Fed. Circ. Cellect Ruling Triggers Significant Patent Risk

By **Curtis Altmann** (January 13, 2024)

Curtis Altmann

Much has been written about the legal arguments in the U.S. Court of Appeals for the Federal Circuit's precedential decision in In re: Cellect LLC, but its practical effects have not been reported.

Here we provide an overview of the decision and examine its potential effects of the decision on existing patent portfolios.

In a case of first impression, on Aug. 28, 2023, the Federal Circuit affirmed the Patent Trial and Appeal Board decision that four patents owned by Cellect LLC were unpatentable under the judicially created doctrine of obvious-type double patenting, or ODP.

On Nov. 13, 2023, Cellect filed a petition for rehearing en banc and a who's who of Big Pharma and industry associations filed amici curiae briefs in support.

Briefly, the Federal Circuit panel held that later expiring patents, granted patent term adjustments under Title 35 of the U.S. Code, Section 154, can be used to invalidate earlier granted patentably indistinct patents under ODP.

A good introduction to ODP case law can be found in the 1972 In re: Vogel decision in the U.S. Court of Customs and Patent Appeals, and more recently in the 1992 General Foods Corp. v. Studiengesellschaft Kohle mbH decision at the Federal Circuit.

Given the interest and number of articles on the Cellect decision, we examined its potential effects on existing patent portfolios. To do so, we developed software to identify such patent families using the U.S. Patent and Trademark Office's Patent Examination Data System's Application Programming Interface.

Starting from an initial patent or application number, reiterative queries of the PEDS API generates a patent family tree de novo including any patent term adjustments, or PTA.

This approach was adopted to ensure that the data relies solely on the U.S. Patent and Trademark Office's records. From this dataset, patent families having a potential Cellect issue — e.g., patent families with at least two patents comprising an earlier granted patent with PTA and a later filed patent without PTA — are labeled as "In re: Cellect hits" and collated for further review.

Our approach was intentionally greedy and ignored potential safe harbor provisions under Title 35 of the U.S. Code, Section 121.

Given the vast number of patents, we focused on patents listed in the U.S. Food and Drug Administration's Orange Book containing 18,782 entries representing 5,525 unique patents, owned by 1,839 applicants.

Here we assumed that the Orange Book, representing high-value patents, would be most carefully scrutinized and curated to ensure their validity and enforceability.

In the initial analysis, all 5,525 Orange Book patents were processed and about 6% of the

total were flagged as In re: Cellect hits. This does not mean that 6% of the patents are invalid given the scope of the search, but assuming diligence for Orange Book patents by the patent owners, it suggests that Cellect could affect a relatively large number of patents.

While largely accurate, the initial "greedy" screen was underinclusive primarily due to requiring the later filed patent to have zero days of PTA. While still in progress, automating the screening process is a challenge.

To evaluate the accuracy of the screen, patent family trees showing the relationship between applications and the associated PTAs were visually inspected.

Given the number of patents for visual screening, we opted to focus on the Orange Book or Purple Book patents held by pharmaceutical companies having at least $10 billion in sales in 2022 — 34 companies. This represented a total of 1551 patents. Among this group, eight companies did not have either Orange Book or Purple Book patent listings.

Trees were generated for all 1551 patents and visually inspected. Of these, 756 patents produced duplicate trees based on the earliest priority application, the root, leaving 795 unique trees for evaluation.

After removing duplicate trees — 756 representing 49% of the total — we examined the remaining 795 trees and binned into one of three categories: "clean," "In re: Cellect hits" and "failed."[1]

From the visual analysis, 479 patents — 31% of the 1551 total, or 60% of the unique trees — were deemed to be clean.

The majority of the families had no PTA or consisted of a single patent and accordingly all these issued patents expire on the statutory date, 20 years from the filing of the earliest application.

Other trees were deemed to be clean where the earlier expiring patent was a divisional application, which assumed the validity of claimed divisional status. That is, the claims fall within the scope of the restriction group and at least one divisional application was filed directly from the restricted parent application.

However, closer analysis of a smaller subset of trees suggests that an assumption that a divisional application benefits from safe harbor under Section 121 may not be correct.

First, according to the Federal Circuit's 1990 decision in Gerber Garment Technology Inc. v. Lectra Systems Inc.:

To gain the benefits of Section 121 there outlined, [the patentee] must have brought its case within the purview of the statute, i.e., it must have limited the claims in its divisional application to the non-elected invention or inventions.

A limited Section 121 analysis of the restriction requirement and the claims was performed in representative cases, but was beyond the scope of the project. Second, in order to retain safe harbor under Section 121, at least one divisional application needed to be filed from the restricted parent application.[3]

By visual inspection, it is clear that at least a subset of the patent families deemed to be "clean" fail the second requirement under Amgen. However, this complication affects a

minority of the clean trees.

