The unitary patent and the unified patent court: Implications, opportunities, doubts, and decisions to be made (I)

ZBM Patents & Trademarks

Barcelona, 27 de febrero de 2023

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Agenda

- Introduction to the new system: UP/UPC (what is a UP and the UPC, jurisdiction, territorial coverage, costs, transitional measures, how to obtain UE, safety net)

- Specific issues related to the new system:
  - Portfolio strategy
  - Prior national rights
  - Safeguards: Double protection/parent and divisional
  - Impact of the new system in:
    - Opposition /limitation proceedings
    - Licenses and collaboration agreements
    - Patents as objects of property
  - Bolar exemption and SPCs
¿What is the Unitary patent (UP)?

- **A single patent:**
  - which is granted with the same effect in all countries participating in the system
  - which is maintained as a unit

- **Supranational validation** instead of a national validation of a European patent

- **Unitary effect** implies:
  - A single fee
  - A single object of property
  - A single court
  - Uniform protection
Coexistence between UP/National validations/national patents

- European patent application (EP):
  - Request of a unitary effect (UP)
    - For the participating member states
  - National validations for:
    - Countries that have not ratified
    - Non-participating countries
    - Countries outside the EU
  - Set of national validations of the European patent
- National patents granted by national offices
Difference between unitary patent and national validations

Jurisdiction for litigation:
Unitary patent => unified patent court

Territorial coverage

Costs:
Validation / Translation / annuities / Agent fees
UPC and its jurisdiction

**UPC:**
- New international court and court system
- Set up by participating Member states
- To deal with centralized *infringement and validity* proceedings of both: 
  - UPs
  - Classic EPs

**Jurisdiction in the transitional period (7 years + 7 years):**
- **Exclusive** jurisdiction for UP
- **Shared jurisdiction** with national courts over *not opted out* EP patents
Territorial scope

- **Initial coverage (17 countries)** – EPC members + EU members + enhanced cooperation + ratification UPC
  - Austria, France, Sweden, Belgium, Denmark, Malta, Luxembourg, Portugal, Finland, Bulgaria, The Netherlands, Italy, Germany, Estonia, Lithuania, Latvia, Slovenia

- **Countries that have signed the UPC but are not yet participating (7 countries)**
  - Cyprus, Greece, Romania, Slovakia, Czech Republic, Hungary, Ireland

- **Non-participating countries (3 countries)**
  - Spain, Poland, Croatia

- **NON-EU EPC countries – not possible to participate (11 countries)**
  - United Kingdom, Albania, Macedonia, San Marino, Turkey, Iceland, Monaco, Switzerland, Liechtenstein, Norway, Serbia
Overseas territories

- Possible **differences in geographical scope** between
  - A European patent validated in the countries taking part in the UPC system
  - A unitary patent

- A **national validation** of a European patent:
  - May cover **overseas territories** that are *not* covered by a UP
  - This depends on the extent to which the EU legislation on which the UP is based has effect in those overseas territories

- Examples:
  - **France**: A UP will not apply in French Polynesia and New Caledonia
  - **Netherlands**: The UP will only give protection in the European part of the Netherlands, it does not cover the Caribbean part
Territorial scope of EP-UE may depend on the time of their registration as EP-UEs.

The unitary effect will depend on the speed of registration.

- Validate also nationally to ensure protection even thought the national validation may turn out to be superfluous.
- If the ratification in a relevant country is imminent: Delay the mention of grant (amendments after R71(3))
Costs

- **Cost until grant:** the same as for any European patent

- **After grant:** savings in translations and savings in agent fees

- **During a transitional period:** a single human translation will be required to inform the content of the patent, but it will have no legal effect

**UPC entry into force**

- **Translations transitional period:** 6 years + 6 years

- **Complete human translation**:
  - FR or DE → EN
  - EN → Translation to another official language of the UE

- **After transitional period**:
  - No further translations, unless a dispute (litigation)
    - High quality machine translation
    - Available free of charge
    - Without legal effect
## Annuity costs

