SPCs
Recent Developments

Young EPLAW Congress

15.04.2019

Manuel Wegrostek

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Selected Topics

- Teva v. Gilead (ECJ 25.07.2018, C-121/17)
  - What are the criteria whether „the product is protected by the basic patent“?
- Abraxis (ECJ 21.02.2019, C-443/17)
  - What if product is a new formulation of an old active ingredient?
- Manufacturing Waiver
  - Draft legislation allowing manufacture of generic and biosimilar medicines during SPC period

Introduction

- What are SPCs?
  - Supplementary Protection Certificate
  - Sui generis IP rights
  - Effectively extending certain exclusive rights granted under a patent beyond the patent's term
  - Intended to protect pharmaceutical research
  - To compensate patent holders for loss caused by the delay between start of patent term and time it takes to obtain marketing authorisation by providing an additional period of exclusivity

Introduction

- Legal Basis
  - Previous Regulations now codified in Regulation (EC) No 469/2009 of 6 May 2009
  - SPCs applied for nationally
  - Regulation intended to harmonise of SPC law throughout EU
  - Regulation 1901/2006 for paediatric extensions (+6 months)

Introduction

- Issues centred around **Art 3 of Regulation (EC) No 469/2009**:

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; [→ Teva v. Gilead]

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;

(c) the product has not already been the subject of a certificate;

(d) the authorisation referred to in point (b) is the **first authorisation to place the product on the market** as a medicinal product. [→ Abraxis]

Introduction

Regulation (EC) No 469/2009

Art 1 - Definitions

- “basic patent” = not just compound patent, also process patents
- “product” means the active ingredient or combination of active ingredients of a medicinal product

Introduction

Important provisions of SPC Regulation

Article 4 – Subject matter of protection

- *(...) the protection conferred by a certificate shall* ***extend only to the product covered by the authorisation*** *to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.*

Introduction

Important provisions of SPC Regulation

Article 5 – Effects of the certificate

- *Subject to the provisions of Article 4, the certificate shall* ***confer the same rights as conferred by the basic patent*** *and shall be subject to the same limitations and the same obligations.*

Teva v. Gilead

- Starting position:
- When is a product protected by a basic patent as required by Art 3(a)?
- "protected" interpreted in different ways by courts and patent offices around Europe
- Same standard as infringement of patent?
  - Art 69 EPC?

Teva v. Gilead

- Starting position:
- Medeva – CJEU 24.11.2011, C-322/10
  - *"Article 3(a) (...) must be interpreted as precluding the competent (IPO) of a Member State from granting a (SPC) relating to active ingredients* ***which are not specified in the wording of the claims of the basic patent*** *(...)."*
  - *"(...) does not preclude the competent (IPO) of a Member State from granting a (SPC)* ***for a combination of two active ingredients****, corresponding to that specified in the wording of the claims of the basic patent (...) where the medicinal product for which the (MA) is submitted in support (...)* ***contains not only that combination of the two active ingredients but also other active ingredients****."*

Teva v. Gilead

- Starting position:
- Medeva – C-322/10
  - Patent for combination of A+B
  - MA for A+B+C+D
  - → SPC for A+B possible
  - As long as active ingredients are **specified in the wording of the claims** of the patent

Teva v. Gilead

- Starting position – post Medeva confusion:
- Actavis – C-443/12
  - "**core inventive advance**" that is the subject of the basic patent
  - But it was a decision on Art 3 (c)
- Eli Lilly – C-493/12
  - Active ingredient must not be identified in the claims by a **structural formula**, may also be considered to be protected where it is covered by a **functional formula**
  - as long as claims relate, **implicitly but necessarily and specifically**, to the active ingredient in question
- Actavis – C-577/13
  - That active ingredient [had to] **constitute the subject matter of the invention**

Teva v. Gilead

- Gilead's SPC for Truvada®
  - a combination of tenofovir disoproxil and emtricitabine
  - SPC granted – Teva seeking invalidation
- Patent EP 915894
  - Describes and claims tenofovir
  - Broad composition claim: "a pharmaceutical composition comprising a compound [acc. to] claims 1-25 and optionally **other therapeutic ingredients**"
- Emtricitabine
  - Not mentioned in patent
  - Not known at priority date

Teva v. Gilead

- Referral by UK High Court
- Justice Arnold considered guidance from Medeva, Actavis v. Sanofi and Lilly insufficient
- Criteria for application of Article 3(a) for combination products?

