

ETHICS IN SCIENTIFIC RESULTS APPLICATION: GENE AND LIFE FORMS PATENTING

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The remarkable development and application of new genetic technologies over the past decades has been accompanied by profound changes in the way in which research is commercialized in the life sciences. As results, new varieties of commercially grown crops with improved or new traits are developed. Many thousands of patents which assert rights over DNA sequences have been granted to researchers across the public and private sector. The effects of many of these patents are extensive, because inventors who assert rights over DNA sequences obtain protection on all uses of the sequences. Extremely valuable to

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breeders in the national agricultural research system is the ability to genotype their collections to get a clear picture of their diversity and how diversity could be enhanced through sharing and access to global collections. The issue of the eligibility for patenting of DNA sequences needs to be reopened. Patents that assert rights over DNA sequences and their uses are, in some cases, supportable, but in others, should be treated with great caution. Rights over DNA sequences as research tools should be discouraged. That the best way to discourage the award of such patents is by stringent application of the criteria for patenting, particularly utility. A more equitable, ethically – based food and agricultural system must incorporate concern for three accepted global goals: improved well being, protection of the environment and improved public health (particular point food from GMO). To mitigate conflict one of the approach to solve problem is ethical and truthful label of GM food, because consumers have a right to choose whether to eat genetically modified foods or not. Interesting examples and risks as consequences of free availability of genetic resources utilization, its transformation, patenting of “new” organism and selling it back to the genetic resource owner are presented. Society has obligations to raise levels of nutrition and standards living by all respect to ethics at each step.

Key words: biotechnology; ethics; GMO, Gene patenting; IPR, plants

INTRODUCTION

Over the past two or more decades, the structure of agricultural input has changed very rapidly - input of private sector in agriculture and food Research and Development (R&D) has grown dramatically, while public-sector investment has remained relatively constant (SHOEMAKER *et al.*, 2001). The use of intellectual property (IP), in the form of plant variety protection certificates and utility patent has also expanded very rapidly over roughly the same time period. More than any other component of agricultural R&D, agricultural biotechnology exemplifies these trends (J.E.M. 2001). Patenting in a specific type of plant biotechnology - plant cultivars is also of interest. Patents for cultivars are now issued whether or not they result from the use of some molecular technique such as gene insertion.

Private firms almost completely dominate cultivar patenting. United States private firms are patenting far more cultivars than do non-US firms. Two crops, maize and soybeans, also account for most of the US utility patents on plant cultivars. Patents represent in Europe only a minor mechanism for technology transfer, access to information (publications) and various forms of capacity and institution building and are important mechanisms to transfer technologies and facilitate their use (ECE, 1995). Few patents are relevant in potato breeding, where the private keep new varieties available for further breeding and claims not to seek profit from poor farmers in developing countries. Clearly, both governmental institutions, universities and private firms devote a substantial proportion of program patenting in agricultural biotechnology to patents that, concern biological control of pests and diseases for plants and animals. Intellectual property issues were and are some of the most

controversial in modern biotechnology (OTA, 1989; LESSER, 1991). In this report the short overview on contemporary research in the field of plant biotechnology and protecting obtained results in the form of patent

BIOTECHNOLOGY

The agricultural commons were created and nurtured by countless generations of breeders and seed-savers without commercial reward, and were bequeathed to mankind at no cost. The ancient practice of farmers and gardeners saving seed from their harvest for planting next season is an inalienable right. Seed saving is essential to adapting plants to local conditions, especially where environmental degradation and global climate change processes occur. Seed must not become a product that can be dealt only to breeding new varieties.

Agricultural biotechnology may be understood as these of organisms or parts of an organism to make or improve products or processes in agriculture. The domestication of plant species and selection of desired characteristics within agricultural species would qualify under this definition. What biotechnology represents today is new knowledge about the natural processes of the DNA replication, breakage, ligation, and repair that has made possible a deeper understanding of the mechanics of cell biology and the hereditary process itself (MC COUCH, 2001; KONSTANTINOV *et al.*, 1993; MLADENOVIĆ DRINIĆ *et al.*, 2002). Although in agriculture the term biotechnology has been most closely associated with genetic manipulation at the DNA level, or genetic engineering, it may refer to a variety of techniques or products. These may include, for example, use of molecular markers in genetic improvement or more general use of genomic information (SMITH *et al.*, 1987; MLADENOVIĆ DRINIĆ *et al.*, 2004). Similarly, the use of enzymes for fermentation in brewing or cheese making would be early examples of a broadly defined food biotechnology. Genetically engineering yeast to modify or improve a baking process would be an example of a narrower or more recent definition of food biotechnology.

