May 15, 2009

The Honorable Jon Leibowitz, Chairman
Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue, N.W.
Room H-135 (Annex I)
Washington, D.C. 20580

Re: Evolving IP Marketplace – Comment, Project No. P093900

Dear Chairman Leibowitz:

On behalf of the member companies of the Biotechnology Industry Organization (BIO), we appreciate the opportunity to respond to the Federal Trade Commission's notice and questions concerning the Evolving IP Marketplace, 73 Fed. Reg. 70645 (Nov. 21, 2008). BIO's membership includes more than 1,200 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 U.S. States. BIO members – the vast majority of whom are small, emerging companies with little revenue and no marketed products – are involved in cutting-edge research and development of health care, agricultural, industrial, and environmental biotechnology products that are revolutionizing patient treatment, greatly expanding our ability to feed a growing world population, and offering the promise of reducing our dependence on oil and other fossil fuels and leaving a cleaner environment for future generations.

The biotechnology industry is singularly dependant on its intellectual property. It is not uncommon for a biotechnology company to expend hundreds of millions of dollars and work for more than a decade before it reaps its first dollar of product revenue. This is due to the huge investments in time and money required to bring a product through the discovery and lead optimization phase and, in the case of healthcare products, preclinical testing, and then clinical trials required to gain market approval. Both pharmaceutical and agricultural products are subject to extensive regulatory approval before commercialization. The early stages of biotechnology product development are most vulnerable to fluctuations in the capital markets. At these early stages a patented idea can and must generate the interest of investors, entrepreneurs, and corporate partners. Among other factors, investors in the biotechnology sector look to a robust patent portfolio before funding the development of a particular technology. Without capital

investment, biotechnology R&D will lessen and promising technologies will not be developed. The certainty that comes from knowing an invention discovered 10-15 years prior to coming to market can be protected provides the incentive for investors to fund high risk biotechnology products. And the strength and scope of biotechnology patents provides investors the assurance that their investments may some day be recouped.

Patent rights are not only critical to ensure continued funding of biotechnology innovation. The extraordinary investment of time, money, and scientific resources necessary to bring a new biotechnology product to market cannot normally be borne by any one entity, however well-funded. Technology transfer, research joint ventures, development partnerships, and sales or licensing of whole technology platforms are commonplace in the biotechnology industry as candidate products require ever larger investments on their path from research discovery to regulatory approval and marketing. This value chain of biotechnology innovation would not be possible if multiple parties would not be able to effectively share and allocate the risk and investment burden of biotechnology R&D in a vibrant and orderly marketplace for biotechnology IP. Because a stable valuation of intellectual property assets is critical to the biotechnology business model, BIO's members are highly alarmed by persistently advanced proposals that would change the substantive standards for determining patent damages awards. In particular, substantive changes to the definition of reasonable royalty awards hold the potential to upset settled expectations over the value of biotechnology patent rights in the marketplace, and to interfere with the way biotechnology companies and research institutions today transfer patent rights for agreed-upon value. Our members believe that proposals for substantive royalty reform such as the one currently pending in H.R. 1260 are ill-conceived and insufficiently justified, and urge the Commission to carefully scrutinize all assertions made in this debate.

With respect to the Commission's questions in its Federal Register notice of November 21, 2008, BIO associates itself with the comprehensive February 10 submission by the Pharmaceutical Research and Manufacturers of America. BIO writes separately to address a particular aspect of the Commission's fourth question, which asks whether the legal rules governing patent damages result in appropriate damages awards, and how problems, to the extent they exist, should be addressed. During the Commission's workshop on December 5, 2008, and again during the February 11/12 2009 workshop, it was suggested by some participants that perceived problems resulting from current judicial damages determinations could be addressed by redefining the claimed invention, for damages purposes, by reducing it to its "essential elements" – a concept that was transposed from last year's Supreme Court decision in *Quanta Computer, Inc. v. LG Electronics, Inc.*, 128 S.Ct. 2109 (2008). *Quanta* dealt with a particular aspect of the doctrine of patent exhaustion, which provides generally that the initial authorized sale of a patented item terminates all patent rights to that item. *Id.* at 2115. *Quanta* addressed the applicability of the doctrine in situations where the item is sold in incomplete or unfinished form, and must first be finished, assembled, or combined by the purchaser before it meets all the limitations of the patent claim. The Court held that, under such circumstances the authorized sale of an article that "substantially embodies" a patent exhausts the patent holder's rights and prevents the patent holder from invoking patent law to control postsale use of the article. An article "substantially embodies" a patent if, first, its only reasonable and intended use is to

practice the patent and, second, it includes all of the "essential" or "inventive" features of the patent. *Id.*, at 2122.

BIO believes that the *Quanta* case and its "essential features" concept is not apposite to the royalty valuation question. *Quanta*, fundamentally, is not a case about the size or appropriateness of a royalty – it only addresses when in the distribution chain so much of the patented invention has been sold that it would be unfair to allow the patent owner to control, or collect additional royalties from, further downstream sales.

