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State Street Alters Landscape of Biotechnology and Bioinformatics Industries

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Inventions involving inputting, calculating and storing of numerical data are now patentable subject matter so long as they produce a "useful, concrete and tangible result." This ruling by the United States Court of Appeals for the Federal Circuit in *State Street Bank & Trust Co. v. Signature Financial Group Inc.* 149 F.3d 1368, 47 U.S.P.Q.2d 1596 (Fed Cir. July 23, 1998) was reported in 153 N.J.L.J. 1252 (September 1998). It established the edict that a data processing system which uses a mathematical algorithm to calculate data for administering mutual funds constitutes a practical application of the algorithm that can be patented. On January 11, 1999, the U.S. Supreme Court denied review, thereby providing clear, unequivocal confirmation that computer-driven, financial services software can be patentable, even if the software does little more than calculate numbers used to manage assets. State Street, No. 98-657, (U.S. January 11, 1999).

The attention generated by *State Street* has emanated primarily from the financial services, insurance and investment industries. Prior to State Street, the United States Patent and Trademark Office had issued over 1,000 patents in the area of finance, accounting and business management. The enforceability of these patents, however, was questionable. *State Street* dramatically changed this landscape, and in so doing, created a valuable opportunity for financial, banking and insurance institutions to exploit their previously unpatentable intellectual property rights (e.g., financial software) through licensing, leveraging strategic alliances, and other financially rewarding means. A lesser, but significant interest has arisen from *State Street*'s, ancillary holding: that patents directed to business methods are subject to the same legal requirements for patentability as those applied to any other process or method. *State Street*, 149 F.3d at 1377, 47 U.S.P.Q.2d at 1604. As Acting Commissioner of Patents and Trademarks Q. Todd Dickinson recently reported, the final quarter of 1998 in the wake of *State Street* witnessed issuance of more than 300 business method-type patents. Brenda Sandburg, "Patent Applications Flow Freely", *Legal Time*s, Feb.

22 1999, at 12. This number is likely to increase in view of the Supreme Court's recent ratification of the Federal Circuit court's decision.

Further evolution of *State Street* has provided basis for protecting process claims employing mathematical algorithms. In *AT&T Corp. v. Excel Communications, Inc.*, (Fed Cir., No. 98-1338, April 14, 1999), the Federal Circuit extended *State Street* to process claims that "apply" a mathematical algorithm to produce a useful, concrete and tangible result without preempting other uses. *Id.* slip op. at 5-6. The case involved AT&T's U.S. Patent No. 5,333,184, which covered technology directed to aiding long-distance carriers. AT&T's patented technology provided differential billing treatment for subscribers that was dependent upon whether a subscriber call was placed to a party having the same or a different long-distance carrier. The AT&T patent disclosed a message record for long-distance telephone calls which was enhanced by a primary interexchange carrier ("PIC") indicator that defined the long-distance carrier used by the caller. Enhancement was accomplished by employing subscribers' and call recipients' PIC's as data, applying Boolean algebra to those data to determine the value of the PIC indicator, and processing that value through switching and recording mechanisms to create a signal useful for billing. *Id*. at 6. The claimed process defined the steps required to automatically route interexchange calls between an originating subscriber and a terminating subscriber, generate a message record for the call, and add a PIC indicator to the message record. *Id.* at 2. The patent issued with independent process and apparatus claims as well as a number of dependent claims.

AT&T filed suit against Excel for infringing its process claims. The district court granted Excel's motion for summary judgment of invalidity based upon the failure of the claims to define statutory subject matter. The Federal Circuit reversed and remanded, comparing the process claims to *State Street*'s machine claims. The court concluded that the claimed process applied a mathematical principle to produce a useful, concrete, tangible result. Moreover, the result was obtained without pre-empting other uses of the mathematical principle. Accordingly, like the claims in *State Street*, the *AT&T* claims comprised statutory subject matter, even absent physical transformation of the data and supporting structure in the specification. *Id.* at 5-6. After *AT&T*, patent protection is not only available for apparatus claims which produce a useful, concrete and tangible result; but extends as well to process claims that perform this same function. These two claim types, together with a third claim type-- business method claims -- are available after *State Street*. Collectively, they have enabled the biotechnology industry, together with its emerging bioinformatics component, to obtain a myriad of different patent rights. These can, in turn, be used by industry players to garner additional revenue.

