Editorial: Biotechnology: legal, ethical and related issues

S. Visalakshi and P.K. Ghosh

Biotechnology is steadily unveiling its potential to create new products, processes and eco-friendly services. Furthermore, it is useful in finding answers to hitherto unsolved questions of biology. The thinking of human beings in understanding, identifying and treating diseases and creating, maintaining and protecting new types of plants and animals has been reshaped by the application of biotechnology. This field of knowledge has made it possible for man to manipulate and to create living organisms to channel parts of their energy to yield products of use to man.

Biotechnology should now be specifically attributed to the new branch of knowledge where hetereologous nucleic acid stretches, including genes, promoters, enhancers, markers and terminators, could be inserted, by human intervention through use of constructs, into unrelated hosts. The transformed hosts can be further isolated and maximised with a view to using them for advantage in certain fields of activity such as agriculture or inducing conditions into them to maximise the expression of the target genes. This phase is followed by isolation of the gene products by the application of appropriate downstream processing techniques and technologies as in the production of recombinant DNA drugs. Unregulated modification or incorporation of trans-genes into hosts, including new hosts, by methods such as the treatment of organisms with short wave length light or mutagenic chemicals, or inducing the fusion of related or unrelated cells to create new cells, or to cause the creation of somato totipotent cells from single cells with regard to hormonal regulations, were branches of old biotechnologies. Such technologies often get mixed up and get integrated, in the hands of different authors, as parts of biotechnology. Consequently, different countries have different definitions of biotechnology. There is indeed advantage in taking a broad view of the scope of biotechnology in the context of using this science for global economic gains.

The enormous potential of this field of knowledge endows man with powers that initially created fear and speculation. In the late 1970s and early 1980s, there was a strong and unified resistance from people all over the world, but specifically from developed nations to such activities and progress of knowledge. There was much debate about whether such applications were sustainable or whether they would lead to destruction when carelessly applied. Many scientific myths were created, envisaging the emergence of new and powerful new species/life forms which could be uncontrollable and could play havoc with the environment and humankind. In the course of time, such fears proved to be unfounded as nothing uncontrollable by human intervention could be created or found in actual practice. The speculation still prevails, though research in new biology continues more cautiously. Public awareness has increased and sufficient knowledge bases have been created to dispel the myths. The USA takes a serious role and is shifting emphasis from its responsibilities as a mere provider of funds for biotech

research to the outcome of such research, by initiating risk assessment and by proper management of units.

Different governments throughout the world have established regulatory norms and created machinery to oversee the creation, exploitation of new life forms and release these units into the environment. These are based on different ethos; some countries have resorted to controlling at the outcome (Product) level (exploitation stage), whilst the more conservative ones have stressed the importance of overseeing the whole process from generation of new methods of production and services to the ultimate release of new life forms, as well as products, into the environment. To a reader of the literature in this area, both the arguments seem to have validity in their specific contexts.

Biosafety could be defined as the policies and procedures adopted to ensure the environmentally safe applications of biotechnology. A national biosafety system to regulate production and release of genetically modified organisms is considered essential in any country with a biotechnology program. Regulation is a process by which governments ensure that the uncertainty and risks of a new technology can be contained within manageable limits. This is undertaken to overcome public resistance to technological advances and is incorporated into a receptive social context. Regulatory procedures devised to limit uncertainty, also serve the purpose of channelling the flow of forthcoming public resistance and this regulation, in fact, becomes an integral part of the shaping of new technology. According to Harvey Brooks [1] a regulated technology goes beyond the "knowledge of how to fulfil certain human purposes in a specifiable and reproducible way". Thus regulation is a kind of social contract that specifies the terms under which the state and society agree to bear the costs and risks for the benefits given by a technology viz. biotechnology.

In a matter of two decades, biotechnology has moved from moratorium to market due to this process of social accommodation. This is the reason for the pace with which research in biotechnology has transcended to a flourishing industry with the promise of great benefits for small, and easily controllable, risks. This transformation was brought about quickly in Europe and North America and was achieved by adoption of laws and regulations to control the risks at lab level, for research, and field level, for release into the environment of genetically modified organisms. The scientific community also played a role in this process in assuring the public of the use of sound scientific principles to assess the risks of biotechnology.

Measures to ensure the safety of genetically modified organisms are indispensable to research in this area. New technologies have risks that demand careful consideration in advance of wide-scale adoption in the field. Biosafety measures are necessary as a matter of sound public policy; they are also increasingly required as a precondition for donor funding of biotechnology research. These concerns have prompted both developing and industrialised countries to implement biosafety guidelines governing testing, safe use and handling of GM crops in the environment. Different countries perceive differently the problem of regulation of biotechnology in the specific context of releasing GMOs into the environment. The understanding of risk varies with each national context. Accordingly the techniques vary in the process of legislation, bureaucratic reorganisation and expert advice etc. The limitless scientific unknowns, during this process, were reduced to a few familiar paradigms of assessment and control.