The "essential features" concept that was proposed by participants in the Commission's workshops has its origin in the 1942 Supreme Court decision in *United States v. Univis Lens Co.*, 316 U.S. 241 (1942). In that case, the Univis Lens Company, the holder of patents on eyeglass lenses, had licensed a purchaser to manufacture lens "blanks" and to sell them to other Univis licensees at agreed-upon rates. Licensed downstream purchasers would grind the blanks into the patented finished lenses for retail sales at fixed prices. The United States sued Univis under the Sherman Act, alleging unlawful restraints on trade, and Univis asserted its patent on the finished eyeglass lenses as a defense. The *Univis* Court held that the initial sales of the lens blanks exhausted the patent because, even assuming that that the patent was not fully practiced until the blanks were ground and polished by the purchasers, and that sale of the blanks by an unlicensed manufacturer would constitute contributory infringement, each blank "embodied essential features of the patented device" and was without utility until it was ground and polished into the patented lens. *Id.*, at 249. The *Univis* Court stated:

> [W]here one has sold an uncompleted article which, because it embodies essential features of his patented invention, is within the protection of his patent, and has destined the article to be finished by the purchaser in conformity to the patent, he has sold his invention so far as it is or may be embodied in that particular article. *Id.*, at 250.

Univis, explained the Supreme Court in *Quanta*, "concluded that the traditional bar on patent restrictions following the sale of an item applies when the item sufficiently embodies the patent-even if it does not completely practice the patent-such that its only and intended use is to be finished under the terms of the patent." *Quanta*, at 2116-7.

In *Quanta*, LGE had licensed patents to Intel Corporation under agreements that authorized Intel to manufacture and sell microprocessors and chipsets using LGE's patents, but apparently intended that Intel's downstream customers would have to take a separate license from LGE in order to combine the purchased Intel microprocessors and chipsets with other computer components into finished patented computers. Quanta purchased microprocessors and chipsets from Intel and then manufactured computers using the purchased parts in combination with other components. LGE sued, asserting that this combination infringed the LGE Patents. In the Supreme Court, Quanta argued that the sale of the microprocessors and chipsets exhausted LGE's patents in the same way the sale of the lens blanks exhausted the patents in *Univis*. In both cases, the articles that were sold did not fully practice the patents and had no use other than to be finished, or assembled, into the patented product.

The Court agreed, stating first, that, like the *Univis* lens blanks, the microprocessors and chipsets had no reasonable use other than to incorporate them with other parts into the patented computer system. Second, like the *Univis* lens blanks, the microprocessors and chipsets constituted a material part of LGE's patented invention and all but completely practiced the patent. The Court observed that

> [i]n each case, the final step to practice the patent is common and noninventive: grinding a lens to the customer's prescription, or connecting a microprocessor or chipset to buses or memory. The Intel Products embody the essential features of the LGE Patents because they carry out all the inventive processes when combined, according to their design, with standard components. *Id.*, at 2120.

Importantly, the Court defined the "essential" or "inventive" features of the patent in the negative, i.e. as elements other than the "common processes" or the "addition of standard parts" which the purchaser must undertake, without otherwise having to make any "creative or inventive decision," to fully practice the patent. *Id.*, at 2119-20. In summary, *Quanta* teaches that if a patentee or licensee sells, in an authorized sale, an unpatented article that substantially embodies the patent, whose only reasonable purpose is to be finished or assembled into the patented article, and such finishing or assembly is then predictably undertaken by the purchaser using only routine and common steps, then that first sale was the one where the patentee collected its royalty. It is a case about the timing – not the value – of a royalty.

Thus, while *Quanta* can be read to stand for the simple proposition that a patent doesn't grant the right to collect a subsequent royalty after the invention has, "essentially," already been sold, nothing in the opinion (or other Supreme Court jurisprudence) supports the notion that a patent owner is entitled to collect a royalty based on no more than the "essential features" of an invention. Yet, proponents of substantive royalty reform appear to be using *Quanta's* "essential features" concept in precisely this way, i.e. as a definitional device for narrowing the invention, for damages purposes, to something less than what was patentable in the U.S. Patent and Trademark Office, affirmed valid in court, and proven to be infringed. Previous proposed definitional devices of this kind during the 109th and 110th Congress included a reduction of the patented invention to its "inventive contribution," its "patentable features," its "novel and nonobvious elements" or, as currently pending in H.R. 1260, "the patent's specific contribution over the prior art." After extensive discussion and a debate spanning three Congresses, it was recently recognized in the Senate Judiciary Committee report on S. 515 that the existing substantive law on patent damages should not be altered, and that proposals aimed at compensating a patentee only on the value of the "gist" of the invention should be abandoned in favor of a more a modest approach effecting procedural-only reform of damages calculations.

