IAM

Federal Circuit's latest obviousness-type double-patenting decision is a huge relief for patentees

Adam Houldsworth
09 September 2024

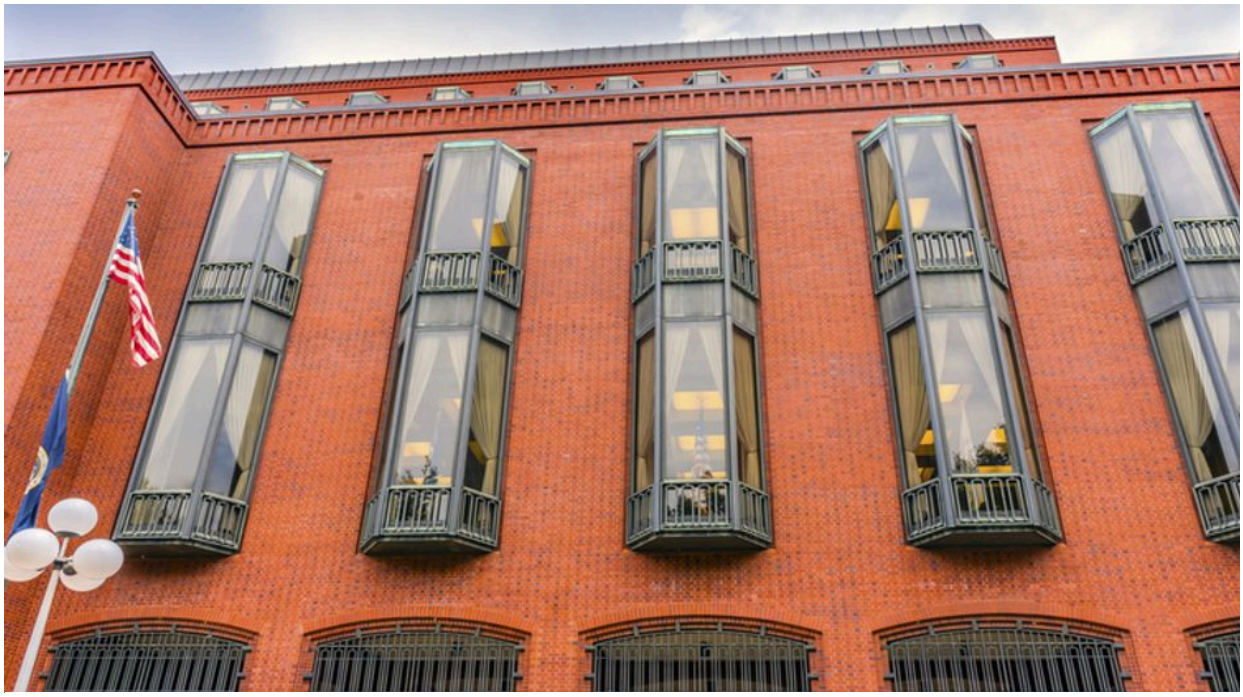

Image from Shutterstock/Bill Perry

IP owners – especially in the life sciences – will breathe a sigh of relief following arguably the summer's most significant patent-related legal decision: the Federal Circuit's **ruling** on obviousness-type double-patenting (OTDP) in *Allergan v MSN Laboratories.*

The judgment has removed some of the worst dangers for patentees that were created by the appellate court's landmark ***In re: Cellect* decision**, which sent shockwaves through the IP landscape 12 months ago. *Allergan* is especially good news for patent owners in view of the proposed rule changes being proposed by the USPTO, which would create new hazards for patentees seeking to avoid OTDP challenges by filing terminal disclaimers.

OTDP is a doctrine, created by the Federal Circuit's 2001 ***Eli Lilly v Barr Laboratories*** judgment, which prevents IP owners from extending their monopoly over an invention by obtaining a later patent with claims that are patentably indistinct from a commonly-owned earlier patent. Where a patent is rejected by the USPTO based on OTDP, it can be salvaged in one of two way: either by changing the claims to cover a patentably distinct invention, or by filing a 'terminal disclaimer' that limits the term of the patent to the expiry date of the IP right which also claims the same patentably distinct invention and that guarantees the patents will always have the same owner. A granted patent subsequently found to be guilty of OTDP will be invalidated if a terminal disclaimer has not already been made.

