Patenting in animal breeding and genetics

M.F. Rothschild[1], Graham Plastow[2] & Scott Newman[3]

[1]Department of Animal Science, Iowa State University, Ames, Iowa 50011 USA
[2]Sygen International and [3] PIC USA, P.O. Box 348, Franklin, Kentucky 42135 USA

Key words: intellectual property, patents, ethical social and economic issues, software development, conflict interests.

Introduction

While herdsmen have practiced the art of animal breeding since the beginning of domestication of livestock, the science of animal breeding is only now entering its second century. From its roots in Mendelian inheritance to developments in modern quantitative genetics our field has grown and enlarged its base science to include modern molecular sciences. The practical applications have been to genetically improve the animals that produce meat, milk and other products of economic value. Animal breeding as commerce has always "protected" its endeavors commercially by developing breed societies and using pedigrees to protect the intellectual property developed by the master breeders. The advent of molecular biology, sequencing of genomes and the development of cloning, have brought with them increasingly large sums of money to the field. These developments are anticipated to be applicable to the genetic improvement of animals. There is a "circle" here, as investment needs to be stimulated to drive research, which in turn needs to yield value in a way that can be extracted and which in turn stimulates further investment. There are alternatives e.g. co-ops or federal funding for the common good, but these do not necessarily work in the prevailing environment of global agriculture. Patents, primarily once only associated with chemistry, engineering and physics, are now therefore utilized in the field of animal genetics to protect the intellectual property that is developed. The purpose of this paper is to discuss forms of intellectual property, in particular patents and patent law, and to suggest ways it might impact the field of animal breeding and genetics.

Forms of Intellectual Property

Intellectual property (IP) comes in several different forms and is protected in different ways. The simplest definition is that IP is the personal property resulting from the creative or "inventive" work of an individual or individuals. The protection of this IP is described in a large body of law that includes copyrights, trademarks, trade secrets, and patents. Brief descriptions of some of these forms of protection are presented in Table 1. Copyrights are used to protect IP that includes articles, books, web pages, computer software (e.g., PEST, an animal breeding program) and music. In general, copyrights involve limited formal procedures. In many cases the creative work can be implicitly copyrighted by merely adding the ã symbol, but registering the mark provides formal legal protection. Trademarks are protection used to identify the source of the owners' goods, products or services. As with copyright they can be informal (simply using ™) or formally registered (®). Trademarks, in a general sense, relate to Appellations of Origin (Lesser, 2002), which are often applied to specific products like wine or champagne that are required to be from a certain origin and have a specific level of quality. In animal genetics good examples of trademarks are "Berkshire Gold™", signifying a pork product that is 100% Berkshire in origin and "PICmarq™ signifying gene marker information used in selection of pigs sold by PIC. A trade secret represents IP that is not divulged by the owner and therefore confers some competitive advantage. Trade secrets have no time constraints, as long as the information is kept secret. Examples of trade secrets in animal breeding might include specific information to make specialized synthetic lines or specialized selection programs and indexes. While there is a body of trade secret law (in the US called the Uniform Trade Secret Acts) that can serve to protect a technology from theft, the degree of protection afforded is dependent on the technology itself and the means used to keep the information secret. More recently the definition of trade secrets has become a potential issue for the protection of seedstock (see *www.aoc.state.nc.us/www/public/coa/opinions/2004/030328-1.htm*).

Patents likely represent the largest form of intellectual property and their development is rooted in a global body of law[1]. Patents were developed to "*promote the progress of science and useful arts, by securing for limited times, for authors and inventors, the exclusive rights to their respective writings and discoveries*" (Article 1, Section 8, US Constitution, discussed in Fretz and MacKenzie, 2002). Patents are meant to reward the inventor for

Table 1. Common forms of intellectual property protection.

Form	Definition
Copyrights	Provides rights to the creators of certain kinds of material to control the various ways in which their material may be exploited, including: copying; adapting; issuing; renting and lending copies to the public; performing in public; and broadcasting. In many cases, the author will also have the right to be identified on his or her work and to object to distortions and mutilations of his work.
Trademarks	Any "sign" used to denote the trade source (or the origin) of the goods and services. They include "any letter, word, name, signature, numeral, device, brand, heading, label, ticket, aspect of packaging, shape, color, sound or scent". Trademarks are an asset and as such may be licensed and assigned by the owner of the trademark. Examples include "Berkshire Gold™" and "Certified Angus Beef™"
Trade Secret	Any information that can be used in the operation of a business or other enterprise and that is sufficiently valuable and secret to afford an actual or potential economic advantage over others. It can exist in a combination of characteristics and components, each process, design and operation of which, in unique combination, affords a competitive advantage and is a protectable secret. It need not be essentially new, novel, unique or complicated. It may be intrinsically simple and nevertheless qualify as a secret, unless it is common knowledge and, therefore, within the public domain. Examples include selection indexes used by breeding companies.
Patent	Property right granted by nations, which gives the holder the exclusive right to exclude others from manufacture, use, or sale of the invention. Patent property rights exist for a period of 20 years from date of application. Patent property rights may be sold, assigned, mortgaged, licensed, willed or donated and be the subject of contracts and other agreements. The owner has the opportunity to profit by manufacture, sale, or use of the invention or by charging others for making or using it. See Table 2 for examples.