Our analysis identified 279 unique patent trees as having potential Cellect issues — 18% of the total, or 35% of the unique trees.

This indicates that Cellect may be a very serious issue. The average number of In re: Cellect hits was 20% per company and only two companies, presenting 47 unique trees, had no In re: Cellect hits. One company's portfolio had 63% of the unique trees flagged with a potential Cellect issue and another had 35%.

To further evaluate the risk, certain In re: Cellect trees were examined for the presence of terminal disclaimers manually as electronic records providing the terminally disclaimed patents or applications are unavailable. In even fewer cases, the claims themselves were analyzed and cleared based on statutory category — e.g., method versus composition, kit, etc.

Statutory categories are often, but not always, distinct.[4]

While useful as a first pass, statutory categories are not sufficient to distinguish the claims, since determination is "whether the differences in subject matter between the claims" … render their claims 'patentably distinct'," as per the Federal Circuit's 2014 Abbvie Inc. v. Mathilda and Terence Kennedy Institute of Rheumatology Trust decision.[5]

Over 100 In re: Cellect trees were examined and annotated with terminal disclaimer information and many remained with potential issues.

Typically, this involved incomplete disclaimer of patents. Incomplete disclaimer of patents is suggested where a later filed patent disclaims an earlier patent which in turn disclaims an even earlier patent — B disclaims A, C disclaims B, but C does not disclaim A.

This is among the most common patterns observed, particularly when the filing dates are separated by many years. Whether this results in a risk turns on a proper claim analysis.

For large patent families, the number of patents and number of terminal disclaimers makes visual inspection difficult, if not impossible.

In select cases, we examined the claims in detail and identified patent families that we believe have bona fide problems if the Cellect decision is upheld.

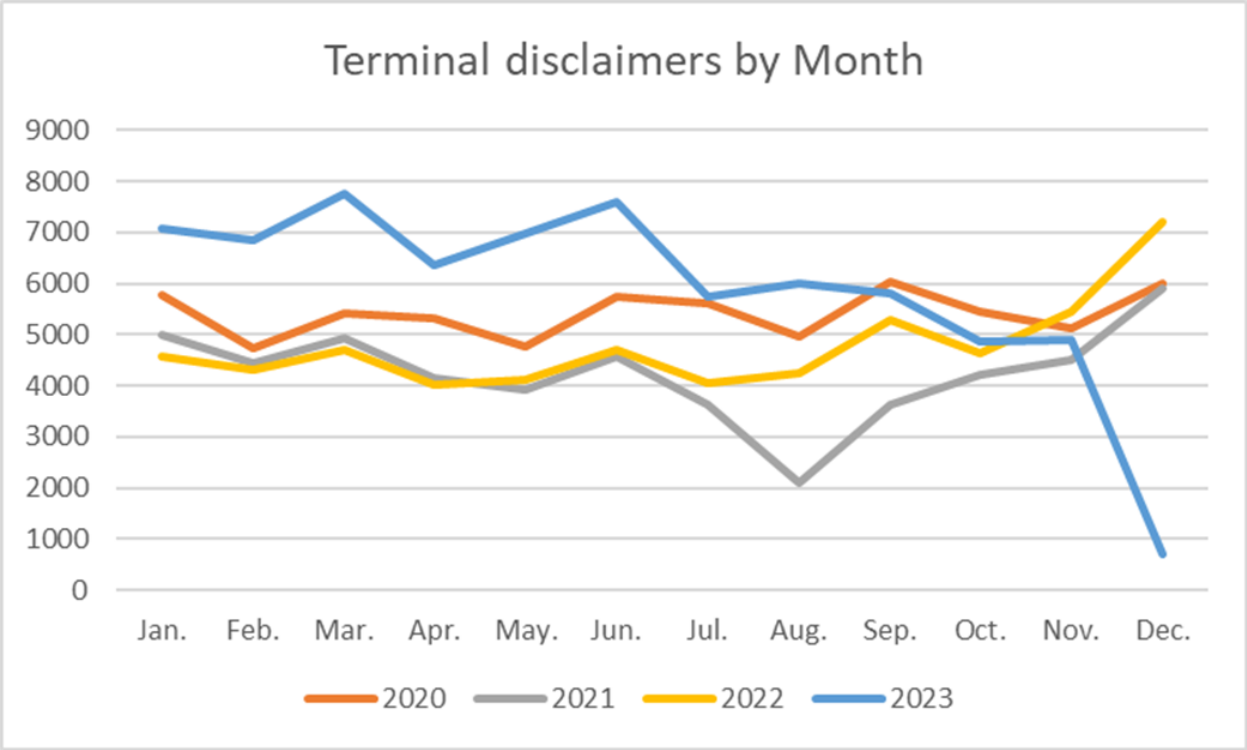
Notably, one of the holdings of the Cellect decision is that ODP, if not specifically addressed during prosecution, meets the threshold for a substantial new question of patentability to properly trigger reexamination proceedings.[6]

Thus, it is possible that a competitor could trigger a reexamination of the patents based on this new threshold and highlights the need to carefully review existing portfolios.

