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Review

The social, moral, ethical, legal and political implications of today's biological technologies: An Indian point of view

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The last 50 years have seen an increasing emphasis on ethical, moral, social, legal, political and economic implications of science for reasons that are discussed in this article. Biotechnology has been no exception to this trend. Areas of biotechnology where the above implications have been important, are briefly described. Ethical and related issues in today's biology-based technologies are discussed with special reference to India. Examples of technological exploitation within a country, or of one country by another, using modern biology-based technologies are given. The possible implications of one new and emerging biology-based technology are discussed. It is concluded that a well-informed and knowledgeable society is the only assured insurance against possible misuse of biology-based technologies of today and tomorrow, including their use for the exploitation of people. The recent decision of the Prime Minister of India to set up a National Knowledge Commission is mentioned in this context.

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1 Introduction

Till the beginning of the last half century, there was no serious or continuing debate on ethics in science and technology. The scattered cases where ethics could have been an issue were largely in the area of biology. Examples would be the case of the midwife toad just after World War I, documented eloquently in Arthur Koestler's book of the same title [1], the case of the Piltdown man in the beginning of the 20th century which fraud took some forty years to uncover [2], and the issues pertaining to eugenics that Francis Galton first raised in 1883 [3]. The cases of the midwife toad and Piltdown man have been among the most celebrated cases of scientific fraud, probably perpetrated to discredit Darwin, and eugenics even a hundred years ago touched important social issues; yet none of them raised any serious question of ethics that needed to be contended with on a continuing basis.

The realization that science has a social purpose and, therefore, must contend with its various implications, and that it raises issues that cannot be confined to the community of scientists alone but must involve the entire society, came to the fore with two major events: J D Bernal's book titled *Social Functions of Science* [4] first published in the 1930s, and the dropping of the two atom bombs on Hiroshima and Nagasaki in August 1945. In fact, the discussion that followed the latter event around the world – and continues with increasing vigour as time passes by – vindicated what Bernal had said in his book. Since then, ethical, moral, social, political, economic and legal issues arising out of science and technology have increasingly begun to occupy center-stage, so much so

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Abbreviations: AID, artificial insemination by donor semen; **ART**, assisted reproductive technologies; **CCMB**, Centre for Cellular and Molecular Biology at Hyderabad; **GMOs**, genetically manipulated organisms; **IVF**, in vitro fertilization; **mAbs**, monoclonal antibodies; **MNCs**, multinational corporations; **NGOs**, non-governmental organizations; **PET**, positron emission tomography; **PPVFR** Act, Protection of Plant Varieties and Farmers Rights Act, Government of India, 2001; **TRIPS**, Trade–Related Intellectual Property Rights Agreement; **US**, United States of America

One US dollar equals approximately 43 Indian rupees though, in buying power, one US dollar will probably equal about eight Indian rupees.

that, today, many of the leading journals of science – both specialized ones (such as *EMBO Reports, Human Reproduction,* and *Reproductive Biomedicine Online)* or those covering many fields (such as *Nature* and *Science*) – have regular discussions of the above issues in their columns, and Governments of many countries have become acutely aware of the need of their active and informed involvement in such discussions, be they related to uses of nuclear energy, exploitation of mineral and biological wealth, release of genetically manipulated organisms (GMOs), assisted reproductive technologies (ART), human cloning, or work on stem cells (this list is by no means exhaustive).

Why, then, this change in a span of five to six decades?

2 The origin of the various linkages of biological technologies

Till the first quarter of the 20th century the rate of progress in science and technology was slow and was compatible with the rate of social change. Therefore, societies then had no difficulty in absorbing the changes brought about by advances in science and technology. Understandably, therefore, in spite of inherent dangers, the discovery of radioactivity or of X-rays and their wide application at the beginning of the last century, did not raise any hue and cry. Today, the speed with which science and technology are advancing is far greater than the speed with which societies can absorb the changes they bring about. Besides, unlike in the past, science and technology are now intimately and irretrievably intermeshed into the very fabric of our existence. Both the above factors have created an ideal environment where societies can be easily exploited by scientists and technologists – and, by inference, industries, the rules being that the larger the industry [as is the case with multinational corporations (MNCs)], the larger the scope and the possibility of such exploitation. On the other hand, today, there is an increased awareness of basic human rights and increased commitment to democratic values in both the developed and the developing or the least developed world. Consequently, the emphasis on ethical, moral, social, legal, economic and political implications of advances in science and technology has vastly increased. Ethical questions currently arise in doing science, in managing science, in communicating science, and in using science – that is, in the practice of technology [5].

As it turns out, biology and biotechnology (I use this term here to cover all modern biology-based technologies) dominate this discussion. This is so for the following three reasons:

1. Many biological truths – such as those in the areas of evolution, genetics, and the neurological basis of aesthetic experience [6] – touch and impact all of us, are easy to communicate to the lay public (including the politicians), and are generally easily comprehended. They negate widely–held traditional beliefs, including those based on religious dogma and, therefore, lead to a kind of intellectual turmoil in the minds of people.
2. There has been a dramatic upsurge in the use of modern biological knowledge though, unfortunately, not always for universal human gain.
3. Modern biotechnology offers unprecedented scope for unethical exploitation of man by man, both in peace and in war (declared or undeclared). This would be the focus of this article.

Bad precedents, justified fear, and suspicion, have led to the emergence around the world of powerful non-governmental organizations (NGOs), both national and international, that aim to underscore and prevent such exploitation, though not always within a framework of reason and accurate information. Examples would be Green Peace which is international, and Gene Campaign which is Indian, both of which have played a major role in influencing policies in the area of biotechnology.

Before we go on further, we should look at what today's biotechnology covers.

3 Scope of biotechnology

Today's biotechnology is largely comprised of the following areas:

(1) Genetic engineering of microbes, plants and animals (including marine animals). Genetically engineered microbes are widely used for large-scale production of drugs and vaccines of great importance, such as insulin, erythropoietin and hepatitis B vaccine at very low cost. Genetically engineered plants – for example those that make their own pesticides or are resistant to weedicides – are already in the market. Thus, well over 60% of the acreage under soya bean in the United States (US) has now genetically engineered soya bean that is resistant to the weedicide, Roundup. Genetically engineered plants are also poised to produce vaccines. Inadequately controlled release of genetically engineered plants in the environment, largely in the US (such as soya bean mentioned above), has come under severe and justified criticism from a wide range of responsible and serious-minded scientists and environmentalists. Genetically engineered animals would be the future sources of cheap protein-drugs which they would secrete in abundance (1–15 mg/ml) in their milk, bringing down the cost of production to as low as a few dollars per gram.

