

NOTE: This disposition is nonprecedential

**United States Court of Appeals
for the Federal Circuit**

M. R. MIKKILINENI,
Plaintiff-Appellant,

v.

ROBERT STOLL, COMMISSIONER OF PATENTS,
Defendant-Appellee.

2010-1362

Appeal from the United States District Court for the Eastern District of Virginia in case no. 09-CV-1412, Judge Leonie M. Brinkema..

Decided: November 9, 2010

M.R. MIKKILINENI, of Washington, DC, pro se.

RAYMOND T. CHEN, Solicitor, Office of the Solicitor, United States Patent and Trademark Office, of Alexandria, Virginia, for the defendant-appellee. With him on the brief were MARY L. KELLY and SCOTT C. WEIDENFELLER, Associate Solicitors.

Before GAJARSA, LINN, and DYK, *Circuit Judges*.

PER CURIAM.

M. R. Mikkilineni (“Mikkilineni”) appeals from a decision of the U.S. District Court for the Eastern District of Virginia dismissing his claims with prejudice under Federal Rules of Civil Procedure 12(b)(1) and (6). *Mikkilineni v. Stoll*, No. 09-CV-1412 (E.D. Va. Apr. 30, 2010). We *affirm*.

BACKGROUND

Mikkilineni filed a patent application which discloses and claims “a method to fall-asleep by learning to use the process-algorithm in the brain [to] transform brain-neurons into a different[]physical state and produce melatonin and serotonin . . . without the use of drugs.” Appellee’s App. A64–65. Mikkilineni’s claims were rejected in a non-final rejection under 35 U.S.C. § 101 as non-statutory subject matter. During a meeting with Mikkilineni and his patent attorney, the examiner explained that he was required to reject the claims as non-statutory subject matter based on the United States Patent and Trademark Office’s (“USPTO”) Interim Patent Subject Matter Eligibility Examination Instructions (“Interim Guidelines”).¹ The Interim Guidelines provide that “[p]urely mental processes in which thoughts or human based actions are ‘changed’ are not considered an eligible transformation.” USPTO, Interim Examination Instructions for Evaluating Subject Matter Eligibility Under 35 U.S.C. § 101 (Aug. 25, 2009), *available at*

¹ The Interim Guidelines were issued by the USPTO to aid patent examiners in evaluating subject-matter eligibility during the time between this Court’s decision in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), and the Supreme Court’s decision in *Bilski v. Kappos*, 130 S.Ct. 3218 (2010).

http://www.uspto.gov/web/offices/pac/dapp/opla/2009-08-25_interim_101_instructions.pdf.

The Interim Guidelines were posted on the USPTO's official website with a notice requesting public comment and indicating a deadline for receipt of comments. Though not required to do so, the USPTO also published a request for comments in the Federal Register. *See* Request for Comments on Interim Examination Instructions for Evaluating Patent Subject Matter Eligibility, 74 Fed. Reg. 47,780 (Sept. 17, 2009) ("Request for Comments"). The Request for Comments included an explanation that the Interim Guidelines were interpretive guidance based on the USPTO's current understanding of the law, stating specifically that the "Examination Instructions do not constituted substantive rule making and hence do not have the force and effect of law." *Id.* The Request for Comments further advised that "[r]ejections are and will continue to be based upon the substantive law." *Id.*

Mikkilineni filed a response to the Office Action and, one day later, filed suit under the Administrative Procedure Act ("APA") to challenge the USPTO's Interim Guidelines, alleging that the USPTO violated 5 U.S.C. § 553(b)–(c) by failing to provide notice and an opportunity for comment on interim interpretive guidance issued by the agency. Complaint, *Mikkilineni v. Stoll*, No. 09-CV-1412 (E.D. Va. Apr. 30, 2009). The district court granted the USPTO's motion to dismiss under Federal Rules of Civil Procedure 12(b)(1) and (6). We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review orders dismissing under Rules 12(b)(1) or (6) de novo. *Boyle v. U.S.*, 200 F.3d 1369, 1372 (Fed. Cir. 2000). On appeal, Mikkilineni contends that: (1) the Interim Guidelines are substantive rules improperly

promulgated without notice and comment rulemaking, and (2) the USPTO examiner improperly rejected his application. We reject both claims.

