Key lessons for Life Sciences from the first 18 months of the UPC



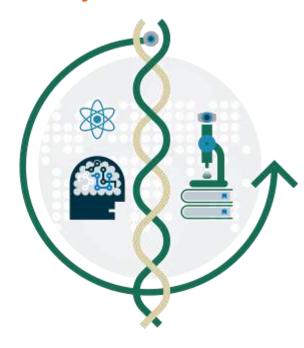
19 November 2024



Welcome to Osborne Clarke's Life Sciences Academy!

Housekeeping:

- The webinars will take place once a month.
- Questions to be submitted via the chat function or email.
- All participants will receive a recording of the webinar.
- We are always happy to receive feedback, comments and topic requests for the future sessions.
- Overview of previous and upcoming webinars on our website: <u>Life Sciences Academy by Osborne Clarke | Osborne Clarke</u>





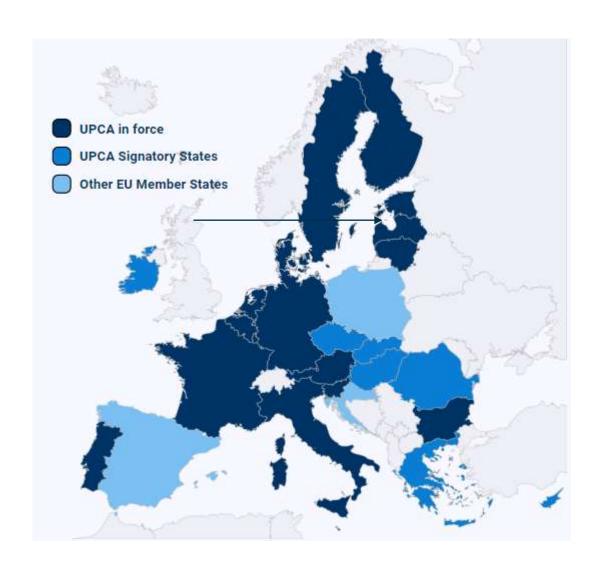


New geography of a European patent dispute



Territorial Scope | Where to go?

- Local Divisions (DE(x4), BE, NL, DK, etc.)
- Regional Divisions (Nordic/Baltic)
- Central Divisions (Paris, Munich, Milan)
- Appeal (Luxembourg)
- Old approach during transitional period (to 2030 or even 2037)
- New UPC approach
- Hybrid of UPC and non-UPC litigation



Building a Litigation Team

- Multidisciplinary teams playing to strengths and in command of RoP from national practice
- Familiarity stifles creativity
- "EPO on steroids"? No.
- UPC judges looking to future, make sure your team is too
- Germany is not the only option use national cultural/procedural differences to your advantage