<table>
<thead>
<tr>
<th>Year</th>
<th>UP</th>
<th>25 MS</th>
<th>EEUU</th>
</tr>
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<tbody>
<tr>
<td>2</td>
<td>35</td>
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<tr>
<td>3</td>
<td>105</td>
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<tr>
<td>6</td>
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<td>990</td>
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<td>1.175</td>
<td>6.463</td>
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<td>2.105</td>
<td>9.584</td>
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<td>14</td>
<td>2.455</td>
<td>11.028</td>
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<td>15</td>
<td>2.830</td>
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<td>16</td>
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<td>17</td>
<td>3.640</td>
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<tr>
<td>18</td>
<td>4.055</td>
<td>16.166</td>
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<td>19</td>
<td>4.455</td>
<td>17.729</td>
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<tr>
<td>20</td>
<td>4.855</td>
<td>19.227</td>
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<tr>
<td><strong>SUMA</strong></td>
<td><strong>35.555</strong></td>
<td><strong>160.633</strong></td>
<td><strong>13.460</strong></td>
</tr>
</tbody>
</table>

## Annuities + professional fees comparison

### EPO

### National offices

Annuities based on the annuities from 01/01/2020
Timeline with transitional periods and provisional measures

- 19.01.2022: Protocol on provisional application starts
- 17.02.2023: Ratification DE
- 01.06.2023: Simultaneous start
- 01.01.2023: Sunrise period: opt-out registration
- 01.03.2023: Obligation to provide a translation to register the UP
- + 7 years (+ 7 years): Opt-out/opt back in registration for classical EPs
- + 7 years (+ 7 years): Shared jurisdiction of the UPC with national courts for classical EPs
- End of all transitional measures

Transitional period EPO:
- Early request for UE Delay of grant (5 months)
- Sunrise period: opt-out registration (3 months)
- Obligation to provide a translation to register the UP (6 years + 6 years)
- Exclusive jurisdiction (7 years + 7 years)
Early request UE / Delay decision to grant

Entry into force PPA: 01.01.2023
Start EPO transitional period: 01.06.2023
Ratification Germany: 17.02.2023
Entry into force UPC: 01.06.2023

EPO R71(3): 27.02.2023
4 months

Reply to R71(3) + Early request UE

Publication decision to grant
5-6 weeks

Registration UE
1 month
1-2 weeks?

Publication decision to grant

Request UE

Publication decision to grant
¿How is the unitary effect obtained?

- Request of unitary patent of a granted EP before the EPO
  - No later than **1 month** after the date of mention of the grant has been published in the EP bulletin.

  1 month vs. the usual 3 months for current Spanish validations!

- **In writing**
- In the **language of the proceedings** (different than CPE, use Form EPO with the 3 languages)

- **There are no fees** for the application for a unitary patent (to speed up the registration)
Conditions for registering the unitary effect

- Substantive requirement: European patent granted with **the same set of claims** in all participating Member States (25 MS)
- This means that **all these countries must be designated in the European patent.**

- If withdrawal of designations
- If claims are limited differently for a state

- Example to have withdrawn a designation or have limited the claims differently: Prior national rights

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**Diagram:**
- **FR** to **EP** with 18-month publication and **FR**
Registration of unitary effect

Mention of grant of the EP patent published in the EP bulletin

Request for unitary effect

Request filed within 1 month

Are the substantive requirements met?

Reestablishment of rights
Time limit: 2 months

Request not filed within 1 month

Are the formal requirements met?

Rejection of the request

Possibility to correct deficiencies within 1 month, non-extendable

Registration of unitary effect
Appeal of the decision of the EPO to reject UE

- **Lodge an application** at the registry to reverse the decision of the EPO
  - In the language of the proceedings / Within 3 weeks / Fee: 1000 Eur
- **Standing judge to decide** the application
  - May invite the President of the EPO to comment on the application
  - Decide the application within 3 weeks
- **Statement of appeal by proprietor or EPO** against the decision of the standing judge
  - Decision within 3 weeks / Fee: 1000 Eur
- **Standing appeal judge to decide**
  - May invite the other party to comment
  - Decision within 3 weeks

- Parties bear their own costs
Rules relating to time limits deviating from the EPC

- EPO carries out all the tasks for registering UE
  - In general, in accordance with the internal rules of the EPO, but not all procedural EPC provisions are relevant for UP
  - Rule 20 of the UPR: list of EPC provisions that are applicable

- Procedure for registration UE:
  - **Periods** specified by the EPO have been **shortened**
    - The minimum period to 1 month
  - No extensions of time limits
  - Late receipt of documents: no later than 1 month
  - Re-establishment of rights shortened to 2 months

- Procedural economy and legal certainty (UE decision before the deadline of national validation)
Safety net

- It may be that the request for unitary effect is only rejected at a later stage after the deadline for national validation in certain countries has passed.

