Obviousness-Type Double Patenting

Tom Irving, Finnegan
University Texas/USPTO
March 24, 2023

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Obviousness-Type Double Patenting

- Legal Disputes
  Obviousness of species over genus, if those are the facts; genus over species is more difficult.

- Strategies

  - Distinguish the rejected claims as patentably distinct over the ODP reference (either based on information already of record or, if needed, by collecting further evidence of nonobviousness).
    - For species over ODP reference claim, develop objective indicia for patentability during prosecution for the claim in question and for possible use if claim in question is rejected during prosecution, as well as if appeal and/or litigation ensue.
  - File a terminal disclaimer.
  - File a statutory disclaimer of ODP reference claim(s) in situation where the claim rejected for ODP is in a patent application; case law firmly against if ODP reference and claim in question are in issued patents.
    - 35 U.S.C. 253(a) authorizes disclaiming "any complete claim."
    - Once reference claim is dedicated to the public, no basis for ODP.

Species Over Genus ODP Reference Claim

- Federal Circuit cases require motivation and reasonable expectation of success for ODP of species over domination genus.

- Consider whether ODP rejections are supported by motivation *from the prior art; sometimes can be from the ODP reference BUT . . .*

- ODP reliance on specification of reference patent is limited.

Federal Circuit on Species / Genus ODP

- ODP of species over genus *need motivation and reasonable expectation of success.*
- **"To be sure, obviousness is not demonstrated merely by showing that an earlier expiring patent dominates a later expiring patent.… It is well-settled that a narrow species can be non-obvious and patent eligible despite a patent on its genus**."
  - *Abbvie Inc. v. Mathilda and Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1379 (Fed. Cir. 2014) (finding later species ODP where "prior art references provided ample motivation to narrow a previously patented genus of ... pharmaceutically-acceptable anions to a few" (cleaned up)). See also *UCB, Inc. v. Accord Healthcare, Inc.*, 890 F.3d 1313 (Fed. Cir. 2018), *cert. denied* (U.S., Feb. 19, 2019) and *Takeda Pharm. Co. v. Torrent Pharms. Ltd.*, 2020 U.S. Dist. LEXIS 18069 (D. NJ Feb. 4, 2020), *aff'd*, 844 Fed. Appx. 339 (Fed. Cir. 2021).
- "In the context of claimed chemical compounds, an analysis of nonstatutory obviousness-type double patenting—like an analysis under § 103—entails **determining, *inter alia,* whether one of ordinary skill in the art would have had reason or motivation to modify the earlier claimed compound to make the compound of the asserted claim with a reasonable expectation of success**."
  - *Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1298 (Fed. Cir. 2012).
  - Consider lead compound analysis.

Limited Reliance on Reference Specification

- Federal Circuit has only authorized reliance on specification in limited circumstances.
- "While we stated in *Kaplan* that it is impermissible to treat a 'patent disclosure as though it were prior art' in a double patenting inquiry, we further reaffirmed the holding in *In re Vogel*, 57 C.C.P.A. 920, 422 F.2d 438 (CCPA 1970), that **certain instances may exist where a patent's disclosure may be used**."
  - *In re Basell Poliolefine Italia S.P.A.*, 547 F.3d 1371, 1378–79 (Fed. Cir. 2008).
- "Where a patent features a claim directed to a compound, a court must consider the specification because the disclosed uses of the compound affect the scope of the claim for obviousness-type double patenting purposes."
  - *Sun Pharm. Industries, Ltd. v. Eli Lilly and Co.*, 611 F.3d 1381, 1387 (Fed. Cir. 2010).

Title search: Obviousness Type Double Patenting

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First appeared as part of the conference materials for the
18th Annual Advanced Patent Law Institute session
"Challenges to Obviousness Type Double Patenting, Including patents with PTE or PTA"