

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: Collect*, 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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In re: Collect, LLC

PTE vs. PTA

- Known prior to *Collect*: 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 *Collect*: 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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"Red Flag Warning: Patent Stakeholders Beware Shifting Double Patenting and Terminal Disclaimer Practice"