- There might not, therefore, be time to get national validations *in lieu* of a unitary patent if the request for unitary effect fails.

- Most countries taking part in the UP are providing a "safety net" in their national law.
  - It means it will be possible to validate a European patent *late* in that country if a request for unitary effect has been rejected.
## Safety net

<table>
<thead>
<tr>
<th>Country</th>
<th>Safety net envisaged</th>
<th>Safety net not envisaged</th>
<th>Safety net under consideration</th>
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<tbody>
<tr>
<td>Bulgaria</td>
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<tr>
<td>Belgium</td>
<td>X</td>
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<td>Czech Republic</td>
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<td>Denmark</td>
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<td>Germany</td>
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<td>Estonia</td>
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<td>Hellenic Republic</td>
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<td>France</td>
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<td>Ireland</td>
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<td>Italy</td>
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<td>Cyprus</td>
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<td>Hungary</td>
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<td>Netherlands</td>
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<td>Sweden</td>
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How the new system affects the portfolio strategy

- New EU package introduces new options but also uncertainties, and entail making new decisions:

1. For existing **granted European patents**:
   - Whether or not to avoid the jurisdiction of the UPC
     - **Opt-out**: Only possible during a transitional period (regarding jurisdiction) starting 01.03.2023
     - After the transitional period: national patents are the only ones that will remain under the jurisdiction of the national courts

2. For **European patents applications when granted**:
   - **Unitary patent or national validations** (within or outside the jurisdiction of the UPC)
Developing a basic strategy

Consider the following factors to decide whether choosing for the unitary effect and for the jurisdiction of the UPC (pros and cons UP and opt-out):

- **Territorial scope**
  - How many countries do you want protection?

- **Costs**
  - Unitary patent less expensive if wide EU coverage
  - Single fee but loss of flexibility by not being able to abandon the patent only in some countries during the life of the patent
  - Will a UP save you costs?

- **Simplification of the administrative procedure**
  - UP easier to administer Do you have a big portfolio? Are you a company that manage your patent portfolio in-house?
Developing a basic strategy

- **Competent court:**
  - Cost
  - Effect of its decisions (Ease of enforcing rights across Europe vs. revocation in all countries at once)
  - How likely are you going to enforce the patent?
  - Is your patent strong?

- **Risk of prior national rights**
- **Risk of central revocation**
  - Can you mitigate the risk?
  - Have you considered to use both systems at the same time? Divisionals, file national patents in key jurisdictions
Developing a basic strategy

For **patent applications** that you want to **choose unitary effect**

- Before the system entry into force: Have you considered to use the EPO transitional measures?

- If your object is to **transfer**
  - Review license policy
    - Are you generally licensing in several countries?
    - Do you expect litigation in some country?
    - Should there be any changes to the terms included in your existing licenses or your collaboration agreements?
  - Have you considered declaring the willingness to grant licenses? (reduction of annuities)
Strategic considerations depending on the type of company / institution

- Public research centers
- Universities

- Companies with small patent portfolios (with low litigation-validity conflicts)
- Start-ups

- Companies with medium and large patent portfolios or even small ones with high conflict

For new patents, the patent strategy will take precedence from a financial point of view:
- For classical EP patents consider opt-out

For new patents, the patent strategy will take precedence from a financial point of view:
- But action before UPC could be devastating
- For classical EP patents consider opt-out

Costs will not be the main factor
- Litigation strategy will take precedence:
  - The strength of the patent
  - If a nullity action is expected
  - If an opposition is ongoing
  - Whether actions against infringers are to be brought centrally at the UPC
  - The bias/uncertainty of the UPC
- Contractual obligations
What impact can have the prior national rights when the new system is in force?

- Prior national rights
  - National applications of 1 or more states designated in the EP application
  - Filing date are prior to the filing or priority date of the EP application
  - Published as national applications or patents on or after that date
  - Only relevant for novelty and for such contracting state (CS)

- EP patent applications: Same options as the current system
  - Withdraw the designation for such CS (No unitary effect is possible)
  - File different claims for such CS (No unitary effect is possible)
  - Limit the existing set of claims in such a manner that the national right of earlier date is no longer relevant (Open the option of unitary effect)
What impact can have the prior national rights in unitary patent?