The benefits that are hoped for from the biotechnology based on genetic engineering include: (i) increased productivity of crops, growth rates and ratio of plant product which could be used; (ii) increased quality of crops, including nutritional quality and storage properties; (iii) adaptation of plants to specific environmental conditions; (iv) broaden plants tolerance to stress; (v) production of substances in food crops and (vi) utilization of new raw materials. Ecological and scientific studies to produce better crops and farming practices should lie at the heart of biotechnology. Future potential of genetic engineering to produce more nutritious and safer food than we consume now, by the breeding of new varieties of crops excluding the naturally occurring toxins and carcinogens that we consume everyday from the food.

Some transgenic crops still contain antibiotic resistance genes when they are grown (MLADENOVIĆ *et al.*, 1991; MARTINCAN *et al.*, 1994; KONSTANTINOV *et al.*, 1993., KONSTANTINOV *et al.*, 1997; KONONOV *et al.*, 1997). This concern lead to rejection of a maize with an inserted *Bt* gene that control resistance to European

corn borer, that was being marketed by Ciba-Geigy (COGHLAN, 1996). Studies in mice and rats of the protein product of the marker *NPTII* gene which control *neomycin* resistance found it as safe for consumption (FUCHS *et al.*, 1993). Therefore particular variety of soybeans would have had to be labeled under FDA policy. However it has been decided to abandon development of this variety (NESTLE, 1996).

The major concerns are ecological and have been the subject of a number of studies and reports (OTA, 1988, 1991; RUDELSHEIM *et al.*, 1994). The issue has, and continues need to be addressed by scientific studies. Prospective effect has been partially controlled by the Convention on Biological Diversity, which regulates collecting of species after 1993 in the wild. It does not regulate the use of the samples from botanical gardens that were collected before this, and also it does not regulate the resources found in the oceans of international waters (TANGLEY, 1996). It covers the country of ownership, but inside countries there are also disputed claims to which community has rights. This new approach contrasts with the practice which still continues among many researchers for free exchange of materials, and there are unresolved ethical questions about whether one country or group can claim ownership of a species. Another approach would be to see them as the common heritage of all species and all humanity.

GRAFF *et al.* (2002, 2003a, b) offer definition of agricultural biotechnology broader and it includes such areas as crop resources that may not have been developed using the techniques of molecular biology. They defined different kinds of technologies: resources transformation platforms and traits, and found that some institutions tended to combine different types of technology, dependent on the type of firm. On the research input side, data on investment in the agricultural biotechnology would be valuable (XIA and BUCCOLA 2005). Breakdown of the investment by technological area and other indicators of research objective would add even more. Unfortunately, detailed data in agricultural biotechnology are often either unavailable or nonexistent.

In developing countries plant breeding is public service to support development program that reach near-subsistence farmers that are not likely to become customers of private sector. For the most important food crops, public activities are at the basis of the Green Revolution and significantly contributed to free distribution of the half - bred materials and finished varieties. The new technologies may facilitate their work for poverty reduction only if they can access them.

Use of the licenses for help to undeveloped countries have been used to make individual technologies available for research and for development. Such licenses are generic, rather than dealing with individual transfers, and with opening require explicit action and communication to facilitate actual technology transfer. Open-source is another model for increasing access and reducing transaction costs. Philosophy of innovation in networks with weak - informal - ties as opposed to a linear organizational structure with formal contracts would underlie an "open innovation system". Despite various initiatives to promote open source strategies the models do not seem to gain much importance in more product oriented

biotechnology research (SHOEMAKER *et al.*, 2001; GRAFF *et al.*, 2002; http://www.cfra.org/resources/issue_brief_patenting.htm).

A number of factors could explain the unprecedented increase in applications for patents. According to HALL (2004) the initial structural break was largely accounted for by firms in electrical and computing technology. In addition, other related technological areas, such as software and information technology, witnessed a rapid increase of innovation and new firm creation over much the same period as the increase in patents. The new molecular and genomic tools used in genetically engineering plants have also vastly enhanced the enforceability of intellectual property protection by providing new and more powerful means of establishing that someone has illegally used a protected variety. It is now possible definitively characterize plants and seeds at the molecular level by establishing their unique “fingerprints” in a manner similar to that used for DNA profiling in criminal cases. It is also possible to detect the use of the protected varieties or genetic material in breeding new varieties (KORTUM and LEMER, 1999).

The so-called “farmer's privilege” that allows farmers to harvest and legitimately use propagating material derived from the crop grown from the original and legitimately obtained propagating material for subsequent cropping cycles on their own farm should be a right. These are the processes which maintain and improve local biodiversity and adaptation that will be crucial as global climate change arises.

PATENTING IN AGRICULTURAL BIOTECHNOLOGY

The face of plant breeding research has changed significantly due to the rapid technological developments in the field of genomics and to revolutionary changes in the legal and policy environment in which plant scientists and breeders are working.

