



THINK FORWARD

Dietary Supplement Patents Swallowed by the Products of Nature Exception

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It has been just over three years since the U.S. Supreme Court adopted a threshold test for determining patentable subject matter eligibility under §101 in *Alice Corp. Pty. Ltd. v. CLS Bank Int'l.* 134 S. Ct. 2347 (2014). This landmark decision, however, left unresolved several issues, such as whether claim construction is required before determining eligibility, the applicable evidentiary legal standard, and any objective test for determining patent eligibility of natural products. Recently, a district court in the Southern District of California decided, on a motion to dismiss before claim construction, that dietary supplement patents were ineligible for patent protection as encompassing products of nature. *Natural Alternatives Intn'l, Inc., v. Allmax Nutrition Inc.*, Dkt. 64, 16-cv-01764 (S.D. Cal. 2017). This decision reinforces a trending uptick since the *Alice* decision in swift disposal of patent cases with no claim construction.

Since *Alice*, about 90% of cases determining subject matter eligibility under 35 U.S.C. §101 on a Rule 12(b)(6) motion to dismiss have been resolved before claim construction. The Federal Circuit has reasoned that, although an ineligibility determination requires a full understanding of the claimed subject matter, there is no requirement that a court engage in claim construction when there is no claim construction dispute relevant to the eligibility issue. *Cleveland Clinic Found. v. True Health Diagnostics LLC*, No. 2016-1766, Dkt 48 at 12 (Fed. Cir. June 16, 2017). However, where a patent owner proposes constructions for terms, courts will assume all facts alleged by the patent owner to be true, and adopt the proposed claim constructions in the light most favorable to the patent owner in adjudicating motions to dismiss. *Content Extraction & Transmission LLC, v. Wells Fargo Bank, Nat. Ass'n*, 776 F.3d 1343, 1349 (Fed. Cir. 2014). Therefore, it is important that a patent owner facing a challenge to its patent(s) under §101, raise claim construction issues in responsive pleadings or propose construction of terms at issue.

Patentability under §101 is a question of law. However, the applicable legal standard when deciding whether a patent covers patentable subject matter is unclear. The law is unsettled on whether a party attacking validity under §101 must overcome a presumption of validity by a "clear and convincing" standard. *Genetic Techs. Ltd v. Bristol-Myers Squibb Co.*, 72 F. Supp. 3d 521, 526-27 (D. Del. 2014). A potential challenger to a patent should raise subject matter ineligibility challenges early in an infringement proceeding, possibly obviating the need for experts, extensive discovery, and claim construction. On the other hand, a patent owner facing an ineligibility challenge should identify the need for factual discovery before resolution of eligibility issues; otherwise, objecting to the applicable legal standards and appropriate burdens of proof may be seen merely as an academic exercise.