What is Bioinformatics?

Bioinformatics is the application of computer technology to biology to harness the voluminous amount of genetic information emerging from numerous biological research endeavors. It is essential for the use of genomic information to understand human diseases and the identification of new molecular targets for drug discovery. As

biologists create genetic roadmaps of living beings, bioinformaticians harvest that information through use of specialized computer software programs for database creation, data management, data warehousing, data mining and global communications.

On one level, bioinformatics is associated with database generation, maintenance and analysis of nucleic acid and amino acid sequences obtained from the genomes of many living things. The human genome project, a massive research effort having as its directive the mapping of all DNA strands, or genetic codes, found in the human body, is one such example. Prerequisite to completion of this task is the identification of about 3 million base pairs, or combinations of nucleotide molecules, that form the building blocks of DNA. Strands of DNA made up of nucleotide base pairs are found in each cell of a living being. Thus, every human has about 3 million base pairs in every cell of his or her body. The genome project is scheduled for completion in 2005. By then, scientists, for the first time, will have a complete inventory of the parts that join together to make up a human cell. At the same time, biologists are mapping the genomes for other living things, such as zebra mussels. See, "Bioinformatics Research Team Works On Probe of the Zebra Mussel's DNA Sequence," *Times Union*, September 26, 1998. The availability of automated sequencing procedures has exponentially increased the rate at which these nucleotides, or base pairs, are identified. This, in turn, has resulted in the generation of a prodigious amount of data.

The overwhelming volume of generated data has restricted the options available for use in unraveling the genetic code of living beings. For this purpose, computer software that catalogs and manipulates this information presently represents the only viable approach. Advantageously, bioinformatics has become the tool that enables science and industry to turn these leviathan storehouses of biological data into meaningful information.

On yet another level, bioinformatics occupies a central and essential role in drug discovery. Classical drug discovery has largely proceeded on the basis of trial and error. For every minor breakthrough, numerous failures have been documented. Bioinformatics has essentially replaced bench chemistry in the hunt for better drugs. High throughput screening and combinatorial chemistry provides a bioinformatics framework by which researchers can identify synthetic molecules for treating human disease or new drug targets for therapeutic intervention. Similarly, bioinformatics allows researchers to evaluate a tremendous number of candidate chemicals across large patient populations. These techniques thus allow science and industry to radically shorten research and development time and expense, while exponentially increasing the number of materials available for drug discovery.

Bioinformatics is also viewed as a mechanism that furthers the advance of genomic-based medicines. For example, scientists hope to link raw DNA sequence information to the biology involving the function of proteins and the nature of diseases. They are seeking clues that aid the location of DNA fragments coupled with biochemical triggers which can turn a gene off or on, or up or down, in various parts of the human body. Once this knowledge base is unraveled, further research could unearth a new crop of drugs, which may then be fine-tuned to match the genetic

codes of individual patients.

Industry estimates suggest that the quantum of information made available to drug discovery companies by the human genome and related projects doubles every 14 months. "Biotechnology Investments, Ltd: Seed Funds Launch of New Bioinformatics Company", *Bioaccess*, December 1, 1998. This will further the pharmaceutical industry's need to halve discovery times by the year 2000 and increase the number of development candidates threefold. See "Re-inventing Drug Discovery - The Quest for Innovation and Productivity," *Anderson Consulting Report*, dated October 15, 1997.

Bioinformatics has thus become the latest frontier in the discovery of new medicines and public health issues. It is certain to influence the future of drug development, pharmacogenetics, clinical trial management and patient stratification in the clinical testing process. It has also become a driving force furthering agribusiness interests in sustainable development and environmental protection by improving, for example, crop production.

