DNA Not Patentable in the SDNY

This week, Judge Sweet of the Southern District of New York ruled that patent claims directed to isolated DNA sequences, and methods of comparing or analyzing these sequences to identify a predisposition to cancer, constitute unpatentable subject matter and are invalid under 35 U.S.C. § 101 (1952). This sweeping ruling, if upheld, may impact numerous patents directed to "isolated DNA."

The patents at issue, directed to two genes linked to certain breast and ovarian cancers, were challenged by a consortium of research groups, civil rights organizations, patients and medical organizations. At issue were two categories of claims: (i) isolated DNA coding for polypeptides with a specified sequence; and (ii) methods for identifying a predisposition to cancer based on analyzing or comparing sequences to detect mutations.

After providing a detailed background of the parties and the relevant science, the Court turned to the validity of these claims under § 101. The Court distinguished *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F.2d 95 (S.D.N.Y. 1911) — Judge Learned Hand's decision upholding a patent on purified isolated adrenaline — and similar cases relied on by defendant-patentees, finding that such cases were decided on novelty grounds (embodied today in § 102) rather than on the issue of patentable subject matter addressed by § 101. Finding a common theme in Supreme Court, Appellate and District Court jurisprudence spanning from 1874 to the present, Judge Sweet noted that courts have consistently refused to award patent protection or uphold patents directed to isolated compounds whose "qualities are the work of nature." Judge Sweet ruled that claims directed to "isolated DNA" are among this lot, having their "defining characteristic" not based on structural differences from their naturally occurring counterpart, but based upon the essential information the DNA conveys in encoding proteins — information present in both native and isolated form. *Ass'n For Molecular Pathology v. U.S.P.T.O.*, 09-4515, at 125 (S.D.N.Y. Mar. 29, 2010). The Court ruled that because this essential informational characteristic of isolated DNA is preserved, it is not "markedly different" from native or naturally occurring DNA, and is thus unpatentable under § 101. *Id.* at 122-25.

Sweepingly, Judge Sweet noted that the U.S. Patent and Trademark Office has been issuing isolated DNA claims under an erroneous practice and faulty premise that DNA's "purification from the body, using well-known techniques, renders it patentable by transforming it into something distinctly different in character." *Id.* at 3. While a researcher must go through extensive and costly effort to isolate DNA, that isolation does not alter the "fundamental quality of DNA as it exists in the body nor the information it encodes." *Id.* Thus, Judge Sweet concluded that claims directed to isolated DNA are insignificantly distinct from their natural counterparts, unsustainable as a matter of law and constitute "unpatentable subject matter under 35 USC § 101." *Id.* at 4.

Similarly, Judge Sweet held that the method claims of the patents-at-issue directed to "analysis" and "comparisons" of DNA sequences constituted "abstract mental processes," also unpatentable under § 101. Judge Sweet stated that such claims based on acts of gathering data on human DNA and comparing them

against the isolated DNA "are basic tools of scientific and technological work." *Id.* at 135. Referencing the recent Federal Circuit *en banc* opinion of *In re Bilski*, 545 F.3d at 953, Judge Sweet concluded that there is nothing "transformative" in analyzing or comparing the patented gene sequences against patient DNA, but rather constitutes mere "abstract mental processes" undeserving and unqualified for patent protection under § 101.

An appeal of this decision to the Federal Circuit is all but certain, and it may ultimately lead to a Supreme Court ruling on patentable subject matter — an issue that the high court narrowly avoided just four years ago. *Lab. Corp. of Am. v. Metabolite Labs., Inc.*, 126 S.Ct. 2921 (2006), *certiorari* granted on the issue of § 101, then denied as improvidently granted.

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