Analysis of different countries' regulatory mechanisms has shown that there are basically two types of basis for regulation – 'product based' and 'process based'. In the first case the products are scrutinised for evolved standards, irrespective of the method of

production. The latter case involves a more expansive view, incorporating standards for the process of production as well as for the products.

These regulations are based on perception of risk at different levels namely the physical risk and social risk. The physical risk includes risks to health and the environment that are different in kind and magnitude from the risks created by the natural process of genetic combination and recombination. The social risks range from commodification of nature to the elimination of family farms, to severe economic dislocations in developing countries. In addition, political risk – biotechnology increases the distance between decision making experts and the lay public – may be perceived, leading to the exclusion of the public from meaningful control over technology which could transform their lives. The 'product' approach is based on the perception of the 'physical risks' of biotechnology and confidence in science and scientists to contain those risks and control unwanted outcomes [2].

Thus, biosafety regulations strive to strike a balance between protection and promotion at the same time. The legitimisation could be based on faith in science, and its power to find solutions to problems, taking precautionary measures to reduce risks, or 'allowing' the participation of citizens in the process. Examples of these three variants could be the USA, UK and German experiences of evolving Bio-safety regulation. Most of the developing countries either follow USA or UK models.

Part 1 of this special issue (to be published as Vol. 4, No. 4, 2002) begins with two papers on the use of biotechnology in agriculture, from Dr. Sutat Sriwantanapongse of Thailand and from Dr. P.K. Ghosh of India, which deal with the potential of genetically engineered plants in agriculture. It has been argued that biotechnology holds enormous opportunities to produce better plant cultivars, which can be utilised as a comparative advantage in countries with agriculture-based economies. However the use of such high-tech products by the people of the country is connected to the generation of scientific information to establish that the products are safe to the environment and harmless to the people. This involves the question of resolving the safety of these products and, consequently, an acceptable bio-safety protocol needs to be developed, based on the feasibility and reality of public use and transfer of these materials across boundaries. Dr. Solleiro and Amanda Galvez give an overview of the efforts made by different countries in the Latin American region towards the creation of biosafety regulations and the reasons for variance.

The other aspect of the new knowledge, the application of which has given rise to new goods and services, has been the questions relating to protection of such knowledge. The issues specific to biotechnology are found to be more complex than other knowledge packages. The problem starts with the definition of subject matter of patents to include life forms. Moreover, people have found the divide between 'obviousness' and 'new' with regard to life forms to be inadequate in many cases. In the context of human intervention, the stage and extent which would qualify it as the subject matter of a patent is also controversial, especially in inventions emerging from the application of biotechnology. The inherent characteristics of the basic material itself make it vulnerable to pirating and this has led to indiscriminate patenting of their efforts in R&D by many firms which are investing in biotechnology. Biotechnology has created a series of problems for existing patent systems throughout the world. Countries have changed their current laws to conform to the provision for rewarding invention in the field of biotechnology. The debate, however, concerns the problem of providing intellectual

property rights to that which has basically been derived from the products of nature. Some examples are genes and recombinant material of therapeutic value, sequences of nucleotides, plasmids.etc.

Every country has been attempting, in its own way, to circumvent these difficulties and some have introduced various levels of stringency depending upon the level of development of the industrial set-up in the country generally and the development of biotechnology specifically. The developing countries have been continuously pressurised, through many forums, to amend their patent laws to increase compatibility between different countries. Thus, different countries in the developing world are also attempting to grapple with the problems of protection of intellectual property in biotechnology. This has led to some compromises and contradictions. In this volume the issue has been examined in the paper by Dr. Amarella Eastmond, of Mexico. The role of strong protection of intellectual property rights has been considered to be the key for promoting foreign investment in any country. She concludes that those with most to gain from this process are the multinational companies, which are in possession of most of the currently developed intellectual properties in biotechnology. A strong IPR regime, according to the author, would not promote more local innovation.

