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UK GERMANY DENMARK SWEDEN

PATENTS
TRADE MARKS
DISPUTE RESOLUTION
COMMERCIAL AGREEMENTS & TRANSACTIONS
DESIGNS

European Patent Landscape

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OVERVIEW

- Updates on patents - referrals to Enlarged Board
- Updates on SPCs
- Unitary Patent and Unitary Patent Court
- Brexit

Double patenting – new referral to EPO Enlarged Board of Appeal (G4/19)

- Double patenting not explicitly dealt with in EPC
- Not generally allowed since applicant deemed to have "*no legitimate interest*"
- But what counts as "*legitimate interest*"?
- Nestec's application EP 10718590.2 refused by Examining Division
  - claims were 100% identical to Nestec's patent from which EP 10718590.2 claimed priority
- Does internal priority count?

Another referral planted! - plants obtained exclusively by an essentially biological process

Article 53(b)

- European patents shall not be granted in respect of: … (b) plant or animal varieties or essentially biological processes for the production of plants or animals …

Rule 28(2) (in force from 2017)

- Under Article 53(b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process.

T1063/18

- Amended Rule 28 is in conflict with Article
- New referral by EPO president

SPCs for old active ingredients? - 1

Article 3

Conditions for obtaining a certificate

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;

(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.

Neurim (CJEU decision C-130/11)

- Second medical use patent: melatonin for treating insomnia
- Earlier veterinary authorisations for melatonin
- Hence, on the face of it, Article 3(d) is contravened - was SPC allowable?

SPCs for old active ingredients? - 2

"the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal product does not preclude the grant of a supplementary protection certificate for a different application of the same product for which a marketing authorisation has been granted,

provided that the application is within the limits of protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate."

How broadly can *Neurim* be applied???

SPCs for old active ingredients? - 3

- Abraxis (CJEU decision – C 443/17)
  - Abraxane® - albumin bound Paclitaxel nanoparticles
  - MAs for “new formulations” of ‘old’ active ingredients do not qualify for “first MAs” under Article 3(d)

- Santen (pending CJEU referral – C 673/18)
  - Ikervis® - ciclosporin for treatment of keratitis
  - Asks for clarity on concept of “different application” in *Neurim*

  Watch this space!

SPCs: when is a product “protected”?

- Not enough for Product to infringe patent for it to be “protected”
  - Patent to A does not protect A+B
  - *Medeva* (C-322/10) - says that the active ingredients of the combination have to be “*specified in the wording of the claims of the basic patent*”
  - *Lily v HGS* (C-493/12) – says that functional definitions may suffice
- Spectrum of specificity

Infringement test → **Express definition in claims**

SPCs: when is a product “protected”?

- ***Teva v Gilead* (CJEU Decision C-121/17)**

SPC covers tenofovir disoproxil (“TD”) and emtricitabine

- Product marketed as TRUVADA
- Claim 27:

  “*A pharmaceutical composition comprising a compound according to any one of claims 1-25 [Claim 25 recites TD] together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients*”.

SPCs: when is a product “protected”?

- CJEU Decision puts forward a two-pronged test:
- ...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:
- [a] **the combination** of active ingredients must necessarily, **in the light of the description and drawings** of that patent, **fall under the invention** covered by the patent; and
- [b] each of those active ingredients must be **specifically identifiable, in the light of all the information** disclosed by the patent.

SPCs: when is a product “protected”?