(2) Gene therapy would allow a person suffering from a disabling genetic disorder to lead a normal life.

(3) Immunotechnologies, such as manufacture of monoclonal antibodies (mAbs) for diagnosis and therapy. As

human mAbs are difficult to produce in the laboratory, genetically engineered plants are likely to find wide application in the production of human mAbs. An alternative would be to produce cheaper humanised mouse mAbs for which technologies exist today.

(4) Tissue culture, both of plant and animal cells, for micropropagation of elite or exotic materials (such as orchids), production of useful compounds such as taxol (the widely used anti-cancer drug) and vanillin, and growing in the laboratory of "natural" tissues such as arteries for arterial graft or skin for burn victims.

(5) Stem cell culture, which would involve purification and isolation of stem cells from various tissues, and their directed development to give the desired tissue which could then be used, for example, for transplantation. Stem cells can be either totipotent (as most plant cells are) – that is, they have the capability to produce any desired cell type or organ of the body under specified conditions – or they could be pluripotent, that is, they are capable of developing into several though not all cell types or organs. As embryonic stem cells are more likely to have capabilities nearing totipotency than stem cells from adult tissues, the immediate emphasis in the area of stem cells is in the direction of establishing cell lines derived from early human embryos.

(6) Enzyme engineering and technology involving, for example, immobilized and/or stabilized enzymes, new or modified enzymes, new classes of enzymes such as ribozymes, or new enzymatic routes, to produce important organic compounds.

(7) Increasing photosynthetic efficiency to increase biomass production in the plant, using the same amount of light and other inputs.

(8) New DNA technologies such as DNA fingerprinting; sequencing of genomes; development and use of new molecular markers for plant identification and characterization; development of DNA-based probes for diagnosis of inherited disorders; antisense technologies; and computing using DNA.

(9) Use of modern biological techniques for validation, standardization and manufacture of (where necessary, appropriately modified) indigenous drug formulations based on plants.

(10) Peptide synthesis to make new drugs or other materials of industrial and/or commercial importance [such as salmon GnRH analogue to induce ovulation in fish]. Some 1000 peptides are already in the catalogues of peptide-supplying companies.

(11) Assisted reproductive technologies such as artificial insemination (using husband's or donor semen); *in vitro* fertilization (IVF); intracytoplasmic sperm injection; and techniques involving egg donation, surrogate motherhood, or embryo transfer.

(12) New cloning technologies, especially cloning of genetically engineered animals that would produce useful products.

(13) Organ transplantation, especially xenotransplantation – that is, transplanting organs from other animals into humans.

(14) New drug-delivery systems such as liposomes and electrical patches, and use of circadian rhythms to maximise the effect of drugs.

(15) Innovative production of useful substances (such as polyunsaturated fatty acids or Vitamin A) from so far unexplored or sparsely explored sources that are widely available, such as marine organisms.

(16) Inventing of new materials using novel ideas, observations or research findings, such as bacterial ropes, spider silk or biodegradable polymers. For example, bacterial ropes that essentially consist of certain mutant bacteria which have the ability to grow into spaghetti-like structures, when impregnated with certain ions, can be stronger than steel but lighter and biodegradable.

(17) Rational drug design based on advances in biotechnology, such as genome sequencing and on the three-dimensional structure of proteins and other molecules.

(18) DNA vaccines.

(19) New medical diagnostic technologies, such as combination of MRI (magnetic resonance imaging) and PET-scan (positron emission tomography scan) for correlation of structure and function in normal and diseased individuals.

(20) Biosensors, for example optical sensors using special thin films for detection of bacteria.

(21) Use of microbes (selected or genetically engineered) for effecting chemically difficult transformations.

(22) Bioremediation, for example of affluent or waste.

(23) Processing of low-grade ores using microorganisms.

(24) Bioinformatics.

(25) Nano-biotechnology, the latest addition to the repertoire of biotechnologies.

(26) Biological warfare.

4 Biotechnology in India

While modern biology took root in India in the late 1950s, beginning with three institutions (Regional Research Laboratory – (presently called Indian Institute of Chemical Technology) at Hyderabad, All India Institute of Medical Sciences at New Delhi, and Tata Institute of Fundamental Research at Mumbai), biotechnology did not do so till the early 1980s. The three following events could be considered as landmarks in the actual development of biotechnology in the country:

1. The setting up of a National Biotechnology Board by the Government of India in 1982 which eventually developed into a full-fledged Department of Biotechnology of the Government of India in early 1986, even

though neither of them delivered what they were expected to deliver [7, 8].

2. The setting up of Biocon at Bangalore in 1978 by a young woman entrepreneur, Kiran Mazumdar, with the objective of making industrial enzymes. Biocon is, today, the flag-ship company of Indian biotechnology, with a turnover last year (2004–2005) of Indian Rupees 6.5 billion [9].
3. The setting up of Shantha Biotechnics Private Limited in Hyderabad by an electrical engineer, Varaprasad Reddy, in 1993. Shantha Biotech as it is popularly called, was the first company in India to make a genetically engineered product – the Hepatitis B vaccine. It brought down the price of this vaccine in the country by nearly 50-fold. The technology for production of the vaccine was developed at the Centre for Cellular and Molecular Biology (CCMB) in Hyderabad.

As of writing this article there are at least 368 biotech companies in the country with a total turnover of nearly Indian Rupees 45 billion, the top 20 accounting for 84% of the above revenue [9]. The turnover of Indian biotech companies accounts for about 1% of the global biotech turnover.

I have documented the history of the development of modern biology and biotechnology in India in detail elsewhere [7, 8].

India has the following advantages in regard to the development of biotechnology: enormous biodiversity in regard to flora and fauna; the largest human biodiversity, with some 450 minor and nearly 40 major ethnic groups; an 8000 km-long coast line with rich marine life; the right ambient temperatures all through the year in most parts of the country; trained manpower with experience in most of today's biology-based technologies; clinical material of immense diversity; excellent infrastructure; expertise of a high order in information and communication technologies; low labour and infrastructural costs; abundant land; world-class institutions (for research or in industry); and a 5000-year old civilization that has generated and used knowledge.

