Out of Sequence

Pacific Biosci. v. Oxford Nanopore, No. 2020-2155 (Fed. Cir. May 11, 2021)

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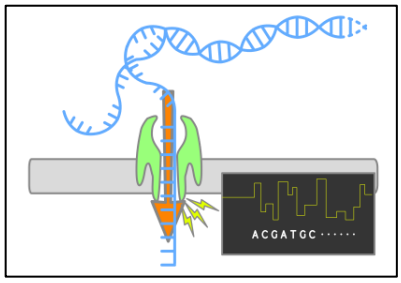
On May 11, 2021, The Court of Appeals for the Federal Circuit (the "CAFC") held two Pacific Biosciences of California, Inc. ("PacBio") patents, U.S. Patent Nos. 9,546,400 and 9,772,323 (the '400 and '323 Patents), invalid for lack of enablement under 35 U.S.C. § 112. PacBio had asserted these patents against Nanopore Technologies, Inc. and Oxford Nanopore Technologies, Ltd. (collectively "Oxford") in the District of Delaware. The jury found the patents infringed, but not enabled. This case illustrates the hazards of stretching one's claim to cover more than one has yet invented.

PacBio's two patents in suit, which share a specification, claim methods for high-throughput genetic sequencing by passing a polynucleotide chain (such as DNA or RNA) through a small aperture (the "nanopore") via an electric current. Individual nucleotide bases are then identified by monitoring changes in the electrical current. The patents provide more technically correct figures, but, as is often the case, Wikipedia best illustrates the gist:



Enablement requires that a patent's disclosure teach the full scope of the claimed invention such that a person of ordinary skill in the art (POSA) could practice it without undue experimentation.[1] This determination is guided by the eight *Wands* factors.[2] PacBio relied on expert testimony that at the time a POSA would have been able to practice the claimed method on ***synthetic*** DNA simulating a specific "hairpin" aberration. However, the claims covered ***all*** types of nucleic acid templates. And, Biological DNA was never successfully sequenced via nanopore technology until 2011, two years after the patents' 2009 priority date. Further, a 2012 conference audience's reaction to ***Oxford's*** announcement of having done so signaled that it represented a major advancement even then. Thus, a POSA as of the priority date and with the disclosure of '400 and '323 patents may have been able to perform *some* very limited types of nanopore sequencing, but not for the full range of nucleic acids claimed.[3]

Enablement supports the foundational *quid pro quo* of patent law: you disclose how your invention works in exchange for a time-limited monopoly on it. A patent applicant may be tempted to cut the track and patent more than it has yet successfully reduced to practice (e.g., to get the jump on its competitors), but does so "at the peril of losing any claim that cannot be enabled[.]"[4]

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[1] *McRO, Inc. v. Bandai Namco Games America Inc.*, 959 F.3d 1091, 1096 (Fed. Cir. 2020); *Amgen Inc. v. Sanofi*, 987 F.3d 1080, 1084 (Fed. Cir. 2021).
[2] *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988)
[3] *See Idenix Pharms. LLC v. Gilead Sciences Inc.*, 941 F.3d, 1149, 1161 ("Where, as here, working examples are present but are very narrow, despite the wide breadth of the claims at issue, this factor weighs against enablement.").
[4] *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1381 (Fed. Cir. 2012)