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European patent prosecution & litigation: EPO & CJEU

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Any questions after the webinar? Email us directly or contact registrations@dyoung.com.
Slides and a recording of this webinar will be emailed to you later this week.

Webinar agenda

EPO Board of Appeal decisions

- T384/15 – A Timely Intervention
- T2026/15 – By Your Own Admission
- T1280/14 – Switching lines of defence in appeal

CJEU decisions on SPCs

- C-121/17 – Teva v Gilead – SPCs for combination products
- C-527/17 - Boston Scientific v DPMA – SPCs for medical devices

T384/15 – A Timely Intervention

Article 105 EPC – Intervention of the assumed infringer

(1) Any **third party** may … **intervene** in opposition proceedings **after** the opposition period has **expired**, if the third party proves that

(a) proceedings for infringement of the same patent have been instituted against him, or

(b) following a request of the proprietor of the patent to cease alleged infringement, the third party has instituted proceedings for a ruling that he is not infringing the patent.

(2) An admissible intervention shall be treated as an opposition

- For an A105 intervention to be possible, a valid opposition must **already** be on file

T384/15 – A Timely Intervention

Enlarged Board of Appeal decisions G3/97 and G4/97

- Opposition by indirect opponent (“strawman”) admissible
- Provided not an attempt to circumvent the law by an abuse of process
- In particular, EP attorney firms / law firms **may** file oppositions in own name without naming client
- Common tactic in EPO oppositions to disguise “real” opponent

T384/15 – A Timely Intervention

Opposition and appeal proceedings:

- Santarelli (EP attorney firm) filed opposition as a “strawman”
- Opposition rejected – patent maintained as granted
- Santarelli filed appeal
- Interventions filed by Bose GmbH and Bose Ltd during appeal proceedings

T384/15 – A Timely Intervention

- Proprietor requested interventions be held inadmissible, arguing:
- Santarelli a “strawman” acting for Bose Corp (parent company)
  - Same controlling party behind both “strawman” and interveners
  - Should be considered a “joint opposition” (G3/99) by all parts of Bose – therefore intervening subsidiaries not true “third parties”
- Interventions an attempt to circumvent the law contrary to G3/97
  - “Strawman” opposition gives EPO no way of telling whether interveners are or are not “third parties” according to A105

T384/15 – A Timely Intervention

- Board found interventions admissible
- Interveners are **different legal entities** to opponent - so are "third parties" regardless of whether one of them is instructing Santarelli
- Proprietor provided **no proof** that Santarelli are acting on behalf of either Bose GmbH or Bose Ltd
- No evidence that parties are acting in joint opposition
- Not relevant that EPO can't tell who's instructing "strawman"

T2026/15 – By Your Own Admission

- Rule 137(2) EPC - voluntary amendments allowable as of right
  - In response to extended Search Report (direct filed EPs and Euro-PCTs where EPO was not ISA)
  - In response to R161 communication (Euro-PCTs where EPO was ISA)
- Rule 137(3) EPC – no further amendments may be made without consent of Examining Division
- In practice, ED will give consent if amendments overcome objections

T2026/15 – By Your Own Admission

- Applicant filed Main and Auxiliary Requests in response to Summons to Oral Proceedings – though didn't attend Oral Proceedings
- Main Request refused – lacked novelty and clarity
- Auxiliary Request not admitted under Rule 137(3)
  - did not overcome objections against MR
  - "prima facie" introduced clarity problems – pages of reasoning why
- Application refused

T2026/15 – By Your Own Admission

Rules of Procedure of Boards of Appeal (RPBA)

Rule 12(4) - Board of Appeal has power to hold inadmissible facts, evidence or requests which could have been presented or were not admitted in first instance proceedings

- Combination of R137(3) EPC and R12(4) RBPA gives Board right not to admit requests to which ED denied consent in first instance

T2026/15 – By Your Own Admission

- Applicant appealed
- In Grounds of Appeal, applicant challenged non-admission decision and explicitly asked Board to consider Auxiliary Request
- Applicant argued Board obliged to consider Auxiliary Request, not just make a formal decision that it's inadmissible

T2026/15 – By Your Own Admission

Board agreed with applicant

- Once ED has consented to an amendment, ED is required to review its substance – **cannot** then choose **not to admit it**
- ED gave extensive substantive reasoning as to why request not clear- therefore request **implicitly admitted**
- Even if ED finds a substantive deficiency, can't then choose not to admit it for that reason – would give ED too much power over appeal

T2026/15 – By Your Own Admission

Learnings:

- Good news for applicants
- Shows that ED finding that request not admitted can be appealed
- Consider ED's approach and decide whether it has been analysed in substance
- Boards of Appeal may be dissuaded from depriving applicants of chance to get application granted

T1280/14 – switching lines of defence

Art. 13 RPBA - Amendment to a party's case

(1) Any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered **at the Board's discretion**. The discretion shall be exercised in view of inter alia the complexity of the new subject matter submitted, the current state of the proceedings and **the need for procedural economy**.

