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ETHICAL ISSUES IN PATENTING LIFE FORMS CONCERN TO INDIA-A SURVEY

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ABSTRACT

Advances in biotechnology have made the patenting of life forms a subject of increased interest and controversy. The main goal of this study was to analyze in brief, the ethics of the some individual groups on the patenting microorganisms and life forms in India. This is achieved through realizing some secondary objectives such as identification of the ethical characteristics and its relation to some of the study variables, their attitude towards the patenting microorganisms, their knowledge level about patent and their sources of information about use, storage and disposal of life forms. The study covered few randomly selected states and people of India, and some farmers of Karnataka were included as stratified random sample. The results revealed that the 94% academicians, science, commerce and law graduates and students were aware of WTO, TRIPS, GATT and Patenting but only 15% of arts graduate and farmers have the knowledge about patent. Education and religion signifies in evaluating the ethical issue than the age, gender etc. Electronic media and newspaper are the sources of information that farmers rely on. Farmers should be enlightened about the importance of patenting of life forms and its pros and cons, especially those dealing with the new varieties of crops, food products and medicine.

Keywords: Ethics Intellectual Property Rights Patent Microorganism

INTRODUCTION

Since civilization moral and ethics are taught from generation to generation, meanwhile changing as the civilization passes. In modern society morality and ethics are taught at school level. Ethics is a commonly-used label concerning a complex set of concepts and behaviours[1]. Ethics are distinct from morals which are concerned with the individual's personal character, whereas ethics focuses upon the broader social system in which morals are applied. Hence a sophisticated understanding of ethics recognizes not just an individual's morals but how these are a part of the broader social system, influencing people's behavior, and how people have different morals and ethical perspectives.

In the Jewish, Christian, Hindu and Islamic traditions it means first and foremost that God exists and created the life. There is no doubt that religion has strong appeal for many people and that it holds a powerful grip on how people think of right and wrong. However, social forces shape religion and should be very cautious in appealing to religious convictions to justify ethical claims. The multiplicity of religious facts, and the problem of evil, can at least say this much. In one religion pig is abandoned therefore the insulin from pig pancreas also not acceptable in the earlier days but now insulin from genetically modified microorganisms are accepted.

The birth of modern research ethics began with a desire to protect human subjects involved in this research. The first attempt to craft regulations began during the Doctors Trial[2] of 1946-1947.In light of the balance between public and private interests enables other inventors to learn about them and to develop improvements and alternatives. The costs of bringing a novel medicine to market are substantial and need to be recouped. Therapeutic proteins (gene products) produced directly from DNA sequences that have been developed into medicines, human protein kinase homologues, interleukins and insulin etc. Gene therapy aims to replace a faulty gene with a normal gene by introducing it into the body. The U.S. Supreme Court decision in the Diamond v. Chakrabarty 447 US 303 In 1972 case changed the scenario of patenting living organisms – bacteria named *Pseudomonas putida* to create an oil-dissolving genetically engineered organism were patentable because they did not occur naturally in nature. Later glow fish, soya bean, corn, canola, cotton {ISAAA (International Service for Acquisition of Agri-Biotech Applications) Brief 46-2013; executive summary global status of commercialized biotech/ GMcrops; 2013}

However, ethics is more concerned with developing individuals to have the broader skill of thinking ethically in all parts of their lives, not just in research. This research was conducted in engaging students and individuals with ethical thinking, supports the development of the character and values that have the skills to contribute to a healthy society.

In this study individuals of many categories were asked to complete a questionnaire about their ethical development. Alongside this, interviews were conducted with some individuals about their views on the importance of ethics in patenting microorganisms.

MATERIALS AND METHODS

Sample

A convenience sample of respondents was drawn from 40colleges including Law, Agriculture, Horticulture as well as arts and commerce in selected states of India and also some qualified formers of Karnataka state. Geographically dispersed and diverse group of respondents from urban, suburban, rural areas of sampling was collected.