Bioinformatics has been called "one of the most exciting new areas of genomics". Carl T. Hall, "In Search of 'Something Big'/Ex-Apple exec Delves into Genes," *The San Francisco Chronicle*, March 19, 1998. In fact, industry analysts predict a worldwide market for bioinformatics systems such as software, hardware and databases estimated at $2.2 billion by 2004. Frost & Sullivan *Methods of Drug Discovery Given a Boost by Bioinformatics*, October 5, 1998. Not surprisingly, bioinformatics has found its way into the highest levels of the major pharmaceutical and biotechnology concerns. Several of the leading pharmaceutical houses now utilize software/hardware packages to facilitate the recording, retrieving, and managing of biological data, thereby providing a powerful new setting for drug discovery. For example, Monsanto Co. and Novartis AG currently subscribe to Incyte Pharmaceutical's (Palo Alto, CA) "LifeTools" suite of bioinformatics software. "Genomica, Incyte, NetGenics, Pangea: In Search of a Bioinformatics Operating System," *Bioventure View*, March 1, 1998. Some of the smaller concerns have likewise followed suit. Genomica Corp. (Boulder, CO) believes that there are over 200,00 potential users for bioinformatics software among pharmaceutical, biotechnology and agribusiness companies; regulatory agencies; and research medical genetics companies. *Id.*

The patent paradigm provides a meaningful mechanism for protection of technological innovations. In today's highly competitive market, patent protection is a necessary prerequisite for attaining maximum leverage from research and development investments. Prior to *State Street*, the availability of patent protection for many bioinformatics tools considered essential to the biotechnology industry, was tenuous at best. The inability to base patent rights on technical advances linked to mathematical algorithms prevented biotechnology and bioinformatics companies from securing adequate protection for bioinformatics developments.

Life After State Street

State Street and its progeny will likely change the way in which biotechnology and bioinformatics industries do

business. After *State Street*, patent protection may be attained for mathematical algorithms and related software specifically designed for mining, manipulating and analyzing genetic information. Examples of genetic information for which such mathematical algorithms may be applicable include publicly or privately available DNA, RNA and protein libraries; tools which allow databases, analysis programs and computational algorithms to be accessed within a single platform, software for further modifying this data for physical models, simulations, and the like. Similarly, proprietary processing algorithms, such as those associated with high throughput DNA microarray technology, or combinatorial chemistry methodologies now provide a vehicle for patent protection which safeguards the sizable investments made by companies in these areas.

The ability to patent methods for accessing and manipulating data provides small and large players with means to protect their intellectual property and bolster their market position. Biotechnology and bioinformatics companies can augment or otherwise build patent portfolios based on subject matter circumscribed by *State Street*. New filing strategies and patentable concepts will create offensive and defensive tools for negotiating license and cross-license arrangements, leveraging strategic alliances and settling litigation matters.[1] Timely conducted right-to-use investigations on development products should facilitate implementation of design changes that avoid interference with competitors' patents. Heightened interest in bioinformatics-related inventions will likely cause bioinformatics and biotechnology companies to seek protection for patentable concepts in provinces previously traversed by software companies. Such provinces are likely to involve, for example, securing patent rights in methods of data extraction, methods of tabulating genetic and molecular building blocks and even database design.

Many of the dynamic tools for understanding biological processes and functions are now worthy of patent protection. Development of a comprehensive patent strategy predicated on these dynamic tools should provide a useful mechanism for generation of income and other business benefits. State Street has thus infused the biotechnology and bioinformatics industries with new forms of intellectual property which can be readily identified, protected and exploited. In doing so, the decision has unearthed for biotechnology and bioinformatics companies a significant revenue source and the means to compete effectively in the marketplace.

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[1] 1,635 patent suits were filed in the U.S. District Courts in 1998, and that number is expected to dramatically increase after State Street. Sandburg, supra.

Practice:

Intellectual Property