5 Areas in biotechnology that raise ethical and related questions

Out of the areas mentioned in Section III above, the ones that have major ethical, moral, social, political and legal implications are the following: genetic engineering, tissue culture, new materials such as biopesticides, gene therapy, stem cells, plant-based drug formulations, organ transplantation, bioinformatics, ART, DNA fingerprinting, cloning, and biological weapons. These areas can be classified into four groups: agriculture, medical and health care, reproduction, and defence. In each case, we have one or more of the following possibilities:

1. immense gain for mankind at large, but raising major ethical concerns.
2. intra-country exploitation through unethical practices, thus underscoring the need for the country to have appropriate regulatory mechanisms;
3. inter-country exploitation which encourages and propagates neocolonialism; and
4. explicit and manifest damage to plants, animals and/or human beings, and to the environment.

I will deal with the above, with special reference to India, in the following four sections – except that I would merely touch upon the *gains* from biotechnology as they are already well documented.

6 Modern biology and biotechnology as major agents of change in our views and life styles

Never before in history have scientific advances necessitated such a paradigm-shift in the way we perceive our world, as has happened with the advances in modern biology (and astrophysics) in the last half of century. Let us look at some examples.

1. We have reasonable evidence today that our universe came into existence following what is commonly known as the Big-Bang, some ten to fifteen billion years ago. This event was followed by the evolution of the laws of physics and the formation of elements (that is, physical evolution), the astrophysical evolution leading to the various entities in the universe; interstellar chemical evolution leading to formation of chemical compounds; the formation of our solar system including our own planet; and chemical evolution on our planet which led to the formation of many substances that are found universally in today's living systems.
2. Although we do not know precisely how it happened, there is an enormous evidence that indicates that life originated on our planet from products of chemical evolution mentioned above, perhaps somewhere between 3.5 and 4 billion years ago – and that, subsequently, Darwinian evolution was responsible for the numerous life forms we have had or have now.
3. There is an amazing commonality between the various life forms or species on our planet in respect of their chemistry, biochemistry and even structure at the sub-microscopic level. Thus, DNA is the genetic material of all autonomously replicating life forms; every species makes its pyrimidines from aspartate through an unique biosynthetic pathway; every species metabolises glucose generally in the same manner; all life forms are cell-based; and the mechanism of synthesis of the basic constituents such as proteins is extremely similar if not identical in all the living systems.

4. We today recognize that every specific function of a living system is a consequence of a specific set of chemical entities made in a certain way and organized in space in a specific manner. In other words, function in biological systems is a consequence of its chemistry, biochemistry and structure.
5. We can say with much confidence today that all phenomena pertaining to life, without any exception, have a physico-chemical basis.
6. We may be the progeny of just one woman who lived in Africa some 200,000 years ago.
7. What we are – or, for that matter, what any living organism is – is a consequence of two factors, genetic and environmental. Genetics determines our capabilities while the environment determines the extent to which these capabilities would be converted into abilities.

The above realizations have, at one stroke, discredited religious dogma that gives a religion its identity. They have given us the strongest argument (a) against discrimination based on colour, race, creed, caste, social strata, nationality or language or, for that matter, any factor based on circumstances of birth; (b) in favour of making a distinction between individuals based on objective criteria; (c) in favour of secularism and basic human values and rights as stated, for example, in the United Nation's Charter of Human Rights; (d) in favour of the belief that human problems can be solved only through human effort and not by invoking supernatural powers; and (e) in favour of working towards universal and lasting peace.

We are far from achieving these objectives universally, but there is no doubt that there is an ever increasing impact of modern biological thought, supported by advances in other areas of knowledge, on the socio-political ethos of countries around the world.

Coming to biotechnology, let us briefly look at some gains already achieved and those that can be considered as imminent as a consequence of advance in the various areas of biotechnology. These gains have already impacted – or would impact – substantially our life-styles.

In agriculture, the six-decades old technique of plant-tissue culture that allows one to grow an entire plant from a single cell, has been widely used to rapidly propagate elite plants. Orchids grown through tissue culture as a cottage industry in Thailand make a major contribution today to the country's foreign exchange earnings. The possibilities of the use of appropriately regulated genetic engineering in agriculture are enormous. For example, it is very much on the cards that in the near future, genetically engineered plants (grown in a contained environment) would produce human antibodies for therapy, and oral edible vaccines that could efficiently and at low cost immunize some 120 million unprotected children every year against four common diseases. As of today more than 150 million acres is under GM crops, largely in a few countries of the two Americas. Though there is a great deal of criticism around the world of this having been done without appropriate risk assessment and safeguards, the future of GM plants that may be released for cultivation after the necessary risk assessment, specially when there is no alternative, is reasonably bright. As already mentioned, not before long, animals may be genetically engineered and then cloned to produce extremely cheap drugs (that would be otherwise orders of magnitude more expensive) in their milk. Marker-aided selection is already in vogue in respect of plants, and biopesticides (such as pheromones) have not exhausted their potential yet.

In the area of medical and healthcare, modern biotechnology is well poised to cause a virtual revolution by advances in a variety of areas, such as (i) diagnosis, for example, using monoclonal antibodies, and enzymatic, chromosomal or DNA-based diagnosis of genetic disorders; (ii) new drugs through rational drug design, genetic engineering, peptide synthesis, marine biotechnology, microbial transformations, bioinformatics, protein modification, and validation of standardized traditional plant-based drug formulations; (iii) neutraceuticals and probiotics that would, for example, help recovery after major surgery or chemotherapy; and (iv) new materials such as human collagen and one's own skin grown in tissue culture for burn victims, engineered tissues, biodegradable biopolymers and, hopefully in the future, organs for transplantation from animals such as appropriately genetically engineered pigs or from stem cells. And it is not unlikely that, progressively, chemical industry would be replaced by biotechnological industry, and inorganic catalysts by enzymes, on account of the fact that the latter would be non-pollutive, would need much less energy input, and would largely obviate the problem of by-products.

Not only the above, with the increasing interest around the world in improving physical appearance – as there is an intrinsic reward value of pleasant appearance, including the preference for light complexion in some societies – biotechnology offers new principles and tools for improving appearances, such as scientifically designed creams that would make one fairer. An example would be the Fair and Lovely cream (the largest selling cream in the world) of Hindustan Lever, which was the brain child of Mumbai-based Indian biochemist, K. K. Govind Menon.