In about 50% of the college, students in life sciences were considered eligible to participate. In about 25% of colleges, students in required academic subjects (e.g., Arts and commerce) and Law College students. Remaining 25% Farmers were considered eligible to participate. Random selection of person with personal consent procedures were followed.

2200 individuals participated and completed questionnaires during the survey administration, many are refused to participate and many are quit in between because of subject matter, ethics and religion etc. The final sample, therefore, consisted of 1798candidates. As shown in Table-1, the demographic characteristics of the sample were similar to the national distribution of law college students98%. For some groups, the sample percentage differed from the national percentage by more than 65 percentage points. Specifically, commerce students were overrepresented and Arts students were underrepresented. In addition, farmers were underrepresented. Religion was not considered at the time of random selection of the candidates but considered for the opinion in ethical issue among the sample group.

Questionnaire

As part of a larger study designed to test the reliability of all of the items and the effect of alternative question wording for some items, five very similar forms of the questionnaire were developed. All questionnaires were self-administered and consisted of between 45 and 50 multiple-choice questions and YES or NO. Five questions measured demographic information, two asked to report their age gender and religion, and the remaining items assessed awareness and opinion of patenting life forms concern with Indian scenario. The results related to the alternatively worded and new questions are beyond the scope of this article. Data collection began in May 2015 and was completed in March 2016. The questionnaire was administered individually using different means, personally either printed and electron media like email, telephone and orally to complete. Data were collected and stored in the computer. This technique helps to safeguard privacy because comparable amount of time are required to complete the questionnaire regardless of ethical issues in different religions, age and gender because individuals cannot detect the response of other individual simply by looking at the pattern of responses.

What is your gender?

Male / Female

How old are you?

18–25☐ 26–35☐ 36–45☐ 46–55 ☐56–65 ☐

What is the highest level of education you have completed?

High school graduate ☐

Two-year/associate's degree or some college☐

Four-year or bachelor's degree ☐

Graduate or master's degree ☐

Postgraduate degree or PhD ☐

Survey is confidential and people need not provide any personally identifiable information.

* The genetic engineering witnessed many praiseworthy achievements and realized the level of self-sufficiency in food production ex. wheat, BT cotton, etc Yes ☐ No ☐

Some of the ethical arguments that are commonly expressed when supporting patenting of biotechnology inventions are:

* Patent law regulates inventiveness, not commercial uses of inventions Yes ☐No ☐

* Patenting promises useful consequences (e.g. new products/research) Yes ☐ No ☐

* Our country needs to support patents like other countries so biotechnology industry is to Compete Yes ☐ No ☐

*If patenting is not permitted, useful information will become trade secrets Yes ☐ No ☐

* Patenting rewards innovation Yes ☐No ☐

The arguments against patenting include:

* Metaphysical concerns about promoting a materialistic conception of life Yes ☐ No ☐

* Patenting promotes inappropriate human control over information that is common heritage Yes ☐ No ☐

* Some countries do not permit similar patents Yes ☐ No ☐

* Patenting produces excessive burdens on medicine (increased costs to consumers, payment of royalties for succeeding generations) Yes ☐ No ☐

* Increased use of animals means more animal research which may be against animal welfare.

Yes ☐ No ☐

Most of these issues will not be affected by permitting patents, as the issues are similar to those existing prior to the patenting debate (e.g. the distribution of wealth, international competitiveness) (OTA, 1989; Bruce, 1998; Wartburg & Liew, 1999). This issue remains contentious and the fact that different countries have conflicting policy reflects this. The issue is closely related to the commercialization of biotechnology, but some sort of information protection is already accepted as an incentive to invest in research of benefit to society.

Data Collection Procedures

The survey was conducted using hard and soft copies of the questionnaire by e-mails, telephone conversation and personal meeting. The data collectors explained the survey procedures.