From Fretz and Mackenzie (2002) and Lesser (2002).

something new and useful. A simple definition of a patent is that, once granted, it represents a legal monopoly granted by the respective country's government to an inventor (specific to a geographic region), which permits the inventor to prohibit anyone else from making, using, or selling his or her invention for a specific period of time. Once published, the government grants the patent owner a temporary right to exclude all others from making, using, or selling the invention during the term of the patent. Infringement of a patent is a civil wrong and therefore the offended inventor may sue or seek other legal remedies to stop infringement. Patents are intended to protect but not withhold technical information. Indeed, it is also the intention that publication provides a basis from which to stimulate innovation and scientific progress – which would be inhibited if this knowledge were retained in trade secret form. Publication is required, in return for the limited monopoly, and is designed to expand scientific development. For scientists, it is important to note that patents are very different from published papers or other such works. Inventors are not like coauthors in that they must take part in the inventive process and are not just active in the research. Furthermore, patents are not peer-reviewed but are instead assessed by patent examiners who assess the requirements of patentability. A patent must reveal sufficient details, called enabling information, which allows "one of reasonable skill" to duplicate the invention. More importantly, this requirement provides the opportunity to develop new inventions from this description (in return for the rights granted to the inventor, see above). Patents must meet certain criteria if they are to be granted and these criteria are open to interpretation by both the examiners and the lawyers submitting the applications. These criteria include:

1) Nonobviousness or the inventive step which requires that there be a real invention and not a simple result from some obvious extension of existing technology;
2) Novelty, which refers to something created that is new; and
3) Utility or usefulness of the invention.

The breadth of a patent is developed in the claims section and as such some patents, like gene marker patents, may enjoy very wide coverage across species while others may be limited to a single polymorphism in one breed. The coverage allowed will change over time as the definition of novelty and nonobviousness changes as the knowledge base changes so that what is "custom and practice for one skilled in the art" changes.

Other fine points should be noted: Patents may be related to a process, a product produced by a process or dependent on another patent. In the US, patents can be applied for one year after publication or public disclosure

[1]Such laws and their interpretation are subject to change and the authors are neither lawyers nor experts on patent law; the descriptions contained herein are meant to be general in nature.

but this is not allowed in most other countries. Finally, it should be noted that patents in and of themselves do not ensure economic returns. They must be promoted (used) and protected and can be viewed as tradable assets and licensed or assigned to third parties.

Confusion often exists relative to “international” patents (see *www.cambiaip.org*), which in and of themselves do not exist. Under the Paris Convention Treaty (March 20, 1883, as revised at Stockholm on July 14, 1967, and as amended on September 28, 1979) a group of countries agreed to work with each other to allow patent applicants in these countries a one-year period in which to file an application in one of the other countries without losing the benefit of their filing date. This allowed for any “prior art” that became known after the original filing date in the country of origin but before the filing date in another country could not be cited against the application. Since then, the Patent Cooperation Treaty (PCT) was established in 1970 and allows applicants to delay additional filings in other member countries (although individual countries can be specified at this point, it should also be noted that applications for non-PCT countries can still be made 12 months after the initial filing, but these applications are required to be filed in each of those countries). The PCT currently has 111 member countries. The World Intellectual Property Organization (WIPO) was initiated to receive and process these applications. Under the PCT an applicant is allowed one year to file at the WIPO office and by designating member countries hold the legal rights and original filing date in those designated countries without having file in each country or pay the expense up front. Eventually to obtain a patent in these countries, the application does need to be filed in the national patent offices (the process is called “conversion”), pay fees, have translations done and comply with the regulations of each individual office. The applicant has either 20 months or 30 months, depending on particular country requirements, from the original home country filing date to file in each of these other countries. This process can save money (depending on how and when countries are declared) and most applications are delayed such that additional data can be obtained and in the end they are filed in a few countries at most where protection is really needed.

A Brief History of Patents

The early protection of intellectual property rights can be traced back to Venice in the Middle Ages when master craftsmen prohibited competition from former apprentices for a period of 20 years (Waltersheid 1994). Such laws had considerably different economic effects for the master craftsman, the apprentice and the general public. In terms of protection of intellectual property associated with animals, early breed societies were, in the most general form, designed to protect the intellectual property of the master breeders.

The modern concept of the patent was established in England where, in 1449, King Henry VI awarded a patent to John of Utynam for stained glass manufacturing, and the awarding of this patent established the notion of a state-granted limited monopoly, as the monarchy realized the value of protecting certain arts and industries, including those imported from other parts of Europe (in this case Italy) (Watson, 2001).

The first modern patent act is often thought of as The US Patent act of 1790, where the ideas for the US system were brought over with immigrants from England (Sherwood, 1984), and was developed based on the concern for the rights of the inventor and of society in general. This was followed by similar legislation in France in 1791, and later in other countries (Lesser, 2000). The first US patent was granted in 1790 for potash, and the second was awarded to Eli Whitney for the invention of the Cotton Gin in 1794. The first numbered patent (for tractor wheels) was awarded in 1836.