Varieties eligible for protection are those that are new, uniform, stable (in the sense of reproducing their characteristics in their progeny), and distinct from existing varieties. Principles are: (i) only the first inventor of something patentable can obtain a patent; (ii) the invention must be useful; (iii) the invention must be novel; (iv) the patent must involve a creative step. There are different tests for the novelty.

Different kinds of protection have been available for some time. Legal protection of plant varieties was introduced in the United States long time before development of genetically engineered plants. Since 1930 a type of patent introduced especially for plants, known as a “plant patent,” has been available from the U.S. Patent and Trademark Office (USPTO) in the Department of Commerce, to protect novel clonally propagated (i.e., asexually reproduced) plant varieties including fruit trees, ornamentals, and berries.

Plant patents, like the more common and much older utility patents available for inventions are currently enforceable from the date they are granted until 20 years from the date of application. Since 1970 Plant Variety Protection Certificates (PVPCs) have been available from U.S. Department of Agriculture. The term of protection offered under PVPC is now 20 years for most crops, 25 for trees and vines.

Farmers are allowed to save seed of varieties protected by PVPCs for replanting their crops, but they cannot provide or sell those seeds to others for planting (<http://www.genethics.org>)

It is important to note that plant patents and PVPCs prevent only unlawful proliferation of the variety; they do not prevent the use of protected plant materials for breeding purposes. In contrast, the more broad-ranging utility patents not only prevent seed increase via reproduction of the same variety, they also protect breeders against unauthorized use of protected varieties for breeding and research purposes.

Particular way of the seed production is hybridization. Seed obtained from a hybrid crop (produced from different male and female parental varieties) does not have yield as high as the initial hybrid crop. Thus, breeders of hybrid crops have an effective non legal protection gains replanting by farmers. High private investment in the crop breeding has tended to be concentrated in hybrids, in particular hybrid of maize and horticultural crops. For other crops, most breeding - related research until recently has been largely concentrated in the public sector, in agricultural experiment stations and Universities (WRIGHT *et al.*, 2005).

The development of genetic engineering of plants in the 1980s was accompanied by specific possibility of patentability of various types of life forms, including those created by conventional breeding, and particular sequences of genetic material or DNA such as genes, markers, and promoters (which control the expression of genes in cells), which could be protected by utility patents. It must be stressed out that either positive or negative effect of life form patenting on humankind and environment are unpredictable. Utility patent protection is also available for novel methods of breeding and genetic engineering for new varieties produced by use of new methods and for research tools. Novel plant could be protected by a utility patent on variety or on its genes, by a plant patent (XIA and BUCCOLA, 2005; KONSTANTINOV and MLADENOVIC 2006, 2007, 2009). Novel plant could also be patented as a product of the novel method by which it was produced, such as genetic engineering. Utility patents protect the plant breeder's or inventor's rights to control the use, sale, import, and reproduction of plants that have been patented or that incorporate patented material. Using utility patents, plant breeders can dictate the terms under which such plants can be used and could prevent others from using them for any subsequent breeding or for seed increase via replanting of the harvested seed. Many patented basic materials and methods for genetic engineering in agriculture were generated either in private corporations or in universities and are often licensed exclusively to private businesses (BOETTIGER and BENNETT, 2006). Biotechnology for an Open Society (<http://www.bios.net/>) seeks to generate open-source development of suites of research tools for biotechnology innovation, unhindered by any patent thickets.

Patenting in the agricultural biotechnology differs across entity type and across the time. As fast as patenting grew in broadly defined agricultural biotechnology, it grew even faster in the modern agricultural biotechnology. In the early years of the records there was almost no patenting in modern agricultural biotechnology. In the

period from 1980 - 1984, modern agricultural biotechnology patents averaged about 3% of all agricultural biotechnology patents (GRILLICHES, 1990). By 1996-2000 period patents averaged about 22% of all patents in agricultural biotechnology. Even when patents obtained by modern agricultural biotechnology are extracted from the rest of the agricultural biotechnology sample, agricultural biotechnology patents still grew much more quickly than did total patents. What the patent data do confirm is the current importance of private sector in commercializing agricultural biotechnology, in particular plant -related technologies and modern agricultural biotechnology that relies more on the application of molecular biology (XIA and BUCCOLA, 2005).

