



**National Farmers Union
Special Orders of Business 2011**

GENERIC SEED PRODUCTION AND A COMPETITIVE MARKETPLACE

WHEREAS, price and market competition are essential in the seed and biotech industry for the benefit of producers and consumers; and

WHEREAS, 2014 marks the year when the first genetically modified organism will no longer be protected by a patent; this marks the first patent expiration of a life form and will be met with a host of regulatory challenges which, if left unaddressed, will result in decreased competition in the largely self-regulated seed industry; and

WHEREAS, there are no regulatory processes in place to ensure competition and innovation in the biotech seed industry as trait patents near expiration, while patent laws for other industries, such as pharmaceuticals, provide a regulatory framework through which generic products' entry into the marketplace is facilitated after the end of the initial patent, which is of great benefit to consumers; and

WHEREAS, regulations regarding pharmaceutical patent expiration require companies to make data public regarding their patented product prior to the patent's expiration to provide adequate time for research and development of generic products; such a mechanism is not present for patented life forms, which could result in delayed or complete lack of generic trait production; and

WHEREAS, once a biotech trait goes off-patent, there is no regulatory requirement that a seed company maintain the product's international regulatory approval; therefore, even if generic production of the trait is facilitated, unless a company maintains international regulatory approval of the generic trait, U.S. farmers will be unable to export grain produced from this trait;

THEREFORE, BE IT RESOLVED that National Farmers Union calls upon Congress, the administration, industry and producers to resolve these outstanding biotech patent concerns in a timely and enforceable fashion; and

BE IT FURTHER RESOLVED that a system for maintaining international regulatory approvals for generic traits after patent expiration must be established in a way that enables generic traits to be available for all farmers if they choose to use genetically modified seed; and

BE IT FURTHER RESOLVED that a product development clause, such as a research exemption, to allow both private and public sector researchers to work with a trait under proper stewardship restrictions before its patent expires, should be a part of genetically modified seed patent law, because a research exemption would allow seed breeders to access data in a timely manner before trait patent expiration in order to advance single-trait or stacked-trait breeding programs. Researchers should not be allowed to bring products containing a patented trait to market before the patent expires, but they should be allowed to develop products under proper stewardship restrictions and seek export market approvals so that products can be brought to market as soon as patents expire; and

BE IT FURTHER RESOLVED that a compulsory program for obtaining a timely letter of access to use data collected by the patent holder for the regulatory process for agricultural biotech products must be established, even as companies may currently negotiate such a letter of access with a patent holder in order to obtain export market approvals, but negotiations may not be successful or may be time-consuming. Fair compensation for data should be required and, in the event negotiations are not successful, a process modeled on the mandatory arbitration process outlined in the Federal Insecticide, Fungicide and Rodenticide Act for the agrichemical industry should be followed.