

## **PATENTING ACTIVITIES IN VETERINARY SCIENCES: CONCEPT, STATUS AND IMPLICATIONS**

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**Abstract:** The number of patent filing particularly in agriculture and allied sector in India followed an increasing trend after patents reformation in 2005. The experience of patenting in veterinary sciences is meagre due to the several reasons like limited birth of innovative technologies in comparison of chemicals, pharmaceuticals and agriculture, lack of self motivation and institutional support for filing the patents. Limitations of non-consideration of parameters like biological processes, methods and animals in whole or any part thereof is not eligible for patenting was also one of the important factor to refrained researchers and scientist in filing the patents related to veterinary science. Moreover, issues of protecting intellectual property (IP) in veterinary science should receive an urgent attention at national and international level particularly from developing countries like India.

**Keywords:** Patents, Concept, Status and Veterinary Science

### **Introduction**

Knowledge about patents in India at policy and decision making level in important public and private bodies are meagre. A patent is a governmental grant of a temporary right to exclude others from making, using, or selling the claimed invention for a limited number of years. Intellectual property protection is in various forms, e.g. patents, designs, copyrights, trademarks, trade practices, domain names, appellation of origin, etc. As soon as the life of patent expires, it passes to the general public domain and now anybody can use it without the permission of the original inventor. It represent the largest form of IP which is good indicators of research and development output. The world of Intellectual Property Rights (IPR) and commercialisation of scientific success is largely one-sided and Western-dominated at present. Patent information and patent statistical analysis have been used for examining present technological status and to forecast future trends (**Mittal and Singh, 2006**).

Creativity and innovations are the new drivers of the world economy. Since, past several decades main drivers for the advanced economies have been technologies and technological innovations rather than manufacturing and agriculture. The ability of the country to generate

novel, useful, patentable innovations is negligible and practically non-existent in the disciplines which have already been targeted as economic growth areas (**Bera, 2008**). The number of Indian patents granted to foreign companies has been found three-times higher than those granted to the domestic inventors. The participation of foreign organizations has been increasing in India and they accounted for 75 per cent of the total patents granted during 2007-2012 (**Kandpal et.al. 2015**). Though, there is an increasing trend of patenting in agriculture and allied sector in India but most of the patents owned by foreign countries other than India. Today possession of land, labour and capital are just not enough for a country to succeed. However, the country has to fetch the real benefits of technology generation and commercialization in terms of patenting.

The number of patents in agricultural sciences is likely to be less due to exclusion of animals, plants and parts thereof and methods of agriculture (Guruprasad *et al.*, 2003). Because of these the situation of patenting even in veterinary sciences is not so encouraging. Moreover, the specific and precise literature on patenting in veterinary science is also not adequately available. To encourage the veterinary scientific community for patenting of useful innovative technologies, efforts have been taken to focus on the general concept and patenting activities in veterinary sciences.

### **Objectives of Patent**

- To encourage inventions by promoting their protection and utilization so as to contribute to the development of industries
- To enjoy the exclusive rights over the invention
- A patent is to ensure commercial returns to the inventor for the time and money spend in generating a new product.

The first patenting related act in India was passed in 1911 by the name of Patents and Designs Act, 1911. The Patents Bill was passed in the year 1970 and the act came into force on 20<sup>th</sup> April 1970. The Patent Act 1970 was expected to provide a reasonable balance between adequate and effective protection of patents on the one hand and the technology development, public interest and specific needs of the country on the other hand. The Patent System in India is governed by the Patent Act, 1970 (No. 39 of 1970) and the Patents Rules, 2003. The patents act has been amended several times in 1974, 1985, 1999, 2002 and in 2005. The Third Amendment of the Patents Act 1970, by way of the Patents (Amendment) Ordinance 2004 came into force on 1<sup>st</sup> January, 2005 incorporating the provisions for

granting product patent in all fields of Technology including chemicals, food, drugs & agrochemicals.

### **Criteria for Patentability**

1. **Statutory Subject Matter** — Invention must fall into one of the five “statutory classes; Processes, Machines, Manufactures, Compositions of matter and New uses of any of it.
2. **Utility** —Invention must be useful and have real world utility; its use must be specific, substantial and credible.
3. **Novelty** —Invention must be truly new, and cannot have existed beforehand.
4. **Non-obviousness** — It is not enough for a new invention to be novel—it must also be “non-obvious” to a person having “ordinary skill in the art.”
5. **Sufficiency of the Disclosure in the Patent Specification as Filed** —Patent applications disclose the best mode for carrying out the claimed invention and provide adequate written description of how to make and use the invention.

### **Patentable Inventions-**

- It must be related to a process or product or both. It should be new (novel)
- It must involve an inventive step i.e. technically advanced as compared to existing knowledge. It must have industrial applicability
- It should not fall under any of the categories of “Inventions- non-patentable” mentioned under Sections (3) and (4) of the Patents Act, 1970- Any device, apparatus or machine or method for committing theft / burglary, Any machine or method for counterfeiting of currency notes, Any device or method for gambling and An invention the use of which can cause injury to human beings, plants and animals.