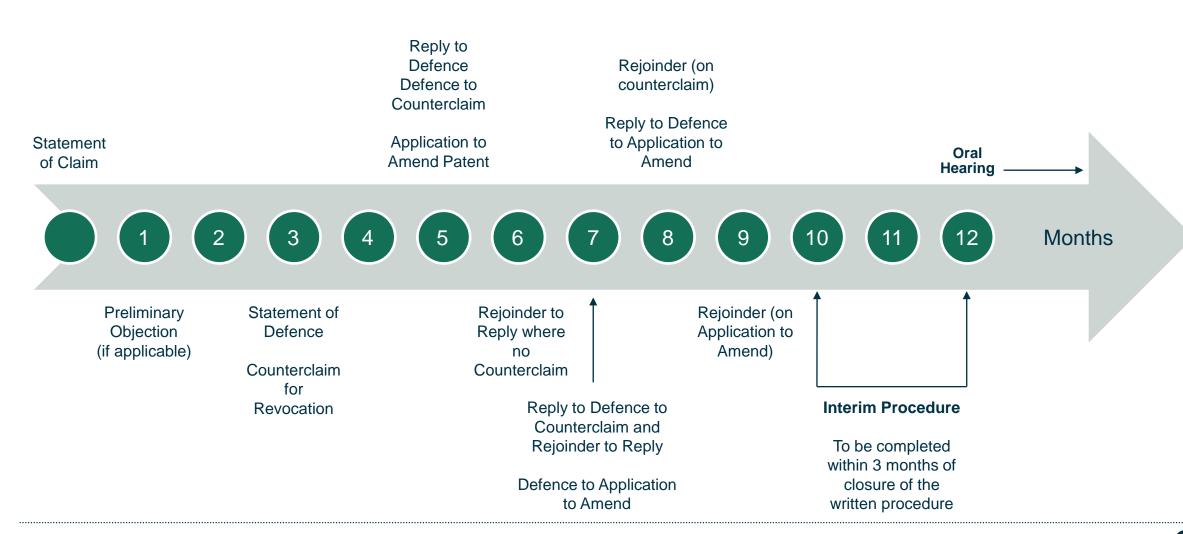




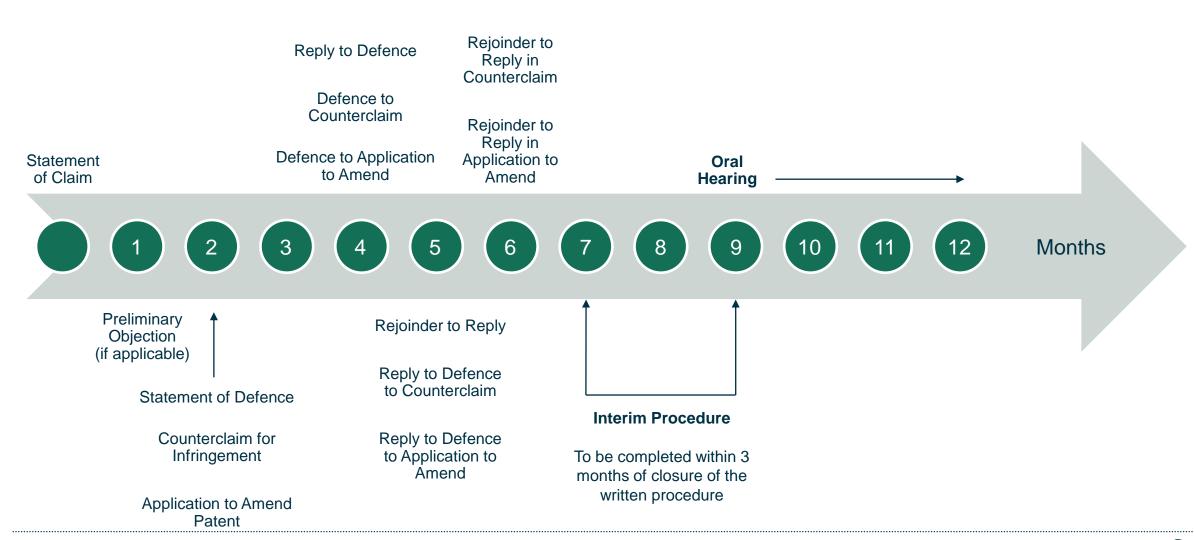
Timelines for UPC actions



Infringement 1st (at Local Division)



Revocation 1st (at Central Division)







Provisional measures



Orders to Preserve Evidence (Saisie), Inspection, Freezing Assets

- The Rules of Procedure include provisions allowing for orders to preserve evidence. Akin to the saisie system in some European jurisdictions. (RoP 192-198)
- May include taking of samples, physical seizure of goods, preservation and disclosure of digital data and passwords. (RoP 196)
- Order not necessarily made without hearing the defendant. Court has discretion whether to inform the defendant and invite submissions from them. (RoP 194(1))
- In exercising its discretion, the court will take account of the urgency of the action, whether reasons given by the applicant that the defendant should not be heard appear well-founded, and the probability that evidence will be destroyed if put on notice. (RoP 194(2))
- If the court decides the defendant should be heard, the claimant may withdraw its request. (RoP 194(5))
- Court may also order inspection of premises etc (RoP 199) and freezing of assets. (RoP 200; 211(1)(c))

Interim / Preliminary Injunctions (PIs)

- UPC has the power to issue interim injunctions taking effect across all UPC Member States.
 (RoP 211(1)(a))
- In deciding whether to order an interim injunction, the court:
 - "<u>may</u> require the applicant to provide reasonable evidence to satisfy the Court with a sufficient degree of certainty that the applicant is entitled to commence proceedings ..., that the patent in question is valid and that his right is being infringed, or that such infringement is imminent." (RoP 211(2))
 - "<u>shall</u> have regard to any unreasonable delay in seeking provisional measures." (RoP 211(4))
 - "<u>shall</u> in the exercise of its discretion weigh up the interests of the parties and, in particular, take into account the potential harm for either of the parties resulting from the granting or refusal of the injunction." (RoP 211(3))
 - "<u>may</u> order the applicant to provide adequate security..." (and shall do so where defendant is not heard) (RoP 211(5))



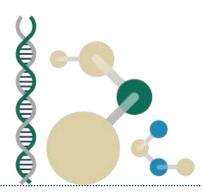
Alexion v Amgen

Timings	Action
19 March	PI filed
1 May	Patent granted!
25 June	LD hearing
26 June	LD decision
17 July	LD reasons
27 July	Appeal filed
4 November	CA hearing
???	CA decision and reasons



Couleur Locale

- Timing?
- Language?
- Saise execution?
- File wrapper estoppel?
- Use of experts?
- Approach to the hearing?
- Commercial arguments?