Even so, patents related to living matter are relatively new since other mechanisms, such as ownership of animals were thought to be sufficient. One of the earliest was granted to Louis Pasteur in 1873 for a yeast strain, but this was done under the belief that it was an inanimate object and not living (Lesser, 2002). The first specialized law applied to living organisms was that of the Plant Patent Act of 1930 in the US which provided what is commonly referred to as Plant Breeders Rights (PBR) to propagate new varieties by asexual methods (Lesser, 1987). In 1961 a similar law was passed in France called the UPOV (International Union for the Protection of New Varieties of Plants - Union Internationale pour la Protection des Obtentions Végétales; *www.upov.int*). Protection in the US was expanded in 1970 with the Plant Variety Protection Act to include sexually reproduced materials. The UPOV was revised in Europe in 1991 to extend its scope to the whole propagating material and to reproduction, conditioning for the purpose of propagation, offering for sale, exporting, importing and stocking for any of these purposes.

It should be noted that under US patent law utility, nonobviousness, and novelty is replaced by uniformity, stability, distinctness and novelty (Lesser, 2002). Uniformity and stability allow the protected variety to be identifiable after repeated generations of multiplication. Important to these acts are “breeder’s rights” which allow breeders to use protected varieties without permission of the owner (Lesser, 2002). This is considered a research exemption as part of Plant Variety Protection legislation – it is statutory. In patent law there is no text for research exemption so the interpretation is based on case law. (Lesser and Mutschler, 2002). The “farmer’s privilege” allow farmers to collect seeds from their crops and use for the next year. For years many seed companies have attempted to halt this practice by asking farmers to sign contracts prohibiting it. Recent technology, like the “terminator” technology (Kaiser 2000) biologically prohibits the practice. An excellent review on many subjects related to patent protection for plants and the economic impacts can be found in Santaniello *et al.,* 2000.

Breeder's rights issues are not as well understood in animals as they are in plants (where breeders can use protected varieties without permission of the owner), but lessons can be drawn (Lesser and Mutschler, 2002). Breeder's rights issues in livestock will be sector-dependent. In poultry, virtually all genetic improvement of purelines and subsequent crossing to produce parent stock is done by the breeding company, who in turn contracts out the growing and finishing of commercial animals. In pigs, breeding companies will often contract out multiplication of pureline improvement (and crossbred production of parent females). In both cases contract agreements would stipulate that the use of any pureline animals for purposes other than agreed to in the contracts would be illegal and grounds for breach.

While the application of patents will likely increase R&D investments for living organisms, the magnitude of those investments will be dependent on several factors, including the size of the market, the product demonstrating a clear positive return on investment, and the product must be easily copyable and readily protectable by trade secrets. Thus animal disease models for minor illnesses (in humans) and synthetic animal breeds that have biological protection would be expected to have little value if patented. Costs of enforcement and royalty collection would likewise present more of a challenge for the dispersed cattle industries than more confined pork and poultry industries.

The dawning of the molecular age in the 1970s and its birth in the early 1980s presented real problems for the protection of IP related to living organisms other than plants. As described in Bent (1989), a French company in 1975 failed to patent a "dwarf, egg-laying chicken hen produced by a process" involving a sex-linked recessive gene. In 1980, the United States Supreme Court in a 5 to 4 decision (*Diamond v. Chakrabarty)* declared that "anything under the sun that is made by man" is patentable. This case concerned the patenting of genetically engineered bacteria that "consume" oil sludge. In 1987, the US Patent trade office issued a pronouncement of the patentability, in principle, of non-human multicellular organisms that were not naturally occurring (Bent, 1989). This was quickly followed in 1988 by the landmark patent on the so-called "Harvard mouse" which was engineered to be susceptible to cancer[2]. In Europe, similar laws were passed allowing patenting of animals and animal-related inventions. From 1995 to 2001, a total of 45 animal patents were granted in the US (Lesser, 2002). Not all developments however are patentable. For instance it is not possible to patent gene sequences by themselves with no specific function (or utility) identified. While these changes in patent law had large economic implications, the social and moral ramifications were also enormous. Discussion of these points is addressed in a later section of this paper.

Animal Breeding and Genetics – Intellectual Property Protection

The general area of biotechnology might encompass many of the patent applications in our field. The US Supreme Court has established guidelines that broadly apply to new areas of technology (Nebel *et al.,* 2002). The Court made it clear in *Brenner v. Manson* that patent utility implied usefulness and not just "any invention not positively harmful to society". Secondly, it expressed reservations regarding a monopoly on compounds with unknown functions, and finally that utility must extend beyond proving that the product is a product of scientific research (Nebel *et al.,* 2002). These general guidelines still apply.