- Substantive requirements for **unitary effect**:
  - Granted with the same set of claims in respect of all participating Member States

- What happen if the national prior art is in one of the member states of the UPCA?
  - A solution such as withdrawal of the designation or different claims is not available
  - The **only solution** which might become available for UPC countries will be **limit the scope of protection of the existing set of claims**
How will the EPO deal with prior national rights?

- **In examination**
  - EPO has started to do searches for national prior rights before the grant of the patent

- **In opposition proceedings:** (Guidelines H-III, 4.4)
  - A national right of earlier date is neither a ground for opposition nor a ground for revocation
  - The *proprietor* in opposition proceeding apart from filling different claims or limit the claims, may *request the revocation* of the patent for the CS
  - What will happen if a national prior art in a *member state of the UPCA* appears during opposition proceedings before the EPO?
    - **For opt-out patents?**
      - may be right not to admit the national prior right
    - **For unitary patents or at the end of the transitional period?**
      - They should be accepted
      - Amendment to the EPC?
Is any safeguard against the effects of a central revocation at the UPC?

- Options discussed but not taken:
  - Alter the geographical scope
    - Does not correspond to the idea of unitary patent
  - Let case law of the UPC decide what to do
    - Uncertainty until the Board of Appeal of the UPC confirmed the decisions

- Option already taken by some contracting member states:
  - Allow double protection (simultaneous protection in the same state, but with different territorial level, e.g. national patent / unitary patent, same filing date) => **Parallel filing options**
  - Only possible in some states

Not only diversify options of avoiding central revocation but also open new strategies in litigation
### Double protection

<table>
<thead>
<tr>
<th><strong>UPCA</strong></th>
<th><strong>EPC (art. 139(3))</strong></th>
<th><strong>National law</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ No rules on double patent protection</td>
<td>▪ It does not prohibit double patent protection by a European patent and a national patent/utility model</td>
<td>▪ Variation from country to country</td>
</tr>
<tr>
<td></td>
<td>▪ Leaves it to the EPC member states whether and on what terms is allowed</td>
<td>▪ Some countries have amended their laws to include new provisions related to double protection</td>
</tr>
</tbody>
</table>
Double protection provisions in the participating UPC MS

<table>
<thead>
<tr>
<th>Participating MS</th>
<th>Double protection allowed for a national patent and EP/UP?</th>
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<tbody>
<tr>
<td>Austria</td>
<td>Yes</td>
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<tr>
<td>Finland</td>
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<td>Portugal</td>
<td>Yes</td>
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<tr>
<td>France</td>
<td>Yes, but for EPs only if are not opted out</td>
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<tr>
<td>Germany</td>
<td>Yes, but for EPs only if are not opted out</td>
</tr>
<tr>
<td></td>
<td>Also, new provision as a safeguard for defendants against</td>
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<tr>
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<td>simultaneous assertion of patents (Article II § 18 IntPatÜG)</td>
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<td>Estonia</td>
<td>Yes, but only for national patent and UP</td>
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<td>Latvia</td>
<td>No</td>
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<tr>
<td>Slovenia</td>
<td>Allowed for EPs under certain considerations</td>
</tr>
<tr>
<td>Malta</td>
<td>No information</td>
</tr>
</tbody>
</table>
Strategic considerations under the new system on parallel filing options

- Think about combining filings in **core European countries**, same or similar protection in a country by:
  
  ![Diagram showing strategic considerations](image)

- For new or pending PCT application consider:
  
  ![Diagram showing strategic considerations](image)
Is any other strategy to mitigate the effects of a central revocation that could be taken by the patentee?

■ What?
  ■ **Split approach** based on a **combination** of parent and divisional:

  ![Diagram of EP, Parent UP, and EP Divisional with opt-out]

  ![Unified Patent Court and National Courts]

■ Also open to choose to **initiate a dispute before the UPC with different patents** (patent in the new system) or **national courts** (patent outside the system)
Parent and divisional strategy cont.

■ When?
  ■ During the transitional period

■ Scope?
  ■ Provisions on double patenting at the EPO (G4/19)
    ■ Small differences may be enough. Largely overlapping subject-matter is accepted
      ■ After EPO issue R71(3) EPC communication. Possibly same examiner. Quick grant expected
    ■ Generally, interest in slow grant
      ■ Advisable to maintain the more limited patent in the UPC
      ■ Strategy of maintaining open the option of new divisional applications for covering activities of the possible infringers gain more importance under the new system
What impact can have the new system in the centralized opposition proceedings at the EPO?

