

## **CLAIM CONSTRUCTION AT PLEADING FOR PATENT-ELIGIBILITY ANALYSIS**

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Commentators have speculated that the Federal Circuit is inching towards requiring a full-blown claim construction for patent-eligibility analysis at the pleading stage.<sup>1</sup> Judge Reyna's recent partial dissent in *Natural Alternatives International, Inc. v. Creative Compounds, LLC*<sup>2</sup> lends strength to the speculation,<sup>3</sup> but the majority of that panel was not quite ready to take the leap.<sup>4</sup> This Comment explores perspectives on this particular issue, although this case is also important in clarifying the eligibility of method-of-treatment claims.<sup>5</sup> This Comment concludes that adopting the patentee's facially-plausible claim construction for

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<sup>1</sup> See, e.g., Gene Quinn, Is the Federal Circuit Closer to Requiring a Real Claim Construction for Patent Eligibility? IPWATCHDOG (Nov. 5, 2018), <https://www.ipwatchdog.com/2018/11/05/federal-circuit-real-claim-construction/id=102993/>.

<sup>2</sup> No. 2018-1295 (Fed. Cir. Mar. 15, 2019).

<sup>3</sup> See *Natural Alternatives*, Dissent Op. at 9 (“This case, and the general development of the law concerning § 101 analysis at the pleading stage, causes me to ask whether the time has come for this court to reconsider whether a Rule 12(c) motion based on § 101 should be decided before claim construction.”).

<sup>4</sup> *Natural Alternatives*, Majority Op. at 5 & n.1.

<sup>5</sup> Some of the patents at issue claim methods of treatment using beta-alanine (an amino acid) provided through a dietary supplement, in order to increase human anaerobic working capacity. *Id.* at 2–3, 6–7. Specifically, the district court found the claims were directed towards the natural law that ingesting beta-alanine increases carnosine concentration in human tissue, which in turn increases the “anaerobic working capacity in a human.” *Id.* at 8. The majority analogized these claims to those in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*, 887 F.3d 1117, 1134–36 (Fed. Cir. 2018). The claims in both cases require affirmative administration of drugs, which the majority suggested to be per se patent-eligible. *Natural Alternatives*, Majority Op. at 8–9 (“These are treatment claims and as such they are patent eligible.”). The majority contrasted these claims with the one in *Mayo*, which “was not a treatment claim, because it was not limited to instances in which the doctor actually decreases (or increases) the dosage level.” *Id.* at 9–10 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012)) (other citations and internal quotation marks omitted). Unlike the claims in *Mayo*, the majority emphasized, the claimed methods in this case and in *Vanda* “go[] far beyond merely stating a law of nature, and instead set[] forth a particular method of treatment.” *Id.* at 11. The majority further held that step two of the *Alice/Mayo* framework requires factual inquiries into whether the claimed invention “would have been well-understood, routine, and conventional,” so judgment on the pleadings was inappropriate as the parties are likely to dispute the factual inquiries. *Id.* at 14; see *infra* note 10 for an explanation of the *Alice/Mayo* framework. The majority also rejected the district court’s finding that the product claims of the supplements themselves were directed to the “natural phenomena of beta-alanine,” because the supplements have characteristics absent in naturally occurring beta-alanine. *Natural Alternatives*, Majority Op. at 16–17. The dissent does not specifically discuss the method claims.

patent-eligibility analysis at the pleading stage strikes a desirable balance between judicial efficiency and fairness.

Natural Alternatives International, Inc. (“Natural Alternatives”) asserted several patents against Creative Compounds, LLC (“Creative Compounds”) in the Southern District of California.<sup>6</sup> Some of these patents claim dietary supplements involving beta-alanine, a natural amino acid (“the Product Claims”).<sup>7</sup> For example, claim 1 of U.S. Patent No. 7,825,084 (“the ’084 patent”) recites: “A human dietary supplement, comprising a beta-alanine in a unit dosage of between about 0.4 grams to 16 grams, wherein the supplement provides a unit dosage of beta-alanine.”<sup>8</sup> The district court granted Creative Compounds’s motion for judgment on the pleadings after adopting Natural Alternatives’s claim constructions for the purpose of that motion.<sup>9</sup> It held that the Product Claims fail the two-step *Alice/Mayo* test, and are thus patent-ineligible.<sup>10</sup> Specifically, the district court found that claim 1 of the ’084 patent “is directed to the natural phenomenon of beta-alanine.”<sup>11</sup>

Writing for the majority on appeal, Judge Moore reversed and remanded. The majority found that the Product Claims are not directed to a natural product, but rather to “specific treatment formulations that incorporate natural products” which possess characteristics absent in naturally occurring beta-alanine.<sup>12</sup> The special “characteristics” here are the supplement’s ability to “effectively increase[] athletic performance” when administered in a sufficiently high quantity.<sup>13</sup> The critical issue is that these requisite characteristics necessary for eligibility are absent from the Product Claims themselves, and are instead supplied by Natural Al-

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<sup>6</sup> *Natural Alternatives*, Majority Op. at 3.

<sup>7</sup> *Id.* at 14.

<sup>8</sup> U.S. Patent No. 7,825,084 col. 22 ll. 26–29.

<sup>9</sup> *Natural Alternatives*, Majority Op. at 5.

<sup>10</sup> *Id.* at 3. The two-step *Mayo/Alice* test works as follows: to ascertain patent eligibility under 35 U.S.C. § 101, a court first determines whether the claims are “directed to” a patent-ineligible concept. If they are, the court then considers “the elements of each claim both individually and as an ordered combination to determine whether additional elements transform the nature of the claim into a patent-eligible application.” *Id.* at 4 (quoting *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 217 (2014)) (internal quotation marks omitted).