Universities may patent as a means to transfer technology to the private sector for further development, to attempt to generate licensing revenue, or perhaps to contribute to the regional economic development through the scientific parks. These motivations for the patenting by the Universities in particular are preferable in the literature rather than analyzed in any detail (JAFFE and LEMER, 2001). Research publications are the alternative measure, although not strictly comparable to patents, because they might represent somewhat more basic research than the research that results in patent applications (XIA and BUCCOLA, 2005). Universities however, do not appear to patent the near-market technologies such as plant cultivars. Available data confirm that the US government only tends to patent in specific agricultural biotechnology research areas rather than broadly across all agricultural areas in which it performs research. This government patenting appears to be mainly in support of technology transfer what is important in agricultural biotechnology in terms of patent counts, but with some exceptions, their patent portfolio mimics the portfolio held by the private sector (HEISEY, *et al.* 2005). Public - sector institutions, that patent, may do so for reasons differing from those motivating private firms (HENDERSON, *et al.*, 1998; JAFFE and LEMER, 2001). Firms patent to protect their inventions, to develop strategic patent portfolios, and to generate licensing revenue (COHEN, *et al.*, 2000, JAFFE, 2000).

BUCCOLA and XIA (2004) assessed the apparent decline in patent quality using citation based measures and proposed two hypotheses to explain this decline. First, a “technological hypothesis” proposed that agricultural biotech patents are moving downstream. Second, a “strategic hypothesis” suggested that firms are patenting more to maximize the value of their patent. They determined that the evidence may support both the technological and strategic hypotheses.

Several examples have been documented of the struggle to obtain all the licenses that are necessary for introducing technologies into developing countries such as use of patents resting on the nutritionally enhanced “Golden Rice”. Numerous patents in the field of agricultural biotechnology turn out to have very little economic value, while “Golden Rice” prove to be extremely valuable (GRILLICHES, 1990). Developed at the Universities in Switzerland and Germany it required a major commercial company to disentangle the thicket of rights and negotiate licenses for all these patents for their use for the poor. No agreement was

reached because negotiations never started since patent holders did not show an interest to negotiate at all (BUCCOLA and XIA, 2004).

Patents increasingly reduce the freedom to operate in plant breeding. Biotechnology companies are known to actively seek patent protection for their products. Knowledge created by the public Universities and research Institutes is often protected in spite of elementary human rights that public resources should not be used to enforce private rights. Patents on life and PBR (Plant Breeder's Right) facilitate enclosure and privatization of the global biological commons. This is inherently unjust and against the public interest. There are various strategies being used to study of Ethical Concerns about Plant Biotechnology. In Japan biology teachers considered there was more risk from genetic engineering than the ordinary public (MACER, 1992; 1994a, 1994b). There is however need for the education about computers, pesticides, nuclear power, biotechnology and genetic engineering. Both benefits and risks were cited by many respondents. Discovery itself may not be wrong, but how we use it or abuse it raises ethical questions.

BIOETHICAL ISSUE OF LIFE FORM PATENTING

Possibility to reach the balance between benefits and risk of science and technology depends on the level of society education of (MACER, 1990; 1992; 1994 a, b). Human population has not simplified opinion about the science and technology. Balancing between good and harm is indispensable for the bioethical concern of the life and is indicator of bioethical maturity of the society. Comparative studies (HOBAN and KENDALL, 1992; MACER, 1995) showed that plant-plant gene transfers are acceptable, animal to animal less, and animal-plant or human-animal gene transfers were least acceptable.

The Group of Advisers on Ethical Aspects of Biotechnology to the European Commission (ECC, 1995) recommended food be labeled to indicate when its composition and characteristics have been substantially modified by genetic engineering techniques. There is substantial equivalence between the new food and a traditional counterpart (e.g. virus resistant plants produced by insertion of the viral coat protein, or herbicide tolerant plants produced by introducing a protein comparable to one already present in a plant but tolerant to a selective herbicide). According to OECD (1996) investigation: (i) there is substantial equivalence between the new food and traditional counterpart, except for the inserted trait (e.g. insect protected plants produced by the insertion of the *Bt* gene or disease resistant plants produced by the introduction of a new protein); (ii) there is substantial equivalence between the new food and a traditional counterpart (e.g. virus resistant plants produced by insertion of the viral coat protein, or herbicide tolerant plants produced by introducing a protein comparable to one already present in a plant but tolerant to a selective herbicide); (iii) there is not substantial equivalence between the new food and a traditional counterpart (e.g. introduction of a gene or genes that encode a trait that significantly alters the plant for use in food or feed, such as production of a new oil or carbohydrate). If substantial equivalence is established they considered that the novel food be treated the same as the familiar one. If there was a new trait,

evaluation it should be done case - by case for the product of the gene. Anyhow, balance must be found between the right of consumers to information and the imposition of unnecessary information which may confuse people over what the major facts relevant to their diet are (NESTLE, 1996). Each state must take responsibility for any risk related to deliberate release of GM organisms into the environment (Van WAES, 2009).