In the area of reproduction, the advances since the birth of the first so-called test-tube baby, Louise Brown, through the pioneering efforts of R G Edwards and Patrick Steptoe in 1978, have been spectacular. If, for a moment, one would consider infertility as a disease, it would then score as the most prevalent disease in the world, as between 10 and 15 percent couples around the world are infertile. The technique of in vitro fertilization and other assisted reproductive technologies today make it possible

for 85 percent of infertility cases to be taken care of. In 2005, an event in London celebrated the birth of over 2 million IVF babies. Recently, a reasonable success has been achieved by Schulman and his collaborators in separation of X and Y spermatozoa which would allow one to have a girl with 93 percent (and a boy with slightly lower) probability [*inter alia*, 10].

The above description of today's biology-based technologies is only illustrative and not comprehensive.

7 Ethical and related issues in biotechnology

7.1 Release of genetically manipulated organisms (GMOs)

There are many examples in contemporary history where release of living organisms in an environment in which they were absent earlier, has led to enormous damage. For example, in India, Parthenium and water hyacinth were unknown at the beginning of the 1950s. Since then, they have become major scourges. Both these plants have spread all over the country. Parthenium allergy is one of the most common allergies in India today, and water hyacinth has choked innumerable lakes, river beds and water passages. Both have led to an enormous expenditure in remedying or controlling the situation arising out of their spread across the country. The origin of these plants is not absolutely clear, though it is believed that Parthenium came as a weed along with the Public Law-480 supplies of wheat from the US to India before the green revolution in India which made it self-sufficient in foodgrains. The story of rabbits in Australia is also well known. Therefore, it is only appropriate that no genetically modified organism is released in the environment unless it has been appropriately tested. I have described elsewhere the details of the tests that, in my opinion, should be conducted, and the criteria that would need to be satisfied, before a GMO is released in the environment [11]. I have also in the above articles mentioned as to how this testing can be done. Unfortunately, no GMO released so far in the world – including India – has gone through such rigorous testing.

The first GMO that was approved to be released in a limited way in India was an Indian version of Monsanto's Bt cotton containing an insecticidal gene from *Bacillus thuringenesis* developed by the the Indian company, Mahyco, in collaboration with Monsanto which now has a controlling interest in Mahyco (this cotton would be, therefore, for convenience' sake, referred to as Monsanto's Bt cotton). There has been widespread criticism about its release permitted by the Government of India in 2002, as this was done violating the laws of the land, ignoring the ground realities in India such as the fact that, unlike in the US where bollworm is the main cotton pest, we have numerous other pests associated with cotton that are not susceptible to the Bt toxin, and suppressing from the public both the results of the trials and the justification of its release.

It was, therefore, no surprise that this Bt cotton failed in several parts of the country [12–15]. The sad part of the story is that, in spite of this, Government of India renewed the permission to Mahyco to continue to market and try the same Bt cotton in several other parts of the country. However, the State of Andhra Pradesh – one of the major States where the early trials of the above Bt cotton were done and one of the largest States of India – has (though after much hesitation and resistance) prohibited the use of Monsanto's Bt cotton [16]. In this context we need to remember that one of Monsanto's conditions of sale of their Bt cotton seeds is that the farmer cannot use the seed of the progeny. Not only that, if even one plant is found in another nearby field, the owner – who did not use Bt cotton to begin with and who, common sense tells us, would be totally innocent – would be liable for prosecution. Such a possibility is very likely as land holdings in India are, often, very small (just a few acres). A further irony is that the Government of India, while approving Monsanto's Bt cotton in 2002, laid down a stipulation (ostensibly to prevent development of resistance to Bt toxin) that in 20 percent of the area planned to be under Bt cotton, a non-Bt, pest-sensitive cotton crop should be planted as a refuge crop. This is obviously unimplementable considering the usually small size of the land holdings mentioned above. The story of Indian Bt cotton until the summer of 2001 has been documented by me elsewhere [11].

Monsanto has been recently, following a complaint filed by the US Securities and Exchange Commission in the District Court for the District of Columbia, fined in its own parent country, for bribing Indonesian officials to plant its Bt cotton in Indonesia [17]. There is also compelling evidence that Monsanto resorted to similar tactics in the State of Andhra Pradesh to escape payment of legally liable compensation to farmers to whom the company sold Bt seeds that failed, vide letter no. C5/Misccc04 of 15th October 2004 from the Joint Director of Agriculture of the District of Warangal in Andhra Pradesh, to Mahyco-Monsanto [18]. Such tactics raise important ethical questions in the extremely important area of the use of biotechnology in agriculture.

In this context, another point deserves to be mentioned. It is widely recognized that while the days of direct colonialism are over, the days of indirect control of a country, or neocolonialism, are by no means over. In such a situation, if a developed country in which just 1–2 per cent of the total population derives its entire income from agriculture and agriculture-related activities, wishes to acquire control of a country like India (or, say, Nigeria) where some 70 percent of people depend for their livelihood totally on agriculture or agriculture-related activities, it would do so by controlling the seed and agrochemical production in the target country. And it would

do that by having its MNCs offer new technologies such as for GMOs, and by exploiting the widely prevalent corruption in many developing countries (such as India and Indonesia, two of the most populous countries of the world) and their inability (India and China would be amongst the exceptions in this regard) to assess appropriately the possible impact of the new technology. The tragedy in India so far has been that the country has had very substantial capabilities – both in the public and the private sector – of making its own GMOs such as Bt cotton. Yet the fact is that these capabilities were not utilized by the Government. The present situation in India has led many responsible people to recommend that seed business in India should be entirely in the hands of the country's own seed industry (in private or public sector) with no foreign direct investment in this sector. If that happens – for which there would be substantial justifiable reasons – one could ask: will such a step be ethical in the light of India's adherence to the provisions of WTO? Would a world trade agreement deserve preference over a nation's food security? These are important issues that would need to be resolved in the immediate future.

