Evolving IP Marketplace -- Comment, Project No. PO93900

The Need for Distinct Claims

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ZymoGenetics, Inc. is a biopharmaceutical company that owes its existence and success to confidence in the U.S. patent system. Its scientists have made numerous patented discoveries and inventions related to human biology and treatment of human diseases. Its inventions are embodied in seven pharmaceutical products on the market and several more in clinical development by ZymoGenetics and its licensees. ZymoGenetics welcomes inquiry by the Federal Trade Commission ("FTC") into the effect of patents on innovation and competition, as well as FTC's involvement in the debates about proposed changes to the U.S. patent laws.

1. First, Do No Harm. Since issuance of FTC's October 2003 report, major changes have been made to the patent laws via decisions by the U.S. Supreme Court and the Court of Appeals for the Federal Circuit. Any additional changes to the patent laws, by legislation or regulation, should be made only after thorough and thoughtful discussion, and preferably consensus, among the many stakeholders affected by those laws. Any changes should be tailored to address specific problems and minimize unintended consequences

2. Provide Adequate Funding for the USPTO. In its 2003 report, FTC strongly recommended that the U.S. Patent and Trademark Office ("USPTO") should receive funds sufficient to enable it to ensure quality patent review. Today, FTC should reiterate that recommendation. It is unrealistic to expect an underfunded patent office to properly conduct searches and examinations and to issue quality patents. Without adequate resources, there is no realistic hope for resolution of the many problems experienced by users of technology and of the patent system.

3. Calls for Changes in the Patent Law Originate from Problems in High Tech. In its 2003 report, FTC highlighted the problems caused by questionable patents, particularly in industries with incremental innovation, like computer hardware and software. Throughout subsequent hearings by Congressional Committees and FTC and in numerous commentaries, it is clear that the industries experiencing the most difficulties with patent law are largely those in computer software and hardware and telecommunications ("High Tech"). In order to address these difficulties, representatives from these industries have proposed changes to fundamental elements of the patent statute, including major revisions to the law of damages and institution of post-grant opposition proceedings. In contrast, the biotech industry is not experiencing the same problems and is not calling for such changes to the law. For the biotech industry, the existing patent laws work well.

4. Evolving Clarity of Biotech Patents. The difference in attitude between biotech and High Tech is due, in part, to the extensive jurisprudence and regulations regarding Section 112 of the Patent Statute, as applied to biotech inventions. The remaining

sections of this submission discuss first the Section 112 standards as applied to biotech inventions, and second, the need for the development of Section 112 standards as applied to High Tech inventions.

A. Section 112, 1st Paragraph -- First Enablement, Then Written Description. The courts and the USPTO have developed rigorous standards for describing and claiming biotech inventions under Section 112, 1st paragraph. These standards did not appear overnight. The biotech industry began in the 1970s when the first biotech companies were incorporated and landmark biotech applications were filed. The following two decades saw the explosive growth of biotech companies and patent applications and the first lawsuits involving biotech patents. Out of those lawsuits came a series of judicial opinions creating rules that biotech applications are required to meet in order to comply with Section 112. Those opinions initially focused on the requirements for "enablement", due to the cutting edge nature and unpredictability of biotechnology. Then, in 1997, the Court of Appeals for the Federal Circuit determined that the enablement standard, by itself, was not adequate for achieving the balance of claim scope versus disclosure of biotech inventions. In order to refine that balance, the Court harnessed the words "written description" in Section 112, 1st paragraph and put them to work as never before. In U.C. v. Lilly, the Court established the written description requirement as a separate element of patentability, at least for biotech inventions (indeed, the written description requirement appears to be almost exclusively applied to biotech inventions). In 2001, the USPTO issued guidelines on Written Description, with examples to aid biotech applicants. While the written description requirement has led to narrower claims, it has also increased the clarity with which biotech inventions are described and claimed.

B. Courts Applied Existing Statutory Language in the Context of Biotech Inventions. The rigorous standards for enablement and written description, as applied to biotech inventions, were developed without the need for amendments to the Patent Statute. Even though it was written long before the birth of biotech, the Patent Statute established the necessary framework for properly describing and claiming inventions. As courts and the USPTO encountered the special challenges presented by biotech inventions, they turned to existing statutory language and put it to work to resolve the particular problems associated with describing and claiming biotech inventions.

C. Voluntary Efforts to Clarify Biotech Inventions. In addition to the judicial decisions described above, biotech applicants have also benefitted from voluntary efforts of biotech researchers to standardize biotech terms. Organizations, such as the Human Genome Organization and The Gene Ontology Project, work to create a common vocabulary for researchers' exchange of information about the structure, processes and functions of genes. The development of a common biotech language continued as the patent offices of the U.S., Europe and Japan reached a consensus regarding sequence listings, which are the rules for naming

new genes and proteins. Those rules were added to the U.S. Code of Federal Regulations and applicants are required to follow them.

D. Greater Clarity of Specifications and Claims Facilitate Biotech Searches and Analyses. Section 112 standards, as well as the standards developed voluntarily by biotech researchers, provide guidance by which the biotech industry uses the patent system. They help applicants use common terminology and draft more comprehensible specifications and claims. They help applicants and patent examiners create criteria for searching the prior art and analyzing the difference between biotech claims and the prior art to determine novelty and non-obviousness. They help biotech entities assess competitors' patents and applications as part of freedom-to-operate analyses and product clearances. They permit biotech entities to estimate the scope of claims likely to issue from a pending application. In sum, the rigorous Section 112 standards applied to biotech inventions have resulted in more certainty of examination and interpretation of biotech patents.