The field of animal breeding and genetics, especially as it relates to farm animals and livestock, encompasses a broad range of species, traits and processes. A simple laundry list of those items that might directly affect our field and require IP protection include, but are not limited to, genes and markers for genetic improvement, statistical methods for genetic improvement, transgenic and cloned animals, methods to measure traits (e.g. use of ultrasonic probes), electronic methods to identify animals, computer software and other written materials. Allied fields like nutrition and veterinary medicine will also have methods or processes such as vaccines, feed supplements or specific treatments. Protection of some of these forms of IP has obvious outcomes in that manuscripts, web pages and software can be copyrighted. Other forms require decisions to protect using the trade secret approach or by the patenting process. While it is clear that some companies dealing with animal genomics have employed the trade secret approach, others have used patents to protect their research and where the results (and patents) are to be used as marketing tools

The number of genetic patents related to genes and markers, methods, equipment and other related technologies for genetic improvement are growing and efforts to find these patents and applications are greatly aided by on-line search engines. Three main public patent databases are available and include the U.S Patent and Trademark Office (*http://patents.uspto.gov/*), the European Patent Office (*http://ep.espacenet.com*) and WIPO (*www.wipo.int*). All allow searching to find published patents but each have different search requirements and specific software needs for full use (Fox, 2004). At one time US applications were not published prior to grant. However, they are now published both in the US and in Europe 18 months after the application has been filed. It is impossible to mention all

[2]In December 2002 the Supreme Court of Canada found that the "Harvard Mouse" was not patentable subject matter under the Canadian Patent Act.

the methods, genes and markers being used for genetic improvement. However, a sample list is provided in Table 2.

Several noteworthy patents are listed in Table 2. US patents 4 683 195, covering PCR and 5 582 979 covering dinucleotide repeats have extremely broad coverage and affect gene discovery and use of many types of genetic (microsatellite) markers. Perhaps the best-known and largest single royalty-generating patent in animal breeding was patent US 5 358 649 involving HAL 1843™. Originally there was some debate in the scientific community as to the validity of the HAL patent since the result seemed obvious once the gene became a candidate (see Fujii *et al.,* 1991). Indeed, the HAL invention was predicted in publications where the strategy for finding the mutation was developed (MacLennan *et al.,* 1990). However, this opinion was based, at least in part, on a misunderstanding of the term obviousness as required for patentability. Even so, it was possible at that time to find different patent agents willing to support or condemn the Halothane patent. In some cases breeders objected to the patent as they thought it protected the use of the animals themselves, including their use in breeding. However, this was subsequently resolved and the patent gained widespread acceptance and use. The patent was subsequently granted in several territories. Other noteworthy patents include US 5 374 526, which was a method to use ESR gene polymorphisms to improve litter

Table 2. Examples of patents[1] involving common methods, genes and genetic markers in livestock.

Species	Date	Patent no.	Title
Chicken	1998	US 5 707 809	Avian sex identification probes
Cattle	1991	US 5 041 371	Genetic marker for superior milk products in dairy cattle
Cattle	1992	US 5 292 639	Association of bovine mitochondrial DNA with traits of economic importance
Cattle	1994	US 5 374 523	Allelic variants of bovine somatotropin gene: genetic marker for superior milk production in bovine
Cattle	1996	US 5 582 987	Methods for testing bovine for resistance or susceptibility to persistent lymphocytosis by detecting polymorphism in BoLA-DR3 exon 2
Cattle	1997	US 5 614 364	Genetic marker for improved milk production traits in cattle
Cattle	2001	US 6 242 191	Methods for assessing the beef characteristics of live cattle
Cattle	2001	US 6 284 466	Double muscling in mammals
Cattle	2001	FR2779153[2]	New nucleotide sequences, useful for genetic identification of cattle
Cattle	2001	W09923248[2]	Assessing lipid metabolism
Sheep	2001	US 6 306 591	Screening for the molecular defect causing spider lamb syndrome in sheep
Pig	1994	US 5 358 649	Diagnosis for porcine malignant hyperthermia
Pig	1994	US 5 374 526	Method for determining genetic marker for increased pig litter size
Pig	1999	US 5 939 264	Genes and genetic markers for improved reproductive traits in animals
Pig	2000	US 6 143 880	Pig myogenin gene and method to identify polymorphisms related to muscle growth
Pig	2001	US 6 183 955	Methods for determining the coat color genotype of a pig
Pig	2001	US 6 291 174	DNA markers for pig litter size
All	1987	US 4 683 195	Process for amplifying, detecting, and/or-cloning nucleic acid sequences
All	1996	US 5 582 979	Length polymorphisms in $(dC\text{-}dA)_n.(dG\text{-}dT)_n$ sequences and method of using the same
All	1997	US 5 646 040	Mammalian tub gene
All	2000	US 6 114 118	Method of identification of animals resistant or susceptible to disease such as ruminant brucellosis, tuberculosis, paratuberculosis and salmonellosis
All	2001	US 6 284 466	Method of detecting genetic polymorphisms using over represented sequences
All	2001	US 6 287 564	Method of identifying high immune response animals
All	2001	US 6 294 329	Use of primers for universal fingerprint analysis
All	2001	US 6 309 853	Modulators of body weight, corresponding nucleic acids and proteins, and diagnostic and therapeutic uses thereof

[1]This represents a sample of patents and applications.
[2]Pending application.

size. The announcement of this method in 1994 (Rothschild *et al.,* 1994) stirred considerable debate, not only on the scientific merit of the method, as it was the first to claim use of a marker for a quantitative trait involving pigs, but also because the patent had been exclusively licensed to one breeding company. Other issues can be highlighted from the patents listed above. Many of these patents have very narrow coverage, confined to individual sequences and polymorphisms. Others have broader coverage relating to large stretches of chromosomes and even many species.