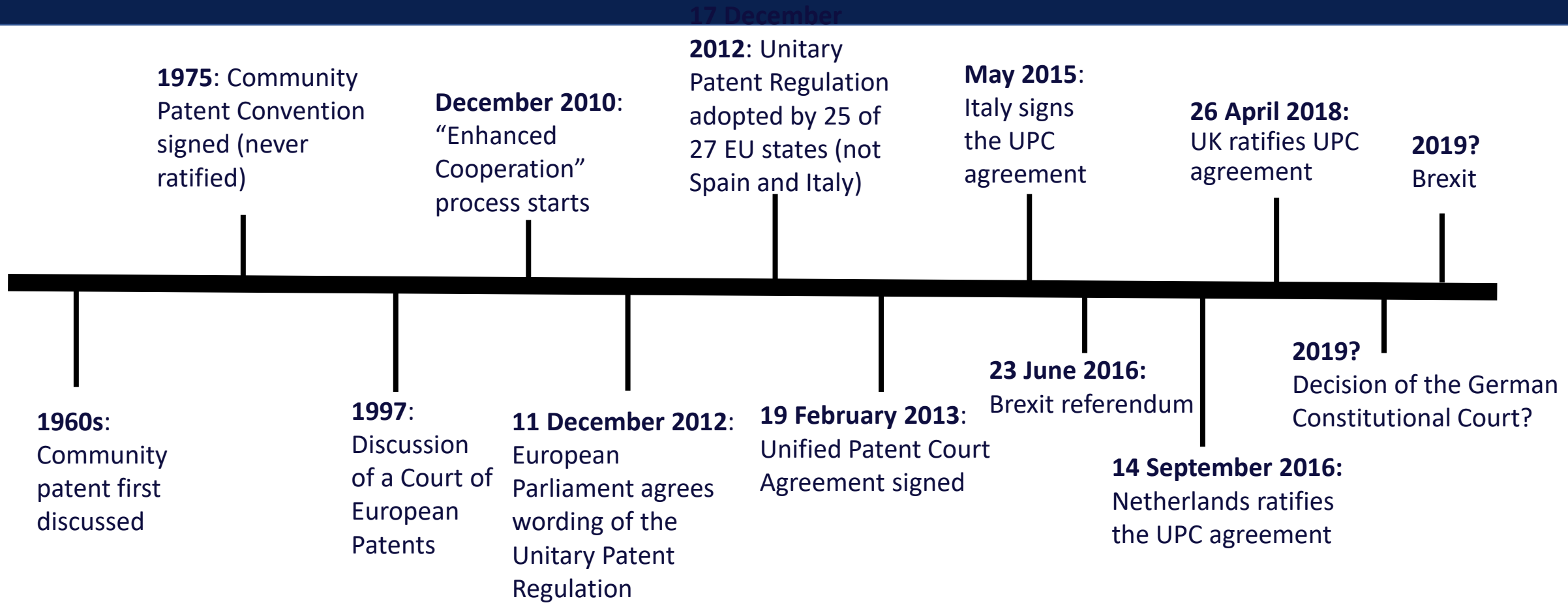
- Royalty Pharma (pending CJEU referral C- 650/17)
  - Patent to DP-IV inhibitors for treating diabetes
  - Sitagliptin not mentioned in patent (but fell within functional definition) and was developed after filing date
  - How specific do functional definitions need to be?

- Sandoz v Searle (pending CJEU referral C- 114/18)
  - Basic patent covered darunavir through a Markush claim
  - Darunavir not individualised in patent
  - Do Markush claims suffice?

SPC manufacturing waiver

- Effects of SPCs curtailed to allow for
  - Export to non-EU countries
  - Stockpiling for day-1 entry to EU market (last six months only)
- Notification requirements
- Expected to enter into force June/July 2019
- Applies to all SPCs filed after entry into force
- Does not apply to SPCs already in effect
- For all other SPCs, applies after three year transition period