The Federal Circuit's recent *Allergan* decision clarified an extremely important OTDP-related question that arose from the court's August 2023 *In re: Cellect* ruling. In last year's judgment, the appellate court had addressed a previously unanswered question: whether a patent should fall foul of OTDP if it has claims patentably indistinct from claims contained in a patent in the same family, and expires later than the other IP right because of a patent-term adjustment (PTA) awarded by the USPTO for undue delays in the granting process.

In re: Cellect

The Federal Circuit had previously ruled – in ***Novartis AG v Ezra Ventures*** – that a patent-term extension (not be confused with PTA) awarded to a life sciences patentee as the result of Food and Drug Administration delays would not render a patent invalid for OTDP if its original expiry date would not have made it invalid on this basis.

However, the appellate court took a starkly different approach to PTAs, upholding an earlier USPTO *ex parte* re-examination decision which found several patents belonging to Cellect to be invalid for OTDP based on terms which had been lengthened owing to PTA. "The expiration date used for an OTDP analysis where a patent has received PTA is the expiration date after the PTA has been added," the Federal Circuit judges ruled. As such, the lengthening of a patent term to compensate for delays at the USPTO could lead to invalidity of that patent for OTDP.

This caused consternation among patent owners, especially in the life sciences where the use of continuation patents (which are more likely to fall foul of OTDP) is more strategically important than in some other industries and where PTA is commercially more significant owing to the millions of dollars that can depend on each day of additional patent protection at the end of a product's exclusivity period. In fact, scores of large pharmaceutical innovators filed amicus briefs in favour of a Cellect application for an *en banc* rehearing, which was denied at the beginning of 2024.

Split in the case law

In re: Cellect did not explicitly address the question of whether an earlier-filed, earlier-granted patent whose term had been extended by PTA could be invalidated for OTDP on the basis of a later-filed, later-granted but earlier-expiring patent.

This created uncertainty regarding a fact-pattern that is common to life sciences patent portfolio management, as **Kevin McNish** of McNish PLLC explains:

"The first patent for a particular drug or medical device often obtains patent term adjustment because of delays in the USPTO's examination process. Later, the patentee files continuations from that first patent. Those continuation applications often experience fewer delays: usually they are assigned to the same Examiner that handled the first patent application, and that Examiner is already up to speed on the disclosed invention and relevant prior art (as opposed to having to it study the invention and search for prior art for the first time).

Because those continuation applications experience fewer delays, they often receive less patent term adjustment, if they receive any at all. Although that set of circumstances can arise for patent applications directed to any technology, experience suggests that those circumstances most frequently arise in the "unpredictable arts," ie, the life sciences."

Federal district court judges provided conflicting answers to this question in late 2023.

In good news for patentees, Judge Williams of the District Court for the District of Delaware dismissed a motion for summary judgment of invalidity in ***Acadia Pharm v Aurobindo Pharm***, holding that there was no precedent for a later-filed, later-issued patent being used as an OTDP reference against an earlier-filed, earlier-issued, later-expiring patent. The judge stressed a passage from *In re: Cellect* which states that patents are entitled to their "duly granted PTAs unless they are found to be later-filed obvious variations of earlier-filed, commonly-owned claims".

This clashed, however, with a full first instance judgment handed down in September 2023 by Judge Andrews, also of the District Court for the District of Delaware, in a dispute between Allergan and MSN/Sun Pharmaceutical. Andrews invalidated a later-expiring term-adjusted patent in view of two later-filed patents in the same family. In the September 2023 decision, the judge rejected Allergan's argument that the patent being earlier-filed and earlier-issued distinguished the case from *In re: Cellect*. This distinction was "immaterial", Judge Andrews declared. He also dismissed Allergan's argument that the policy rationale underlying OTDP was incompatible with the invalidation of an earlier-filed patent.

As such, patent strategists have been keenly awaiting the outcome of Allergan's appeal to the Federal Circuit.

Federal Circuit *Allergan* decision clears up the confusion

The decision recently handed down by Judges Lourie, Dyk and Reyna overturns Judge Andrews' decision and cements the more patentee-friendly approach taken by Judge Williams.