Some confusion existed early in the development of patents in animal breeding as to whether the genes were patented or whether a process or method involving genes and markers was being patented. This was particularly evident in the discussions that followed the ESR patent application (see Rothschild and Plastow 2002). However, the issue of patenting gene sequences has raised both legal and commercial concerns. Is it possible for companies to patent sequences from parts of genes, called expressed sequence tags or ESTs, without knowing their function at the time of patenting? This issue came to the forefront when Craig Venter (then with the National Institutes of Health), and colleagues applied for a patent on recently discovered ESTs. In the first review of the application the patent office rejected all claims for failure to meet the criteria of utility, novelty, and non-obviousness. ESTs do not specifically define gene function but they provide information for isolation of the entire gene and for determining the gene location in relationship to previously mapped QTL. Considerable patent case law exists now exists which relates to their utility, non-obviousness, and enablement (Nebel *et al.,* 2002). The patent office has decided ESTs are patentable if they can be shown that they are useful. However, if the patent does not claim the entire gene sequence then it has limited economic value. Some companies, such as Incyte Pharmaceuticals, have taken the step to protect these ESTs by creating databases that are useful in predicting gene function.

Patent coverage in not just confined to genetic markers and genes. For biomedical research certain lines of animals, primarily mice and rats, have been patented as they carry certain transgenes that make them useful for biomedical research. There are cases where lines of pigs or chickens or other animals have been patented also and in some sense this can be viewed as a specialized extension of early breed development. Patenting of breeds and lines is not universally allowed. Other patents exist for methods involving cellular and animal manipulation and involve processes like stem cell development, transgenic production (i.e. US 6 271 436) and cloning (i.e. US 6 215 041 or US 6 258 998). These will not be reviewed here, but see recent reviews that cover some of these subjects (see Rothschild *et al.,* 2002).

Several advances related to mechanical or electronic devices for measuring traits have been made. These include devices as simple as new artificial insemination catheters to advanced ultrasound equipment, formulas and methods to measure backfat and other traits in livestock[3].

The need for traceability of animals and animal products has spawned a number of inventions and patents including but not limited to electronic ID tags and retinal scanning methods and devices. These can also be found by searching the appropriate web sites.

Considerable discussion has ensued from the efforts of Dr. Robert W. Everett of Cornell University and the Cornell Research Foundation, Inc. for a patent entitled "Method of Bovine Herd Management" which was filed on February 25, 1993 in the United States, with the Canadian application filed on February 15, 1994 (see Schaeffer, 2002). The patents were granted on October 4, 1994 and July 14, 1998 for the United States and Canada, respectively. The invention is for the so-called "test-day model" and its uses. The patent as written is quite extensive and includes claims on the gathering of data, the mathematical treatment of that data, and the subsequent use of the modified data by dairy producers. The patent does not necessarily dictate how test day information is used. The patent limits any organization from collecting, analyzing and dispersing results without permission or reimbursement.

The novelty and obviousness of the Everett-Cornell patent has been seriously questioned. Clearly, the practices of gathering dairy cattle performance data, manipulating it into various forms for use by dairy producers, and the dispersal of the results to producers have existed for nearly 100 years. As critics point out the patent claims rights to a practice that has been public knowledge for a long time. The only novel idea within the patent was the specific mathematical model and procedures that Everett and co-workers developed for the analysis of test day yields. Everett was not the first researcher to apply a model to test day records. It has been demonstrated that the model, as described in the patent, is not necessarily the best model that could be applied (Schaeffer, 2002)[4]. One could wonder what the field of animal breeding would be like had Hazel patented the selection index or Henderson patented BLUP. Yet while quantitative geneticists see these thoughts as sacrilege, molecular scientists accept (but may not like) that the foundation patent for PCR exists and royalties must be paid.

Software Development in Animal Breeding and Genetics

Many computer programs have been written by quantitative geneticists for various livestock industries that can generally be categorized into data analysis and

[3]Table 2, US 4,359,055 and more recent US 5 717 142.