There are many unresolved legal and practical implications of the ethical issues when someone improves upon a variety that another has developed. Example is XA21 gene in rice. This gene is coding an important disease resistance, and based on earlier research by the International Rice Research Institute and its partners in India and Mali, have been patented by the University of California, Davis. After long negotiation University in Davis released the patent for development purposes and even did developed a benefit share mechanism for profits derived from the commercial use of the patent (<http://www.genethics.org>.)

Many medicinal plants have been collected and selected by indigenous groups, local farmers and traditional medicinal healers. Modern approaches can identify the active ingredients and several patents have been issued to these companies. These are being challenged, but the issue needs further ethical resolution. The practical issues of royalty sharing also need to be resolved. It is quite important to have international approaches and support because food products are sold and transported across borders, and a ban in one country could be circumvented if a neighboring country approved its production (HOBAN and KENDAL, 1992).

The issue of Intellectual Property Rights (IPR) in public research could be tackled from different generic angles, including ethics - the role of science and academia in society and political economy (http://www.cfra.org/resources/issue_brief_patenting.htm).

Public research organizations generally use patent protection as part of three strategies: maintaining their position at the frontier of science through maximizing their own freedom to operate, strengthening their position in public private partnerships, and obtaining a return on investment on their research through cash income.

The Aims and Objectives of Plant Breeder's Rights Laws is to encourage plant breeders to produce new plant varieties, and to benefit society with access to new and improved plant varieties and assured food security. Increased use of patents and the PBR, and decreased public investment in the plant breeding are reducing but not increasing the food and crop diversity. PBR is in many cases the way of the public resources privatization. Enclosing the global biological commons should not be permitted (GRAFF, *et al.*, 2003a, b). It could be proposed that breeders be contracted by the community through governments to undertake certain essential work previously carried out by public sector breeders. There are cases when PBR is placed on the variety that has become available through a foreign aid program where local breeders received the material for the purposes of assisting breeders or growers in other countries. Such bio piracy should not be rewarded and exemplary damages should apply (GENE ETHICS, 2007).

Strict liability should apply to gene contamination, especially where the pollen or seed of patented or PBR varieties transfer their genes into the genomes of conventional or organic crops. Plant breeders should not have the greater rights than people whose crops are contaminated by protected varieties. If criminal liability (with penalties of jail and fines) were to apply to alleged infringements of patents and PBR, they should also apply to the inevitable contamination that would ensue from the commercial release of (especially open-pollinated) GM and PBR plant varieties.

Plant Breeders Right (PBR) law is inherently unfair since “inventiveness” is not a criterion for registering a plant variety under PBR. Invention is rightly a core criterion for a patent, which most GM companies use in preference to PBR to protect their varieties. Without an inventive step being required for PBR, biodiversity can be owned by a seed or any other company, with no innovation. This is classical biopiracy. It would be good to reward plant breeders to achieve its goals - development of the new plant varieties to meet the challenges of predicted tough environmental conditions and to ensure food security. Plant breeders have the option of suing to enforce their rights if they regard them as infringed and it seems as sufficient remedy (MACER, 1990).

GENE ETHICS (2007) does not accept that living organisms should be the subject of monopoly ownership under the Patents or Plant Breeder's Rights Acts. Intellectual property rights should only be granted to encourage genuine inventions and should not apply to organisms originally found in nature. Plants are not inventions. PBR is doubly objectionable because, unlike patents, it does not apply the criteria of non-obviousness, inventiveness and reproducibility which must be met for the grant of a patent (<http://www.genethics.org>).

Patent Office has issue as plant patents under the Plant Patent Act and utility patents under the Patent Act for the plants, under a Supreme Court decision that confirms the availability of such utility patents (J.E.M. 2001) despite the existence of more specialized statutes addressing intellectual property rights for specialized plants. It may be in certain cases that there are broader public policy reasons why it would seem contrary to the public interest to grant patents to life forms (http://www.cfra.org/resources/issue_brief_patenting.htm.)

Allowing patents on bacteria and seeds and the possibility of patenting their life forms raises ethical and moral questions (KONSTANTINOV and MLADENOVIC DRINIC 2006). It also raises questions relating to increasing consolidation in agriculture. How family farmers and ranchers are treated in such a legal and regulatory regime will go a long way in determining their future (Usefulness is a criterion for granting a U.S. patent). Increasing of the biological material amount held privately rather than in the public domain as companies, devote additional resources to cost-effective patents. Public plant breeders will lose access to the germplasm. Public research being directed to a greater extent toward satisfying the desires of the firms that purchase the rights to the patents and to a lesser extent toward the desires of farmers, ranchers and consumers. As a consequence it is greater control by firms holding patents of the crops grown from patented seed.