(2) Other parties shall be entitled to submit their observations on any amendment not held inadmissible by the Board ex officio.

(3) Amendments sought to be made after oral proceedings have been arranged shall not be admitted if they raise issues which the Board or the other party or parties cannot reasonably be expected to deal with without adjournment of the oral proceedings.

T1280/14 – switching lines of defence

“Convergent” Approach:

Main Request: A

Auxiliary Request 1: A + B

Auxiliary Request 2: A + B + C

Auxiliary Request 3: A + B + C + D

T1280/14 – switching lines of defence

“Divergent” Approach:

Main Request: A

Auxiliary Request 1: A + B

Auxiliary Request 2: A + C

Auxiliary Request 3: A + D

T1280/14 – switching lines of defence

Opposition History

- Patent proprietor filed 39 Auxiliary Requests
  - AR 1-12 with its own Written Submissions
  - AR 13-39 in response to Opponent's Written Submissions
- At Oral Proceedings, OD maintained patent as granted - Auxiliary Requests never considered

T1280/14 – switching lines of defence

Appeal & Response

- Opponent requested all AR's filed during opposition proceedings not be admitted – late filed, order not specified, excessive number
- Proprietor filed 15 AR's in response - 6 **diverging** lines of defence
  - Line 1: AR's 1, 2 and 4
  - Line 3: AR 8
  - Line 6: AR 15

T1280/14 – switching lines of defence

- Prior to OP, Board requested proprietor to be prepared to comment on diverging lines of defence
- At OP, Main Request found to lack novelty
- Proprietor then tried for the first time to switch to AR 8 and 15 (renumbered 1 and 2)

T1280/14 – switching lines of defence

- Board refused – inadmissible
- Opponent and Board had wasted their time unnecessarily preparing for Line 1 (AR's 1, 2 and 4)
- New AR's represented a **diverging** line of defence from Line 1 AR's – not just a renumbering of requests
- Procedural economy not complied with
- Patent revoked

T1280/14 – switching lines of defence

Learnings as patent proprietor

- Risky to rely upon diverging lines of defence in OP before Board
- Board may adopt a strict approach and admit only one line
- Make Line 1 the main set of requests well in advance of OP

Learnings as opponent

- If proprietor adopts any diverging lines of defence – request they be deemed inadmissible

SPCs – requirements in EU

- **Article 2 EU Medicines SPC Regulation (469/2009)**
- Any medicinal product
- protected by a patent in an EU Member State and
- subject to an administrative authorisation procedure as laid down in EU Directive **2001/83** (human use) or **2001/82** (vet med use)
- may be the subject of an SPC

SPCs – requirements in EU

Article 3 EU medicines SPC Regulation (469/2009)

(a) product **protected** by a basic patent in force

(b) Valid marketing authorisation (MA) under relevant EU Directive

- Directive 2001/83 (human medicines) 2001/82/EC (vet medicines)

(c) product not already been the subject of an SPC

(d) MA is the first MA as a medicinal product

SPCs - CJEU decision C-121/17

- Considers (once again) whether a basic patent *"protects"* a medicinal product for the purposes of Article 3(a) of SPC Regulation
  - CJEU asked several times before – but no clear answers given
  - Only matter all agree on is that infringement test **rejected**
  - Therefore not sufficient for product to simply fall within the claims – *"something more is required"* (Arnold J, UK Patents Court)

SPCs - CJEU decision C-121/17

- Two tests have emerged from previous case law as to whether Article 3(a) is complied with and product is *"protected"* by basic patent:
  - *"specified"* or *"identified"* (C-322/10, *Medeva*)
  - *"inventive advance"* (C-443/12, *Actavis v Sanofi*) or *"sole subject-matter of the invention"* (C-577/13, *Actavis v Boehringer Ingelheim)*

SPCs - CJEU decision C-121/17

- What is meant by “specified”?
- C-493/12 (*HGS v Lilly*) [mono-product SPC]:

‘Article 3(a) [MPR] 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 [European] patent, Article 3(a) … does not, in principle, preclude the grant of a supplementary protection certificate 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 EPC and the Protocol …* ***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.’*

SPCs - CJEU decision C-121/17

- Truvada® - combination of tenofovir disoproxil (‘TD’) and emtricitabine
- Basic patent disclosed and claimed:
  - TD both generally and specifically
  - combinations with ‘other therapeutic ingredients’ generally
- ‘other therapeutic ingredients’ nowhere defined

