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Federal Circuit Affirms Stem Cell Product-by-Process Claims: Lessons in Claim Construction and Inherency from Restem LLV v. Jadi Cell LLC

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The Federal Circuit issued a precedential opinion on March 4, 2025, that serves as valuable guidance for product-by-process claims, particularly in the context of inherency in claim construction. In *Restem, LLC v. Jadi Cell, LLC*, the Court affirmed the Patent Trial and Appeal Board's *inter partes* review final written decision in favor of the patent owner, Jadi Cell, LLC, upholding claims in U.S. Patent No. 9,803,176 (the " '176 Patent") directed to stem cells derived from umbilical cord subepithelial layer ("SL") tissue with specific cell marker expressions ("Claimed Cells").

The Court first analyzed the Board's construction of the '176 Patent terms "placing" and "isolated cell," before addressing inherency and explaining why the Majore article—the prior art reference—failed to anticipate the claims.

Restem argued that the term "placing" in the '176 Patent should be limited to two steps from an exemplary embodiment: (1) isolating the SL tissue from other umbilical cord components; and (2) placing the isolated SL tissue *interior side down* onto a growth substrate. According to Restem, placing the SL tissue interior side down further encourages migration of stem cells onto the substate, increasing the likelihood of successful cultivating. The Court disagreed, holding that while the "interior side down" method may be advantageous, it is not a *required* step to achieve the '176 Patent's claims as not all embodiments include this limitation.

Restem's position derived from the Board's finding that "Majore's process differs from at least the interior-down embodiment disclosed in the '176 Patent" and thus does not anticipate. This, Restem argued reflected limitations consistent with its construction. The Court disagreed, holding that because the specification did not explicitly require that language in allembodiments, it would be improper to narrow the claim language beyond that which the patentee themselves claimed. The Board's mention of Majore's differing process was treated not as claim construction, but as a factual finding related to anticipation.

The Court next addressed the Board's construction of the term "expresses/does not express," after the Board declined to explicitly construe "isolated cell." The Board held "express/does not express" to mean "the marker is confirmed present/absent relative to a control sample," a construction consistent with previous interpretations of "isolated cell" as a cell *population*, not a singular cell.

Restem argued this construction was counter to the '176 Patent's own specification that states "as used herein, the term 'isolated cell' refers to a cell that has been isolated from…" However, its own expert acknowledged that it is undisputed that cell marker expression is based on cell populations, tracking the '176 Patent's prosecution history. Throughout the prosecution, the examiner referred to the claimed invention as a "cell population" or "population of cells," further undercutting Restem's argument. Having construed the applicable terms, the Board explained why Majore, alone or in combination with any other prior art did not nevertheless make the claims unpatentable.

The ’176 Patent claims are written as product-by-process claims—defining the product, at least in part, by how it is made. When considering their validity, “the [Court’s] focus is on the product and not on the process of making it,” *Restem, LLC*, No. 23-2054 (Fed. Cir. Mar. 4, 2025) (quoting *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1369-70 (Fed. Cir. 2009)). This reflects the longstanding pillar of patent law that old products are not ‘re-patentable’ simply by way of inventing a new process. *See e.g.*, *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293, 311 (1884). Thus, for validity purposes the question is: does the product (the Claimed Cells) *inherently* result from the process disclosed in Majore or other prior art? Restem argued that inherency is automatic for product-by-process claims, suggesting that the Claimed Cells inherently result from Majore’s process. The Court, however, rejected that view, finding no evidence or testing that cells produced by Majore’s process would inevitably have produced the claimed cell marker expressions. Because Majore’s cells are produced from umbilical cord tissue while the ’176 Patent utilized only the SL, that alone suggests the processes are distinct. Different products cannot anticipate product-by-process claims and as such, the Court affirmed the Board’s findings that Majore did not anticipate the Claimed Cells.

This opinion and the underlying PTAB decision provide insight that practitioners on both sides of the ‘v’ should consider when dealing with product-by-process claims.

First, inherency must be proven. Where the focus is entirely on the product itself and not the process—as is the case for the validity analysis of these claims—petitioners should be wary of relying on the “natural result” as such inherency arguments are often rejected by the PTAB. Concrete evidence is required. Petitioners, who are likely defendants in a parallel patent litigation, should provide evidence that the product *can* in fact result from the process and argue, where appropriate, for a broader construction of claims to ensure the process *does* in fact result in the claimed product. The patent owner, on the other hand, should emphasize any differences in the products, as Jadi Cell did here, that support a distinct product. The patent owner should use its prosecution history strategically. The Court here gave weight to the examiner’s consistent reference to “cell populations,” showing the importance of a coherent narrative during prosecution. It’s important to understand the difference in strategy for validity and infringement arguments on both sides, as your claim construction arguments will inevitably vary depending on the specific claims, the specification, and the prosecution history as well as your ultimate goal.

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