CJEU:

- Active ingredients do not need to be expressly mentioned in the claims to be ”protected”… BUT

Teva v. Gilead

Ruling pt I:

"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' (…) 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.**" [as in Eli Lilly]

Teva v. Gilead

Ruling pt II:

"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 v. Gilead

- CJEU did not follow Justice Arnold:
  - Only if product embodies the "inventive advance"
- CJEU did not follow AG:
  - Only if "obvious" to POSA
- CJEU did not follow Gilead's argument that Art 69 EPC should be sufficient

→ Case referred back to UK Court

Teva v. Gilead

Take-aways

- Infringement of claim of basic patent alone is never enough
  - But required to fall under extent of protection under (Art 69 EPC)
- In addition, must fall under the invention
  - Assessment by skilled person
  - Problem-solution analysis
- Active ingredients specifically identifiable
- No protection beyond invention covered by the patent!
  - Claims including broad language (e.g. “comprising [unspecified…]”) likely to fail

Abraxis

- Starting position:
- When is the MA **the first MA** to place the product on the market, as required by Art 3(d)?
- Neurim – C-130/11
  - *mere existence of an earlier MA obtained for a veterinary medicinal product does not preclude the grant of a SPC for a different MA of the same product*
  - *provided that the application is within the limits of the protection conferred by the basic patent*

Abraxis

- Abraxane
  - medicinal product by Abraxis, indicated for the treatment of certain cancers
  - contains a substance called ‘nab-paclitaxel’, a combination of nanoparticles of paclitaxel coated with albumin
  - more efficient than earlier formulations of paclitaxel
  - protected by EP 0 961 612
  - Prior MA grant for Abraxane, paclitaxel was marketed in another form by other companies under previous MAs

Abraxis

- UK Comptroller General of Patents turned down application:
  - although a new and inventive **therapeutic use** of an old active ingredient permitted
  - does not extend to a new and inventive **formulation**

High Court of Justice referral:

- Is Article 3(d) to be interpreted as permitting the grant of an SPC where the MA (…) is the first MA within the scope of the basic patent to place the product on the market (…) and where the product is **a new formulation of an old active ingredient**?

Abraxis

- Abraxis argument:
  - MA for Abraxane was the first within the scope of the basic patent – [but not the first for paclitaxel]
  - Under *Neurim*, a later MA could be considered the 'first MA' within the meaning of Article 3(d), because the application in the later MA is the first to be within the scope of protection of the basic patent being relied on for the SPC

Abraxis

- CJEU:
  - First, look at definition of "product" under Article 1(b):
    - Remember definition of "product": active ingredient or combination of active ingredients of a medicinal product
    - Should a new formulation of an old active ingredient be regarded as a product **distinct** from the product consisting solely of the same active ingredient?

Abraxis

- CJEU:
  - No definition of “active ingredient”
    - as used in pharmacology → does not include substances forming part of a medicinal product which do not have an effect of their own
  - Substance which does not have any therapeutic effect of its own is not covered by the concept of ‘active ingredient’
  - Present case: Albumin acts as a carrier – no therapeutic effect

  → New formulation is **not** a distinct “product”

Abraxis

- CJEU continues:
  - Since it is the same "product", the "**first authorisation**" (=MA) in the terms of Article 3(d), a subsequent MA cannot be the first
  - Must be the first MA for a medicinal product incorporating the active ingredient or the combination of active ingredient at issue