INSTEAD OF CONCLUSION

The patenting of life forms raises public policy issues. Social and ethical issues require careful analysis and debate in order to evaluate and, possibly, to reform the basis for the issuing life form patents. Bioethics combines risk assessment, the concept of avoiding harm, with an assessment of benefits, the concept of doing good or beneficence. It is important to ask whether there are any new risks compared to traditional plant breeding. Good examples are various risks in method of genetic engineering (recombinant DNA technology) application and life form patenting with obvious consequences: (i) the risk of unintentionally changing the genes of an organism; (ii) the risk of harming that organism; (iii) the risk of changing the ecosystem in which it was involved; (iv) the risk of harming the ecosystem; (v) the risk of change, or harm, to any other organism of that species or others, including human beings (who may even be the target of change). The extent to which a change is judged to be a subjective harm depends on human ethical values and permanent consideration whether nature should be “intransient” or in some way modified. This relates to the facts that this technology is at least unnatural if not dangerous.

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REFERENCES

- BOETTIGER, S., A. B. BENNET (2006): Bayh - Dole: If we knew then what we know now. *Nature Biotechnology* 24,320–323.
- BUCCOLA, S., and Y. XIA (2004): The rate of progress in agricultural biotechnology. *Review of Agricultural Economics*, 26, 3-18
- COGHLAN, A.(1996): Engineered Maize Sticks in Europe’s Throat. *New Scientist*, 8 (6 July 1996)
- COHEN, W.M., R.R. NELSON, J.P. WALSH (2000): Protecting their intellectual assets: appropriability conditions and why US manufacturing firms patent (or not) (working paper 7552). Cambridge, Mass.: National Bureau of Economic Research.
- DRINIĆ MLADENOVIĆ, S., S. TRIFUNOVIĆ , G. DRINIĆ, K. KONSTANTINOV (2002): Genetic divergence and its correlation to heterosis in maize as revealed by SSR-based markers. *Maydica*. 47, 1-8
- DRINIĆ MLADENOVIĆ, S., J. SRDIĆ, G. DRINIĆ, K. KONSTANTINOV (2004): Genetic divergency of maize inbred lines based on molecular markers. In “Genetic variation for plant breeding”. pp. 53-56. Eds. J.Vollman., H. Gausgruber and P. Ruckebauer.
- ECE (ECONOMIC COMMISSION OF EUROPE).ECE (1995): Inventory of Safety Guidelines in Biotechnology (ECE/SC.TECH./47). Geneva: United Nations, <http://www.fao.org/docrep/003/x9601e/9601e02.htm> (
- FUCHS, R.L. et al.(1993): Safety Assessment of the *Neomycin Phosphotransferase II* (NPTII) Protein. *Biotechnology* 11, 1543-7
- GENE ETHICS (2007): Submission on a review by ACIP: Enforcement of Plant Breeder’s Rights. Issue paper. March.2007. <http://www.genethics.org>
- GRAFF, G. D., G. C. RAUSSER, A. A. SMALL (2002): Agricultural biotechnology’s complementary intellectual assets. *Review of Economics and Statistics* . 85, 349 – 363