### **Non-Patentable inventions-**

- An invention which is frivolous or which claims anything obviously contrary to well established natural laws.
- An invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment.
- The mere discovery of a scientific principle or formulation of an abstract theory.
- The mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way.
- A method of agriculture or horticulture.

- Any process for medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.
- Inventions relating to atomic energy

### **Types of Patent**

Three types of patent are granted under the provisions of the act, namely

1. An Ordinary Patent
2. A Patent of Addition
3. A Patent of Convention

A second type of classification of patent is

1. Product Patent
2. Process Patent

### **The Life of Patent**

In respect of an invention claiming process of manufacture of a substance intended to be used as food or medicine- 5 yrs from the date of sealing or 7 yrs from the date of patent whichever is shorter. For all the technology, term of patent is 20 years.

### **Expiry of Patent**

- The patent has lived its full term.
- The patentee has failed to pay the renewal fee.
- The validity of the patent has been successfully challenged by an opponent by filing an opposition either with the patent office or with the courts.

### **How to Approach for Filing the Patent in India?**

Patent system in India is administered under the superintendence of the Controller General of Patents, Designs, Trademarks and Geographical Indications (CGPDTM), appointed under sub-section (1) of Section 3 of the Trade Marks Act, 1999. The Patent Office comes under the Ministry of Commerce & Industry. The Office of the CGPDTM is located at Mumbai. The Head Office is at Kolkata. The branch offices are located at Mumbai, Delhi and Chennai.

#### ✓ **Applications for Patents**

An application for a patent may be submitted by

- Any person claiming to be the true and first inventor of the invention.
- Any person being the assignee of the person claiming to be the true and first inventor in respect of the right to make such an application.
- By the legal representative of any deceased person who immediately before his death was entitled to make such an application.

#### ✓ **Procedure for the grant of Patent**

1. After filing of Patent Application a Request for Examination should be filed

2. After examination of application by patent office and objections, if any, are raised thereto.
3. After removal of all the objections, the Patent is granted and is advertised for Opposition Purposes.
4. The Patent is open for third party opposition, if any, for a period of one year from the date of advertisement.

✓ **Documents to be submitted along with Patent application**

- Application Form in duplicate (Form 1)
- Provisional or Complete Specification (Form 2) In case of provisional specification the complete specification must be filed within 12 months.
- Drawing in duplicate if necessary
- Abstract of invention in duplicate
- Information of Undertaking listing the no., filing date and current status of each foreign patent application. (Form 3) in duplicate
- Priority Document
- Declaration of Inventor ship (Form 5)
- Power of Attorney if filed through patent agent (Form 26)
- Fees to be paid in Cash/ Cheque/ DD.

✓ **Fees-**

The fees payable under section 142 in respect of the grant of patents and applications therefore, and in respect of other matters for which fees are required to be payable under the act shall be as specified in the first schedule. The amount of the fees varies from 1000-4000. The fees, payable under the act may either be paid in cash or may be sent by bank draft or cheque payable to the controller of patents.

**Patenting Activities in Veterinary Sciences**

India is huge country of animal biodiversity contributing large quantity of milk, meat, egg, draught power, fibre, manure etc. generating rural employment. In order to improve the sustainable productivity of livestock in India, it is absolutely necessary to increase technological inventions and their protection. Animal scientists have now started to protect their intellectual property and these protective measures have alarmed other scientists and the public. The diversification in Indian agriculture was also noticeable during the period 2005 to 2012 as dairy products and animal husbandry registered 19.0 and 5.78 times increase in

patenting activity over the period 1995–2004 besides development of new plants and processes (10.87 times) and horticulture and cultivation forestry rising (5.87 times). In India, the number of patent grants has increased significantly in all the fields of agricultural sciences particularly in the fields of transgenic, agro-chemicals and animal vaccines after the introduction of patent reforms in 2005 and accumulation of the applications during the transit period (**Kandpal et.al. 2015**)

The study was conducted to monitor the trend of patenting activity in agriculture sector during 2005 to 2012 in India based on 3,718 published patent applications and 1,041 granted patents of the Indian Patent Office. It is observed that there was gradual increase in patenting activity during 2005 to 2012 in different sectors of agriculture. Maximum percentage of patent applications were filed in biocides, pest repellents or attractants and plant growth regulators (60%), followed by new plants or processes for obtaining them (9.35%), animal husbandry, silk rearing or breeding new animal breeds (7.48%) and (5.91%) horticulture, cultivation, forestry (**Mehta et.al. 2014**).