I

Under § 553 of the APA, certain agency actions require prior public notice and comment. 5 U.S.C. § 553. Generally speaking, “substantive” rules require notice and comment, while “interpretive” rules do not. 5 U.S.C. § 553(b)(3)(A); *Lincoln v. Vigil*, 508 U.S. 182, 195–96 (1993); *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920, 927 (Fed. Cir. 1991). A rule is “substantive” where it causes a change in existing law or policy that affects individual rights and obligations and “interpretive” where it “merely clarifies or explains existing law or regulations.” *Animal Legal Defense Fund*, 932 F.2d at 927.

Mikkilineni argues that the Interim Guidelines are substantive rules within the meaning of the APA because they substantively deprived him of his rights by requiring the Examiner to reject his claims under § 101. This argument is without merit. The USPTO’s Request for Comments explicitly states both (1) that the guidelines are “based on the USPTO’s current understanding of the law and are believed to be fully consistent with binding precedent,” and (2) that the guidelines “do not have the force and effect of law”; thus, “[r]ejections are and will continue to be based upon substantive law.” 74 Fed. Reg. at 47,780.

Our decision in *Animal Legal Defense Fund* is almost directly on point. See 932 F.2d at 920. In that case, the plaintiffs argued that a notice issued by the USPTO in response to the Supreme Court’s decision in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), was substantive rulemaking and, as a result, must be promulgated via notice and comment rulemaking. *Animal Legal Defense Fund*,

932 F.2d at 923–24. The notice, which stated “that the PTO ‘now considers non-naturally occurring, non-human multicellular organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. § 101,’” mirrored the Supreme Court’s holding in *Diamond*. *Id.* at 922–923; *see also Diamond*, 447 U.S. at 309. This court rejected the plaintiff’s argument, finding that the USPTO notice was interpretive rather than substantive. *Animal Legal Defense Fund*, 932 F.2d at 931.

Accordingly, we conclude that the Interim Guidelines are interpretive, rather than substantive, and are thus exempt from the notice and comment requirements of § 553 of the APA. *See Lincoln*, 508 U.S. at 195–96; *Animal Legal Defense Fund*, 932 F.2d at 927. As a result, the district court’s dismissal under Rule 12(b)(6) was proper.

II

The district court also correctly held that it lacked jurisdiction to review the examiner’s non-final rejection. Under the APA, final agency action is required before judicial review is permitted. 5 U.S.C. § 704. As a general rule, two conditions must be met for agency action to be considered final under the APA: (1) “the action must mark the ‘consummation’ of the agency’s decisionmaking process—it must not be of a merely tentative or interlocutory nature”; and (2) “the action must be one by which ‘rights or obligations have been determined,’ or from which ‘legal consequences will flow.’” *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (internal citations omitted).

There has been no final agency action in this case. The non-final rejection of Mikkilineni’s claims did not constitute the consummation of the agency’s decision making process. Mikkilineni’s claims are still pending—no final rejection has been entered. All prosecution in his application has been stayed pending the outcome of this

litigation. After a non-final rejection, the applicant may reply to the rejection and “the application or the patent . . . will be reconsidered and again examined.” 37 C.F.R. § 1.112. When the examiner issues a final rejection Mikkilineni may appeal to the Board of Patent Appeals and Interferences (“Board”). Only after a Board decision affirming a final rejection is judicial review available. Additionally, the non-final rejection by the examiner is not an action from which legal consequences will flow—in theory, Mikkilineni could still overcome the non-final rejection and receive a patent. As a result, the district court’s dismissal under Rule 12(b)(1) was proper.

AFFIRMED