- **Opposition**
  - Affect the entire patent (e.g., UP and EP-ES).
  - **Advantages** of oppositions:
    - Centralized revocation before the EPO
    - Well-established rules
    - It is the only cheap route when the patent must be revoked in countries that:
      - have not joined the UPC (Spain, Poland) or
      - can’t join because they are not a MS of the EU (Turkey, Switzerland…)
- **Limitation**: It must be started within 9 months from the grant of the European patent
Opposition proceedings

- It is not expected that the number of oppositions will fall

- **Opposition fee much lower** than the basic fee for revocation or the fee for a counter-claim for revocation at the UPC (840 € vs. 20000 €)

- It can depend on the speed at which the Boards of Appeal of the EPO decide appeals in opposition

  - The [RPBA20](#) in force since of 01.01.2020 have also the aim of enhancing the throughput of the Boards

  - The Boards of Appeal are steadily reducing their backlog
Central revocation at the UPC

The Unified Patent Court (UPC) will offer opponents a second chance by providing another forum for central revocation (in respect of the UPC states)

Revocation actions at the UPC will not replace EPO oppositions, but they will supplement them.

It is possible to file a revocation action or a counterclaim for revocation before the UPC:

- if the opposition period has not expired or
- if opposition proceedings are currently pending

If infringement action before the UPC, more sense to file a counterclaim for revocation than an opposition.
Opposition vs. central revocation at the UPC

**Opposition at the UPC**
- Entire EPC territory
- Time limit of 9 months. Reply to opposition 4 m
- Written procedure + oral hearing
- Fees: 840 Euros
- Parties' own costs
- Possibility of using a straw man
- EPO can accelerate opposition procedure upon request UPC if revocation action to the same patent

**Central revocation at the UPC**
- Only UPC participating MS
- Deadlines shorter (e.g., Statement of defense 2 m)
- Written procedure + Interim procedure + oral hearing
- Court Fees: 20,000 Euros
- Cost orders to the parties. Usually losing party. Including costs for simultaneous interpretation
- Possible counterclaim of infringement
- UPC may stay proceedings in case of opposition to the same patent when decision expect rapidly and may request EPO for acceleration
### When Opposition/central revocation at the UPC

#### When opposition
- If still within the 9-month opposition period
- If the patent has been opted out
- If limited budget
- If you can afford waiting for a decision
- If there is interest in invalidating the patent in non UPC countries (e.g., ES)
- If you want to use a straw man

#### When UPC
- If you have missed the opposition period
- If there are national prior rights
- If sufficient budget
- If a quick decision is needed
- If you have a good case and expect to win the case and recover costs

#### When both
- If new and pertinent prior art is found and it can no longer be introduced into the pending opposition proceedings (late filing)
- If costs do not play a role
- If you want to apply pressure on the patentee and force him to provide his arguments and claim amendments as soon as possible
Limitation at EPO

- Central review of the patent by the proprietor

- The proprietor can request a **limitation before the EPO** of its European Patent **by an amendment of the claims** as long as the patent remains valid in one member state of the EPC.

- As for an opposition, the decision to limit the EP will always **affect the entire patent** e.g., UP and EP-ES.

- It is designed to avoid costly national disputes over the validity of a EP patent.

- The procedure may be useful when **relevant prior art** is discovered after grant of the EP patent.
Limitation at the EPO or at the UPC

- Not possible to limit just the unitary patent in a limitation procedure ex-parte
  - e.g., not possible remedy for prior national rights in a UPC participating member state

- If opposition at the EPO is pending => a request for limitation at the EPO may not be filed

- Possible request the limitation of the UP in contentious proceedings at the UPC (inter-partes)
  - e.g., possible if prior national rights in a UPC participating member state is found after grant

- There is no corresponding disposition

- Faced with a request for nullity before the UPC => the proprietor could file a request for limitation before the EPO
  - e.g., for restricting the scope of the entire EP patent
What impact will the new system have on licensing and collaboration agreements?