Given the interest of the various parties filing amici curiae and the large number of articles reviewing the case, many parties are aware of the sea change that Cellect has potentially unleashed. With this in mind, we sought to examine whether USPTO terminal disclaimer filings correlated with the decision.

Using Google's BigQuery cloud based system, we determined the number of terminal disclaimer's filed per month for the years 2020 to 2023. The following graph, showing a

40% increase in terminal disclaimer filings between December 2022 and June 2023, suggests that patent owners may be responding to the Cellect decision. Of course, this does not exclude other causes or coincidence.



Breaking out the data by technology center, many art units exhibit an increase in the total number of terminal disclaimers filed in 2022 and 2023 when compared to 2021. Interestingly, Technology Centers 1600 and 1700 lag behind the other technology centers, particularly in the computer fields, despite similar numbers of filings. Thus, there is some support for the proposal that patent owners have become more aggressive in the filing of terminal disclaimers following the Cellect decision.

Table 1: Terminal disclaimer filing per Technology Center

Technology Center	TD's per year			Percent Change		
	2021	2022	2023	2021-2022	2022-2023	2021-2023
1600	7200	7360	7924	2%	8%	10%
1700	5380	5630	5979	5%	6%	11%
2100	5009	5781	6467	15%	12%	29%
2400	9595	9595	11858	0%	24%	24%
2600	5750	7109	8822	24%	24%	53%
2800	5665	6731	8270	19%	23%	46%
3600	5181	5981	7459	15%	25%	44%
3700	6470	7464	8332	15%	12%	29%
3900	1140	219	139	-81%	-37%	-88%
2900	1354	1257	445	-7%	-65%	-67%

Finally, in the course of examining hundreds of patent trees, certain issues became evident in priority claims. While the priority claims of the majority of trees have no obvious anomalies, a significant number revealed two types of potential problems. These issues will be explored in a subsequent article.

In sum, at a high level of review, there appears to be significant risk in subsequent child applications — or follow ups of previously filed patent applications — which may be unpatentable under the judicially created doctrine of obvious-type double patenting due to the Cellect decision and patent owners should be reviewing their portfolios and addressing the issue.

If not addressed, a third party could take advantage of the situation and attempt to trigger a reexamination proceeding. Fortunately, as long as the patents remain pending, a terminal disclaimer can likely be filed, curing any potential defects.

Generally, we believe that terminal disclaimers can be filed strategically with limited downside, though each case should be decided on the facts and after a careful claim review. If our assumption that Orange Book and Purple Book patents are of particular value and thus more curated than other patents, the risk to patents not listed therein may be significantly higher than presented here.

Curtis R. Altmann is a partner at Hoffmann & Baron LLP.

Ohio State University student Kazuki Hayashi contributed to this article.

[1] Production of a tree failed (135, 9% of the total, or 17% of the unique trees) primarily

due to gaps in the data available from the USPTO, particularly for patent families claiming priority to a US provisional application through a PCT application filed in a non-US receiving office.

[2] Gerber Garment Tech., Inc. v. Lectra Sys., Inc., 916 F.2d 683, 688 (Fed.Cir.1990) (emphasis added).

[3] See, Amgen Inc. v. F. Hoffman-La Roche Ltd, 580 F.3d 1340, 1354 (2009) ("Our decisions in Applied Materials and Symbol Technologies thus establish that a patent need not have issued directly from a divisional application to receive § 121 protection. In other words, intervening continuation applications do not render a patent ineligible for § 121 protection so long as they descended from a divisional application filed as a result of a restriction requirement.") (emphasis added).

[4] See In re Boylan 392 F.2d 1017 (CCPA 1968), in re Braithwaite 379 F.2d 594 (CCPA 1967);
Criteria for determining whether claimed inventions are distinct or independent may be found in the Manual of Patent Examining Procedure ("MPEP") at § 806. The MPEP, while informative, does not have the force of law. In re McDonald, 43 F.4th 1340,1348 (Fed.Cir. 2022).

[5] Abbvie Inc. v. Mathilda and Terence Kennedy Institute, 764 F.3d 1366 (Fed.Cir. 2014) citing Sun Pharm. Indus., Ltd. v. Eli Lilly & Co., 611 F.3d 1381, 1385 (Fed.Cir. 2010).
[6] See In re Cellect at 1230.