<sup>11</sup> *Id.* at 16.

<sup>12</sup> *Id.*

<sup>13</sup> *Id.* at 17.

ternatives's proposed claim construction of "dietary supplement."<sup>14</sup> Like the district court, the majority adopted plaintiff Natural Alternatives's claim constructions given the posture of the motion.<sup>15</sup> The court was therefore able to find the requisite characteristics that naturally occurring beta-alanine cannot achieve, rendering the claims patent-eligible.<sup>16</sup>

Judge Reyna dissented in part because the majority "relies on an erroneous claim construction."<sup>17</sup> Finding no other sources supplying the requisite "characteristics" besides Natural Alternatives's "erroneous" claim construction, Judge Reyna concluded that the Product Claims are patent-ineligible.<sup>18</sup> Unlike the majority which accepted Natural Alternatives's claim construction wholesale, Judge Reyna examined Natural Alternatives's proposed claim construction and found it "improperly imports limitations into the claims, incorporates a definition that is contrary to the plain meaning of the terms, and is flawed because it is contradicted by the written description."<sup>19</sup> But reluctant to perform an independent claim construction in the first instance, Judge Reyna concurred with the majority that this case should be remanded to the district court.<sup>20</sup> Judge Reyna suggested the district court should perform a formal claim construction before revisiting the § 101 issue.<sup>21</sup>

A court has three options on claim construction when performing patent-eligibility analysis at the pleading stage:

- (1) engage in formal claim construction,
- (2) adopt the patentee's construction, or
- (3) adopt a preliminary construction without a formal claim construction process.

Even when a court purports not to have done claim construction, it still has to implicitly interpret all the claim terms in some way to arrive at its

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<sup>14</sup> *Id.* at 8, 17 (Natural Alternatives defined "dietary supplement" as "an addition to the human diet, which is not a natural or conventional food, which effectively increases athletic performance when administered to the human over a period of time.")

<sup>15</sup> *Id.* at 5.

<sup>16</sup> *Id.* at 16–17.

<sup>17</sup> *Natural Alternatives*, Dissent Op. at 2.

<sup>18</sup> *Id.* at 2, 7–8.

<sup>19</sup> *Id.* at 5.

<sup>20</sup> *Id.* at 8–9.

<sup>21</sup> *Id.* at 9.

judgment. It is thus practicing option 3. Commentators have heavily criticized this option because, at the pleading stage, a court typically arrives at a preliminary claim construction absent a thorough review of intrinsic and extrinsic evidence or complete briefing and analyses from the parties.<sup>22</sup> Indeed, many judges have expressed discomfort with ruling on § 101 issues with only a perfunctory, facial review of the claims.<sup>23</sup> However, a formal claim construction under option 1 is costly.<sup>24</sup> It wastes judicial resources especially when the patent-in-suit is clearly unpatentable under § 101. Therefore, option 2 could serve as a reasonable compromise where the court adopts the patentee's claim construction as long as it is facially plausible. This option conforms to the heightened federal pleading standard established in *Twombly* and *Iqbal*, which requires the plaintiff to allege facts suggesting "plausible grounds."<sup>25</sup> The plausibility pleading standard aims to achieve fairness and efficiency by "striking a balance between the claimant's interest in having her day in court and the defendant's interest in avoiding the harassment of meritless suits."<sup>26</sup> Option 2 achieves the same goal: on one hand, it is fair to the patentee because presumably it would propose a claim construction most in its favor; on the other hand, this approach further conserves judicial resources because it doesn't require a full-

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<sup>22</sup> See *Quinn*, *supra* note 2.

<sup>23</sup> Judge Reyna cited several cases on this point. See *Natural Alternatives*, Dissent Op. at 9–10 (“See *Bancorp Servs., L.L.C. v. Sun Life Assur. Co. of Canada (U.S.)*, 687 F.3d 1266, 1273–74 (Fed. Cir. 2012) (“[I]t will ordinarily be desirable—and often necessary—to resolve claim construction disputes prior to a § 101 analysis, for the determination of patent eligibility requires a full understanding of the basic character of the claimed subject matter.”); see, e.g., *Loyalty Conversion Sys. Corp. v. Am. Airlines, Inc.*, 66 F. Supp. 3d 829, 835 (E.D. Tex. 2014) (Bryson, J.) (“[T]he Court has waited until after the claim construction hearing in this case to rule on the [Rule 12(c) motion] in order to ensure that there are no issues of claim construction that would affect the Court’s legal analysis of the patentability issue.”); *Prescriber, LLC v. AO Capital Partners LLC*, No. 6:14-CV-440, 2015 WL 11578559, at \*6 (E.D. Tex. Mar. 31, 2015) (denying Rule 12(b)(6) motion without prejudice to conduct claim construction and obtain a full understanding of the claimed invention relevant to a § 101 analysis).”).

<sup>24</sup> See *Quinn*, *supra* note 2 (“In order to solve a legitimate problem related to the costs associated with getting to a litigated resolution, patent eligibility has become stretched and tortured.”).

<sup>25</sup> *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007); accord *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (“To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’”) (quoting *Twombly*, 550 U.S. at 570).

<sup>26</sup> Daphna Kapeliuk & Alon Klement, *Contracting Around Twombly*, 60 DEPAUL L. REV. 1, 8 (2010).

blown claim construction to weed out meritless cases—if the claims are not patent-eligible even under the most favorable reading, a formal claim construction would only waste everyone’s time.

The majority in *Natural Alternatives* got it right by adopting the patentee’s claim construction because it is facially plausible, even though Judge Reyna could be right that the construction will eventually be found erroneous. The Federal Circuit should continue this practice. ■