→ MA granted for nab-paclitaxel **cannot be the first MA** granted for that product, regardless of it being the first under the basic patent

Abraxis

- CJEU on Neurim:
  - Neurim not overturned
  - The ‘exception of a narrow interpretation of Article 3(d) does not apply to cases of a new formulation of the product at issue
  - Neurim may turn out to be a limited exception, possibly only applying in situations where the previous use of the active substance was a veterinary use, followed by human use

Abraxis

- Open questions post Abraxis:
  - Second medical use? (see Santen – C-673/18)
    - Question on the concept of “different application” expressed in Neurim – limited to veterinary followed by human use?
  - New and inventive dosage regime?

Manufacturing Waiver

- 14.02.2019 Draft regulation on introducing an exception to the protection granted by a SPC for export purposes and/or for stockpiling
- 20.2.2019 agreed by Council of the EU
- Aim to “remove the competitive disadvantages faced by EU-based manufacturers (…) vis-à-vis manufacturers established outside the EU in global markets”

Manufacturing Waiver

- New rules would allow, under certain circumstances:
  - (**anytime**) manufacture of generics or biosimilars exclusively for the purpose of **export** to countries where there is no protection (expired or never existed)
  - (during the **last six months of an SPC**) manufacture of generics or biosimilars exclusively for the purpose of **stockpiling** for later sale within MS

Manufacturing Waiver

- Conditions for waiver: Manufacturer ("maker") must
  - **Notify** both the authorities of the member state of production and to the holder of the SPC at least three months in advance
  - **Duly inform** all those involved in the commercialisation of the product
  - **Affix specific logo** to the packaging of the product indicating clearly that it is only for export

Manufacturing Waiver

- Controversy and Lobbying
  - Notification period now 3 months, before 28 days
    - Originators: Enough to obtain a PI?
    - Generics: Frivolous litigation
  - Labeling and notification requirement criticized by generics (“medicines for europe”)
  - No disclosure of exact manufacturing location (trade secret), only member state
  - “Third countries”: only non-EU
    - current draft does not specify that no protection should exist in third countries
  - Application only for SPCs for basic patents expiring after 1.1.2023

Manufacturing Waiver

Background

- More comprehensive reform of SPC law was scrapped
  - Bolar exemption
  - Unitary SPC
- Original proposal of EU commission was broader (2 years before SPC expiry)

Next Steps:

- Draft Regulation 6638/19 amending Regulation (EC) No 469/2009
- Still needs to pass EU Parliament
- Possible before elections in May 2019?

SAVE OUR PLANET

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Supplementary Protection Certificates

Update on German case-law

Young EPLAW

Brussels, 15 April 2019

Philipp Widera, LL.M. (King´s College London)

Overview of developments

- Decision by the **Federal Patent Court**
  - *Sitagliptin III* (referral to the CJEU) – 17 October 2017
  - *Truvada* – 15 May 2018

- Decision by the **District Court Dusseldorf**
  - *MSD v various generics* – 1 October 2018

- Presentation by **Judge Prof. Meier-Beck**
  - What about equivalents?

Sitagliptin III
Factual Background

Pre-Teva

- The case concerned an application for an SPC for ***Sitagliptin***.
- The basic patent in force concerns the treatment of Diabetes mellitus by administration of DP IV-inhibitors.
- The patent defined the claimed substances functionally whereas claim 2 protected the group of active compounds of DP IV-inhibitors. *Sitagliptin* was not individualized as specific compound in the patent.
- The SPC application was rejected on the grounds that it was not individually disclosed in the patent.
- The decision was appealed and the Federal Patent Court referred the case to the CJEU.

