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Fed. Circ. Inherency Ruling Refines Obviousness Framework

By Lawrence Kass (January 29, 2025, 6:51 PM EST)

Patent practitioners have long grappled with how to analyze inherent properties in obviousness determinations — particularly whether inherent properties require their own "reasonable expectation of success" analysis.

The U.S. Court of Appeals for the Federal Circuit has now definitively eliminated this requirement while providing a flexible framework for evaluating modifications to chemical and biological compounds.[1]

In Cytiva Bioprocess R&D AB v. JSR Corp. last month,[2] the court addressed challenges to patents on chromatography matrices used in antibody purification.[3]

The case reached the Federal Circuit after earlier proceedings at the Patent Trial and Appeal Board and district court. After the PTAB ruled that 79 claims were unpatentable and four claims were patentable, the U.S. District Court for the District of Delaware denied Cytiva's request to lift a stay and proceed on just the four surviving claims.[4]

The patents covered antibody purification methods using modified proteins. The prior art had shown that a specific protein modification improved protein stability under alkaline cleaning conditions used in antibody purification.[5] The prior art also suggested this same beneficial modification could work on other similar sections of the protein.[6]

The core dispute revolved around whether making this same modification to another particular section to stabilize the protein would have been obvious to someone skilled in the field.[7]

Cytiva, the patent holder, argued that JSR needed to prove why a scientist would specifically choose to modify that particular section rather than other sections. According to Cytiva, without justifying the choice of that specific starting point, the modification could not be considered obvious.[8]

The court disagreed, holding that special justification is not required for choosing one of several starting points when the prior art suggests all of them could work. The court rejected requiring separate analysis of choosing which protein section to modify, calling it the type of constricted analysis that the U.S. Supreme Court criticized in KSR International Co. v. Teleflex Inc. in 2007.[9]

The modified protein turned out to have certain antibody-binding capabilities, which Cytiva did not dispute were natural results of the modification. A separate issue was whether these inherent binding



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properties needed their own obviousness analysis. When a property is inherent in an otherwise obvious invention, there is no need to show a reasonable expectation of success in achieving that property.[10]

The Federal Circuit also rejected an argument that JSR needed to conduct a formal lead compound analysis — a framework typically used in chemical cases to prove why a skilled person would select a particular starting compound to modify.

The patent owner argued that without proving why someone would specifically choose to modify their selected protein region rather than others known in the field, the challenger couldn't establish obviousness.

The court disagreed, holding that this rigid framework is unnecessary where the prior art expressly suggests modifying any of several options. This aligns with the court's recent shift away from formalistic tests in favor of flexible obviousness analysis under KSR, particularly where the prior art identifies multiple viable starting points.

Finally, the Federal Circuit rejected the board's different standards for process and composition claims.[11] For composition claims, an inherent property could not prevent obviousness. But for process claims, the board required proof that the skilled artisan would have known about that property.

Here, the board found the composition claims obvious despite a newly discovered binding property, but found the process claims not obvious because it believed the artisan needed to know about this binding property in advance. The court rejected this distinction, explaining that the claimed binding property was inherent regardless of claim type and required no separate expectation of success.[12]

The court explained that inherent properties can affect patentability only when prior knowledge of the property is needed to motivate making the invention in the first place. Simply discovering a new property of an otherwise obvious invention is not enough to support patentability.[13]

The Federal Circuit's framework essentially creates a streamlined path to invalidity challenges when properties inherent to the prior art are claimed without being essential to the objective motivation for creating the invention.

While the decision attempts to preserve protection for claims where knowledge of inherent properties provides the motivation to combine or modify prior art, the practical effect may be to narrow the scope of patent protection available for discoveries of new properties in known compositions or processes.[14]

Practical Implications

Cytiva is particularly noteworthy because it shows the court's willingness to find obviousness when prior art suggests multiple viable starting points — in other words, when any of several compounds could serve as the starting point for modification.

Practitioners can gain valuable insights by comparing Cytiva with previous Federal Circuit inherency rulings and should be mindful of two inherency scenarios in obviousness challenges:

• Where knowledge of a combination's inherent feature is required for the motivation to combine but is lacking (combination is nonobvious); and

• Where motivation to combine exists independent of an inherent property that is merely claimed as a feature (combination is obvious).