The challenge for biodiversity rich countries is to guard against bio-piracy of their indigenous animal genetic resources, and to safeguard technologies that they have been using. Another concern is the export of genetic material to countries that did not ratify the Convention on Biodiversity (**Scholtz and Mamabolo, 2006**).

More than 80 patents have been filed by the scientist researchers working in the area of veterinary science research at Indian Veterinary Research Institute, Izatnagar. Moreover, total 11 patents have been granted for the livestock technologies developed by the institute ([www.ivri.nic.in](http://www.ivri.nic.in)). However, more than 25 patents have been filed during the last 5 years by the National Dairy Research Institute, Karnal. The institute has developed the various technologies in the research area of dairy science.

Some of the technologies developed and commercialized in the recent past in the field of livestock farming by ICAR institutes Area specific mineral mixture for different agro – ecological zones (example- MINKAM-UT is a quality product researched & developed by Indian Veterinary Research Institute, Izatnagar & licensed technology transferred by National Research Development Corporation, New Delhi (Patented) fortified with Vitamins (A, E & D3 & Probiotics). ‘Crystoscope’ is a field tool used for determining optimum time for fertile insemination or for timely heat detection in cattle and buffalo, “Olinall” herbal ointment for treatment of chronic skin ailment, FMD vaccine, complete feed block technology developed using locally available unconventional feed, cost effective detoxification technologies for oil

cakes, bypass nutrient technology for high yielding bovines, PPR vaccine, low cholesterol ghee etc. National Dairy Research Institute (NDRI), Karnal successfully produced a male buffalo calf named 'Shresth' through the new and advanced 'hand-guided cloning technique' (It is an advanced modification of the Conventional Cloning Technique).

In livestock sector, patents have been granted for gene sequences with utility such as genetic markers. A New Zealand company, AGMARK claimed a patent on the "Booroola" gene which regulates the ovulation rate in sheep. The Booroola gene can be traced back to Bengal sheep which were imported from Kolkata and crossed with Merinos (**Kohler-Rollefson, 2005**). Roslin Institute and PPL therapeutics (Scotland) Ltd have been claimed a patent (EP 0765390) for the gene construct of bovine alpha-lactalbumin is taken from 'vechur' Indian cattle breed. The unique genetic quality of this breed is the high milk fat content ranging from 6.02 to 7.86 percent. The European patent office granted a patent-EP 849990 on Dolly, a cloned sheep, to the Roslin Institute Edinburgh in 2001 (**Ramesha, 2011**).

The east African Boran cattle breed has been patented in Australia. A series of patents on pig production (Methods of Breeding in pigs) has been implemented in some 160 countries through Monsanto. The Monsanto (USA) patent applications were published in February 2005 at the World Intellectual Property Organisation in Geneva. US7718360 B2 - Composition (RCUD) for protecting and repairing DNA from oxidative damages and a method thereof; (**Chakrabarti et al, 2010**). CSIR, India- **Redistilled Cow's Urine Distillate (RCUD)** having benzoic acid and hexanoic acid components, with ammonia content ranging between 5-15 mg/l, and optionally along with anti-oxidants was found useful for protecting and repairing DNA.

**Natco Pharma Ltd. V. Bayer Corporation**- Germany based drug manufacturing firm Bayer Corporation invented a drug called SORAFENIB TOSYLATE used in the treatment of primary kidney cancer and advanced primary liver cancer sold under the brand name NEXAVAR. The generic drug company Natco requested Bayer for a Voluntary license but the request was denied. So Natco filed an application in controller of patents court for grant of a compulsory license. **MANHATTAN**- A team of researchers from Kansas State University's College of Veterinary Medicine has received a U.S. patent to control and treat fusobacterial infections in humans and animals. Fusobacterium is well known for causing liver abscesses in cattle and sheep, and has been identified as a human pathogen that causes some periodontal or gum diseases, topical skin ulcers, Lemierre's syndrome and other conditions. Patent No. 9,308,247, "Compositions and Methods for Detecting, Treating and

Protecting against Fusobacterium Infection," covers a wide variety of technology uses, including expression systems, adjuvant, gene therapies, injectable solutions, oral compounds and vaccines.

### **Conclusion**

The patenting in veterinary sciences is meagre might be due to non-consideration of parameters like biological processes, methods and animals in whole or any part thereof is not eligible for patenting. The patent reformation in year 2005 allowed patenting of product and process in all fields of science including veterinary science which has accelerated the activity of patenting in India. The specific and precise literature on patenting in veterinary science is inadequate. The need and importance of patenting of technology is being recognized in India, an increasing trend, development of financial agencies and technology appraisal agencies for patenting in veterinary sciences is needs to be strengthened. Issues of protecting intellectual property (IP) in veterinary science should receive an urgent attention at national and international level particularly from developing countries like India. Public-private partnerships model contributed significantly to address the R&D gaps and generate technologies at affordable prices in the field of veterinary sciences along with agriculture in the backdrop of product patent regime.

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