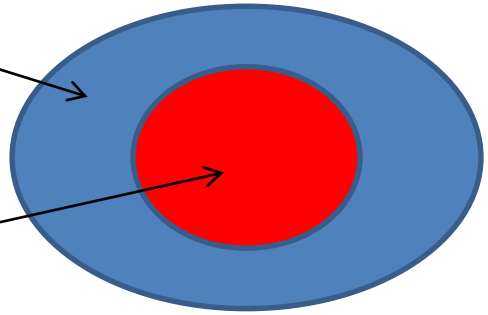
Sitagliptin III
Grounds of the decision

- In essence, the court wants to know whether the product in question has to fall within the patent‘s

extent of protection *(Schutzbereich)*

or the

subject matter *(Schutzgegenstand).*



- The Federal Patent Court seems to be of the opinion that the product has to fall within the patent‘s subject matter (with reference to *Medeva*). Hence, an individualized disclosure in the patent is required.

- However, the court recognizes the different approach by the UK High Court following the “inventive advance test”.

Truvada (German Teva-case)

Pre- *and* Post-Teva

How is that even possible?

Truvada (German Teva-case)
Factual Background

- The case concerned a revocation action against an SPC for tenofovir disoproxil in combination with ***emtricitabine***.

- While tenofovir disoproxil was specified in the claim, the parties were in dispute whether the active ingredient *emticitabine* was specified in the wording of claim 27 of the basic patent by the term "other therapeutic ingredients" .

- The FPC revoked the SPC because the active ingredient emtricitabine was not "sufficiently concretized" as part of the subject-matter of the invention claimed in the basic patent.

  - *Decision was handed down pre-Teva but the grounds were issued post-Teva!*

Truvada
Grounds of the decision

- The underlying question was:

  How to deal with patents claiming ***functionally defined active ingredients?***

- In other words: *Sitagliptin III* revisited but this time without referral.

- A generic functional term can, by itself, sufficiently concretize a specific active ingredient **only if the specific medicinal effects are already reflected by the functional term**. If other types of active ingredients having different modes of action, there is no "implicit but necessary and specific" disclosure to the specific active ingredient at issue.

- No need for an assessment of an "inventive advance" or the like.

- Federal Patent Court sees itself to be in line with *Teva.*

MSD v various generics
Factual Background

Post-Teva

- The case concerned a successful appeal against an *ex-parte* PI. Validity of the SPC is not sufficiently secured so that a revocation is likely.

- The SPC in suit protected ezetimibe or pharmaceutically acceptable salts thereof in combination with ***simvastatin***.
  - There was a second SPC protecting the mono-product ezetimibe based on the same patent which had lapsed.

- Validity was in doubt <u>not because of</u> lack of Art. 3 (a) but rather Art. 3 (c), i.e. that the product shall not have already been the subject of a certificate.

MSD v various generics
Grounds of the decision

- Re Art. 3 (a):
  - Based on *Teva*, there is no room for an "inventive advance"-test.
    - Both active ingredients are mentioned in the claims -> No problem!

- Re Art. 3 (c):
  - An SPC should be granted **for compensating for the duration of the authorization procedure** but not for the effort/cost associated with the authorization procedure.
  - Furthermore, there is no room for a second SPC (based on the same patent) but a different MA for a combination product unless this combination is the **"core inventive advance"** according to the CJEU.
  - This "core inventive advance" is different from the patent law inventive step:
    - The effect must differ from the mono-combination.
    - Indications must be present in the patent specification.

Presentation by Judge Prof. Meier-Beck (3 December 2018 at GRUR in Düsseldorf)

- Ever since *Medeva* the CJEU has been crystal clear so there was **no need for any referral.**

- With *Teva* (handed down by the **Grand Chamber**), the CJEU wanted to make a final point.

- **Art 69 EPC** is decisive when assessing Art 3 (a). Nevertheless, the interpretation has to be based on "SPC-law" and not patent law:

  - He disregards the FPC's view as well as the infringement test.

  - He favours an assessment based on the **extent of protection *but* in light of SPC-law**:

  If the patent protects "A+B", then there is no SPC for "A+B+C". While the latter infringes the patent, the patent itself only covered "A+B".

  SPCs for equivalents would be possible because the basic assessment is (still) based on Art 69 EPC.

