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IP CASE OF THE WEEK

Maintaining § 101 "Till the Cows Come Home"

ChromaDex, Inc. v. Elysium Health, Inc., 2022-1116, (Fed. Cir. Feb. 13, 2023)

By: Edward Runyan and Alexander Bennett | February 17, 2023

In a patent dispute between plaintiffs ChromaDex and Dartmouth College and defendant Elysium Health over spilled milk, the Federal Circuit affirmed the Delaware District Court's grant of summary judgment in favor of the Elysium Health, based the subject matter of the asserted patent being patent-ineligible under 35 U.S.C. § 101. The plaintiffs appealed claiming that their patent on an isolated compound differs from the related, naturally occurring compound found in cow's milk. Neither the District Court nor the Federal Circuit found this argument compelling--both courts explaining that the claims were directed to a natural phenomenon in violation of § 101, and that the alleged significant increase in "NAD+ biosynthesis" and higher concentration of the isolated compound, called "NR", were not part of the claims.

Section 101 states that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." However, the Supreme Court, citing *Myriad Genetics*, explained that laws of nature, natural phenomena, and abstract ideas are not patentable. In recent years, and particularly after the Supreme Court's *Alice* decision, the Patent Office and District Courts across the country have rejected a large number of patents and applications relating to abstract ideas, such as computer-implemented business methods, under § 101. The Federal Circuit here, however, reconfirmed that § 101 is just as applicable to patents directed to natural phenomena.

The Federal Circuit explained that, as in *Myriad Genetics*, mere isolation of a compound that naturally exists is not sufficient, on its own, to confer patent eligibility. The court explained, quoting *Chakrabarty*, that a claimed composition must have "markedly different characteristics and have the potential for significant utility," to be patent-eligible, and noted that the claimed isolated compound was "no different structurally or functionally from its natural counterpart in milk." Notably, the broadest claim of the patent required a "combination" that is an admixture of *any one or more* of 23 different carriers, one of which was "a sugar". Since "milk is an admixture containing a sugar (lactose)," the court found that the claims were only differentiated from milk due to the "isolated [NR]". ChromaDex and Dartmouth argued that the isolation of the composition allows for significant increases of its desirable effects. The panel noted that although that may be true, the claims failed to actually include the purported advantages the plaintiffs relied on. The Federal Circuit further noted that in addition to the claims' ineligibility as products of nature, they were also ineligible because they "lack[ed] an inventive step because they are directed to nothing more than the [same] natural principle (i.e., compositions that increase NAD+ biosynthesis) that rendered the claims patent-ineligible."

The lesson here is that when walking the line of Section 101, a failure to include any "markedly different characteristics" in the claims of a patent can be a fatal mistake. The plaintiffs might have had more luck had they claimed an actual method for isolating the NR and had they kept in mind that claiming many elements in the alternative invites validity challenges, since the presence of just *one* listed element (such as sugar) in the prior art can invalidate such a claim.