The Hon. Michelle K. Lee
Under Secretary of Commerce
Director, United States Patent and Trademark Office

Via email to 2014_interim_guidance@uspto.gov

Re: December 16, 2014 Interim Guidance on Patent Subject Matter Eligibility

March 16, 2015

Dear Director Lee,

The undersigned national and regional biotechnology industry associations appreciate this opportunity to comment on the USPTO's December 16 Interim Guidance on Patent Subject Matter Eligibility (the "Interim Guidance"). We write to express our appreciation for the USPTO's sustained outreach and its continuing dialogue with the patent user community on the topic of patent-eligible subject matter, and for its in-depth process for revising its prior March 4 Guidance (the "March Guidance"). However, we also wish to voice our continuing concern over the recent judicial and administrative expansion of nonstatutory patent law governing the patent-eligibility of certain classes of biotechnology inventions in the United States.

Together, our associations represent thousands of biotech businesses, academic and nonprofit research centers, technology transfer organizations and other entities dedicated to biotechnological innovation throughout the world. Our increasingly global industry provides breakthrough products and technologies that combat debilitating and rare diseases, reduce our environmental footprint, provide food security, use less and cleaner energy, and drive economic growth.

Internationally harmonized, science-based regulatory and legal frameworks are important for competitiveness and innovation to ensure faster and more equitable access to new biotech products and processes for patients, farmers and consumers around the world. It is in this context that we note with concern the significant departure from internationally accepted norms of patentability that is taking hold, in U.S. jurisprudence and administrative USPTO practice, with regard to industrial, agricultural, and pharmaceutical preparations of naturally-derived substances, compositions, and processes.

Inventive preparations based on naturally-occurring substances have historically been of great importance in biotechnology, and innovation in this area has been spurred, at least in part, by the availability of patent protection. This is true for every sector of biotechnology, ranging from vaccine technology to crop protection products, plant biotechnology, industrial

enzymes, diagnostics, immunosuppressants, anticancer compounds, and antibiotic drugs. Just this past January, major U.S. publications such as the Wall Street Journal, the Washington Post, and the New York Times featured prominent stories about a new, potentially ground-breaking antibiotic that was discovered in a soil-dwelling bacterium from a field in Maine.[1] The news articles explained the tremendous promise of such molecules in battling the spread of infections which were once treatable, but which, today, due to emerging antibiotic resistance, can once again kill. Years of investment and clinical testing are required before such new, structurally unique molecules can be deployed in clinical practice. Incredibly, the claims to this ground-breaking antibiotic stand rejected in the USPTO as patent-ineligible subject matter.[2]

Sadly, it is no longer news that such promising naturally-derived compounds today encounter hurdles to patentability in the United States that would not exist in most other major industrialized countries. Throughout the summer and fall of 2014, our member companies reported rejections in the USPTO of applications for antibiotics, medicinal molecules, industrial enzymes, vaccines, organic crop protection compositions, molecular markers, and other preparations that were first discovered or derived from natural starting materials. Our members were greatly concerned that the March 2014 Guidance cast a wide net that precluded patentability not just of novel naturally-derived molecules, but also of industrial preparations thereof (such as multipart pharmaceutical compositions), as well as industrial or therapeutic methods for using them.

Central concerns about the patentability of such molecules persist among our members today, but we do believe that the revisions in the PTO Interim Guidance move in the right direction. It is, at the present time, too early to tell how the Interim Guidance will actually impact prosecution practice compared to the March Guidance, but we do note that the Interim Guidance has been simplified, the prior multiple factors and subtests removed, and the basic two-step analysis has been streamlined. The Interim Guidance appears to allow for more flexibility, but with such flexibility comes ambiguity that reflects the unsettled state of the law in the U.S. courts. For our members, the most informative aspect of the Interim Guidance lie in the PTO's concurrently-published practice examples, which we view as an improvement over the examples provided in the March Guidance. For the most part, the new examples better illustrate how close cases should be decided, and this should prove helpful during prosecution and claim drafting. We are hopeful that some types of claims, such as those involving combination products, multipart compositions, or therapeutic or industrial methods of using naturally-derived substances, will now undergo more rational and productive examination than was the case under the March Guidance.

