

September 9, 2010

The Honorable Tom Vilsack  
Secretary  
U.S. Department of Agriculture  
1400 Independence Ave., S.W.  
Washington, DC 20250

Dear Secretary Vilsack:

We are writing today to bring to your attention a court case that has the potential to negatively impact the United States' global competitiveness in agriculture. In particular, we are concerned about the possible elimination of DNA-based patents that protect investments and innovations in agricultural biotechnology, not only for private sector researchers, but also for public researchers such as those within your Department's Agricultural Research Service and at Land Grant universities. We request that you engage with the U.S. Department of Justice (DOJ) and appropriate officials at the White House to ensure that the federal government actively defends the patent eligibility of DNA-based inventions.

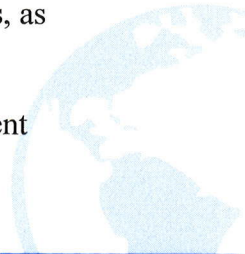
Earlier this year, in a lawsuit filed by the American Civil Liberties Union (ACLU) against a genetic diagnostic testing company named Myriad Genetics, among others (hereinafter "the ACLU case"), a federal district court ruled that isolated DNA sequences are not eligible for any patent protection, because they are derived from natural sources. In this particular case, the patented DNA molecules are important for clinical breast cancer testing – but the reasoning of the district court was so expansive that patents on animal, plant, bacterial or viral DNA preparations are now also in serious question. As an example, patents on genes that confer drought resistance or those with improved nutritional qualities or high-yielding biomass crops are clearly now at risk by this court decision.

Currently, the Department of Justice is in the process of determining what position the federal government will take on the patentability of genetic materials in this case, which currently is on appeal to the Court of Appeals for the Federal Circuit and may eventually go to the United States Supreme Court. We are bringing this case to your attention, because we are unsure whether DOJ has sufficiently appreciated the implications of the case outside of the human clinical diagnostics area, and to ensure that the U.S. government's position is determined only after all affected agencies have had an opportunity to consider and weigh in on the matter.

An ultimately negative outcome in this case would greatly and negatively impact our ability to meet the nutritional demands of an ever increasing world population, to mitigate harmful impacts of global climate change, and to reinvigorate the American economy through agriculture. Such a future requires massive investment and innovation in the areas of crop agronomics and yields, as well as advanced biofuels from purpose-grown energy crops and other environmental technologies. Yet such massive investment and innovation can proceed only if we have the ability to protect the inventions that will spur progress in this field through the use of the patent system.



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Patent protection on these basic inventions provides investors with the assurance that their investments are protected, and often provides the platform upon which a more diversified and robust R&D program can be funded and expanded. This is particularly true for the hundreds of small biotech start-ups on the cutting edge of biotechnology innovation. This innovation pipeline will in turn lead to subsequent domestic job creation in the area of agricultural biotechnology, creating thousands of new, high-paying American jobs in the process. Eliminating the very basic patents protecting inventions in this sector will undoubtedly have a negative effect on the availability of venture capital, decreasing the speed at which innovation will occur and the breadth of the potential R&D portfolio.

To ensure that this lawsuit over one human clinical diagnostic test does not tear down a whole class of intellectual property that is important to the rest of the U.S. economy and the biotech industry alike, it is essential that the U.S. government strongly defend the patentability of such basic biotech inventions. We urge you to review this matter closely and let the Department of Justice and appropriate officials at the White House know the importance of biotech patent protection to our global competitiveness in the field of agriculture. Drastic and overbroad legal changes, such as eliminating or casting a huge cloud of uncertainty over a whole class of patents, will only serve to discourage innovation, resulting in reduced investment and lost jobs at a time when the country can least afford it and when private access to capital for investment in innovative technologies is already hard to obtain.

We believe the strength of the American patent system – and with it, the U.S. biotechnology industry – lies in the breadth and scope of what is considered patentable subject matter. It has been this approach that, since the Supreme Court’s 1980 landmark decision in *Diamond v. Chakrabarty* holding man-made, oil-degrading bacteria eligible for patenting, has spurred U.S. global leadership in the life sciences and has provided the United States with one of its greatest global competitive advantages. If the Department of Justice fails to support the patent eligibility of DNA sequences in the ACLU case on appeal, the United States could become the only industrialized nation that does not permit such patents – thus, abdicating our role as the world leader in this field, undermining U.S. economic competitiveness, and potentially closing the door on those future innovations that can help the United States and the rest of the world address some of the greatest challenges of the 21<sup>st</sup> century.

We respectfully request your help to influence the outcome of this critical issue, and thank you in advance for your consideration of our concerns.

Sincerely,

James C. Greenwood  
President and CEO  
Biotechnology Industry Organization

Oliver Peoples, Ph.D.  
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Richard Hamilton, Ph.D.  
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