Decision Time: The Unified Patent Court Begins in 2023

 The Unified Patent Court ("UPC") is set to begin on June 1, 2023. Under the UPC framework, a single court proceeding could result in simultaneous revocation of European Patents across multiple European Union ("EU") countries, including France and Germany.

A three-month "Sunrise Period" is set to begin March 1, 2023. If a request is filed during the Sunrise Period, patent owners can "opt-out" specific patents from the UPC, such that they never become subject to the UPC unless the patent owner decides to withdraw the opt-out. However, the opt-out procedure is not necessarily straightforward. Importantly, if not done correctly ***and*** completed within the Sunrise Period, any patent challenged by a third party within the UPC will irrevocably be confined to the UPC's jurisdiction. Given the high stakes, patent owners should begin assessing which patents they would like to opt-out of the UPC and ensure that the necessary parties are involved in the opt-out procedure. Parties to license agreements, collaboration agreements, and the like should evaluate their existing agreements to see if they are UPC ready. Further, parties to future agreements should take the UPC into account when drafting those agreements.

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Canadian Patent Examination Will Soon Be More Expensive, Less Flexible and Require Additional Care in Prosecution to Avoid Loss of Rights

Canadian Patent Examination

Significant fee increases will be effective at the Canadian Intellectual Property Office ("CIPO") on October 3, 2022 related to excess claims (claims over 20) and the number of examination reports it

issues during prosecution. These changes may negatively impact the breadth of patent protection an applicant could pursue in Canada and will likely also require additional care in strategic filing choices during patent examination. Prior to October 3, 2022, applicants should consider requesting examination for pending applications in order to minimize the impact of these fees (the fee increase will not apply to patent applications for which a request for examination is filed prior to October 3, 2022).

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The Unified Patent Court is (Finally) Coming to Europe and Bringing Some Pretty Fundamental Changes with It

Seven years after the Member States of the EU signed the Agreement on a Unified Patent Court ("UPCA"), the Unitary Patent ("UP") and the Unified Patent Court ("UPC") are likely to commence during the second half of 2022. This promises to bring significant changes to patent protections across Europe, potentially making it easier to both assert *and invalidate* a patent in 24 Member States. Importantly, if current European Patent ("EP") holders wish to opt out of the UP in favor of the existing EP regimen, it will require that they take affirmative steps to do so.

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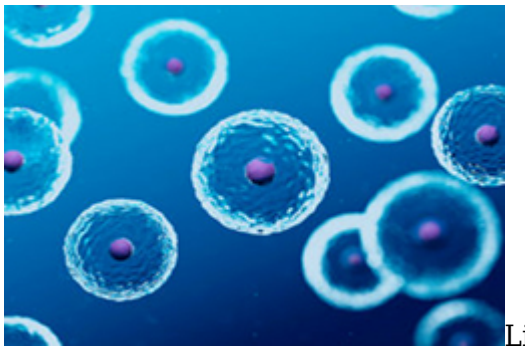
A Primer on Patenting Ranges

Clinical drug candidates are often claimed in a patent as a pharmaceutical composition or formulation with a specified concentration range of the drug or an excipient; as being purified within certain temperature or pH ranges; or in a method of treating a disease by administering the drug at a certain dosage range. For a claim to be patentable over any prior disclosure, the claim must be novel and nonobvious. But how would a drug developer know that the claimed ranges are patentable over a prior disclosure of overlapping or broader ranges?

Read the **insight**.

Strategic Considerations for Seeking Patent Term Extension (PTE) and Its Scope for Drug Products



Life science companies developing new therapeutics – both small molecule and biologic – know that obtaining long patent term for their products is a key driver of valuation and revenue. A particular challenge in this respect is minimizing the loss of patent term during drug development. Fierce competition in the marketplace often requires that innovators patent their drug products as early as possible in the development process, but because the clock on a United States (patent's lifespan starts running the moment it is filed, years of valuable patent term are often lost as a product navigates the regulatory approval process. An important method to mitigate these losses can be found in the Patent Term Extension ("PTE") provisions of 35 U.S.C § 156, which provide statutory compensation for the substantial time and resources expended by an innovator to bring a new drug to market. In a nutshell, PTE restores a portion of the patent term, up to five years, that is lost during the period a new drug or medicinal product is awaiting pre-market regulatory approval in the U.S.. When a new chemical entity ("NCE") – either a small molecule or a biologic – is approved by FDA as a therapeutic, a patent claiming either the NCE or its method of use may be entitled to PTE.

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