Collapsing and editing procedures: After the questionnaire, the data were entered into the standard table randomly without making any categories like age, gender and religion. These procedures exclude questionnaires that do not have more than 20 valid responses or have the same response option 15 or more times in a row. Although many questions contain multiple response categories, standard responses reports divided into,for example, people who responded that they never see the labels on the products in the market are classified as “aware,” whereas those who re-ported that they see the labels on the products in the market are classified as “non aware.” Because to examine how the data perform in standard reports, these same procedures were followed for the analyses reported. In addition, the five questions not relevant to analyze in the questionnaire were eliminated from the analyses for this study.

Statistical analysis: The data were subjected to statistical analysis by using Statistical Package for Social Sciences (SPSS, 14.0).

RESULTS AND DISCUSSION

It is not that recombinant techniques clearly violate any moral view in particular. Rather it is the case that recombinant DNA technology poses questions not previously raised within any traditional moral theory. Because the decision to award a patent may be publicly perceived as at least implicitly a decision to condone any and all uses of the invention, it may be have to first resolve objections concerning morally problematic uses of certain biotechnological innovations before attempt a consensus on monopoly of the innovations.

An alternative and more familiar rationale asserts that a patent provides an incentivethat fosters ingenuity and effort. There is reason for scepticism whether a patent must be available in order to induce a given result. ‘‘The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available,’’ noted the Supreme Court of the United States in affirming the patent on the oil-eating bacterium, ‘‘suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides’’[3]. There arrived for filing a spate of plant patent applications in Europe, many presumably from European companies, quickly after the first plant patent was allowed there in 1989, which suggests that the research had long before been done.

Collecting data is only one step in a scientific investigation, and scientific knowledge is much more than a simple compilation of data points. The world is full of observations that can be made, but not every observation constitutes a useful piece of data.

The thoughtful and systematic collection, analysis, and interpretation of data allow them to be developed into evidence that supports scientific ideas, arguments, and hypotheses.

Though it may sound straightforward to take ethical and moral issues data, the process of analyzing and interpreting those data is actually quite complex. India is diverse country and some are sensitive matters and there are no consistent measurements are available. One could simply take an average of all of the available measurements for a period but that number would not take into account the natural variability within and uneven distribution of those measurements.

Data interpretation is not a free-for-all, nor is all interpretations equally valid. Interpretation involves constructing a logical scientific argument that explains the data. Scientific interpretations are neither absolute truth, it is a personal opinion.

They are inferences, hypotheses about what the data mean, based on a foundation of scientific knowledge and individual expertise stepping stone for the future arguments and amendments.

Prior to TRIPS, India's patent system had been regulated by the country's Patents Act of 1970 (Patents Act). To begin making India's law consistent with TRIPS, the Patents Act was amended in 1999 and 2002.[4] In addition, India is required to make further changes by January 1, 2005 in order to become fully TRIPS compliant.

Table 1: Distribution of respondents according to level of knowledge relating to patent in Percentage (N=1798)