- UPs in terms of licensing:
  - They can be **exclusive** or **non-exclusive licenses**

- The UP is a unitary right
  - It can only be **assigned in its entirety (all UP MS)**
  - It can be **licensed in individual UP MS**
  - Even for **parts of the territory of such a state**

- Assignments and licenses shall be entered into the UP Register (single entry, simplification of the procedure, lower costs)

- However, registration will not be a pre-requisite of an assignment to be legally effective
  - No disposition in the regulations about registration process (proposal of applicability rules EPC)
Ownership /co-ownership situation

- If only one applicant for all states:
  - No problem.

- If co-ownership of EP patent:
  - Needs to coordinate for the decisions to be made: opt-out, UP, who listed as first applicant (applicable law to the contract different to applicable law to the UP as object of property)

- If different owners for different countries:
  - Upon registration of UE, they become join proprietors
  - Such co-owners also need to coordinate for the decisions to be made
  - The question remains, whether each of the owners could separately dispose of their parts of the UP by assignment
Should we review the existing agreements?

- It is advisable to review at least the key existing agreements

- Most current agreements do not have provisions on the new system
  - Unlikely the current provisions can cover the new situations
  - Preferable to address this issue before a conflict
  - Different grades of cooperation

- Consider possible changes on provisions related to:
  - Decisions of opt-out
  - Decision of enforcing the patent
  - Decision on defending the patent
Licensing provisions in relation to the opt-out decision

- **About the decision whether opt-out or not:**
  - It is *up to the patentee* to file the opt-out or withdraw it
  - **Exclusive licensee:**
    - May want to influence or control the decision of opt-out, and to opt back in
  - In new licenses:
    - Try to stipulate who has the right to make the decision on whether to opt out
Licensing provisions on who can be a party to an action before the UPC

- **About the decision to enforce a patent:**
  - **Exclusive licensee:**
    - Has the authority to enforce a patent without consent from the patentee unless provided otherwise in the license
    - Need notification to the patent proprietor
  - **Non-exclusive licensee:**
    - Can bring an action if the agreement expressly provides for it and the patentee is informed
    - The **patentee** may join an action commenced by a licensee
    - Both patentees and non-exclusive licensees should check their licenses to agree with who can be a party to an action before the UPC
Who should defend the validity of a patent subject to a license?

About the decision to defend the validity of a patent:
- Before an infringement action by a licensee, validity can only be contested if the patentee participates.
- The other party will have to bring a revocation action against the patentee.

Exclusive licensee: It seems reasonable that could have also the control of the defense (their business is directly affected).

If multiple licenses, rights often best kept by licensor:
- Licensor will want to have a degree of control and coordination in relation to revocation proceedings.
- If revocation counterclaim is successful:
  - Loss of the patents in the designated states
  - Impact on agreements with other licensees
Licenses of right

- **Requirements:**
  - The patent must be granted with unitary effect
  - The proprietor should file a statement before the EPO stating that he is prepared to allow any person to use the invention as a licensee in return for appropriate consideration

- **Reduction of fees** falling due after receipt of the declaration by 15%
  - Possible reduction by about **5.000 euros** over the maximum 20-year life of a patent

- **Simplification:** single entry in the UP register

- In case of dispute: UPC will determine the appropriate amount
- It can be withdrawn at any time
  - If the license is withdrawn, the amounts should be returned
  - The withdrawal does not take effect until the amounts are returned

- Not available if there is an exclusive license registered in the UP Registry
What is impact of the new system on the patents as objects of property?

- EP until grant the provisions of the EPC apply
- **After grant:**
  - EPC does no have detailed provisions and refers to national law of each of the countries for the individual national parts
- **UP:**
  - **Art 7 reg. 1257/12** direct reference to national law, but the UP must be **governed by the property law of one country**
  - Which national law applies?
    - The law of the EU participating MS where the applicant has his residence or principal place of business.
    - For non-participating MS the applicable law is German law
    - The applicable law does not change even in case of transfer of the patent
      - Why? Because determines several issues related to the asset
Law applicable to UPs as objects of property for joint applicants

- **A. Join applicants**: the law of the participating member state in which the joint applicant named first on the European Patent Register has its residence or principal place of business

- **B.** If first joint applicant does not have its residence or its principal, and in the absence of principal, its normal place of business in an EP-UE MS, then next joint applicant

- **C.** If the previous A-B do not apply to any of the applicants, the law of the participating member state where the first joint applicant has a place of business

- **D.** If any of A-C do not apply, the law of the participating member state where the second joint applicant has a place of business (if not applicable, go to next applicant)

- If A-D do not apply, the laws of Germany
What is the governing law for an UP with co-owners?