SPCs - CJEU decision C-121/17

- After filing basic patent, Gilead found that TD / emtricitabine combo was particularly effective - combination received MA
- Gilead granted SPC in 2008 for combo based on basic patent
- C-322/10 (*Medeva*) and subsequent CJEU decisions cast doubt on validity of many combination SPCs
- Generic companies sought to invalidate combination SPC

SPCs - CJEU decision C-121/17

- Followed test of C-493/12
- Complied with if, **at basic patent filing date**:

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 that patent*', and

b) **each** of those actives must be **specifically identifiable**, in the light of all the information disclosed by that patent

SPCs - CJEU decision C-121/17

UK Pat Ct (Arnold J) – applying CJEU decision

- *"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."*
- TD as sole active embodied the technical contribution and specifically identifiable – but not emtricitabine or combination
- SPC revoked

SPCs - CJEU decision C-121/17

Learnings for SPCs generally:

- Is there evidence that research on which patent based can be linked to product?
  - Preferably in the application as filed
  - May be more tricky for patents based on early-stage biological testing (e.g. to identify target or antigen)
- Consider all possible basic patents

SPCs - CJEU decision C-121/17

Learnings for combination SPCs:

- Are both elements of combination product A+B *"specifically identifiable"* in claims
- Does patent contain data showing that A+B *"inventive advance"* over mono-products A and B?
- If not, can applicant provide evidence that A+B was an invention over mono-products A and B **at priority date of patent**?
  - Merck Atozet UK SPC – proved by expert witness statement

SPCs - CJEU decision C-527/17

- Article 3(b) requires valid MA under EU Directive 2001/83 (or 2001/82) - requires safety and efficacy testing
- Medical devices also require regulatory approval under EU legislation – also requiring safety and efficacy testing
- Can an SPC be granted for a medicinal product which is an integral part of a medical device?

SPCs - CJEU decision C-527/17

- Paclitaxel (Taxol®) first approved for medical uses in 1993
- Boston Scientific found that paclitaxel inhibited or reduced proliferation and migration of cells in blood vessel wall and thus counteracted the risk of restenosis following angioplasty
- Obtained patent – relevant claim:
  "*Use of taxol for the preparation of a medicament to maintain an expanded vessel luminal area*"

SPCs - CJEU decision C-527/17

- Boston Scientific produced a paclitaxel-coated stent (Taxus®)
- Device underwent regulatory assessment under EC Directive 93/42 (Medical Devices Directive) by German medical device agency
- As part of that process, paclitaxel subject to assessment by Dutch medicines regulatory agency
  - Legal basis EC Directive 93/42, Annex I, section 7.4
- Approval granted and certificate of conformity (CE mark) awarded

SPCs - CJEU decision C-527/17

- Boston Scientific filed SPC application for device with German PTO
- Argued that review process to obtain CE mark involved in-depth review of safety and usefulness of paclitaxel in conjunction with device
- Argued this procedure equivalent to the MA procedure for medicines under Directive 2001/83 and SPC should be allowable
- German PTO considered arguments persuasive – but referred to CJEU as other Patent Offices considered otherwise

SPCs - CJEU decision C-527/17

Question referred to CJEU:

'Must Article 2 of Regulation [No 469/2009] be interpreted as meaning that, for the purposes of that regulation, an authorisation under Directive [93/42] for a combined medical device and medicinal product within the meaning of Article 1(4) of [that directive] is to be treated as a valid [MA] under Directive [2001/83], where, as part of the authorisation procedure laid down in Annex I, Section 7.4, first paragraph, to Directive [93/42], the quality, safety and usefulness of the medicinal product component has been verified by the medicinal products authority of a Member State in accordance with Directive [2001/83]?'

SPCs - CJEU decision C-527/17

- **CJEU said no**
- EU legal definitions of “medicinal product” and “medical device” **mutually exclusive**
- “Medicinal product” - any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions **by exerting a pharmacological, immunological or metabolic action**, or to making a medical diagnosis
- “Medical device” - any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, intended by the manufacturer to be used for human beings for the purpose, inter alia, of diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap, and **which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means**

SPCs - CJEU decision C-527/17

- A substance which acts upon the body with action **ancillary** to that of the device that it incorporates and principal mode of action **cannot** be classified **independently** from that device
- It is therefore not a medicinal product, within the meaning of Directive 2001/83, **even if** it could be classified as such if used separately
- Therefore substance cannot be considered a “medicinal product” in context of SPC regulation
- Even if similar to an MA in accordance with 2001/83, not an MA per se

SPCs - CJEU decision C-527/17

- CJEU decision appears to close the door for now on attempts to get SPCs for device / substance combinations
- But SPC regulations currently under review by EU commission
- Possible that amendments to Regulation may allow SPCs for medical device / substance combinations in the future

Questions and future webinars

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