- GRAFF, G. D., S. E. CULLEN., K.J. BRADFORD., D. ZILBERMAN and A.B. BENETT (2003a): The public private - structure of intellectual property ownership in agricultural biotechnology. *Nature Biotechnology*, 21, 9, 989 – 995.
- GRAFF, G.D. S. E. CULLEN, S.E., BRADFORD, K.J. ZILBERMAN, A.B. BENNETT (2003b): The public-private structure of intellectual property ownership in agricultural biotechnology. *Nature Biotechnology*. 21, 989-995.
- GRILICHES, Z. (1990): Patent statistics as economic indicators: A survey. *Journal of Economic Literature* 28(4), 166 1-1707.
- HALL, B. (2004): Exploring t he patent explosion (working paper 10605). Cambridge, Mass.: National Bureau of Economic Research.
- HEISEY, W. P., L.J. KING, D.K. RUBINSTEIN (2005): Patterns of Public Sector and Private Sector Patenting in Agricultural Biotechnology. *Ag Bio Forum* 8, Article 3.
- HENDERSON, R , A.B. JAFFE, M. TRAITENBERG (1998): Universities as a source of commercial technology: A detailed analysis of university patenting, 1965–1988. *Review of Economics and Statistics*, 80: 119-127.
- HOBAN, T.J., P.A. KENDALL (1992): Consumer Attitudes about the Use of Biotechnology in Agriculture and Food Production. Raleigh N.C. North Carolina State University
- JAFFE, A.B. (2000): The US patent system in transition: Policy innovation and the innovation process. *Research Policy*, 29, 53 1 - 557.
- JAFFE, A.B., J. LEMER (2001): Reinventing public R&D: Patent policy and the commercialization of national laboratory technologies. *RAND Journal of Economics*, 32: 167-198.
- J. E. M. (2001): *Ag. Supply, In. v. Pioneer Hi-Bred International, Inc.*, 534 U.S.
- KONONOV, M. E., B. BASSUNER, S.B.GELVIN (1997): Integration of T-DNA binary vector “backbone” sequences into the tobacco genome: evidence for multiple patterns of integration. *Plant J.* 11, 945 – 947.
- KONSTANTINOV, K., S. MLADENović DRINIĆ, T. ĆORIĆ, D. IGNJATOVIĆ, G. SARATLIĆ, J. DUMANOVIĆ (1997): Maize as host for *Agrobacterium* . In: *Genetics, biotechnology and breeding of maize and sorghum*. Ed. A.S.Tsaftaris. Published by The Royal Society of Chemistry, Cambridge CB4 4WF, UK.
- KONSTANTINOV, K., S. MLADENović DRINIĆ (2006): Ethical aspects of investigation and results of utilization in the field of Genetically Modified Organisms. In “Bioethics in Science and medicine” pp. 117-131. Eds. D.Marinković, K.Konstantinovic, Z. Magić Published by Serbian Academy of Science and Arts and Serbian Genetics Society.
- KONSTANTINOV, K., S. MLADENović DRINIĆ (2007): The ethics and transgenic organisms. In: “Improvement of agricultural production in Kosovo and Metohia”. pp.214 – 228. Ed. D. Knežević, Published by Family Press, Kragujevac Serbia.
- KONSTANTINOV, K., S. MLADENović DRINIĆ., V. ANDJELKOVIĆ and M.BABIĆ (2009): Ethics in scientific results application: gene and variety patenting. XXIth International Conference EUCARPIA “Maize and Sorghum Breeding in Genomics Era”, Bergamo, Italy, 21-24 June. Book of Abstracts
- KORTUM, S. J. LEMER, (1999): What is behind the recent surge in patenting? *Research Policy*, http://www.cfra.org/resources/issue_brief_patenting.htm
- LESSER, W.H. (1991): *Equitable Patent Protection in the Developing World: Issues and Approaches*. Christchurch, NZ: EUBIOS Ethics Institute.
- MACER, D. R.J. (1990): *Shaping Genes: Ethics, Law and Science of Using Genetic Technology in Medicine and Agriculture*. Christchurch, NZ: EUBIOS Ethics Institute.

- MACER, D.R.J. (1992): Attitudes to Genetic Engineering: Japanese and International Comparisons. Christchurch, NZ: EUBIOS Ethics Institute.
- MACER, D. R.J. (1994a): Bioethics for the People by the People. Christchurch, NZ Eubios Ethics Institute
- MACER, D.R.J. (1994b): Perception of Risks and Benefits of in vitro Fertilization, Genetic Engineering and Biotechnology. *Social Science and Medicine* 38,: 23-33
- MARTINCAN, B., T.A. VOCLHER, R.A.SANDERS (1994): On defining T-DNA. *Cell*, 6, 1032 – 1033.
- MC COUCH, S.R. (2001): Is biotechnology an answer? Who will be fed in the 21st century? Washington, DC: IFPRI, ERS, and AAEEA. In K.Wiebe, N. Ballenger, & P. Pinstrup- Andersen (Eds.)
- MLADENović, S., K. KONSTANTINOV, M.DENIĆ, B.TADIĆ (1991): Recombinant DNA technology in maize breeding. VI. Foreign gene influence on maize genome expression after plant transformation by different technologies. *Genetika*. 23, 191 – 204.
- MLADENović DRINIĆ, S., J. SRDIĆ, G. DRINIĆ, K.KONSTANTINOV (2004): Genetic divergence of maize inbred lines based on molecular markers. Book of proceedings of EUCARPIA Conference "Genetic variation for plant breeding", pp.53-57, Tulln, Austria.
- NESTLE, M. (1996): Allergies to Transgenic Foods - Questions of Policy. *New England Journal of Medicine* 334, 726-7
- OECD (ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT) (1996): Food Safety Evaluation. Paris: OECD Meeting
- OTA (U. S. CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT) (1991): Biotechnology in a Global Economy. Washington: U.S.G.P.O., OTA-BA-494, October 1991
- OTA (U.S. CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT) (1988): New Developments in Biotechnology, 3: Field Testing Engineered Organism, Genetic and Ecological Issues. Washington: U.S.G.P.O., OTA-BA-350, May 1988
- OTA (U.S. CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT) (1989): New Developments in Biotechnology, 4: Patenting Life. Washington: U.S.G.P.O., OTA-BA-370, March 1989
- RUDELSHEIM, P. *et al.* (1992-1994): Safety Assessment of Deliberate Field Use of Genetically Modified Plants. European Commission BRIDGE Program
- SHOEMAKER, R., J. HARWOOD, K.RUBENSTEIN, T. DUNAHAY, P.HEISEY , L. HOFFMAN *et al.* (2001): Economic issues in agricultural biotechnology (agriculture information bulletin no. 762). Washington, DC: USDA ERS Resource Economics Division. Available on the World Wide Web: <http://www.ers.usda.gov/publications/aib762/aib762.pdf>.
- SMITH, J.C.S. (1987): Gene markers and their uses in the conservation, evaluation and utilization of genetic resources of maize. (*Zea mays*, L.) International training session management - of gene banks. Raleigh, NC.
- TANGLEY, L. (1996): Ground Rules Emerge for Marine Bioprospectors. *BioScience*.46, 245-9
- VAN WAES J.. (2009): Maize variety testing for registration on national catalogue and the impact of new technologies. XXIth International Conference EUCARPIA "Maize and Sorghum Breeding in Genomics Era", Bergamo, Italy, 21-24 June. *Maydica* 54, 139 – 153,
- WRIGHT, B. D., P. G. PARDEY, C. NOTTENBURG, B. KOO (2005): Agricultural innovation: Economic incentives and institutions. In R. E. Evenson, P. Pingali, and T. P. Schultz, eds. *Handbook of agricultural economics*. Vol. 3. Amsterdam: Elsevier.
- XIA, Y., S. BUCCOLA (2005): University life science programs and agricultural biotechnology. *American Journal of Agricultural Economics*, 87(1), 229-243.

