC for irbesartan + HCTZ (in force) based on claim 7 for irbesartan combined with a diuretic
- HCTZ not specifically mentioned in claims or description
- Combination SPC valid (art 3(a) complied with)?
- Yes, by the standard of the CoA in Lundbeck:
  - **skilled man would immediately think of HCTZ when reading 'a diuretic', so the combination is part of the subject matter of the claim**
    - **Claim interpretation takes into account description and drawings *and* cgk of skilled person at priority date**

DE
Sanofi v Actavis 15-8-12

- **Same result, similar reasoning**
- **Requiring too high a level of specificity is impracticable and undesirable**
- **Sufficient to use more generic terms as long as the skilled person upon reading of a claim understands the specific compound was meant to be included**
- **Skilled person would understand a diuretic to (at least also) include HCTZ**

FR
Sanofi cases

- **Tribunal de Grande Instance Paris 10-8-2012:**
  - **Term diuretic not precise enough to cover HCTZ**
- **Tribunal de Grande Instance Paris 3-10-2012 (but other judge)**
  - **HCTZ sufficiently identified by ‘a diuretic’.**

UK
Actavis v Sanofi 20-9-12

- **Case on the merits, another reference to CJEU (pending as case C-443/12):**
  - **What are the criteria for deciding whether 'the product is protected by a basic patent in force' in article 3(a) of the Regulation?**

- **Suggested answer by mr Justice Arnold:**
  - **A combination product only qualifies for SPC if the *combination* (not merely one ingredient) embodies the 'inventive advance' of the patent**

Arnold J suggested combination product test

- **Advantage:**
  - **wording of the claim (which could be manipulated) not decisive**
  - **in line with object of Regulation to provide adequate protection for *inventions***
- **Disadvantage:**
  - **Complicated exercise to determine inventive advance (it is generally assumed the infringement test was rejected because it was considered to be too complicated)**
  - **Regulation must be applied uniformly by patent offices so simple test is required**

Dutch approach

- **Argument: Irbesartan + HCTZ not inventive over irbesartan alone, so no separate SPC merited**
- **No separate requisite (nor nullification ground) that SPC must be in conformity with aim and purpose of the Regulation (i.e. no requisite that the product must be inventive)**
- **Combination irbesartan + HCTZ is another product than irbesartan by the definition of the Regulation, so no reason to assume SPC will be nullified**
- **It must be accepted that use of definitions always leads to borderline cases**

Further reference (C-493/12) Eli Lilly v HGS 10-10-12

(1) same as in Actavis v Sanofi

(2) Are the criteria different where the product is *not* a combination product

(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?

Danish Patent Office guidelines on Medeva test

- **The product passes the test if**
  - **described by a chemical name or a structural formula, i.e. specifically mentioned or being comprised by a Markush formula**
  - **the product is specified by functional terms**
  - **the basic patent in an administrative re-examination could be limited so that the combination of the active ingredients remains in the wording of the claims of the basic patent**

Further uncertainty after Medeva: only one SPC per patent?

- in Medeva CJEU (referring to Biogen) said that
  - **'in a situation such as in the main proceedings (…) where the patent protects a product, in accordance with article 3(c) of the Regulation, only one certificate may be granted for that basic patent.'**
- UK patent office:
  - **Practice that more than one SPC is allowable per patent *provided* that each SPC is directed towards a different active ingredient is not amended**
- Dutch patent office:
  - **Medeva means: only one SPC per patent**

NL
Georgetown v Patent Office 12-10-12

- **Not clear that CJEU really meant one SPC per patent**
- **Such rule could be circumvented by filing several (divisional) patents**
- **Question referred (pending as case C-484/12):**

  - **In the situation that a basic patent in force protects several products, does regulation 469/2009 […], more specifically article 3 (c) preclude the grant of a certificate for each of the protected products to the holder of the basic patent?**

NL
Sanofi v Teva

- **In preliminary injunction proceedings:**
  - **up to Medeva, Biogen, was widely interpreted to mean that one SPC *per product* per patent could be granted**
  - **This rule should still be applied (awaiting the CJEU's answers)**
  - **If the CJEU had meant to deviate from this, it would have done so explicitly**

DE
Sanofi v Actavis

- One SPC per patent rule rejected
- Similar reasoning as in NL p.i. judgment

  - **Argument that only inventive combinations would warrant SPC next to mono SPC rejected**
    - **not supported by the Regulation**
    - **It cannot be inferred from the Regulation, in particular article 14, that a different approach should be taken towards a combination product which is protected by a separate patent on the one hand and a combination product covered by a sub-claim on the other hand.**

UK
Actavis v Sanofi

- **Reference to CJEU, similar question as in NL Georgetown**
- **If Arnold J's suggestion on article 3(a) is followed, the answer follows from it**
- **It cannot be assumed that CJEU did not intend to change the law because it had not said so explicitly, pointing at the Neurim ruling after the earlier Pharmacia and Yissum decisions.**

Thank you for listening