Continuing our discussion on genetic engineering, let me give you an interesting potential example of thaumatin (produced by a plant that is native, for example, to Nigeria), a protein which is 5000 times sweeter than sugar. I personally believe that by selecting appropriate plants through tissue culture and, perhaps, by genetically modifying thaumatin, it may be possible to increase the yield of thaumatin and its sweetness to 50,000 times that of sugar. When that happens, for most purposes where sugar is used only as a sweetening agent, thaumatin would easily – cost and convenience-wise – replace sugar. When that happens, some seven million workers involved in the cultivation of sugarcane and manufacture of sugar in the third world alone, would face unemployment. Would that be ethical?

7.2 Tissue culture

One would normally think of tissue culture as one of the safest and most innocuous biotechnologies which is neither polluting nor likely to pose any ethical or related problems, but look at this possible scenario. In Malagasay, some 75,000 farmers are employed in cultivation of vanilla. It is perfectly possible that in the years to come, vanilla that is marketed would come from plant parts grown in tissue culture. What would then happen to the 75,000 farmers employed in vanilla cultivation in Malagasay? An appropriate solution would be that the Government of Malagasay should be the first to develop this technology and train the farmers in its use, including value addition. But the problem is: how many Governments, especially of the developing countries, do look into the future in this manner? This is a world-wide challenge: to look into the future of biotechnology and prepare ourselves to use it for maximizing gain to mankind in an ethical framework.

7.3 Stem cells

In India, the work on stem cells is fortunately being encouraged and, hopefully, there would soon be a law permitting ART clinics to offer supernumerary embryos for stem cell work under specified conditions [19]. There have been no protests from any quarter in regard to work on stem cells in India. This is in stark contrast to the stand of the President of the US in regard to research using human stem cells. There is clearly a need for an international stem cell agreement [20].

7.4 Plant-based drug formulations

It is estimated that, in India, there are some 40,000 distinct plant-based drug formulations that are a part of the four documented Indian systems of medicine – the Ayurveda, the Unani, the Siddha, and the Tibetian systems – and the undocumented tribal systems of medicine. Some seven thousand plants are already known to be used in these formulations, and there are, perhaps, another three thousand waiting to be documented as most tribal formulations are still not in public domain. (Ten percent of India that has a population of over a billion, continues to be tribal, living predominently in forests.). Let us now look at the following scenario.

We are able to persuade a tribe in India to part with its formulation so that we may submit it to a rigorous procedure of standardization and validation to find out whether or not it works, as has, indeed, happened in several cases. And it turns out that it works. We now manufacture and market this formulation. Who should then benefit by it? Shouldn't a part of the profits go to the tribe that has used the formulation for a long time and established its validity in their own way? We have only confirmed what they have known for a long time. If the profit has to be shared, what should be the principles for such sharing? These are still unanswered questions that raise important ethical and moral issues in view of the increasing emphasis around the world on plant-based drug formulations.

7.5 Organ transplantation

As is widely known, the pig seems to be the most suitable animal for xenotransplantation of organs on humans. It is well on the cards that a genetically engineered pig would be soon available commercially in which the mechanism that leads to the hyperacute rejection of a pig organ when transplanted into human beings, would have been rendered ineffective. Transplantation of organs from such a pig on to a human being would then be no different from homotransplantation, for the success of which the protocols are already available and well established. When this

becomes a reality, what about the Islamic world? Will they accept a pig organ for, for them, pig is an unholy animal.

7.6 Bioinformatics

The day is not far off when, using DNA chips, it would be possible for a physician to tell a parent as to what the diseases are that a new-born child is likely to suffer from as it grows up. There is no problem for a physician if the disease is like sickle-cell anemia, or thallasemia, or cystic fibrosis as, in such cases, the child is bound to suffer from the disease. But what about the susceptibility genes where, according to current information, the doctor can only indicate the chances that the child would have of suffering from the disease – let us say, type II diabetes? We still do not know what are the life-style or other factors that lead to the conversion of the susceptibility status to the disease status in the carriers of such genes. In the absence of this knowledge, let us assume that the physician tells the mother that there are 50 percent chances of her child suffering from diabetes after the child crosses 40. But it happens that the child doesn't suffer from the disease and leads a normal life all through. Could he, later, sue the doctor for keeping him and his family on tenterhooks that he may suffer from the disease? On the other hand, if the physician does not tell the parent about the presence of the gene in the child, and it turns out that the child does suffer from the disease when it grows up, the child and the parent can again sue the doctor saying that he withheld information which could have prepared them for the disease scenario. How do we tackle this dilemma?

7.7 Assisted reproductive technologies and cloning

Perhaps, the most important ethical question in ART is: who should be the sperm or egg donor and who may act as the surrogate mother. In India, so far, the sperm and egg donors have been close relatives or close friends of the infertile couple or their families. In the case of surrogacy, again, it is generally a close relative who agrees to act as a surrogate mother for a couple who cannot or do not want to carry their own child, though advertisements for surrogate mothers are not unknown. A plethora of problems can and have arisen on account of such situations in regard to ART in India. I have discussed these problems in detail elsewhere [21,22] but let me give here a few examples.

Traditionally, if a couple is infertile in India, the family places the blame on the woman even though we know today that in about half the diagnosable cases a male factor is the cause of infertility. Even if the mother-in-law is convinced that her son has a problem, she would want this to be kept as close a secret as possible. She, therefore, takes the daughter-in-law to an infertility clinic and asks the doctor to inseminate her by the semen of the husband's brother or of a close family friend. The daughter-in-law would normally have no say in this regard. The psychological stress that she will go through for the rest of her life, including during pregnancy, on account of the knowledge that the biological father of the child she is carrying is someone whom she knows and has social interaction with all the time, would not be generally a matter of concern to the rest of the family in India. Now imagine the following scenario. A few years later, the mother-in-law and the daughter-in-law quarrel which is not uncommon in our country as the joint family system is still in vogue but under pressure on account of the changed circumstances. The mother-in-law says publicly that her daughter-in-law has committed adultery and names the person with whom, according to her, the adultery has been committed. DNA fingerprinting will establish that the basis of mother-in-law's allegation that the child is not the daughter-in-law's husband's child but of another man is correct, as infertility clinics are, as of today, not required to keep appropriate records. There will be no way that the daughter-in-law can establish that she never slept with the man who is the biological father of the child and that she was – in spite of her protestations – artificially inseminated with his semen on account of the insistence of the mother-in-law, which is *not* adultery. Such situations, and many variations of it, make the use of the semen of a person known to the infertile couple or their family, for artificial insemination, unethical. The same would be true of oocyte donation. The national guidelines for accreditation and supervision of ART clinics in India that have just been finalized by the Government of India and would, hopefully, be converted into a law by the time this article appears, prohibit such practices and demand anonymity of the donor of the semen or the oocyte [19]. These guidelines permit payment to the donor of the semen or the oocyte by semen banks who must maintain anonymity of the donor but provide all information about the donor to the couple who is going to use donor's germ cells.