To the extent supporters of substantive royalty reform continue to propose *Quanta's* "essential features" concept, BIO believes that its use in the damages context would be as unavailing and inapposite as the previously-proposed definitional devices above. For one, in applying the notion of "essential features," the Supreme Court dealt with *articles* that were sold in incomplete form, having no reasonable use other than to be subjected to routine "finishing" or assembly with standard parts by the purchaser. By limiting the use of this concept to the analysis of products sold or assembled – and not to claim language or elements – the Court steered clear

of a dissection of the infringed patent claim into essential and non-essential elements. There is nothing in *Quanta* that would endorse transposing the "essential features" concept into a royalty valuation – let alone a royalty valuation focused on dissecting claims. In fact, the term "royalty" does not make a single appearance in the Quanta decision.[1] Quanta does not concern itself at all with the size of a damages award, royalty rates, or royalty basis, much less parse out measures of damages in terms of the importance of sold items to patented inventions containing them. Reading such insights into the Quanta decision is pure speculation.

Second, the Supreme Court recognized that its "essential features" concept cannot be applied to inventions made up of a combination of prior art elements, as there is no single "inventive" element in a claim whose elements all consist of preexisting parts. *Id.,* at 2121. To argue that combination inventions would therefore be exempt from an "essential features" royalty calculation is unavailing. The reality is that it is impossible to sort inventions into those that are combinations of prior art elements, and those that are not. Mechanical and electronic inventions, for example, would always be classified as "combinations." Even new chemicals, proteins and genetic inventions can, on some level, be viewed as mere assemblies and arrangements of prior art chemical elements, amino acids and nucleotides. Judge Learned Hand recognized as much when he wrote:

> All machines are made up of the same elements; rods, pawls, pit-mans, journals, toggles, gears, cams, and the like, all acting their parts as they always do and always must. All compositions are made of the same substances, retaining their fixed chemical properties. But the elements are capable of an infinity of permutations, and the selection of that group which proves serviceable to a given need may require a high degree of originality. It is the act of selection which is the invention; and it must be beyond the capacity of common-place imagination**.** *B.G. Corp. v. Walter Kidde & Co.,* 79 F.2d 20, 22 (2nd Cir, 1935).

Even if it were possible to classify any given patent claim as a non-combination or combination claim, and to apply an "essential features" concept only to the valuation of the former and not the latter, little would be accomplished other than to drive widespread changes in claim drafting to emphasize the new combination of old elements that make up any invention. In effect, therefore, forcing the use of an "essential features" concept in the valuation of patent claims would subject whole classes of technologies to different royalty standards, depending only on whether the technology lends itself more or less readily to combination claiming.

Third, it is just as important to emphasize what *Quanta* is *not* about: The Supreme Court nowhere said that LGE had already captured the value of the "essential features" of its invention in its first sale, and cannot now capture the additional value of only routine and standard parts that were subsequently added by Quanta, and that LGE hadn't invented. Instead, the Court saw the problem in this case as an attempt to capture the value of the same invention twice – not as an attempt to capture the value of elements that were added by Quanta.

[1] The term "damages" shows up two times, both in FN 7, where the court states that "exhaustion operates to eliminate patent damages" at least under the facts of that case. Thus, Quanta might fairly be read to say that the doctrine of patent exhaustion can be a bar to recovering patent damages associated with the infringement of method claims where the accused article substantially embodies the claimed method.

This distinction is critical for purposes of the long-standing "royalty for the gist of the invention" debate. In the *Quanta* opinion, the Court stresses how Quanta had to make no creative or inventive decision of its own when it combined the unpatented microprocessors and chipsets in the final infringing product, and how the components that Quanta added were merely standard parts, added using no more than routine processes. *Id.*, at 2020. It is this emphasis on the routine and non-inventive nature of the infringer's activities that make clear that the Supreme Court simply did not intend its decision to be applied to the valuation of royalties: If the Court were concerned that LGE should not recover the value of elements that were added by Quanta - and that LGE hadn't really "invented," it should not matter whether Quanta's additions were extraordinary or routine, or creative or non-inventive. Why should a patentee recover lower damages (based on only the "essential features" of the invention) if the infringer's activities are merely routine, and higher damages if the infringer's activities are extraordinary, creative, and inventive? The incongruity of such an outcome illustrates that neither *Quanta* nor *Univis* is applicable in determining the value of the use made of an invention, and that their "essential features" concept has no place in determining the appropriate size of a royalty award.

To the extent that proponents of royalty reform complain of exploding patent litigation, systematically overcompensated plaintiffs, and rampant extraordinary verdicts, BIO believes that these concerns have not been sufficiently substantiated to warrant legislative changes that would reduce patent valuation across the spectrum of the U.S. economy, including biotechnology. Any policy recommendations should be limited to procedural reforms that must be carefully crafted so as not to interfere with the orderly judicial development of the law in the area of patent damages.

Respectfully submitted,

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