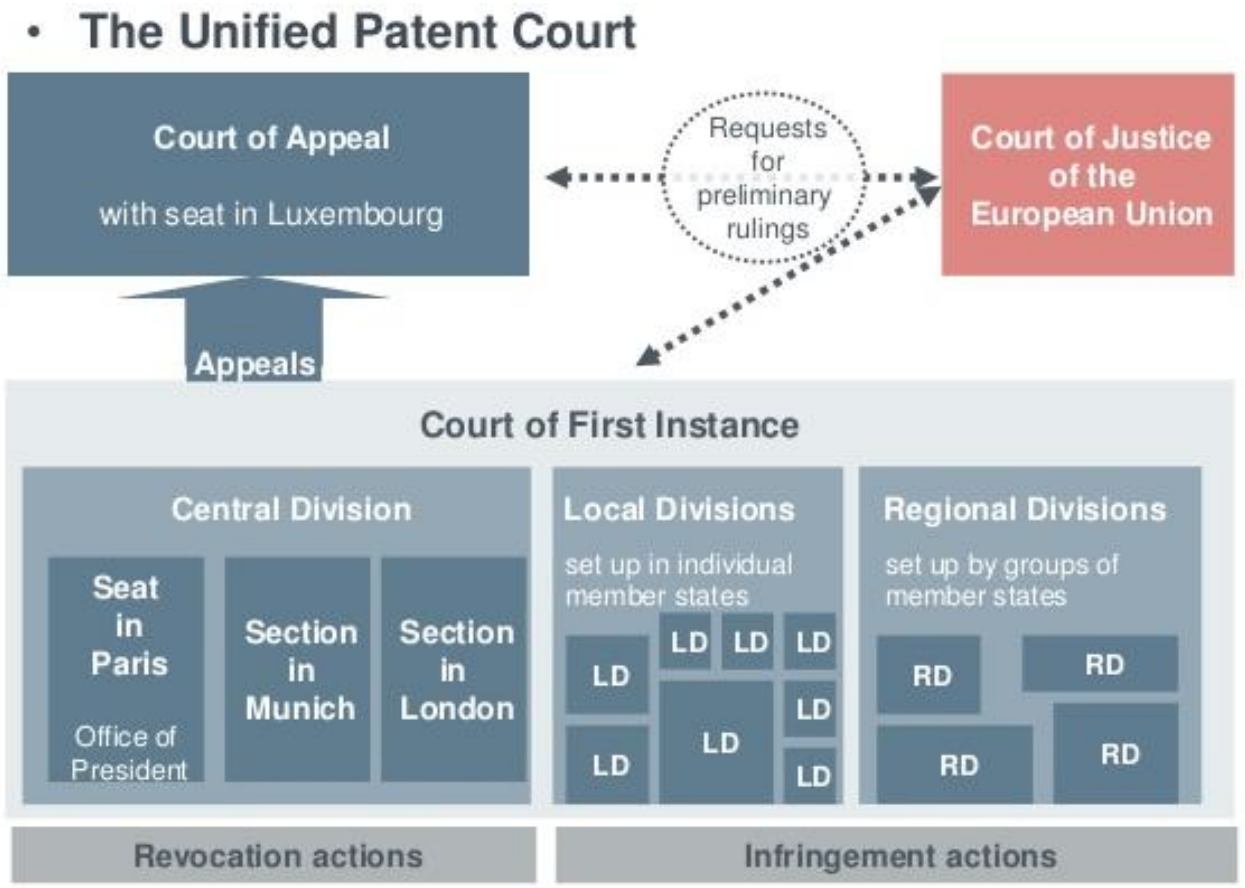
Unified Patent Court – A Brief (Long) History



What the Unitary Patent Does

- Uniform protection across “member states”.
- Single renewal fee to maintain a patent across “member states”.
- Allows post-grant amendments, transfers or revocations to automatically apply across all “member states”.
- Reviewed & granted by a single body (the EPO) for all “member states”.
- All claims must be translated into English, French and German before grant (an English language version will always be available).

Structure of the UPC



Advantages/Disadvantages of the UPC

Potential Advantages

- Single patent instead of a ‘bundle of national patents’.
- Single (significantly lower) maintenance fee.
- Single enforcement system.
- Do not have to engage in multiple litigation battles for the same patent.
- Lower cost of translation (single translation required).
- Single patent covers 600 million people in the worlds 2nd largest economy.

Potential Disadvantages

- Revocation applies European-wide – same as opposition period but throughout the life of the patent.
- Uncertainty of having to use Unified Patent Court – although current law (EU, international and national) will be taken into account.
- Costs may be higher if only a couple of “member states” are of interest to the rights holder.