Let me narrate another unusual case which would support the view that the practice that is being followed today in India – that is, of using sperm or egg of a person intimately known to the family – is unethical. One woman – more courageous and self-reliant than usual – was taken by her mother-in-law to an infertility clinic to be inseminated at an appropriate time later by the semen of a close friend of the husband, whom the woman knew well. An advance was paid to the clinic for the procedure of AID (artificial insemination by donor semen) to be performed on the woman later on. Some time later, the woman went back to the clinic, this time all by herself, and asked that the money that was paid to the clinic as advance on her behalf, be returned to the woman. When the clinic asked as to why this request was being made, the woman said that this was so because she was now pregnant. The doctors at the clinic were naturally puzzled and asked her as to how she became pregnant. She then answered that since she was going to be inseminated by the semen of

her husband's friend, whom she knew very well, she saw no harm in going and sleeping with him at an appropriate time just for once. The pregnancy was a natural consequence of this act which she did not consider as unethical, for she had promised to herself that she will never sleep with that man again. She clearly did not perceive any difference between being inseminated by the semen of a person whom she knew very well, and sleeping with him just once for achieving the objective of AID without having the family spend any money. I leave it to the readers to judge whether, given the circumstances I have mentioned, what she did was ethical or unethical.

As regards surrogacy, the above-mentioned guidelines for ART clinics in India permit a relative of the same generation to act as a surrogate; of course, a total outsider could also do so. This is an improvement over the present situation in India where, in many cases, a woman has delivered her own grandchild by acting as a surrogate for her son's child. The new guidelines also require that the surrogate mother registers in the maternity hospital in her own name, even though the birth certificate would be in the name of the biological parents. This would obviate problems like the one that one of the most respected and ethical maternity hospitals in my city (Hyderabad) faced, when the doctor-in-charge, totally on humanitarian grounds, agreed to register a woman who was acting as a surrogate for her sister, in her sister's name. After the registration and examination of the patient, the doctor realized that there would be a problem if the woman does not survive the delivery. Whose death certificate would the doctor sign?

The new guidelines for accreditation and supervision of ART clinics in India that I have mentioned above, when implemented, will help in curbing unethical practices in the area of ART. The guidelines prohibit reproductive cloning but permit therapeutic cloning; they also expressly prohibit creation of any inter-species hybrids. The latter was considered necessary in the light of the report that in China, a pregnancy was established after insemination of a female chimpanzee with human sperm, but was terminated during the Cultural Revolution. It has been widely believed that the idea of the Chinese was to breed a race that would have the minimal intelligence of a human being but the strength of a chimpanzee, something reminiscent of the scientifically unsound ideas relating to eugenics during the first half of the last century in many parts of the world.

7.8 DNA fingerprinting

It is surprising that such a useful and clean technology as DNA fingerprinting [23,24] can raise ethical question, but here is one example.

Not long ago, a case of immigration was referred to a DNA fingerprint expert by the British immigration authorities. In this case, an Indian couple living in England with two children, had a third child in India while they were visiting the country. When they wished to take the third child back to England, the immigration authorities asked them to establish that they were the biological parents of the child, to rule out the possibility that they were bringing an abandoned child for sale in the United Kingdom. When the expert did the DNA fingerprinting of the entire family, he found that while the child born in India was the child of the husband and wife who were taking it to England, one of the two children living with them in England wasn't their child. The wife had committed adultery without the husband being aware of it. The question that the expert faced was, what to say to the immigration authorities. If the truth was told to them and later became known to the parents, the family may break up. On the other hand, would hiding the truth be ethical ? What the expert finally decided was to answer only the question that he was asked by the immigration authorities, and keep to himself the other information that he had. Did the expert do the right thing by telling only a part of the truth?

7.9 Biological weapons

It is most unfortunate that modern biotechnology has given a new face to the art and science of making and using biological weapons. Biological warfare is upon us. I have discussed its history and various ramifications in a series of articles [25]. We can today design ethnic weapons that would affect only a particular segment of world's population. For example, Americans above 50 are known to have a depleted immune response. The depleted immune response in the older Americans could be a consequence of the fact that they have lived in a virtually semi-sterile environment so that their immune system has not been challenged enough and could have atrophied. On the other hand, we in India are being continuously challenged by low levels of infection in our environment and, therefore, our immune system is likely to be robust. If this is true, we may be able to exploit this difference to produce an ethnic-specific weapon. Would that be ethical?

The list of biological weapons on which considerable work has been done includes nearly 60 bacteria, viruses, other organisms, and toxins. (Examples would be: viruses that cause smallpox, Ebola fever, Marburg fever, Lassa fever, and various haemorrhagic fevers; bacteria that cause anthrax, plague, glanders and tularemia; and toxins such as botulin and ricin.) How ethical is it to manufacture and store them as is being done by many countries? Great Britain, the US, the erstwhile USSR (now Russia), Canada, Germany, South Africa, Japan, Iraq, Iran, Syria and North Korea are known to have had extensive biological weapons development programme. In 2003, the NIAID at the National Institutes of Health in the US, was to receive US $ 1.5 billion for developing means of combating agents causing small pox, tularemia, anthrax, plague, haemorrhagic fever (including Ebola, Marburg

and Lassa fever viruses), and botulin toxin. Botulin is the most deadly poison known to us, its LD50 (the amount required o kill 50 percent of the exposed individuals) for human beings being 6 nanograms per kilogram weight, that is, approximately 40 nanograms per person. We may thus need just half-a-kilogram of botulin to kill the entire population of the world, and the delivery of it would be easy: just put it in the water supplies as botulin is an intestinal toxin. Then, there are pests that can be released to destroy agriculture.