The PTO also helpfully announced that it would consider functional characteristics of the claimed invention in support of patent-eligibility, but it is unclear whether the PTO's

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[1] See, e.g.: *New class of antibiotic found in dirt could prove resistant to resistance*, The Washington Post, January 7, 2014, available at: http://www.washingtonpost.com/news/speaking-of-science/wp/2015/01/07/new-class-of-antibiotic-found-in-dirt-could-prove-resistant-to-resistance/ ; *Scientists Discover Potent Antibiotic, A Potential Weapon Against a Range of Diseases,* The Wall Street Journal, January 9, 2014, available at: http://www.wsj.com/articles/scientists-discover-new-antibiotic-a-potential-weapon-against-a-range-of-diseases-1420654892 ; *New Antibiotic Stirs Hope Against Resistant Bacteria*, The New York Times, January 7, 2014, available at: http://www.nytimes.com/2015/01/08/health/from-a-pile-of-dirt-hope-for-a-powerful-new-antibiotic.html?_r=0 .

[2] Application S/N 14/095,415

understanding of "function" comports with what many in the user community had hoped. For example, in a claim to an isolated or purified preparation of a naturally-occurring medicinal molecule, applicants should be able to argue that isolation or purification of the molecule allows, for the first time, to formulate it in exact amounts in a pharmaceutical preparation, and to use it at precise doses to treat disease while avoiding side effects – that, in this sense, isolating the molecule conferred on it a "function" as disease-treating agent. It is unclear whether such reasoning is sufficient or even relevant under the Interim Guidance to support patent-eligibility of an isolated or purified naturally-occurring substance, and we would welcome further clarification.

Importantly, even under the revised Interim Guidance, isolated enzymes, proteins, pure preparations of naturally-occurring medicinal molecules, fungal and bacterial antibiotics, nucleic acid probes and primers, certain fermentation products, molecular markers, and similar preparations apparently continue to be patent-ineligible, or appear to be patentable, if at all, only at significant loss of claim scope.[3] This will be a matter of concern for our members going forward. We are troubled that the standards for patentability of nature-based products thus continue to be manifestly different between the United States and its major trading partners in Europe, Japan, Korea, Canada, Australia, China, and other major industrialized countries. Foreign applicants who first file their priority application under different legal standards in their home countries are likely to encounter traps for the unwary when they enter the United States. The more the USPTO can elaborate on its applicable legal standards (for example, "markedly different" and "significantly more" have no distinguishable meaning when translated into some foreign languages), and the more examples it can provide to illustrate when a difference between a claimed molecule and a natural one becomes legally significant, the better this would be for foreign applicants.

During the summer and fall of 2014 our members also noticed that the frequency of 101-rejections in the USPTO increased noticeably, but that the way these rejections were being applied fluctuated widely between examiners, ranging from perfunctory rejections or mere recitation of the March factors to very elaborate multi-page rejections. Likewise, 101 rejections were raised against certain kinds of claims in some applications while other examiners in other cases with very similar claims did not raise 101 rejections. We encourage the USPTO to take steps to ensure consistent application of the Interim Guidance going forward. Examiner training, and possibly a process for internally reviewing 101 rejections for consistency and quality during the implementation period should be considered.

Finally, it is fair to restate that there was cautious optimism and a sense of improvement among our members when the USPTO promulgated its Interim Guidance on December 16. Unfortunately, such optimism is tempered by the expectation that the USPTO's efforts to bring stability to this area of patent law could easily be undone by ongoing or future developments in the United States courts, whose precedential decisions the USPTO is bound

[3] This is illustrated by practice example 4, drawn to "Antibiotic L," which describes an application containing a patent-eligible claim to an isolated antibiotic. The background facts for this example explain, however, that the hypothetical specification is enabled and described only for a particular, non-natural crystalline form of Antibiotic L. It is clear that such an antibiotic would be patent-eligible not because it is presented as an isolated preparation, but because it is presented in a particular, non-naturally-occurring crystalline structure. In prosecution practice, claims presented against such a background would become severely limited because of required amendments or prosecution history estoppel.

to follow. We are concerned that our members will be prosecuting patent applications on a shifting slate for some time to come, and going forward a more stable solution is needed. No policy reason has been articulated for singling out important segments of socially beneficial biotechnologies for disfavored treatment under the patent law. Likewise, there has been no discussion about whether rejecting patent applications on antibiotics, vaccines, industrial enzymes and similar products makes sense as a matter of industrial or innovation policy. Indeed, policymakers in the United States have been surprisingly uninvolved in this issue, and the expansion of extrastatutory patent law in this area seems to be driven largely by judges and private litigants. Yet, the state of section 101 jurisprudence, even just in the biotechnology space, is ripe for a policy dialogue outside the forum of the courts. We encourage the USPTO to open such a dialogue and to explore options for bringing lasting stability to this area of U.S. patent law.

Respectfully submitted,

ASEBIO – The Spanish Bioindustry Association

BIO Deutschland e.V.

BIA, The UK BioIndustry Association

Biotechnology Industry Organization (BIO)

EuropaBio

HollandBIO

Japan Bioindustry Association