Conclusions

- In Germany, the situation regarding Art. 3 (a) seems to be clear:
  - What is decisive is the **subject matter** of the patent (not the **extent of protection**).
  - No room for an “inventive advance”-test (at least for Art. 3 (a)).
- Is the Federal Patent Court right?
  - Meier-Beck seems to propose a different view.
  - Still no guidance as to equivalents.

Thank you!

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YOUNG EPLAW – 15 APRIL 2019

SPCs – Recent Developments

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Class-based claims: Pending CJEU reference

Sandoz/Hexal v Searle C-114/18 (pending)

UK First instance [2017] EWHC 987 (Pat) (Arnold J)

- Product underlying the SPC is Darunavir, an anti-retroviral protease inhibitor marketed as Prezista®.

- Invalidity argument: Darunavir is not specified or identified in any of the claims of the basic patent; it is not “protected by” that patent: Article 3(a) of the SPC Regulation (Regulation (EC) No 469/2009).

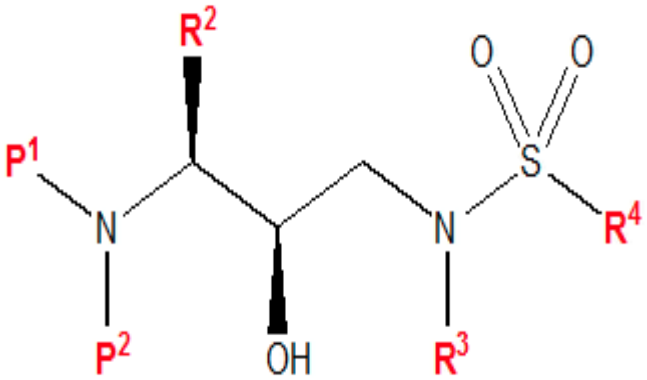
- Both sides were agreed that there is no **specific** reference to Darunavir anywhere in the underlying basic patent’s specification.

Sandoz/Hexal v Searle C-114/18 (pending)

UK First instance [2017] EWHC 987 (Pat) (Arnold J)

- However, and importantly, the claims of the underlying basic patent include Markush formulae which cover Darunavir if the appropriate selections are made.

Formula I



Sandoz/Hexal v Searle C-114/18 (pending)

UK First instance [2017] EWHC 987 (Pat) (Arnold J)

- **Key issues**:

1. Can a compound be sufficiently specified/identified in the wording of the claims for Art 3(a) purposes if it is one member of a large class of compounds disclosed within a Markush formula.

2. Did the "unusual" P^1 substituent in Darunavir need to form part of the common general knowledge available to the skilled team at the priority date?

- Arnold J upheld the SPC (for what it's worth, I think this is right)
- Appealed to the UK Court of Appeal.

Sandoz/Hexal v Searle C-114/18 (pending)

UK Court of Appeal [2018] EWCA Civ 49 (Floyd LJ leading judgment)

- Provisionally agreed with Arnold J that the SPC is valid. There is a “spectrum of specificity” following Eli Lilly v HGS C-493/12.

- However, Floyd LJ decided that a CJEU reference was necessary to determine:
    1. Level of specificity required for a Markush claim to satisfy Art 3(a)
    2. How clearly recognisable a compound must be to satisfy Art 3(a), and whether such an analysis is anchored to the priority date

- Why…?

Sandoz/Hexal v Searle C-114/18 (pending)

UK Court of Appeal [2018] EWCA Civ 49 (Floyd LJ leading judgment)

The UK CoA was concerned about diverging case law between Germany and the UK:

- Does Art 3(a) require that the specific chosen substituents in question must be amongst those which the skilled person would be able to identify based on his common general knowledge **at the priority date** (the "**common general knowledge**" test)?

- At least arguable: Floyd LJ referred to the German Courts in *Sitagliptin (Royalty Pharma C-650/17 (pending))* – the German Courts stated that the functional formula in that case and the Markush formula in *Sandoz v Searle* are "absolutely comparable" for the purposes of Art 3(a).