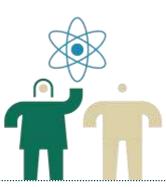


The Trial



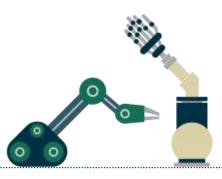
The Trial – Sanofi v Amgen Munich CD (16 July 2024)

- Cases 1&2, first full infringement and validity hearing
- Presiding Judge (DE, legal), J-Rapp (NL, legal and technical), Technical Judge (DK)
- Less than a full day
- Experts seen but not heard (hybrid flexible use of technology)
- Started with claim construction indication to parties as to issues to be addressed
- Inventive step used German approach not EPO approach



Take Home Points

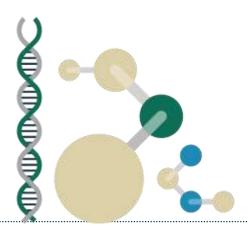
- VERY front-loaded, VERY aggressive deadlines, VERY inflexible approach to extensions
- Not the EPO, not the local national patent court either
- Inventive step test evolving
- Expert Evidence (at least in German) not given precedence
- Decide how you want your case to be heard and choose LD/RD accordingly



Influence of non-UPC Courts on UPC litigation – just this month

Panasonic sued Xiaomi in UK, DE and UPC [Telecoms]

- Global FRAND licence to be determined in the UK end of Oct, with full licence terms due Dec 20204/Jan 2025
- Panasonic and Xiaomi have committed to the UK court's full licence
- UK Court of Appeal found that Panasonic should offer Xiaomi a licence for the <u>interim</u> period until UK court's full licence
- Xiaomi have accepted the interim licence and therefore UPC infringement litigation is largely redundant – as Xiaomi is licensed to the patents in issue on an interim basis and then will be on a final basis once the full licence terms have been determined – so no threat of an injunction against Xiaomi
- Both Panasonic and Xiaomi requested the UPC stay





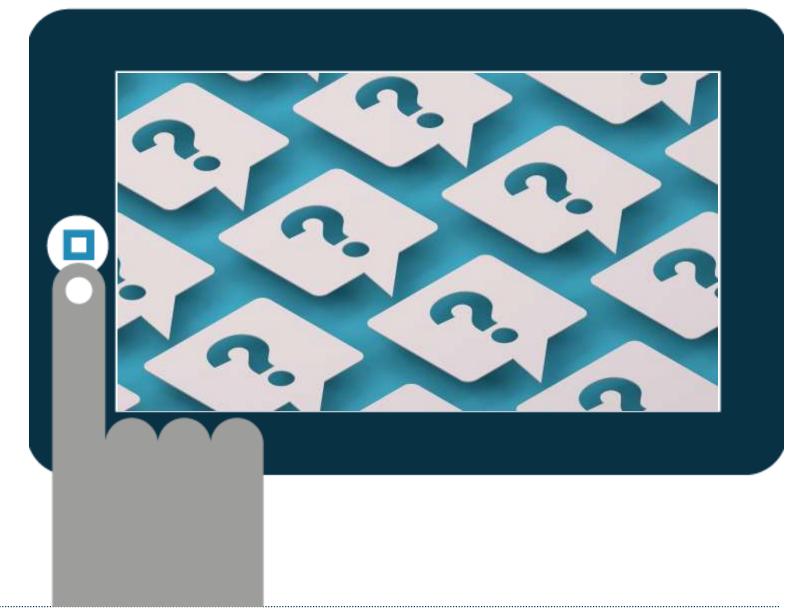
Key takeaways



POINT 1

POINT 2

POINT 3





Your speakers





Will James
Partner
United Kingdom

T +44 207 105 7774 will.james@osborneclarke.com

Will is a patent and IP specialist with extensive expertise in two distinct sectors – life sciences and technology, with a particular interest in the application of artificial intelligence to both - which allows him to draw on his scientific training in biotechnology and neuroscience. Heading up Osborne Clarke's UK Life Sciences and Healthcare sector, Will offers strategic IP services to biotech, pharmaceutical and medical device clients, helping them navigate complex landscapes of patent and IP issues.



Tim HarrisPartner
United Kingdom

T +44 207 105 7144 tim.harris@osborneclarke.com

Tim is ranked in the Legal 500 as a 'next generation' pharma and biotech lawyer. With a long-held interest in the field allied to his scientific training, Tim is a firm believer in the transformative power of life sciences and the remarkable impact they can have on people's lives.

Today Tim's principal focus is on patents and related rights, providing strategic advice and litigation expertise in the English Court and Unified Patents Court principally to innovator biotech and pharma companies.



Valentin de le Court Partner Belgium

T +32 2 515 9362 valentin.delecourt@osborneclarke.com

Valentin has over fifteen years of experience in innovation-related intellectual property law, including four years of practice in China. His area of expertise covers contentious and non-contentious IP matters, with a focus on patent law, trade secrets protection and management, open innovation contracts, and China-related IP strategies.



Thank you