[4]The Cornell patent was disputed by the Canadian Dairy Network in a filing for re-examination in March 2001 to the Canadian Intellectual Property Office, which ruled against the CDN in March 2003, thereby proclaiming the patent to be valid for Canada.

prediction tools, decision support tools and teaching tools (there is some overlap between the latter two). In the animal breeding and genetics community developers of the code (where code is available) do not actively communicate through a "community" of users to make improvements to the code, peer review, and code improvement *per se*. It is interesting to note that there has been no impetus for developers of software in animal breeding and genetics to develop an open source-based community (Newman and Golden, 2002). We define open source as software for which the source code is distributed or accessible via the Internet without charge or limitations on modifications and future distribution by third parties. There is a substantial base and tradition of freely distributed applications software for analysis of animal breeding data. There are probably many reasons why animal breeders have not embraced a more formal mechanism for protecting these applications using open source licensing. Probably the most significant is that animal breeding software has such a limited market that there is not much threat of co-opting the application into a proprietary environment. Many animal breeders use their software as a way to communicate their ideas to colleagues, and a formal process of open source protection would be a burden with a perceived limited value. Finally, some animal breeders perceive that institutional administrators are reluctant to allow them to freely distribute software. Often, this is viewed as giving away something that may have revenue generating potential. Most institutional administrators do not understand the limited size of the market for these applications. In order to avoid having the software bottled-up in a debate over the merits of seeking open source licensing, that would require administrative intervention, breeders simply release software into the public domain, unprotected.

Opportunities for developing networks and communities of developers for software development are required and would likely be welcomed if leadership were provided. However, until granting agencies require it from animal breeders, as they do for many bioinformatics development efforts, animal breeders will continue to freely distribute their code without protection.

As explained previously, copyright is a separate class of protection from patents, and involves fewer formal procedures. Copyright arises automatically once an original effort has been started and some aspect of it has been fixed in a tangible medium of expression (Field, 2000). Registration of copyright is required only if legal action is warranted. By copyrighting software, it becomes illegal to copy or distribute the software or its documentation without permission from the copyright holder. However, this means only the source code, or executable image is protected from unauthorized copying. It does not supply adequate protection of the ideas. Intellectual property such as features, function, or screen layout is not protected by copyright.

The open source community has developed the "copyleft" method as a process for making computer program free software and requiring all modified and extended versions of the program to be free software as well (*www.gnu.org/copyleft/copyleft.html*). In its simplest form, copyleft states that anyone who redistributes software, with or without changes, must pass along the freedom to further copy and change the software. This prevents individuals or groups from making changes to software and then turning the result into a proprietary product. Again, this does not protect the ideas in the software. However, this is not normally a problem for copyleft developers because one of the reasons to copyleft software is to demonstrate use patterns and procedures. One of the real benefits of copyleft source code is its ability to show other developers alternative patterns for accomplishing tasks.

Alternatives to Patenting

An article in the New York Times (Milstein, 2002) described technology developed by Plantronics, Inc. to reduce microphone noise. As the company was not ready to utilize the technology, they chose to post a description of the invention on IP.com (*www.ip.com*) to establish the invention's legal existence. This is known as prior art in patent law and is the mechanism or basis for judging novelty and nonobviousness. The invention is judged against everything publicly known prior the filing date including earlier patents and other published material. This disclosure is also known as defensive publishing. However, while this prevents patenting in Europe immediately upon public disclosure, in the US there is still a one-year grace period that allows patenting after such disclosure. Competitors will gain access to the invention through publication, but it removes or reduces the risk that someone else will receive a patent on the technology, putting the "original" inventors at a future competitive disadvantage including a requirement to pay license fees.

The Foresight Open Source Disclosure Project, developed by the Foresight Institute (*www.foresight.org*) in association with IP.com, is one way to help open source developers establish prior art for their developments. For a small fee a document submitted to the disclosure project via IP.com becomes part of a database made available to patent officers from all over the world to help in conducting prior art searches before a patent is awarded.

Ethical, Social and Economic Issues

Many ethical and social issues have been raised related to patenting of animals and genes (Bent, 1989; Dresser, 1988; Evans, 2002). These include:

1) patenting of animals or genes will be destructive to nature and allows humankind to play "God";
2) patenting will devalue animal life and hence human life;
3) patenting will increase animal suffering;
4) patenting will lead to a decline in genetic diversity of animals and threaten a species existence;

5) patenting speeds the trend toward commercialization of academic research and
6) patenting will undermine conventional farming and lead to increased industrial farming systems.

Early humans domesticated animals and master breeders and geneticists have transformed them into productive species. Was this playing "God" or interfering with nature? The use of transgenics for making specialized animal lines for disease research is certainly adapting nature but does it devalue life and is it unethical or immoral? These are value judgments that most in society have decided are acceptable (Evans, 2002). Certainly some lines have been (and need to be) drawn to delineate what is acceptable and unacceptable. For example, most people and governments have concluded that while cloning of animals is acceptable (at least for research purposes), cloning of humans, for whatever reason, is immoral, unethical and to be avoided.

Animal welfare and animal rights issues continue to be at the forefront of livestock production and biomedical research (Evans, 2002). Individuals who believe that animals have "rights" will likely be opposed to patenting any invention derived from animal research. The most commonly cited examples are those relating to transgenic animals (eg., early transgenic pigs) in which some animals had health problems (Kevles, 2002). Production and patenting of specialized lines of rodents for biomedical research that have a tendency to develop specific diseases is also considered unethical by animal rights activists (Evans, 2002). If, however, individuals believe that animal rights are subordinate to those of humans, but that they deserve proper care and welfare then the issue of patenting is much less of a concern.

