

Alice/Mayo and the Printed Matter Doctrine

C.R. Bard Inc. v. AngioDynamics, Inc., 979 F.3d 1372 (Fed. Cir. 2020)

By: Adam Reis & Peter Danos | December 22, 2020

The Court of Appeals for the Federal Circuit (“CAFC”) recently issued a decision providing guidance for analyzing patent eligibility under 35 U.S.C. § 101 when a claim includes limitations directed to “printed matter.”

C.R. Bard., and Bard Peripheral Vascular, Inc. (collectively, “Bard”), and AngioDynamics, Inc. (“AD”) are manufacturers of vascular access ports, which are devices implanted underneath a patient's skin that allow medical providers to regularly inject fluid into the patient’s veins without needing to start an intravenous line each time. As of 2005, the FDA warned that such devices are approved only when labeled. Bard developed such a label for its ports, described as “... a radiographic marker ... etched in titanium foil on the device and a triangular shape and small bumps that were palpable through the skin,” and obtained FDA approval.

AD then sought and obtained FDA approval to market its own ports. Bard sued AD, alleging infringement of several patents containing limitations drawn to the identification label. After trial, the District Court granted AD’s judgment as a matter of law finding the asserted claims invalid under the “printed matter doctrine.” Bard appealed.

“[P]rinted matter encompasses any information claimed for its communicative content, and the doctrine prohibits patenting such printed matter unless it is ‘functionally related’ to its ‘substrate,’ which encompasses the structural elements of the claimed invention.” Here, it was undisputed that the asserted claims included printed matter. Thus, the CAFC solely evaluated whether the printed matter was functionally related to the remaining claimed elements. To support its position, Bard contended that “the information conveyed by the markers provides new functionality to the port because it makes the port self-identifying.” The CAFC disagreed, finding that such a position would “eviscerate” the doctrine and holding that the content conveyed by the markers was not entitled to patentable weight.

In a matter of first impression, the CAFC addressed the applicability of the printed matter doctrine to 35 U.S.C. § 101.¹ A two-step *Alice* evaluation governs the § 101 analysis: (1) whether the challenged claims are directed to a patent ineligible concept, and if so; (2) whether the challenged claims add an inventive concept sufficient to transform the claims into a patent-eligible application.² The CAFC explained that a claim may be found patent ineligible if “directed solely to non-functional printed matter” and the claim lacks an inventive concept.

The CAFC found the claims were not solely directed to printed matter, because “the focus of the claimed advance is not solely on the content of the information conveyed, but also on the means by which that information is conveyed”—specifically, “allow[ing] the implanted device to be readily and reliably identified via x-ray” Further, the CAFC found the evidence was insufficient to establish the claims lacked an inventive concept because the “evidence did not establish that radiographic claimed marking was routine and conventional” Thus, the CAFC found the asserted claims patent eligible.

Given the printed matter doctrine’s focus on conveying information, the CAFC compared Bard’s claims to those assessed in several recent cases dealing with data transmission patents. Thus, the CAFC may be suggesting an approach for practitioners to conquer *Alice* by focusing claims on the nonroutine method by which information is transmitted and highlighting the ways in which that method improves the functionality of the claimed technology.

¹ Historically, the printed matter doctrine was used to conclude that certain limitations were not entitled to patentable weight in assessing novelty and obviousness under 35 U.S.C. §§ 102 and 103.

² *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 218–221 (2014).