- Are the German Courts right? Structural vs Functional definitions.

Sandoz/Hexal v Searle C-114/18 (pending)

UK Court of Appeal [2018] EWCA Civ 49 (Floyd LJ leading judgment)

- Floyd LJ: “Undesirable consequences” of adopting the common general knowledge test anchored to the priority date.

- A better approach? The “immediately recognise” test:

“whether the skilled person, considering the claims of the patent on the one hand and the structure of the product in question on the other, would **immediately recognise** that the active ingredient in question is one of those specified by the formula”

- On the facts, held that this test was satisfied for Darunavir.

Sandoz/Hexal v Searle C-114/18 (pending)

Thoughts?

- Sandoz win = potentially far-reaching consequences.

- Of over 200 SPCs on new chemical entities (NCEs) between 1994-2011, between 25-33% do not contain a claim to the specific chemical compound that forms the medicinal product.

- These patents either contain:
    - Markush claims; or
    - A list of compounds that includes the chemical compound (i.e. disclosed as part of a wider class).

- A win could open significant validity challenges to NCEs.

Third Party SPCs: Pending CJEU reference

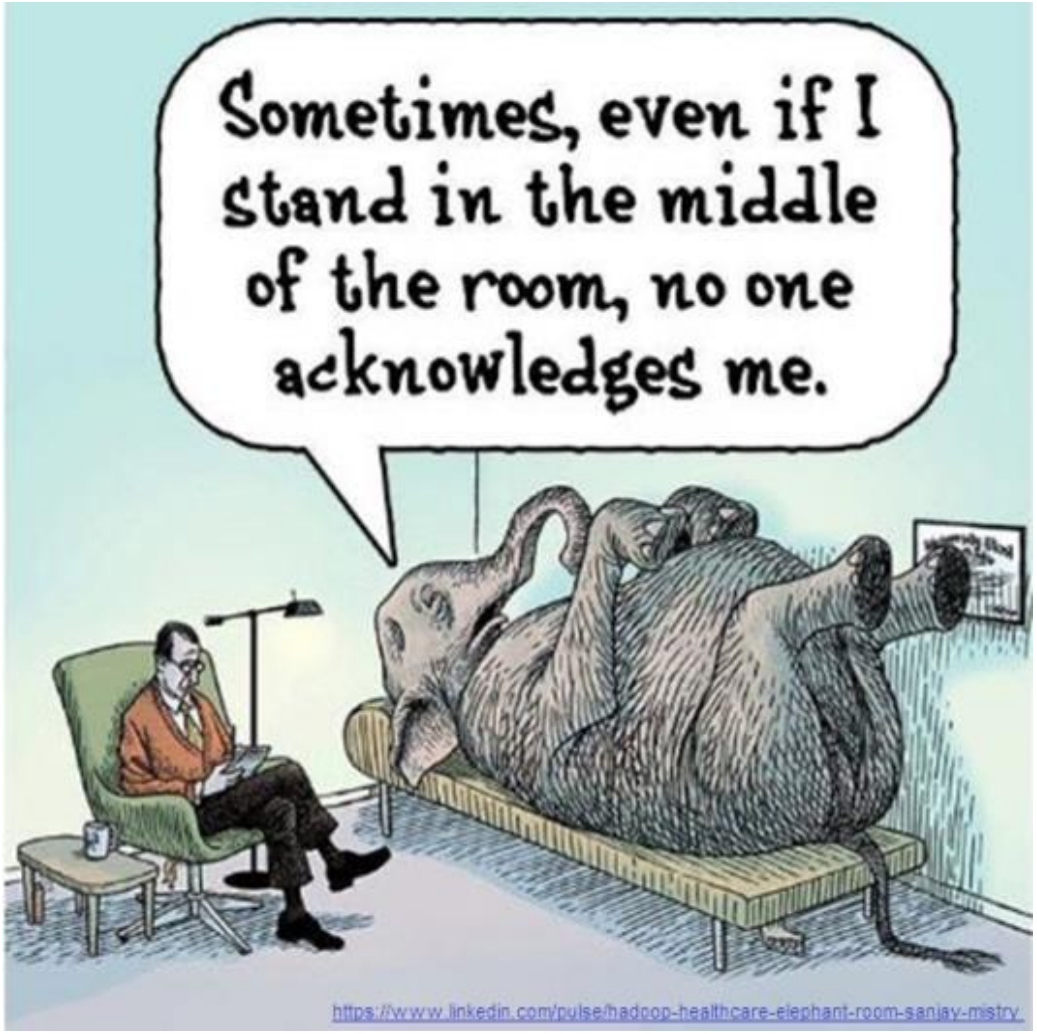
A third-party SPC allows a patent holder to extend its monopoly based on another company's marketing authorisation