Unitary Patent Procedure

- Request for Unitary Effect must be filed within one month of date of grant:
  -Re-establishment is possible up to three months after grant;
  -EPO decides, although appeals are to the Unified Court;

- Registration for Unitary Effect will be available to:

(a)EPs that are pending when the new procedure starts;
(b)EPs that are filed after the new procedure starts;

- Single renewal fee due annually:

-Six month grace period available for missed renewals;
-Based on the 'Big 4' – total cost after 20 years is less than 25% of current full validation.

- Possible to opt out.

Pre-Requisites for the UPC to Commence

1. 13 signatory states ratify the UPC Agreement (UPCA).

2. The 3 signatory states which produce the largest number of patents must ratify the agreement.

3. Brussels I Regulation amendment enters into force.

The Brexit Effect

Technical Issues

- No ‘exit’ provisions in the UPCA.
- Lack of clarity as to “member states” must be members of the EU (although note CJEU’s Opinion 1/09).
- Only upon the entry into force of a withdrawal agreement or end of Article 50 extension period do treaties cease to apply.
- UPC submits to EU law, the jurisdiction of the CJEU, and requires its courts to make article 267 TFEU references where needed.
- Possibility that an agreement for the UK to remain in the UP system will require EU/UPCA treaty change.

Current Status of Brexit

- Leave date pushed back to 3 October 2019, though could end sooner.
- Unlikely that Withdrawal Agreement will pass through Parliament.
- There may be further delays.
- No deal now looks unlikely.
- A softer Brexit may happen, which may make the UPC easier for the UK to join.
- May be no Brexit at all, although this is likely to require a further referendum.

German Constitutional Complaint

- Filed by Dr Ingve Björn Stjerna, a Düsseldorf based IP specialist (we think).
- Questions UPCA's doubtful legal viability.
- Likely to be heard by BVerfG (German Federal Constitutional Court) in 2019.
- One possibility BVerfG upholds Dr Stjerna's complaint in some manner.
- More likely it will be rejected, but the timing may be political.

Questions Remain…

- Could the UK actually participate after Brexit?
- Is Germany willing to proceed to start up the system with no certainty as to the legality of the UPC?
- Do other participating states still want the UK in the UPC?
- Will any change to the UPCA require a referral to the CJEU?

UPC – The Current Status

For now, the UPC project remains uncertain but still possible.

In some ways, there is little patentees can do but wait.

However, thought should be given now to patent portfolios and licensing arrangements, as when/if UPC happens, it will happen fast!

Current Status of European Patent Litigation

Currently a significant body of EU Regulations governing jurisdiction, recognition and enforcement of judgments in civil and commercial matters. Through EU Membership, the UK and all major EU states are furthermore party to relevant international conventions:
-2005 Hague Convention on Choice of Court Agreements
-2007 Lugano Convention

EU Regulations ensure legal certainty and predictability for litigants and decisional harmony across the EU:
-Brussels I Recast, Rome I and Rome II Regulations create a coherent system, if a complicated one.

EU jurisdictions selected in choice of court agreements are given priority, weaker parties are protected. A judgment given by the English courts is treated as if it was given in the Member State of enforcement.

Current Status of European Patent Litigation

Theoretically harmonised, but there are many differences.

Different approaches in different jurisdictions to:

- Procedure
- Damages
- Costs
- Injunctions/licences
- Preliminary injunctions

Examples:

- **Germany** – bifurcated system - Creates issues e.g. co-ordination of timetable.
- **France** – TGI exclusive jurisdiction. Revocation actions are rare.
- **The Netherlands** – centralized court system. Possible to get a Pan-European injunction.

Post-Brexit….

- Brexit will leave a large gap in the area of civil justice and judicial cooperation.
- Current regime cannot, in its entirety, be maintained unilaterally via a Great Repeal Bill, as the Brussels I Recast and II bis Regulations require reciprocity.
- If UK would continue to enforce Member State judgments without any formalities, EU Member States would not be obliged to do the same.
- Unclear how these considerable gaps will be filled.
- In short, a complicated system will get more so, particularly in cross-border litigation, but the EPO will operate in the same way.

THANK YOU – ANY QUESTIONS?

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AWARD-WINNING FULL SERVICE INTELLECTUAL PROPERTY PRACTICE

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