This distinction is illustrated by comparing Cytiva to the Federal Circuit's 2017 ruling in Honeywell International Inc. v. Mexichem Amanco Holding SA DE CV.[15]

In Honeywell, the Federal Circuit upheld patentability because knowing the combination's stability would have been necessary to provide any motivation to combine its independently unstable components.

By contrast, Cytiva held that discovering and claiming inherent properties cannot support patentability when they are merely natural results of a combination that was obvious for unrelated reasons.[16]

Distinguishing between these scenarios can be particularly important in inter partes review proceedings because IPR challengers must carefully tie inherency arguments to specific teachings in patents and printed publications rather than broader evidence available in district court.

Practitioners should consider that Cytiva's reasonable expectation of success holding likewise may be particularly important in IPR proceedings.

In a petition in Azurity Pharmaceuticals Inc. v. Exelixis Inc. this month, petitioners argued Cytiva relieved them from proving reasonable expectation of success in achieving a property inherent in an obvious combination.[17]

This exemption potentially removes a challenging burden for petitioners, while patent owners may now have to either contest that a property is truly inherent or to demonstrate that knowledge of it provided the necessary motivation to combine.

When applying this framework, practitioners may also wish to consult the Federal Circuit's 2024 decision in Purdue Pharma LP v. Accord Healthcare Inc.,[18] which involved patents on controlling inherent manufacturing impurities in OxyContin.

The court found the patents obvious even though Purdue was first to identify a key impurity in the manufacturing process. While this was an important discovery, the court found it wasn't enough for patentability because ordinary scientists in the field could have found the same impurity through standard testing methods.

Notably, both Purdue and Cytiva demonstrate the Federal Circuit's commitment to flexible obviousness analysis over rigid frameworks. While Cytiva rejected requiring formal "lead compound" analysis when prior art expressly suggests modifications, Purdue clarified that discovering a previously unknown impurity, while relevant to nonobviousness, does not automatically end the obviousness inquiry.

Both decisions emphasize evaluating obviousness from the practical perspective of scientists in the field — what they would reasonably do and find using standard methods — rather than through rigid legal tests.

JSR's successful invalidation of all challenged claims positions it strongly for the resumed Delaware

litigation. After the PTAB's mixed decision finding some claims patentable, Cytiva had attempted but failed to lift the district court stay to proceed on just those claims. With the Federal Circuit's reversal finding all claims unpatentable, JSR appears well positioned for the eventual resumption of the district court proceedings.

The Cytiva decision provides two key clarifications for patent practitioners.

First, when prior art explicitly suggests multiple viable options, the rigid lead compound analysis can be bypassed in favor of a more flexible obvious-to-try approach.

Second, and most significantly, the court eliminated the need to show reasonable expectation of success for inherent properties of obvious combinations, unless knowledge of those properties provides the motivation to combine.

This streamlines the analysis of claims reciting inherent features.

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[1] The Federal Circuit has consistently moved away from rigid frameworks in patent law following KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007).

[2] Cytiva Bioprocess R&D AB v. JSR Corp., 122 F.4th 876 (Fed. Cir. 2024).

[3] Id. at 879-80.

[4] Cytiva Bioprocess R&D AB v. JSR Corp., 1:21-cv-00310, ECF No. 90 (D. Del. Aug. 11, 2023).

[5] Cytiva, 122 F.4th at 881.

[6] Id.

[7] Id. at 881-82.

[8] Id. at 882.

[9] Id. at 884-85.

[10] Id. at 889 (quoting Hospira, Inc. v. Fresenius Kabi USA, LLC, 946 F.3d 1322, 1332 (Fed. Cir. 2020)).

[11] See Michael Green, Lawrence Kass and John Molenda, A Comprehensive Overview of PTAB Trends for Biologics, Law360 (June 26, 2023) (discussing the JSR Corp. v. Cytiva BioProcess R&D AB IPRs).

[12] Cytiva, 122 F.4th at 887-88.

[13] Id. at 888-89.

- [14] Id. at 889-90.
- [15] Honeywell Int'l Inc. v. Mexichem Amanco Holding S.A. DE C.V., 865 F.3d 1348 (Fed. Cir. 2017).
- [16] Cytiva, 122 F.4th at 890 (discussing Honeywell).
- [17] Azurity Pharms., Inc. v. Exelixis, Inc., No. IPR2025-00427, Paper 1 at 33-34 (P.T.A.B. Jan. 9, 2025).
- [18] Purdue Pharma L.P. v. Accord Healthcare, Inc., No. 2023-1953 (Fed. Cir. Dec. 30, 2024).