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The patentability of algorithms

For bioinformatics companies, *State Street* may be the road to patent protection.

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It is customary in biotechnology patent practice to claim DNA, protein molecules, and related variants in accordance with the claimed invention¹. Variants may be isolated from natural sources (homologs), may be entirely synthetic, or both. They may encode a polypeptide sequence identical to the claimed nucleic acid but differing in nucleotide sequence because of the redundancy of the genetic code. Other variants may be described by the functional equivalents of the gene product encoded by the claimed nucleic acid and its variant.

In general, both the DNA and protein molecules of the invention can be defined with reference to "sequence identity," which refers to a comparison made between two molecules using the algorithm of choice. Establishing sequence identity is important because the inference can generally be made that analogous function follows from sequence similarity. With recent improvements in methods of isolating mRNA and the construction of cDNA libraries, companies are now able to obtain large numbers of sequences that they can compare with sequences in GenBank. They generally employ a search algorithm to determine regions of sequence homology, and then these sequences are aligned according to the homology². The algorithm itself and the homology scoring calculations are invaluable in ascertaining nucleic acid homologs of known sequences.

Historically, the US Supreme Court has held that abstract ideas in general and mathematical algorithms in particular are unpatentable subject matter because they do not fall within the four statutory classes of a useful (1) process, (2) machine, (3) manufacture, or (4) composition of matter, or any new and useful improvement thereof³. Therefore, without patent protection, companies have avoided the disclosure of the exact algorithm incorporated in their sequence analysis systems. In light of this fact, it has been very difficult for biotechnology companies that discover, isolate, and/or purify novel protein homologs to enable a person, to the satisfaction of the US Patent



and Trademark Office, to make and use these homologs without disclosing the algorithm used to establish sequence identity⁴. As one might imagine, companies have been torn between the enablement requirement of the patent laws and the desire to protect their proprietary rights to the specific algorithm.

The US Court of Appeals for the Federal Circuit (CAFC) has potentially reconciled these opposing objectives in a recent decision. In *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*⁵, the invention relates generally to a computer and software configuration that provides means for daily allocation of pooled assets for two or more mutual funds. The trial court held that the invention "involves no further physical transformation or reduction than inputting numbers, calculating numbers, outputting numbers, and storing numbers."⁶ On appeal, however, the CAFC stated that "the mere fact that a claimed invention involves inputting numbers, calculating numbers, outputting numbers, and storing numbers, in and of itself, would not render it nonstatutory subject matter, unless, of course, its operation does not produce a useful, concrete, and tangible result."⁷

Although the patent at issue in *State Street* was directed to calculations performed by financial software, the court's reasoning extended further to address any algorithm for performing calculations. In its decision, the court ruled that unpatentable mathematical algorithms are merely abstract ideas constituting disembodied concepts or truths that are not "useful." Therefore, in order to be "patentable an algorithm must be applied in a 'useful' way."⁸ The court's analysis of whether the algorithm is applied in a useful way consists of determining whether a mathematical algorithm is recited, and if so, whether the algorithm is applied to physical elements or process steps that qualify as 35 USC § 101 subject matter⁸. A patent claim that is drafted applying the

algorithm to a specific structure or process step would be patentable subject matter under the court's reasoning⁷.

For example, a claim could be written to describe a method of determining the sequence identity of known protein X and unknown gene product Y, where one of the steps includes the application of the algorithm. Alternatively, a claim may be drafted to a machine programmed with sequence software like the following hypothetical patent claim: a data-processing system for managing and comparing sequence listings, comprising (a) a computer processor means for processing sequence data; (b) a storage means for storing sequence data on a storage medium; (c) a first means for initializing the storage medium; and (d) a second means for processing sequence data regarding homology comparisons between a reference sequence and a query sequence. The CAFC in *State Street* determined that a claim similar to this hypothetical patent claim was patentable subject matter.

Given the importance of algorithms to sequence identity determinations and the importance of identifying new proteins homologous to proteins with known therapeutic uses, *State Street* should prove to be an important case. The decision provides bioinformatics companies in particular with the opportunity to protect their proprietary algorithm, while also affording them the opportunity to enable the public to make and use the claimed invention. How great an impact this decision will have on the biotechnology industry as a whole remains to be seen, but one thing is certain: companies should begin to think about incorporating a set of claims in their patent applications relating to the method of identifying sequence homology, and if applicable, machine claims to the system for carrying out this process.

1. Agris, C.H. *Nat. Biotechnol.* **16**, 1075 (1998).
2. See, for example, Smith, T.F. & Waterman, M.S. *Adv. Appl. Math.* **2**, 482 (1981); Needleman, S.B. & Wunsch, C.D. *J. Mol. Biol.* **48**, 443 (1970); by the search for similarity method of Pearson, W.R. & Lipman, D.J. *Proc. Natl. Acad. Sci. USA* **85**, 2444 (1988); or by computerized implementations of these algorithms (GAP, BESTFIT, FASTA, and TFASTA in the Wisconsin Genetics Software Package Release 7.0. Genetics Computer Group (Madison, WI).
3. 35 USC § 101.
4. 35 USC § 112 Paragraph 1.
5. 149 F.3d 1368 (Fed. Cir. 1998).
6. *State Street Bank v. Signature Financial Group*, 927 F. Supp. 502, 515 (D. Mass. 1996).
7. *Id.* at 1473.
8. *Id.* at 1474.

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