WINSTON & STRAWN LLP

CLIENT ALERT

Moderna Has Standing to Appeal Because of Risk of Infringement Suit, But PTAB's Rejection of Moderna's Invalidity Arguments Is Affirmed

MARCH 9, 2022

ModernaTx, Inc. v. Arbutus Biopharma Corp., No. 2020-2329 (Fed. Cir. Dec. 1, 2021)

The Federal Circuit affirmed the PTAB's decision that the claims of U.S. Patent 8,058,069 ("'069 patent") are nonobvious. In this appeal, Moderna had argued at an *inter partes* review that the '069 patent was unpatentable because all claims would have been anticipated by and/or obvious over various prior art references. The '069 patent is owned by the Respondent Arbutus.

The '069 patent is directed to "stable nucleic acid-lipid particles (SNALP) comprising a nucleic acid (such as one or more interfering RNA)," as well as methods of making and delivering the SNALP. The court found that Moderna had standing to appeal because it had "demonstrated enough of a risk that it will be faced with an infringement suit based on the combination of its own activities in developing the COVID-19 vaccine, Arbutus's broad public statements about its extensive patent coverage in this area, and Arbutus's refusal to grant a covenant not to sue."

The court addressed Moderna's two arguments regarding obviousness: (1) that the PTAB erred by failing to apply a presumption of obviousness based on overlapping ranges in the prior art, and (2) that Moderna had in fact shown a motivation to optimize the lipid components of the prior-art nucleic acid-lipid particles, and that the phospholipid is a result-effective variable. With regard to the first argument, the Federal Circuit reaffirmed its holding from *In re Applied Materials, Inc.*, 692 F.3d 1289, 1298 (Fed. Cir. 2012) "that evidence that the components 'interacted in an unpredictable or unexpected way could render the combination nonobvious." The court found that Arbutus had demonstrated "that the properties of nucleic acid-lipid particles depend on the particle as a whole, rather than on any one component." Furthermore, the court found "the possibility of calculating multiple different ranges for the phospholipid cuts against Moderna's argument that there is a clearly taught overlapping phospholipid range that compels the application of a presumption of obviousness." With regard to the second argument, the court found that "[e]ven if we accepted Moderna's argument that the phospholipid range is a result-effective variable, we would have to conclude based on the record that the other lipid components in the prior art nucleic acid-lipid particles are result-effective variables." According to the court, "[t]hen the question would be whether Moderna showed that reaching the claimed ranges for these result-effective variables would have been achievable through routine optimization." The court found that Moderna failed to make such showing because Moderna provided evidence of general considerations for each individual component, but did not "address the interdependence of the claimed lipid components and how adjustments would affect the nucleic acid-lipid particle as a whole."

The court ultimately affirmed the PTAB's decision finding that the '069 patent was nonobvious.

2 Min Read

Related Locations

Charlotte | Chicago | Los Angeles | New York | Silicon Valley | Washington, DC

Related Topics

Patent Trial and Appeal Board (PTAB) | Infringement | Patent

Related Capabilities

Patent Litigation | Intellectual Property

Related Professionals

David Enzminger

Brian E. Ferguson

Kelly C. Hunsaker

Ivan Poullaos

Mike Rueckheim

Danielle Williams