It has been suggested that the use of gene markers and highly selective breeding, or the use of transgenics and cloning, will greatly reduce genetic diversity leading to future problems for agricultural production (as well as a reduction in the "quality" of life of the animal. Certainly these methods have the potential to remove within-line/breed variation but they are likely to increase between-line variability. However, it may be argued that the patent system in fact encourages diversity as it promotes and helps establish, via patent-related deposits of biological materials, a broader genetic diversity (Bent, 1989). Related to this area is the issue of patenting of products from animals or plants from developing countries. Should companies be allowed to sample and alter wild stocks and to subsequently earn great sums of money by then selling them to both developed countries and back to the countries from where they were obtained? Some individuals say patenting encourages this so-called biopiracy and some countries are moving to address these concerns (Evans, 2002). An extension of this is the issue of species integrity. The development of transgenic pigs for xenotransplantation and other species with human genes for human protein production threatens the genetic differences that determine species. While consideration of xenotransplantation has slowed due to fears of retroviruses and diseases like mad cow disease and AIDS, as Evans (2002) points out this dispute over species integrity "is not empirical" but it is tied up in the individual and societal views on nature and "the notion of awe and wonder." It is likely, no matter how repugnant this process is to some, there will be development of transgenic lines of animals for biomedical research (not food production) and applications that do encompass genes from other species.

In a perfect world, public support of research would be 100% of required funding and all IP would be publicly available in the country of origin. Many US public institutions are now funded at about 40% of total budgets and pressures to obtain outside funding are growing. Companies supplying funding expect to "own", through licensing agreements or otherwise, the IP that results. Protection of IP can provide research partners a greater basis for trust and exchange of ideas and help insure that public institutions focus research on areas of high relevance and high potential for royalty streams. Commercial relationships also aid in technology transfer, employment opportunities for students and may allow for research opportunities not available in the public sector. Fretz and MacKenzie (2002) have suggested that:

1) such activities serve the public good;
2) short term, low quality research should not be favored to obtain funding;
3) management of IP must be a balance of serving the institution, funding agency and public;
4) independence of the researcher and institution must be maintained;
5) the mission of the public institution is not altered and
6) conflicts of interest should be avoided. Institutions must be proactive in balancing funding, IP protection and commercialization.

Does patenting increase the likelihood of "industrial farming?" Economic and governmental issues certainly play a role in the size of the average farm and the level of commercialization of farming. It can be argued that if large companies have exclusive licensing arrangements for genetic tools then small breeders will be disadvantaged. However, market pressures related to size of operation and efficiency of production are much larger influences on the industrialization of farming and livestock production than patenting. For example, the number of individual pig farming operations in the US has dropped from 196 000 to 74 000 over the last 10 years; patenting played no role in this decline. In addition, there are restrictions that ameliorate this problem including the non-patentability of natural processes and "farmers' rights".

Other issues regarding patenting that have an economic basis can also be elucidated. Langinier and Moschini (2002) provide an excellent review of the economics of patenting and the benefits and costs that are derived. While inventors would prefer broader claims, limited claims encourage competition and further innovation. Complex products often require building on other patents. Unfortunately, new development can be blocked by other patents (especially at the leading edge) and this has negative effects on both the developer as well as the public. Licensing of patents exclusively to one company may benefit that company and segments of the public but might also limit further innovation and not be in all the public's best interest. Langinier and Moschini (2002) concluded, "that continued efforts are required to improve the workings of the patent system" to improve the economic performance of the system.

Conclusions

The modern field of animal science and particularly animal breeding and genetics has changed markedly in the last two decades of the 20th century. The changes expected in the first two decades of the 21st century are likely to be even larger with sequenced genomes, transgenic livestock and cloned animals becoming the norm. These discoveries and their uses represent the intellectual property or creative or "inventive" work of individuals. It has been said by Bruce Lehman, United States Commissioner of Patents and Trademarks, "the only wealth there is in the world is the wealth that comes from the human mind." It seems only reasonable that the development of such wealth be protected and allowed to grow. Companies have long known this and have protected discoveries by keeping trade secrets and filing patents. More recently, animal breeders in universities and in governmental research labs have begun to also protect their inventive works through patenting. This change has alarmed and threatened some amongst us and raised economic, legal and ethical questions. How this new paradigm will affect public education and public support of research remains to be determined. Patents in themselves do not prevent the spread of knowledge. In fact in many ways they have aided technology transfer in the livestock industry. Certainly the "landscape" of farming and livestock production has changed with increased vertical integration of production such that there is considerably more control from farm to processing to the consumer's table. This structure has allowed new inventions to be moved more quickly into the market place and at times have disadvantaged certain sectors of livestock production and farming. For example, early adopters of the use of bovine growth hormone to increase milk production disadvantaged those producers who failed to use this product when milk prices were high. As consumer studies have shown, it is not the patenting that worries people but the safety of the products and the level of access to the general public that exists. We do face large challenges. We must be assured that patenting will continue to promote progress and not prevent it. Patent applications must not be frivolous and the real costs of patenting must be reasonable and in line with the benefits they provide. Certainly the present high cost of obtaining patent coverage is now beginning to lessen the number of applications. Some of the profits from patenting must be reinvested into the research system to promote future discovery. Finally, as scientists and inventors we must work to see that inventions that are produced have usefulness for society, do not harm animals or humans and do the most to promote the public good.