Frequently cited example: Eli Lilly v HGS [2012] EWHC 2857 (Pat); C-493/12; [2014] EWHC 2404 (Pat)

- Eli Lilly holds an MA for the antibody product tabalumab
- Tabalumab binds to Neutrokine-α
- HGS holds a patent including the following claim:

> 13. An isolated antibody or portion thereof that binds specifically to:
>
> (a) the full length Neutrokine- α polypeptide (amino acid sequence of residues 1 to 285 of SEQ ID NO:2);

- HGS applies for (and ultimately obtains) an SPC relying on the tabalumab MA.



Lilly v Genentech [2019] EWHC 388 (Pat) (Arnold J)

The UK Court has referred the issue to the CJEU:

"43. In my judgment the law on [the third party SPC] issue is not clear. In my opinion the policy arguments recognised by the CJEU in Eli Lilly and Teva CJEU and by the [UK] courts in Novartis v MedImmune and Sandoz v Searle support Lilly's interpretation. …The arguments advanced by Genentech cannot lightly be dismissed, however." (Arnold J, para 43)

Referred Question:

"Does the SPC Regulation preclude the grant of an SPC to the proprietor of a basic patent in respect of a product which is the subject of a marketing authorisation held by a third party without that party's consent?"

Sweep-up

Teva v Gilead [2018] EWHC 2416 (Pat) (Arnold J)

- Arnold J suggested the SPC was invalid when referring the Art 3(a) question to the CJEU.

- No surprises: Arnold J invalidated Gilead's SPC when the case came back down from the CJEU…and reiterated his desire to adopt a "core inventive advance"-type test:

"Rather, the combination must be one that the skilled person would understand, on the basis of the description and drawings and their common general knowledge, to ***embody the technical contribution*** *made by the patent."*

Boston Scientific C-527/17

- No SPCs for medical device authorisations under the Medical Devices Directive (Article 1(4) of Directive 93/42/EEC).

- Article 2 of the SPC Regulation must be interpreted to the effect that a CE-mark approval for a medical device comprising an active ingredient as an integral part cannot be equated to an approval in accordance with the Medicinal Products Directive (Directive 2001/83/EC).

- Companies should consider the lack of SPC when determining regulatory strategy within the EU.

The ‘B’ Word

The ‘B’ Word

https://www.gov.uk/government/publications/changes-to-spc-and-patent-law-if-uk-leaves-the-eu-without-a-deal

Brexit No-Deal Guidance – key points

- If you have an application for an SPC pending on exit day, you will not need to refile that application with the UK IPO.

- CJEU judgments:
    - Judgments of the CJEU that were issued before exit day will continue to apply to the (automatically) retained EU law.
    - Post-exit = not binding (room for divergence?)

- Reliance on MAs will need to be UK MAs, or authorisations granted by the European Medicines Agency which have been converted into UK authorisations.

- UK SPC term will remain the same: will still be calculated based on the first authorisation in the UK or the EEA.

Questions?

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