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Strategies in the pharma sector: opt-in or opt-out, a chance to test the UPC in the early stages

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Opt-out and opt-in

What is it?

Opt-out: pull your EP patents/EP patent applications out of the UPC jurisdiction

Opt-in: push your EP patents/EP patent applications back into the UPC jurisdiction

Is it an action point?

Opt-out: yes, if you want – you actively need to opt out an EP patent/EP patent application for it not to fall within UPC jurisdiction

Opt-in: yes, but only after opt-out

→ no active step needed to let EP patents/EP patent applications stay within UPC jurisdiction

→ **default (= no action!): EP patents fall within UPC jurisdiction**

Opting out

Subject-matter of opt-out

Opt-out available **only** for

- ✓ EP patents
- ✓ published EP applications
- ✓ SPCs based on EP patents

→ opt-out NOT available for UP patents nor for SPCs based on UP patents

- SPCs are automatically opted out with their basic EP patents
- Opt-out must be requested in respect of all states for which EP patent has been granted/which have been designated in the EP application (not just UPC states or EU states!), i.e. on behalf of the (real) owners in all states!
- Opt-out **automatically deemed to be withdrawn** if EP patent owner requests unitary effect

Opting out

Duration of opt-out option

Once unitary patent package starts operating,
for 7 years (potentially prolonged by up to 7 extra years):



- a) infringement/non-infringement actions relating to EP patents (and SPCs based on EP patents) can still be brought before EU national courts
- b) patent owner can opt out from UPC jurisdiction for EP patent and/or SPC based on EP patent (unless action is already pending at UPC)
- c) opt-out can be withdrawn = opt-in (unless action is already pending at EU national court)
- d) if opt-out is not withdrawn, EP patent remains opted out for its lifetime

Opting out

When can you opt out?

Sunrise period

Start date: March 1, 2023

Operation of UPC

Start date: June 1, 2023



Why you should NOT opt out

Pros of keeping UPC jurisdiction

- **Single litigation with decision automatically applicable in all UPC states - this is particularly favorable if the decision holds that there is infringement and grants anti-infringement measures**
- **Speedy issuance of decision - this is not necessarily the case in several UPC countries today**
- **Technical judges at least for revocation actions, possibly also for infringement actions**
- Possibility of litigating in English if EP patent is in English
- Possibility of litigating in Italian before local division in Milan



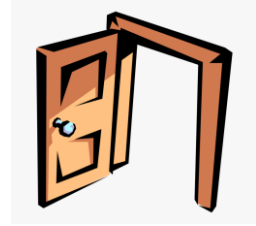
Why you should NOT opt out

Factors favoring keeping UPC jurisdiction

- How likely will the EP patent become involved in litigation?
- How many UPC countries will be affected? Where (in the UPC countries) is the EP patent still in force?
- Is there more than one owner for the EP patent? If so, do they all agree to the opt-out? Can they all be reached?
Are they all the real owners?
- What is the litigation budget of the EP patent owner? Is the EP patent owner used to litigation?
- Does the case lend itself to UPC procedure more than national procedure? E.g. saisie for evidence collection
- Does the case lend itself to UPC case law more than national case law? E.g. validity, infringement

Why some are considering opt out

Possible reasons of staying out of UPC jurisdiction



- UPC = new system with yet-to-be-developed case law
→ so opt-out first and opt-in later? Litigate “test” cases? Help create case law?
- Particularly aggressive competitors may file revocation actions at UPC in addition to/as an alternative to oppositions at EPO
- Already granted EP patents were obtained based on previous litigation system (no trade-off re: validation and renewal fee costs)
- If following national litigation in one UPC country the EP and/or SPC is revoked in that country, the EP and/or the other SPCs survive in the other UPC countries (while in a UPC revocation action the EP and/or all SPCs would be automatically revoked in all UPC countries)
→ e.g. in case of **country-by-country budgets/business organization** rather than EU-wide budgets/business organization

Opt-out: factors to consider

✓ What to look at when deciding whether to opt out

- field of technology – e.g. pharma v. other
- market dynamics
- litigation budget and litigation likelihood
- competitors' activities in Europe – e.g. throughout all of the UPC countries or only in some?
- other???





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