There is, indeed, no doubt that biological weapons are the most dreaded ones today – far most dangerous than nuclear, chemical or conventional weapons. It is, therefore, unfortunate that the Fifth Review Conference on the Biological Weapons Convention held in December 2001, turned out to be a disaster, and that the US refused to sign the proposed inspection and verification protocol for biological weapons. Has this been ethical?

8 Unethical practices: exploitation within India

Some examples of unethical practices in India, for example in the area of ART, have been given in the preceding section. A few other examples now follow.

In 2001, before the Government of India gave permission for commercial use of the first GMO in the country – the Monsanto's Bt cotton – a Bt cotton was planted in over 10,000 acres in the State of Gujarat in the country. In spite of enormous scientific and technological capabilities in the country, the Government did not attempt to find out the source of this cotton and took no action against those who were responsible for this unapproved illegal and unethical action, and illegal Bt cotton seeds continue to be in the Indian market [26].

What this incident emphasizes is the need not only for appropriate regulatory mechanisms but for a machinery to implement the regulatory provisions in the area of biotechnology. Therefore, in the guidelines [19] referred to earlier, for accreditation and supervision of ART clinics in India, in the preparation of which I had a role, a detailed mechanism of how it is intended to ensure that these guidelines are followed is given.

Then there are acts of omission that stand out. For example, it is not realized that the green revolution in India was brought about by varieties that bred true and not by hybrid seeds. In fact, there are reasons to believe that the green revolution would have never happened in India, leading to self-sufficiency in food in a record time, if hybrid seeds were used. Till the hybrid seeds came in the market, the seed business was largely in the hands of farmers and not in the hands of MNCs. Today's biology opens the door for scientists to determine the molecular basis of hybrid vigour and to genetically modify accordingly the varieties that breed true. This would truly empower the farmers in a country such as India, as they will be able to save, use, sow, resow, exchange, share or sell their seeds (unless they are branded seeds of an appropriately protected variety) – something that is now expressly permitted by the Protection of Plant Varieties and Farmers' Rights (PPVFR) Act passed by the Government of India in 2001. This Act has been widely hailed as a step in the right direction. It recognizes the farmer not just as a cultivator but also as a conserver of the agricultural gene pool and a breeder who has bred several successful varieties. The Act also acknowledges the rights of rural communities. If the farmer uses the registered name of the breeder informally while selling the seed, he is protected if it can be shown that he did not know that there was a new law in place which places some restrictions on his traditional rights including the right to sell seeds. The other important provisions of this Act that have a direct bearing on agricultural biotechnology are mentioned below.

- Breeders wanting to use farmers varieties for creating Essentially Derived Varieties (EDVs) cannot do so without the express permission of the farmers involved in the conservation of such varieties.
- Anyone can register a community's claim over a land race and have it duly recorded at a notified center. If the claim on behalf of the community is found to be genuine, a procedure is initiated for benefit sharing so that a share of profits made from the new variety goes, on behalf of the community, into a National Gene Fund.
- By providing an appropriate liability clause in the section on farmers rights in the Act, the farmer is, in principle, protected against the supply of spurious and/or bad quality seed.
- On registration, the breeder has complete rights of commercialization for the registered variety. These unequivocal rights include the right to produce, sell, market, distribute, import or export a variety – in short, full control over production and commercialization.
- The Act has provisions for researchers' rights, which allow scientists and breeders to have free access to registered varieties for research.
- The Act includes public interest clauses, like exclusion of certain varieties from protection and the grant of a compulsory license.

Unfortunately, the Indian Government has (as of writing this article), before the Parliament, a new Seeds Bill 2004 that attempts to supercede the above-mentioned PPVFR Act which, even though passed four years ago, has not yet been notified by the Government of India. It is widely believed that this has been on account of pressures of MNCs. The new Seeds Bill deviates from the PPVFR Act on key issues, like the parentage of a variety, conditions for multilocational testing, the agency that will conduct these tests, public access to information on grant of registration, price control, and the treatment of farmers' varieties. For example, the PPVFR Act requires the decla-

ration of the origin of the variety to be registered, with adequate details, but the proposed Seeds Bill does not. The PPVFR Act allows pre-registration opposition which the new Seed Bill does not. The proposed Seeds Bill also does not accord recognition to the numerous contributions of the farming community over the ages. It is silent on the origin and the ownership aspect of a registered variety for trade, which will lead to unrestricted commercialization of varieties in the public domain, including farmers' varieties, by private parties. Further, there are no provisions of benefit sharing after commercialization, as is the case in the PPVFR Act. The new Seeds Bill, in fact, seeks to nullify the need for seeking a plant breeder's right in order to obtain rights to market a new variety. This would allow evasion of the public interest liabilities that are linked to the plant breeders' rights.

9 International Exploitation

Agriculture and healthcare industries are surely the largest in the world. With their many linkages, they are crucial for human progress.

I have already mentioned as to how one could control the destiny of an agricultural country like India by controlling its seed and agrochemicals production. Two such incidents that actually happened in India in the 1980s and provide solid support to the above view, have been documented by me elsewhere [27]. (I was personally concerned with both these incidents.) In fact, it may not be a tall claim that the TRIPS (Trade-related Intellectual Property Rights) Agreement as it is presently worded, would not have ever been paraded for universal approval, had biotechnology and its applications to agriculture and medical and healthcare not achieved the dimensions that they have in the developed countries in the last three decades.

The TRIPS Agreement, officially approved in 1993, is widely perceived in India as being highly discriminatory and an agreement that opens new doors of exploitation of developing countries by the developed countries. There has been an enormous criticism of the TRIPS within the country, a lot of it from highly responsible quarters, over the last ten years; the same has also been true of the Third Patent Amendment Bill passed in 2005 by the Government of India to ensure India's adherence to TRIPS with effect from 1st January 2005 as was agreed in 1993. The main points of the above criticism are as follows:

1. According to a report [28] of the Sub-Commission on Human Rights of the United Nations' Economic and Social Council, "The implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefit of scientific progress and its applications, (including) the right to health." "There are apparent conflicts between the intellectual property right regime embodied in the TRIPS Agreement, on the one hand, and international human rights law on the other".
2. Article 27.1 of TRIPS that demands product patent, is discriminatory as it puts a discount on the special capabilities that a country like India has in the area of organic chemistry which enables its scientists to devise alternative, cheaper and better routes for making drugs. This work surely involves a great amount of creativity, and has made the drugs produced in India the cheapest in the world. For example, the cost in India of ranitidine is less than 1%, of diclofenac less than 1.2%, and of piroxicam less than 2.5 % of the price of these drugs in the US [28]. With the passage of the Third Patent Amendment Bill in India, the prices of drugs, it is widely believed, are likely to increase dramatically, thus eroding substantially any national programme of medical and healthcare [29, 30].
3. Neither the TRIPS Agreement nor the Third Patent Amendment Bill of India expressly prevents patenting polymorphs, hydrates, isomers, metabolites, salts, esters, purity level forms, particle size variants and forms or derivatives giving only a marginal or incremental advantage such as a high blood concentration; they thus leave avenues open for the developing countries who file most of the patents around the world, for ever-greening of their patents in the area of, say, drugs.
4. Article 34 of TRIPS states that the burden of proving that a patent has not been infringed, lies on the defendant and not on the patentee. This is expressly unfair. It must also be recognized that an infringement of an Indian patent, say by an American Company, will have to be fought in America which would be extremely expensive for India. On the other hand, infringement of an American patent by India would be fought in India which would be very cheap for an American company.
5. There is no clause in the TRIPS Agreement or the Third Indian Patent Amendment Bill to the effect that the patent application should be specific and not general. For example, while a particular monoclonal antibody with a defined sequence against a particular antigen may be patentable, the patent should not be able to cover all monoclonal antibodies against the same antigen.
6. In Article 31 of TRIPS on compulsory licensing, the terms "reasonable" or "adequate" in regard to the commercial terms and conditions, the time period and the remuneration, have not been precisely defined, thus leaving much scope for protracted negotiations which may never materialize.

The general feeling in India has been that patenting of microorganisms of any kind (natural or genetically engineered), or any kind of microbiological processes, permitted in Article 27.3 (b) of TRIPS, is unethical and we should

unambiguously state that no life form, or any material derived from it, or any life process, would be patentable, irrespective of its source.

In this connection, it may be mentioned that the terms that are often used in the discussion of intellectual property rights, namely, "invention" and "pharmaceutical substances", have really never been defined in an internationally acceptable manner.

According to the Cartagena Protocol, no country may dispatch GMOs or products such as food derived from GMOs, to any other country without the recipient country's knowledge and approval [31, 32]. Yet in many cases food aid to many countries – such as Phillipines, India, Bolivia, Columbia, Guatemala, Nicaragua, Equador, and African countries – has had, for many years, GM food in it without the recipient country's knowledge or approval [33]. This has surely been unethical, besides being illegal.

10 The future technologies

A dog can distinguish between any two individuals excepting identical twins. This simple demonstration has three important implications. First, it means that all of us are generating individual-specific smell signals. Secondly, these signals must be genetically determined. Thirdly, they must have some kind of a purpose or function, for such a complex system with such tremendous variability would have never evolved and come to stay during evolution, unless it had a significant function. The value of smell signals, or pheromones, in the lower animal kingdom is already well established. Thus, smell signals in the animal kingdom are well known to convey a host of messages such as the presence of a member of the other sex desirous of mating; individual, group or species identity; sex and age; social and reproductive status; presence of predator or prey; health or disease status (perhaps true also of humans, as practitioners of the 3500-year-old Indian Ayurvedic system of medicine will vouch for); trail and territory; emotional status such as that of alarm, need for attention, distress, frustration, desire to be approached or to submit; pain; and greeting or warning [34]. In addition to these functions, an olfactory block for implantation of the fertilized egg – the Bruce effect – has already been demonstrated in rodents [35].

One may then ask: what is the function of human smell signals – the human pheromones – that the dog recognizes? The first pheromone that was isolated by Peter Carlson and Adolf Butenandt in Munich, Germany, more than four decades ago, was from the female silk moth which uses the pheromone to attract male moths. Unethical commercial organizations, including some in India, have already started attributing the same quality to human smell signals in their advertisements [36]. While there is not a shred of evidence which supports what has been said in the unethical advertisements of the kind mentioned above, it is perfectly possible, even probable, that a part of our intuitive behavioural response towards one another is determined by the match or mismatch of our individual-specific smell signals. If the human smell signals recognized by dogs can perform some functions similar to those that smell signals are known to perform in various animals, it is possible that a deliberate application of these signals in an appropriate manner could at least temporarily alter human behaviour. We may indeed not be more than 1 or 2 decades away from doing so. We must begin to think now as to what may be the ethical implications of the acquisition of such an ability. Indeed, externally applied perfumes may adulterate our normal individual-specific smell signals and, therefore, elicit a false response from the others around us. Could that be one of the reasons for the high rate of divorce amongst the more affluent around the world, who are in a position to use perfumes liberally? The smell biotechnology of the future will surely answer questions such as this.

11 Conclusions

I am aware that what I have said above is not comprehensive and is only indicative. However, I hope the above discussion will show that while modern biology and biotechnology have opened up new vistas for man that are poised to transform our beliefs and make our life easier, richer, and more productive and meaningful, they are also likely to open up unprecedented and unforeseen possibilities of exploitation of man by man. The only way to minimize such exploitation – if not prevent it altogether – would be: (a) to have reasonable and implementable national regulatory systems; (b) to ensure that international agreements, including those concerned with trade, are equitable; and (c) to create a knowledge-based society which would be able to assert itself and ensure that reason and larger public interest prevail in regard to what is stated in (a) and (b) above. In this context, it may be mentioned that the Prime Minister of India, Dr Manmohan Singh, has recently constituted a National Knowledge Commission, one of the objectives of which is to make India a knowledge-based society [37–39]. This has been done in the belief that if the Government of a country claims to be fair, honest, transparent and people-oriented, it is much easier for such a Government to govern a knowledge-based society than an ignorant one.

I have every hope that the Biotechnology Journal will, in addition to being a leading professional journal in the area of biotechnology, help (through articles and discussions such as the present one) foster a situation that would ensure that modern biology and biotechnology are used exclusively for the benefit of all mankind without any discrimination or distinction and without any exploitation of any kind anywhere, within a country or between countries.

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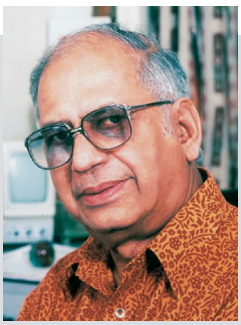

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