Level of knowledge Expression	NK	LK	MK	GK	SD
Meaning of WTO, TRIPS, Patent	30	19	36	15	09.69
Meaning of GMO	28	18	38	16	10.13
Wheat is a GM crop	38	24	26	12	10.64
The fundamental principle of the Patents Act is that subject matter can only be patentable if it is an invention.[5]	60	12	08	20	23.86
Any substance that is prepared or produced by a chemical process cannot be patented--only the process itself is patentable.	68	12	12	08	28.72
Patents are available for processes or methods of production of tangible and nonliving substances like enzymes, hormones, and vaccines.	67	13	12	08	28.08
A process for improving the plant's value or increasing the value of the plant's products is patentable.	62	18	08	12	25.00
The mere discovery of organisms, however, is not patentable.	70	10	10	10	30.00
India has not fully complied with Article 27(1) of TRIPS, which requires protection of all inventions of both products and processes,[6] except plants and animals.[7]	73	17	09	11	30.52
Patent protection is territorial in nature, and therefore, patents granted in India are only valid in India.	77	13	13	07	33.12
The genetic engineering witnessed many praise worthy achievements and realized the level of self-sufficiency in food production ex. wheat, BT cotton, etc.	69	11	12	08	29.38
Insulin, Enzymes, antibiotics ex. Penicillin, tetracycline etc. production from microorganism	79	11	06	04	36.12
The concepts of environmental conservation and maintenance of the soils	20	20	25	35	07.07
Chemical pesticides and fertilizers cause serious damage to the farmers and the environment	03	27	34	36	13.96
Farmers burdened by the high cost of patented animals and crops, they may turn to cheap unpatented strains, that crops will become less diverse, and that more crops will succumb to pests	15	22	28	35	08.52
Effects of the use of GM contamination of soil microorganisms	17	23	30	30	06.27
Effects of the use of GM contamination of insects	22	78	35	25	28.59
Labels on the products in India	31	29	25	15	08.69
Plastic degradable bacteria patent	87	11	01	01	41.60
Oncomouse and oyster were granted patent	84	14	02	02	39.40

NK-no knowledge LK-less knowledge MK- medium knowledge; GK- good knowledge SD- standard Deviation

Table 2: Distribution of respondents according to the usual preventive measures when dealing with GM products (n = 204) in percent

Extent of use Method of use	Not used	Rarely	Sometimes	Always	Mean	SD
GM Plants & Products	86	07	07	00	25.00	40.80
GM Animals & Products	47	23	27	0.5	24.37	19.06
GM Medicines	08	31	61	00	24.75	26.97
GM products	99	01	00	00	25.00	49.33

In the situation, it is very important to study the awareness level of the people regarding approval of patenting by concerned authority with diverse groups of people in detail and creating awareness. The developed countries like America, Japan and Europe are supportive of patenting life forms, when compared to other regions of the world. India also accepting some of the GM products and GMO like BT cotton, brinjal, medicines etc. therefore it's the time to encourage the research to produce useful GM products and organisms for the benefit the country with the confidence of all divergent groups.

The issues surrounding the patenting of life forms, specifically the social and private costs and benefits of the Plant Variety Protection Act (PVPA). The PVPA is a current issue, encompassing all the elements of the economic, social, and moral controversy aroused by the broader issue of patenting life forms generally[8].The mailbox system further allows the inventor to "establish priority dates that serve as evidence of the novelty of their inventions." [9]

In 2014, India registered only 42,854 patents in comparison to china 9,28,177 US 5,78,802 , Japan 325989 Korea 210292 Germany 65965 etc the main reason for less number of patent application filing are lack of awareness on patent system. As per the WIPO statistics, during 2014, India registered 33.2 patents per million population in comparison to 4,205.8 by republic of Korea, 2566.8 by Japan, 1,782.6 by the US and 680.3 by China etc. The safety of products prepared using genetically-altered animals will be monitored by the USDA and the Food and Drug Administration (FDA). The USDA's Food Safety and Inspection Service (FSIS) inspects livestock, poultry, and their food products to ensure they are safe, wholesome, and unadulterated[10.11]. In India also require similar certification and quality control measures by FSI and ISO etc. that should publish the details of the product to reach the common people before release to the market

Key findings from the questionnaires

• Over 99 % of respondents agreed with the process of comparing product and process information and the amount of the GMO on other organism may be exposed to the environment and life forms is called risk assessment. All the data should monitor together, to evaluate a (GMO) genetically modified organism's risks of environment, animals, human and other plant.If the risk assessment require additional testing, the GMO tested only by specially-trained people, or decide not to allow its use. Decisions on risk reduction measures are based on a consideration of both GMO risks benefits When issue a registration for a patent

CONCLUSION

The result just not a statistical representation and response rate but it's the opinion need to be consideration in approval of transgenic life forms patent

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