The Hon. Eric H. Holder, Jr.
Attorney General of the United States

The Hon. Donald Verrilli, Jr.
Solicitor General of the United States

U.S. Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, DC 20530-0001

Re: *Association for Molecular Pathology et al. v. Myriad Genetics et al.*, pending in the U.S. Court of Appeals for the Federal Circuit

Washington, DC., June 12, 2012

On behalf of the 23 undersigned industrial, environmental, food and agricultural biotechnology companies, we write to express our concerns over the pending appeal in the case of Association for *Molecular Pathology et al. v. Myriad Genetics et al* (*AMP*) before the U.S. Court of Appeals for the Federal Circuit. We feel it is essential that it be understood that this case could potentially adversely impact ours and other industries whose activities are far removed from the clinical diagnostic testing context in which this case is commonly discussed.

Companies like ours research, develop, and use modern biotechnology to produce products as diverse as renewable fuels and chemicals, industrial enzymes, fermentates, pigments, dyes, fragrances, flavorants, food additives, bio-based specialty chemicals, cosmetics, and biological fungicides and pesticides for farm and garden use. Farmers around the world today benefit from pest- and-disease-tolerant crops; introduction of increasingly higher-yield varieties continues to increase agricultural productivity; drought-resistant crops are about to be commercialized. Our development pipelines include grains, vegetables, and fruits that are nutritionally improved and stay fresh longer, as well as genetically modified trees that allow for enhanced biomass production and carbon sequestration. Virtually all such products were originally, in some way, modified or derived from natural sources.

We are concerned that the *AMP* case invites, potentially, a broad reinterpretation of the judge-made exclusion from patentability for "manifestations of nature" that would create significant uncertainty about the patentability of technologies unique to the areas in which we conduct our businesses. Visceral and unsubstantiated objections to human "gene patents" should not be grounds for wholesale revision of an area of patent law that has long been settled. For over 100 years, the U.S. Patent and Trademark Office has granted patents on new and useful preparations of naturally-sourced chemicals; fungal, bacterial, or algal cultures; enzyme preparations; and other isolated, purified, or modified

biological products. Such patents have included, during the past 30 years, patents on preparations of isolated DNA from plants, fungi, bacteria, and plant or livestock pathogens. The discovery, modification, and practical adaptation of such inventions for human use requires every bit as much effort, ingenuity, and investment as other inventions that are commonly deemed patent-eligible. Subjecting such inventions to a new and uncertain patentability analysis under a broadened "laws of nature" or "natural phenomena" exclusion that is nowhere to be found in the Patent Act draws into question tens of thousands of issued U.S. patents and upsets longstanding, settled, investment-backed reliance interests. Because the *AMP* case, just like the Supreme Court's decision in *Mayo v. Prometheus,* was developed only in the context of human diagnostic technology without discussion of their broader implications outside that setting, many in our industry are concerned that unless some wider context is added, the very essence of what is patentable in our field of biotechnology will be jeopardized.

The ability to secure patents is essential in ours, as in any industry required to continually push the limits of innovation, in order to compete domestically and in an increasingly competitive global marketplace. Industrial, environmental, food, and agricultural biotechnology companies spend tens, sometimes hundreds, of millions of dollars developing their technologies based upon investment horizons ranging from 5-20 years. Those companies require a high degree of certainty that their investments will generate a reasonable return over such vastly varying timeframes.

The past several years have heralded great changes to patent law as our nation seeks to ensure that its patent system keeps pace and remains competitive with the patent systems of other countries. Biotechnology companies, like companies in many fields, have continued to pursue innovation despite the economic tumult of the last several years and the uncertainty produced by changes to the laws under which they operate. Throughout this time, the patentability of their innovations was never as uncertain as it is in light of the *AMP* and *Mayo* cases. Orderly development of the law is necessary in order to avoid years of delay and uncertainty over what is and is not patentable by companies in our industry. Providing such direction will help our companies grow and innovate while also growing the US economy and providing millions of jobs in the decades ahead. We ask that you carefully consider these implications as you develop the position of the US Government in the pending remand of the *AMP* case to the U.S. Court of Appeals for the Federal Circuit. We also urge you to seek input from a broad range of other stakeholders whose existence is likewise predicated upon their ability to operate under the protection of patents.

Thank you for considering our views and concerns on this important matter.

Respectfully submitted,

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