5. The Need for Clarity for High Tech Inventions. The record of testimony and commentary about Patent Reform is replete with descriptions of problems faced by the High Tech industry. Many of the problems are caused by uncertainty in interpreting High Tech patents and determining claim scope. This lack of certainty is due, in part, to the lack of a common language, as well as to underdeveloped Section 112 standards for describing and claiming High Tech Inventions.

A. Voluntary Efforts to Clarify High Tech Inventions. Members of the High Tech community have proposed practices for improving clarity in High Tech patents. For example, IBM's February 12, 2009 submission to FTC entitled "Improving Patent Clarity" delineates several practical steps that, if used by High Tech applicants, could improve the comprehensibility of applications and facilitate examination of claims, as well as claim construction. The High Tech industry has pioneered the use of standard-setting organizations. Similar efforts among players in the industry could result in common practices used to describe and claim High Tech inventions. FTC should encourage the implementation of practices, such as those proposed by IBM, as well as cross-entity dialogue aimed at improving patent comprehensibility.

B. The Evolving Law of Definiteness, Section 112, 2nd Paragraph. Faced with the challenges of High Tech patents, the courts have re-ignited scrutiny under Section 112, 2nd paragraph. In particular, in a line of cases beginning with the Federal Circuit's 2005 Datamize decision, the courts have begun to scrutinize software and electrical patents under a more stringent "definiteness" requirement. Under this evolving law of "definiteness", claim terms must be supported by a "workable objective standard" or an "objective anchor" in the specification. Thus far, the primary focus has been on "means plus function" claims, apparently common in software patents; the Federal Circuit has stated the need for applicants to disclose corresponding structure such as the software or algorithm used for

performing the claimed function. In September 2008, the USPTO clarified its policy on indefiniteness rejections and has begun applying that policy in decisions by the Board of Patent Appeals and Interferences. FTC should encourage the courts' and USPTO's development of legal standards for "definiteness", particularly in the context of High Tech inventions. The development of more rigorous definiteness standards will permit courts to "weed out the patent thicket", so prevalent in High Tech, by invalidating claims with indefinite terms. Such legal standards will also permit High Tech applicants to evaluate the likelihood that pending applications meet these new standards of definiteness, and hence, are likely to result in issued claims.

C. The Nature of High Tech Inventions Requires "Distinctiveness" in Patent Claims. A key characteristic of many High Tech inventions is that they are designed to operate as a part of a system (such as a computer) or a network (such as a telecommunications network or the internet), where that system or network is the result of hundreds or thousands of contributions, or incremental innovations. Many High Tech inventions would have no value if they were separated from their relevant system or network. They are designed to be "interoperable" with hundreds or even thousands of other components. Because of this characteristic, many High Tech inventions present unique challenges under Section 112, 2nd paragraph; in order for an applicant to describe his or her invention, he or she must also describe the system or network in which is it designed to operate. The evolving standard of "definiteness" will help, but Section 112, 2nd paragraph requires more; it requires an applicant to "particularly point out and distinctly claim what the applicant regards to be his invention". It is not enough simply to describe the invention and its context (the system in which it operates). The claims must distinguish between the applicant's invention and the system or network in which it is designed to operate. The failure of certain High Tech patents to distinctly claim the invention, *i.e.*, distinct from the system or distinct from other system components, is a major source of confusion and unfairness in the patent system.

The Jepson format of patent claiming may be helpful to the High Tech industry to more distinctly claim inventions. The Jepson format allows an applicant to claim an invention as an improvement to existing background technology. One could say that in this format the applicant claims the invention, in part, by conceding that the background technology is not part of the invention. Such a format could prove useful for inventions that are intended to be interoperable or designed to operate as a part of a system or network. FTC should encourage the use of claim formats (such as the Jepson format) whereby the format itself helps distinguish between the invention and the system in which it is designed to operate.

Not all inventions are designed to be interoperable or to operate as part of a system or network. Therefore, not all patent claims will require a Jepson-type format. If an invention is not designed to operate as part of a system, there is no need to distinguish the invention from the other components of the system. But

just as the written description requirement was created and is applied (almost exclusively) to biotech inventions because of specific difficulties of claiming biotech inventions, a distinctiveness requirement would permit courts and the USPTO to resolve specific problems presented by the difficulties of claiming High Tech inventions.

D. Changes Proposed by the High Tech Industry Aim at the Same Problem. Representatives of the High Tech industry have called for statutory changes to the law of patent damages. They propose that, when assessing damages, a court should focus on an invention's "specific contribution over the prior art" or its "essential features". This focus is needed, they say, in order to differentiate an invention from other parts of its environment, including prior art or other components of the system in which the invention operates. Their proposed language is remarkably similar to the text of Section 112, 2nd paragraph -- "particularly point out and distinctly claim what the applicant regards to be his invention".

There is no need to modify the statutory provisions for damages. There is a need to improve the standards by which interoperable inventions are described and claimed. The distinction between such an invention and the system in which it is designed to operate should be made at the time a claim is examined by the USPTO, and when it is scrutinized by a court for validity, for compliance with Section 112, 2nd paragraph. FTC should encourage solutions aimed at ensuring that High Tech claims comply with Section 112, 2nd paragraph, rather than changing the law of damages.