Acknowledgements

Financial support was provided by the Iowa Agriculture and Home Economics Experimental Station, Ames, project no. 3600, as well as by Hatch Act and State of Iowa funds. Support by Sygen International and comments from colleagues are greatly appreciated.

List of References

Bent, S.A. (1989) In "Animal Patents: The Legal, Economic and Social Issues" p 5-14, Editor W.H. Lesser, Stockton Press, New York, USA.

Dresser, R. (1988) Jurimetrics J. 28: 399-410.

Evans, D. (2002) In "Intellectual Property rights and Patenting in Animal Breeding and Genetics" Editors M.F. Rothschild and S. Newman, CAB International, CABI, Oxon, UK, 163-168.

Field, T.G., Jr (2000). Copyright for computer authors. *www.fplc.edu/tfield/CopySof.htm*.

Fox, B. No way to treat inventions. New Scientist, April 3-9, 2004.

Fretz T.A. and Mackenzie, R.D. (2002) In "Intellectual Property rights and Patenting in Animal Breeding and Genetics" Editors M.F. Rothschild and S. Newman, CAB International, Oxon, UK, 85-102.

Fujii, J., Otsu, K., Zorzato, F., deLeon, S., Khanna, V.K., Weiler, J.E., O'Brien, P.J. and MacLennan, D.H. (1991) Science 253: 448-51.

Kaiser, J. (2000) Science 289: 709-710.

Kevles, D.J. (2002) In "Intellectual Property rights and Patenting in Animal Breeding and Genetics" Editors M.F. Rothschild and S. Newman, CAB International, CABI, Oxon, UK pg 17-30.

Langinier, C. and Moschini G.C. (2002) In "Intellectual Property rights and Patenting in Animal Breeding and Genetics" Editors M.F. Rothschild and S. Newman, CAB International, CABI, Oxon, UK, 31-50.

Lesser, W.H. (1987) N. Central J. Agr. Econ 9: 37-48.

Lesser, W.H. (2000) In "Agriculture and Intellectual Property Rights: Economic, Institutional, and Implementation Issues in Biotechnology" pp. 35-52, Editors V. Santaniello, R.E. Evenson, D. Zilberman, and G.A. Carlson, CAB International, Oxon, UK

Lesser, W. (2002) In "Intellectual Property rights and Patenting in Animal Breeding and Genetics" Editors M.F. Rothschild and S. Newman, CAB International, Oxon UK, 1-16.

Lesser, W. and Mutschler, M. (2002) In "Intellectual Property rights and Patenting in Animal Breeding and Genetics" Editors M.F. Rothschild and S. Newman, CAB International, Oxon UK, 103-118.

MacLennan, D. H., Duff, C., Zorzato, F., Fujii, J., Phillips, M., Korneluk, R. G., Frodis, W., Britt, A., Worton, R. G. (1990) Nature 343: 559-561.

Milstein, S. (2002). *http://radon.eecs.berkeley.edu/~hodges/Protecting%20Intellectual%20Property.htm*

Nebel, H., Akrad, L., and Brady, T. (2002) In "Intellectual Property Rights in Animal Breeding and Genetics" Editors M.F. Rothschild and S. Newman, CABI, Oxon, UK, 119-146.

Newman, S. and B. Golden. In "Intellectual Property Rights in Animal Breeding and Genetics" Editors M.F. Rothschild and S. Newman, CABI, Oxon, UK, 147-162.

Rothschild, M. F., Jacobson, C., Vaske, D. A., Tuggle, C. K., Short, T., Sasaki, S., Eckardt, G. R. and McLaren, D. G. (1994) Proc. 5th WCGALP 21: 225-228.

Rothschild, M.F. and Plastow, G.S. (2002) In "Intellectual Property Rights in Animal Breeding and Genetics" Editors M.F. Rothschild and S. Newman, CABI, Oxon, UK, 179-196.

Rothschild, M.F. (2002). Proc. 7th WCGALP (Plenary Session)

Santaniello, V., Evenson, R.E., Zilberman, D. and Carlson, G.A. (2002) "Agriculture and Intellectual Property Rights: Economic, Institutional, and Implementation Issues in Biotechnology" CABI, Oxon, UK.

Schaeffer, L.R. (2002) In "Intellectual Property Rights in Animal Breeding and Genetics" Editors M.F. Rothschild and S. Newman, CABI, Oxon, UK, 233-246.

Sherwood, M. (1984). "The Origins of the American Patent System" Penn State University

Waltersheid, E.C. (1994) J. Patent Trademark Office. Soc. 75: 398-426.

Watson, J. O. (2001). A History of the United States Patent Office. *www.m-cam.com/~watsonj/usptohistory.html*