NORTON ROSE FULBRIGHT

Beware Shifting ODP & Terminal Disclaimer Practices

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Overview

- Both the courts and the USPTO are under pressure to address perceived problems with nonstatutory obviousness-type double patenting rejections and terminal disclaimer practice
- Fed. Cir.
  - *In re: Cellect*, Nos. 2022-1293, 2022-1294, 2022-1295, 2022-1296 (Fed. Cir. Aug. 28, 2023).
  - *Allergan USA v. MSN Labs*, 24-1061 (Fed. Cir. August 13, 2024).
- USPTO
  - *Terminal Disclaimer Practice To Obviate Nonstatutory Double Patenting*, 89 FR 40439 (proposed May 10, 2024).
  - *Request for Comments on USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights*, 87 FR 60130 (proposed October 4, 2022).

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Definitions 1

- **Statutory Patent Term** – 20-year monopoly granted by Article I, Section 8, Clause 8, of the United States Constitution
  "To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."
  – Calculated from the relevant filing date—not the date of issuance
- **Patent Term Extension (PTE)** – "restores" up to 5 years of statutory patent term lost while awaiting FDA review of safety and efficacy of a product (35 U.S.C. § 156)
- **Patent Term Adjustment (PTA)** – "adds" time to statutory patent term to remedy certain USPTO delays (35 U.S.C. § 154)
- **Obviousness-Type Double Patenting (ODP)** – judicial doctrine that precludes claims on an invention in a subject patent (SP) where claim is patentably indistinct from claims of a reference patent (RP)
- **Terminal Disclaimer (TD)** – used to overcome an ODP rejection by disclaiming a portion of subject patent's term that extends past reference patent's term

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Definitions 2

- **Obviousness-Type Double Patenting (ODP)** – judicial doctrine that precludes claims on an invention in a subject patent (SP) where:
  – claim is patentably indistinct from claim of a reference patent (RP), and
  – the patents share a common owner, a common inventor, or are subject to a joint research agreement
  – may be overcome with a disclaimer
- **Terminal Disclaimer (TD)** – used to overcome an ODP rejection by disclaiming a portion of subject patent's term that extends past reference patent's term

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PTE vs. PTA

- Known prior to *Cellect*: interaction of PTE with ODP and TDs
  - ODP analysis is based on Statutory Patent Term's expiration date, not PTE-"restored" (extended) expiration date
  - PTE is added to a SP's term shortened by a TD filed to overcome an ODP issue
- Not known prior to *Cellect*: interaction of PTA with ODP and TDs
  - Split among different district courts over whether an ODP analysis should be based on Statutory Patent Term's expiration date or later, PTA-adjusted expiration date

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First appeared as part of the conference materials for the
29th Annual Advanced Patent Law Institute session
"Red Flag Warning: Patent Stakeholders Beware Shifting Double Patenting and Terminal Disclaimer Practice"