Apart from intellectual properly rights protection, the issues, faced by both developed and developing countries concern the effective transfer and diffusion of generated knowledge. Issues pertain to the high transaction costs of technology transfer and the social acceptability of new knowledge produced. 'Commercialisability' rather than 'usefulness' or 'welfare orientation' forms the basis of choice of problems for research. The increasing tendency to privatise knowledge and effective prevention through IPR devices is foreseen as factors preventing research endeavours in this field. Most of the generation process for command gain has been under the sponsorship of private interests. Money is also becoming increasingly scarce for basic investigations. Such funds are usually available from the government. Eventually there could be a reduction in efforts in basic research, where the emphasis is on understanding basic biological processes, such as the structure of function and relationships, which in the long run could lead to break through discoveries which have implications for several subfields and understanding of new diseases etc. Thus, issues present at the level of generation, transfer and diffusion of knowledge in biotechnology are faced by different countries. Dr. Martha Prevezer and Dr. Simon Shohet from the UK discuss in their paper the case of Great Britain regarding issues of appropriateness and diffusion in biotech R&D. The paper focuses on issues of ownership of new knowledge between universities and industry. It argues that if innovation originates in pharmaceuticals, or in diagnostics, or in scientific instruments, the industry is more responsive to creating links with the science base and, in such cases, industry-institute linkage is stronger and the diffusion of new knowledge is easier. On the other hand, in the case of down-stream processes or marketing innovations which are more important for chemicals, food and energy sector, the industry which already dominates these sectors becomes less responsive to new knowledge occurring outside its own premises; and effective industry/institute interactions are difficult.

Part 2 of the special issue (to be published, concurrently, as Vol. 5, No. 1, 2003) begins with a paper by Visalakshi and Alka Prasad who look at the changes in the research emphasis and forms of output in biotechnology. Research has shifted towards more application-oriented problems, supporting private interests and favouring restricted dissemination of the knowledge generated in public or private funded R&D institutions. This is highlighted by taking the case of hybridoma technology and analysing the outputs

in the chosen field. Regarding the issue of dissemination and diffusion of knowledge generated, Talavera and Perez, from Cuba, suggest, in their paper, a way to facilitate transfer technology by integrating process characterisation in the R&D phase in the case of biopharmaceuticals. The authors further insist that such validation, despite being costly and time consuming, could largely reduce the blocks in the technology transfer and validation leading to more efficient utilisation of results of biotechnology R&D.

In addition to the above problems, which have emerged at the advent of biotechnology development by different countries, there are some serious ethical and moral issues which need great attention. Bio-ethics has become an important issue in some areas of biotech research. These include research in germ-line therapy, enhancement of capabilities of individuals by genetic engineering of specific genes, eugenic genetic engineering comprising attempts to alter complex human traits, production of transgenic animals etc. All concerns involve issues about the creation of new life forms. Currently, somatic cell therapy and genetic engineering for the treatment of recognised diseases is acceptable ethically. In transgenic animal research, the primary focus is on research to speed up the pace of production of plants and animals i.e. research for commercial gain; scientific and medical concerns take a backseat. Teresa Brennen, Peter Wheale and Ruth McNally have discussed some of the issues arising from this. While Brennen's contribution is on forms and new biology based on philosophical arguments, Wheale's article touches upon ethical issues raised by the project on human genome mapping. Dr. Brennan, of Harvard University, USA, has concluded that finally, in the entire ethical debate, the argument outlining a general ethical principle is inconclusive. The paper from Dr. Wheale, of the UK, discusses the wider social and ethical consequence of developments in human genome research. The author argues that international law must address the new comparative advantage emanating from this research which shall be privatised and which shall be created for advantage in trade through intellectual property rights. The paper by Dr. Marilia Bernades Marques from Brazil argues that the bioethical and regulatory considerations, as adopted in Brazil, are contributing positively to local science and health policies. The paper from Dr. Dirk Stemerding and Dr. Jaap Jelsma, from the Netherlands emphasises the public concerns about the developments in genetic engineering research; through the examples of the current Dutch Animal Health and Welfare Act and the creation of a public forum entitled 'Consumer and Biotechnology Foundation', it analyses the social acceptability of gene technology in the Netherlands. Continuing the theme of social acceptance of new technology, Verdurme *et al*.'s paper informs us that not all consumers have similar attitudes towards biotechnology based products. The paper analyses the results of a survey conducted in Belgium on attitudes towards Genetically Modified (GM) food and identifies at least five different segments and emphasises that knowledge of this difference is very important for devising effective communication strategies.

Thus, this volume has a good mixture of various but serious concerns that have emerged with the development of new biology research and application. Though one can observe that the regulatory issue slightly outweighs the other issues, this is not because it is more important but because by chance, more contributors came forward in this area than in the more difficult and specialised area of ethics and legal issues. The editors believe that this volume will be found informative and interesting to its readers.

References

1 Brooks, H. (1980) 'Technology, evolution and purpose', *Daedalus*, Vol. 109, p.66.

2 Jasanoff, S. (1995) 'Product, process and programme: three cultures and the regulation of biotechnology', in M. Bauer (Ed.) *Resistance to New Technology: Nuclear Power, Information Technology and Biotechnology*, Cambridge, Cambridge University Press, pp.311–331.