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<th>Second applicant (principal place of business)</th>
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What would be advisable to do in case of co-ownership related to the patents as objects of property?

- In R&D collaborations / companies working together, agree over whose name is going to be listed first for co-owned patents.

- Check current key agreements and evaluate whether they should be amended.

- Consider developing standard positions for future agreements.

- The UP regulation does not permit co-owners to decide for themselves which laws apply.
  - However, under the laws of most participating member states, co-owners can by agreement override the default rights.
What is impact of the new system on the Bolar exemption?

- **Bolar exemption**: *Clinical studies and other practical requirements for obtaining health authorizations do not involve patent infringement*

- Based on a European Union directive (2004/27/EC):
  - Impose minimum requirements to the EU member states
  - Each state certain amount of discretion as to how implement the Directive

- **Divergences** in the types of trials covered by the Bolar
  - All countries accept that *bioequivalence trials* to introduce a *generic are covered*
  - Some countries implemented the directive with a *broader scope* than the minimum required and include *studies and trials for an innovative pharmaceutical product* e.g., DE, FR, BE
  - Other countries such as the Netherlands denies this possibility
What is impact of the new system on the Bolar exemption?

■ How UPC will interpret Bolar exemption?
  ■ UPC will need to consider national law
  ■ But as there are national inconsistencies, CJEU referral might be required
  ■ Art 27(d) UPCA refers directly to the Human Medicines Directive: It might be interpreted narrowly to the scope of the directive itself (only generic products)

■ Divergence still will exist with non-member participating states (UK, ES)
■ Need of improving legal certainty

■ The European Commission is reviewing pharmaceutical legislation
  ■ Considering to broaden Bolar exemption and/or provide guidelines to clarify the scope
  ■ In such a case automatically will broaden UPC Bolar as it refers to the directive
Supplementary protection certificates (SPCs)


- SPCs provide additional protection for patented medicinal and plan protection products for being subject to clinical trials and long commercialization authorization processes.

Current system:

- Applications for a SPC filed and approved at national level.
- Numerous referrals by national jurisdictions for preliminary rulings by the CJEU on the interpretation of the Regulation on Supplementary Protection Certificates.
  - There is a “fragmentation” of SPCs within the EU.
What is the impact of the new system in the SPCs?

- The unitary patent package no dispositions to modify SPCs to introduce unitary SPC

- After the entry into force of the UPC, a UP can be the basic patent for a SPC application, but
  - It still will have to be filed in each country
  - It still will be a bundle of national SPCs based on UP as the basic patent

- The national authorities in each member State will be responsible for the examination of SPC application and grant based on these patents as they do today

- Appeals against refusal of an SPC application will continue to be heard in national courts
Unitary SPC?

- Political discussion about whether SPCs should have unitary effect or not (several uncertainties)
  - No (clear) legal basis on the regulation
  - Who is going to grant the SPC? (EUIPO, EPO, national patent office, virtual office…)

- New EU Initiative for a single procedure for the granting of SPC across the EU / Public consultation closed on 5 April 2022
  - Main shortcoming: SPCs are granted and administered nationally
  - Problems identified in the initiative:
    - Divergent outcomes of the grant procedures across EU countries
    - Lack of unitary SPC protection for the future unitary patent
    - Suboptimal transparency of SPC-related information
    - High cost and administrative burden for SPC users
Proposed options

- **Baseline scenario**: no policy change
  - The SPC system would continue to operate on the basis of existing EU and national rules
  - Future unitary patents could only be extended by national SPCs

- **Non-legislative instruments**: 
  - Guidelines based on the best practices of national patent offices and the case law of the Court of Justice of the European Union (CJEU)
  - Aimed at further harmonizing the current SPC system (help to solve diverging outcomes and transparency information)
Proposed options

- Legislative changes, possibly combined with non-legislative ones

1. **Creation of a centralized system** for SPC protection in the EU consisting of:
   - **Unitary SPC** complementing the future unitary patent
   - **Unified procedure** for granting (bundles of) national SPCs, without creating a unitary SPC
   - **Combination** of the two

2. **Targeted amendments of the SPC Regulations**
   - On the basis of the best practices of national patent offices and CJEU case law aimed at further harmonizing the current SPC system
Thank you for your attention

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