

Memorandum



To: PSAS

From: EROgden

Re: US Porcine leptin patent

Date: 19 September 2008

Introduction

In the United States, there are two separate applications. One addresses the identification and use of information regarding one or more porcine leptin receptor (pLEPR) gene polymorphisms as a marker to identify animals to serve as breeding stock for enhanced pork production ("pLEPR Patent"). It specifically points out one particular polymorphism of pLEPR gene that results in either a methionine or a threonine amino acid residue at position 69 of the protein that the pLEPR gene encodes. The pLEPR gene is located on porcine chromosome 6 and has been shown to be associated with determination of daily feed intake, among other factors.

The other application provides methods for the production of terminal parent animals (i.e. terminal sires and terminal dams) for use in swine production herds. It provides methods for quickly and efficiently introducing and/or fixing one or more desirable traits or alleles in a swine herd. Alternatively, the methods may be used to eliminate a particular undesirable trait or gene. The invention also provides for herds that have been developed using any of the methods described herein. Additionally, the invention provides for the use of embryo transfer, including marker assisted embryo transfer to facilitate the transfer of genetic material, particularly when it is desirable to maintain the specific-pathogen free status of a herd.

pLEPR Patent

As it currently stands, nine of the thirty claims have been withdrawn and will not be included in the patent. The rest of the claims are currently rejected with a response due on October 9, 2008. The first five claims are rejected because they do not "reasonably provide enablement for a method of genotyping any animal by detecting a polymorphism in the porcine leptin receptor." This is because the claims are for "one or more animals" that the patent examiner read as "'any' animal." The examiner declared that the claims may be read as pertaining to "genotyping 'any' animal by obtaining a sample from 'any' animal." However, the specification does not teach methods of genotyping and trait selection for any species other than pig. Therefore, someone wanting to use these methods would have to "undertake extensive trial and error experimentation to determine if polymorphisms in the porcine leptin receptor are indicative of altered meat quality in any species other than porcine." This rejection is easily overcome by limiting the scope of the claims to pigs. If they want to retain the wider scope of other animals, it will be much more difficult, but given the specification, it is likely they will limit it to pigs alone.

All of the claims are also currently rejected as being indefinite because they fail to particularly point out and distinctly claim the subject matter that is supposed to be the invention. The examiner specifically points out that in claims 1-5, "it is unclear as to whether the method is drawn to genotyping one or more animals or selecting the animal having the genotype to provide the selected trait." In general, the examiner points out the discrepancies between the claims and the other portions of the application. Each is easily surmounted by narrowing the claims to meet the other portions as written.

Finally, claims are also rejected due to anticipation and obviousness. These rejections are the more difficult as the examiner points out various aspects that have been disclosed in previous publications by others. These other applications included a patent by Rothschild, et al. (US Patent 6,458,531), textbooks, and conference presentations. Claims 1, 2, and 4 each are found to be anticipated by various publications and the rest of the claims are rejected due to obviousness. In order to overcome the rejections, the applicants will have to describe the differences between their invention and what was previously disclosed. This generally narrows the claims, if not knocks them out completely. Recent court cases have made it more difficult to overcome obviousness rejections so it will be interesting to see the arguments made to attempt to surmount them.