

Dissecting The Obviousness-Type Double Patenting Debate

By **Jeremy Lowe** (November 27, 2024)

The prohibition against double patenting serves as a cornerstone of U.S. patent law. It is designed to prevent an inventor from obtaining two patents for the same invention or obvious variations thereof.

At its core, obviousness-type double patenting ensures that an invention's exclusivity operates as a single, unified right, prohibiting fragmentation across commonly owned, duplicative patents.

Historically, ODP has been an expiration-based model, relying on terminal disclaimers to align staggered terms, and unify related patents in a way that is tantamount to having all of the claims in one patent.

The U.S. Court of Appeals for the Federal Circuit's August decision in *Allergan USA Inc. v. MSN Laboratories Private Ltd.* signals a potential departure from the traditional expiration-based model by introducing a procedural exception to ODP.

The court held that a first-issued parent patent, which expires later due to a patent term adjustment, may avoid ODP. This exception applies when related continuation patents within the same family issue later but expire earlier due to receiving less or no patent term adjustment.

Critics argue that Allergan introduces a nonstatutory safe harbor for parent patents that risks eroding the clear statutory boundary between exclusivity and public domain access. Supporters argue that Allergan offers much-needed flexibility to ensure that the guaranteed statutory term for the invention is not lost.

This article examines these competing interpretations and whether procedural exceptions like those in *Allergan* align with the statutory framework and historical foundations of ODP.

The Statutory Framework

In examining the statutory language and legislative intent surrounding ODP, both sides of the *Allergan* debate draw on Sections 101, 154 and 253 of the Patent Act.

Both sides generally agree that ODP enforces a single period of exclusivity, consistent with Section 101's language that an inventor may receive "a patent" for each invention. Both also agree that Section 154 defines the limitations and adjustments available for patent terms, and that Section 253 provides a terminal disclaimer option to overcome ODP by aligning the expiration dates.

Critics of the *Allergan* ruling argue that legislative history from the Hatch-Waxman Act and CREATE Act reinforces a statutory, expiration-based interpretation of ODP, reflecting a congressional intent to consolidate ODP patents without procedural exceptions. In 2004, the late Sen. Orrin Hatch, R-Utah, for instance, stated in the CREATE Act that ODP "applies to situations where multiple patents have issued, even if the patents are filed on the same day, issue on the same day, and expire on the same day."



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Conversely, Allergan supporters argue that the statutory language does not explicitly prohibit later-expiring patents from avoiding ODP if they derive from earlier-filed patents when procedural delays by the U.S. Patent and Trademark Office are involved. They contend that strict expiration-based adherence may penalize patentees who face procedural delays, and the flexibility offered by Allergan is an equitable compromise within a rigid framework.

The Nonalienation Principle

The nonalienation principle prevents fragmentation of ODP patents by requiring the preservation of common ownership over the entire enforceable life of the patents. By requiring temporal and ownership unity through terminal disclaimers, the principle ensures that the invention and its obvious variations are simultaneously released into the public domain when the exclusivity period ends.

Proponents of Allergan's procedural flexibility argue that modern patent practices, including the widespread use of continuation applications, make concerns about alienation largely theoretical. They assert that the nonalienation principle, while doctrinally significant, is rarely implicated in practice, as related patents within a family are typically retained under common ownership and enforcement. Procedural advocates also contend that strict adherence to nonalienation may impose unnecessary rigidity, particularly in cases where procedural delays affect the term of a parent patent.

Expiration-based proponents, however, maintain that Allergan risks undermining the nonalienation principle by introducing the possibility of fragmented patent terms. They argue that such exceptions dilute the foundational unity required under Section 101, potentially complicating the public's ability to discern when an invention and its obvious variations will fully enter the public domain. From this perspective, terminal disclaimers serve as a critical statutory mechanism for preventing alienation risks and preserving ODP's doctrinal coherence.

The Unlawful Extension Principle

The principle of preventing unlawful extensions of patent term lies at the heart of ODP, ensuring that an invention's exclusivity does not exceed its statutory limits.

Proponents of Allergan's procedural flexibility argue that the unlawful extension principle remains intact when the exclusivity period is defined by the first-issued patent within a family. According to this perspective, continuation patents reflect procedural realities, such as delays or strategies in prosecution, rather than attempts to unlawfully extend exclusivity. They view patent term adjustments as a statutory remedy for administrative delays to ensure inventors receive the full benefit of the term initially granted to the parent patent. They contend that Allergan aligns with this statutory purpose, allowing the parent patent to retain its adjusted term without being truncated by the expiration of continuation patents.

In contrast, expiration-based advocates argue that patent term adjustments were designed to address administrative inefficiencies for individual patents, not to resolve conflicts arising from overlapping exclusivity periods within a patent family. Section 154 explicitly ties a patent's term to "the application for the patent," and no statutory provision permits the patent term adjustment of a parent patent to extend to its continuations. They maintain that by bypassing terminal disclaimers, Allergan allows for unlawful term extensions across ODP patents, without clear statutory authorization.

The Public Access Principle

The public access principle ensures that a patent's expiration date provides a clear and definitive marker for when the invention and its obvious variations enter the public domain. This principle represents the core bargain of the patent system — a limited period of exclusivity granted to the inventor in exchange for the public's unrestricted access to the invention after that exclusivity ends.

Proponents of Allergan's flexibility maintain that the parent patent establishes the primary exclusivity period and that any earlier-expiring patents within the family do not meaningfully delay public access. From this perspective, procedural adjustments ensure that inventors can fully realize the term granted to the parent patent, without compromising the public's ultimate access to the invention.

Expiration-based advocates argue that staggered expiration dates within a patent family undermine the predictability necessary for the public to rely on expiration as a definitive marker of access. They contend that the Allergan exception prioritizes the individual patentee's benefits at the expense of public certainty regarding when an invention and its obvious variations will enter the public domain. By allowing different expiration dates for patents claiming the same invention, procedural exceptions like Allergan risk blurring the boundaries between exclusivity and public access.

Future Directions for ODP

The Allergan decision highlights the ongoing evolution of the ODP doctrine, revealing increasing tension between expiration-based interpretations and procedural flexibility.

Expiration-based proponents emphasize that Sections 101, 154 and 253 provide a clear statutory framework for addressing duplicative patents. They argue that terminal disclaimers are the exclusive mechanism for resolving ODP conflicts, ensuring predictability and maintaining the public's ability to anticipate when inventions enter the public domain. This framework strikes a deliberate balance between innovation incentives and public access, while preserving the integrity of the patent system.

Proponents of the Allergan exception highlight the need for procedural flexibility in addressing the complexities inherent in modern patent prosecution. They argue that procedural accommodations ensure fairness for inventors who face prolonged administrative delays, allowing parent patents to retain their full statutory term under Section 154 without being constrained by earlier-expiring continuations. This perspective holds that procedural exceptions, like those recognized in Allergan, align with the intent of patent term adjustments, ensuring that inventors can fully benefit from their primary invention's exclusivity.

As courts and Congress consider these competing interpretations, the future of ODP will likely hinge on reconciling these perspectives. A critical question is whether procedural exceptions can be incorporated without undermining the statutory framework's predictability or weakening ODP's foundational principles.

The Allergan decision attempts to address this issue, but in doing so raises more questions and adds new points of tension. The resolution of this issue will have wide implications, influencing patent strategy, public access to inventions, and the balance between incentivizing innovation and maintaining clear boundaries for exclusivity.

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Disclosure: The author submitted an amicus brief in Allergan v. MSN, in support of the petition for rehearing en banc, on behalf of Alvogen PB Research & Development LLC and Inari Agriculture Inc.

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