In re Cellect had not addressed the circumstances under which a claim can properly serve as an OTDP reference, the Federal Circuit explained, finding that Judge Andrews had misapplied the August 2023 precedent. The later-filed, earlier-expiring patents used as OTDP references by the lower court judge ought not have been used as references, they continued, because this was inconsistent with "the purpose of the [OTDP] doctrine, which is to prevent patentees from obtaining a second patent on a patentably indistinct invention to effectively extend the life of a first patent to that subject matter".

This clears away one of the major OTDP risks for patent owners, especially post-*Cellect*. "Previously, patent holders had to make difficult strategic decisions on how to prosecute continuation applications from a first patent that had received patent term adjustment," McNish explains. "It wasn't unheard of for life-sciences patent holders to abandon continuation applications for fear that an issued continuation patent without patent term adjustment might threaten the patent term adjustment or the validity of the first-issued patent via obviousness-type double-patenting."

"That fear is likely to subside post-*Allergan*," he continues. "I anticipate that patent holders in the life sciences will now be more willing to let later-filed continuation applications proceed to issue as patents, even if those patents would expire earlier than their patent-term-adjusted parent patents."

Dechert's **Katherine Helm** and **Blaine Hackman** explain that the risks created by *Cellect* had caused many pharma companies to consider filing terminal disclaimers when PTA had been awarded to earlier-filed patents. "This was especially important for patents that had PTA and a Section 156 Patent Term Extension. If a PTA and PTE-extended patent was found invalid for ODP during the PTA-extended period, by not filing a terminal disclaimer to disclaim PTA, the patentee risked having the patent held invalid for ODP during the PTA period, before the PTE period began," they say in emailed comments to IAM.

"Such an outcome could mean losing years of both PTA and PTE term on a patent that may be the most valuable in the portfolio for preserving exclusivity of a drug or biologic product," state Helm and Hackman.

"Now, after *Allegan*, sanity is restored and patentees may be able to obtain PTA term for many patents that some considered to have been in jeopardy lost only a few months ago," the comment, "which could now mean years of preserved exclusivity on valuable products."

This doesn't mean – of course – that innovators no longer face OTDP risks, especially if they use continuation applications as part of their patent portfolio management strategy. Patents may still fall foul of OTDP challenges based on their patent-term-adjusted expiry date if they were not filed earlier than a patent in the same family with claims that are obvious variants of its own. Moreover, as *Allergan* makes clear, earlier-filed, earlier-issued patents may still be used as OTDP references against patents from other families, as was established in the Federal Circuit's ***Gilead v Natco Pharma*** decision (2014).

As such, innovators must still think carefully about when it would be wiser to avoid continuation filings and to focus on obtaining fewer, more robust patents with highly distinct claims – an option recommended by Daniel Weinger in **this IAM article**, published shortly after *In re: Cellect.*

Patent applicants should also consider seriously whether to file terminal disclaimers for certain patents, and – as McNish argues in another **IAM article** – to decide whether to file terminal disclaimers on granted patents before asserting those rights.

The USPTO's proposed terminal disclaimer rule change

However, the terminal disclaimer option may be about to become less attractive as the result of a rule change being proposed by the USPTO.

Announced on 9 May this year, this proposed change would require patentees to agree to a third condition as part of a terminal disclaimer: "To overcome double patenting the patentee would need to agree that the patent with the terminal disclaimer will be enforceable only if the patent is not tied and has never been tied through one or more terminal disclaimers to a patent in which any claim has been finally held unpatentable or invalid over prior art."

In other words, if any of the patents bound together by a terminal disclaimer is found to have a single claim that is obvious, all of the patents would become unenforceable. As argued by several patent law commentators – including by my colleague Angela Morris in this recent **article** – this would make continuation patent applications more dangerous and significantly weaken patents that are subject to a terminal disclaimer.

The deadline for public comments on the proposal was 9 June, and the patent profession awaits further announcements from the USPTO.

The fact that this cloud currently hangs over the IP landscape, however, makes the recent decision from the Federal Circuit – which removes the need for terminal disclaimers in certain circumstances – even more important for patent owners.

Adam Houldsworth

Deputy Editor
IAM Media
adam.houldsworth@lbresearch.com

View full biography