ETIKA U KORIŠĆENJU NAUČNIH REZULTATA: PATENTIRANJE GENA I ORGANIZAMA

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I z v o d

Razvoj novih biotehnologija zasnovanih na tehnologiji rekombinantne DNK, definisanih kao genetičko inženjerstvo, izazvao je značajne promene u načinu primene i komercijalizacije naučnih rezultata dobijenih u oblasti osnovnih istraživanja, posebno u poljoprivredi, medicini i zaštiti životne sredine. Na hiljade patenata koji daju pravo na vlasništvo nad DNA sekvencama/genima je odobreno istraživačima u privatnom i javnom sektoru. Korišćenjem patentiranih gena, koji kontrolišu važne osobine (otpornost prema bolestima na pr.) stvorene su i uvedene u proizvodnju nove sorte i hibridi najznačajnijih gajenih biljnih vrsta kao što su kukuruz, soja, pirinač kao i mnoge ukrasne biljke. Istraživači koji su vlasnici patenta gena imaju pravo na patentnu zaštitu i transgenih biljaka koje poseduju taj gen. Od posebnog značaja za istraživače u poljoprivredi, posebno u oblasti genetike i oplemenjivanja je mogućnost, korišćenjem genskih proba, karakterizacije genotipova i dobijanje pouzdanih podataka o genetičkoj varijabilnosti, naročito u korišćenju kako u sopstvenim programima tako i u razmeni biološkog materijala sa drugim kolekcijama. Slobodna dostupnost tih proba je jedan od preduslova. Pitanje opravdanosti patentiranja sekvenci DNA/gena i njihovog korišćenja je neophodno ponovo otvoriti jer su patenti u nekom slučaju opravdani a unekom moraju da budu oprezno razmatrani.. Patentno pravo na sekvencu DNA/gen kao eksperimentalni material nije opravdano i treba ga obeshrabrivati. Najbolji način za ograničavanje zloupotrebe je strogo primena kriterijuma za patentiranje, posebno za pravo korišćenja patenata. Mnogo pravedniji, na etičkim principima zasnovan sistem proizvodnje hrane mora da ima ugrađena tri globalna cilja: poboljšanje kvaliteta života, zaštitu životne sredine i obezbeđenje zdravlja populacije sa akcentom na korišćenje hrane proizvedene od GMO. Jedan od pristupa ostvarenju ovih ciljeva je etičko i istinito obeležavanje hrane od GMO, jer potrošači imaju pravo izbora da li žele da koriste genetički modifikovanu hranu ili ne. Interesantan je primer i rizici koji proizilaze iz neograničene dostupnosti i korišćenja genetičkih resursa, njihova transformacija korišćenjem genetičkog inženjerstva, patentiranje "novog" genotipa – organizma a zatim njegova prodaja vlasniku korišćenog originalnog genotipa. Društvo ima obavezu podizanja nivoa kvaliteta hrane i standard življenja uz puno poštovanje etika na svakom stepenu razvoja. U radu su navedeni neki od slučajeva patentiranja koji ne zadovoljavaju osnovne etičke norme.

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