Application of biotechnology to medicine in India – A concern

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The applications of biotechnology in the fields of health and disease, food and agriculture, environment and industry are not dreams anymore, but are fast becoming a reality. In our country application of modern biotechnology has required a base in research and it is a matter of gratification that the quality of research in modern biology has significantly improved over the last decade, mainly due to the support received from DBT and DST. We do have a long way to go since we have problems of having a critical mass in specific areas of research, lack of indigenous capabilities to provide adequate infrastructure and the lukewarm attitude of the industry to research, although there are some signs of awakening.

Among all areas of applications, the area of health and disease has registered the most impressive gains internationally. Apart from the striking advances made in understanding the life cycles of pathogens at the molecular level, recent years have seen dramatic success in solving the molecular abnormalities underlying several genetic disorders. These advances have and will pave the way for newer strategies for therapy. While development of newer drugs, vaccines and newer strategies for therapy are slow processes, the development of diagnostic methods to detect diseases based on all the molecular information obtained has seen a phenomenal progress and a huge global industry with millions of dollars turnover is now functional.

Development of diagnostics for a variety of diseases has been recognized as a priority in India as well. This has led to the development of diagnostic methods for at least a dozen infectious diseases in different laboratories in the country. Many have been developed into kits and MOUs have been signed with industries for manufacture. A new phenomenon is the opening up of small or one-man companies to make identified diagnostic kits, while the established ones do a roaring business with imported kits. Signing of MOUs with industry in this area is no more an exciting proposition for academics, since none of the indigenous kits really reach the market. One reason is the mutual lack of rapport between the two parties, the industry blaming the academia for overclaims and release of half-baked technology, the academia blaming the industry for lack of expertise or help other than putting a nice wrapper on the final product and cooling of interest once the technology is transferred. It is obvious that a diagnostic kit to be used in the field cannot be developed in totality in the laboratory of any academic institution. The problems in the field are understood only through hard experience and these can be overcome only by repeated feedbacks by both the parties. With at least some of the industries having established good laboratories for research and development, many of the field and scale-up problems can be overcome. It is not as if the imported kits were developed to perfection overnight. They have also gone through several iterations. Knowledgeable workers in the field state that many imported kits do not perform as well under the Indian conditions in the field, but by and large one can get away with selling such kits since there is no one to really check on the consequences of wrong diagnosis dished out by diagnostic centres. It is true that the average public feels that the imported kit, costing more, should perform better than the indigenous version. It is also true that often patients approach academic institutions for correct analysis as a personal favour, since two different diagnostic centres give two different values even for standard biochemical parameters.

The main question is whether there is a real commitment to indigenize. While many leaders exhort the scientific community to develop indigenous technology, the field conditions are not exactly congenial for this development. A small example will illustrate the point. Medical diagnostic kits consisting of microtitre plates coated with antigens etc. can be imported free of duty (life saving!) along with other reagents. But if the microtitre plate alone has to be imported, so that the kit can be produced with biologicals generated with indigenous expertise, one has to pay fabulous duty! Therefore, the industry does not have motivation to make the kit in India, apart from the fact that trading with hefty commissions is more lucrative than going through all the hassles as an entrepreneur. As an aside, the polymer chemists in the country should look into this business of microtitre plates, since I am told that the plastics generated in the country are fit only for buckets and not for tissue culture or diagnostic plates.

There is yet another angle to the whole issue that can be highlighted taking the development of AIDS kit in the country as an example. Many countries are vying with each other to produce their own kits, since the market is huge. In India, too, government funding agencies have supported research projects for the development of AIDS kit. As mentioned earlier, a few individuals (mostly former academics) have floated companies and with hard-earned money have ventured into this field with technical help from academic institutions. In addition, imported kits promoted by established companies are doing their rounds. Interestingly, there is no easy mechanism by which the indigenous AIDS kit can be certified for use. It is suggested that one should become a bulk supplier to the WHO to gain entry into the Indian market. The mechanisms involved in becoming a bulk supplier to an international agency are beyond the reach of a small entrepreneur. In be

tween, there would be accusations that the indigenous kit has jumped some international patent. What is the real scenario? Internationally, gene sequences including those of the human are being obtained by the dozens and are being patented, despite the controversy raging on the ethics of patenting DNA sequences There are also arguments based on the difference between discovery and invention, only the latter and not the former qualifying for patent rights It is not exactly clear as to what India has actually agreed to My own recollection is that the recommendations made were not to agree for patenting of life forms or the genes derived but allow for patenting of only microorganisms containing engineered genes Even if a gene sequence were to be patented, if one were to identify after research a small peptide within the gene product, as a suitable target for diagnosis or vaccine, would it amount to jumping a patent? If an innovative process is used to make that peptide, should it not qualify for a product or process patent? If a grace period is available to the country for falling in line with the patenting regime, should not the country use this time to its best advantage? On the other hand, one only sees a total vacuum in terms of guidance and a 'holier than thou' attitude by the bureaucracy

Frankly, there is no agency in India that has the technical expertise to certify and clear biologicals A national standards institution for biologicals has been on the anvil for a long time Before it gets functional, much damage would have been done, with imports flooding and submerging the Indian market. International companies and agencies have a stranglehold on life-saving medical supplies to the country. There is money for everybody in imports and poor 'desi' scientists look foolish with all their efforts at indigenization I have highlighted the problems with just one example, namely diagnostic kits, since these are the easiest to certify and commercialize The problems one would encounter with biologicals and recombinant DNA products to be used as therapeutics, vaccines and in gene therapy would be almost insurmountable in the present environment, since they are all meant for systemic applications. I am told that clinical trials carried out in India are not easily acceptable even within India!

It is a matter of gratification that at least some drug companies are showing enthusiasm to support research towards discovering new drugs This is an extremely important step, since every new drug released by the MNCs after the GATT agreement would not be within the reach of the common man in India The country can produce new drugs or those whose patents will expire in the next few years, at an affordable cost, if serious in-house research is complemented by collaborative research in academic institutions Some initiatives have been taken in this regard. But I have not completely understood one fixation among all drug companies These companies are primarily interested in diseases of the advanced nations. They are all interested in drugs for cardiovascular, hypertensive and autoimmune diseases The only infectious diseases of interest are AIDS and tuberculosis, the latter because of its emergence as a killer in AIDS patients. It is not as if that these diseases are not important to India or the developing world, but who would worry about poor man's diseases such as malaria, leishmania, cholera and other diarrhoeal diseases? In addition, the dreadful scenario of drug resistance is looming large in all these cases I do see a business sense in looking for international patents and markets, but is it not possible to generate drugs for our own diseases at affordable costs and still make a reasonable but not a runaway profit? This would mean use of indigenous expertise and infrastructure and quick certification processes based on a proper assessment of risk–benefit ratio. There is no point in insisting on FDA or foreign drug certification standards for diseases in the country. Incidentally, even internationally there is no taker for vaccines, since they are all essentially meant for the teeming millions of the third world!

I feel that a high-power committee aided by a national debate should examine issues relating to the commercial application of biotechnology to medicine in the country and make concrete recommendations to the government for implementation. Some of the issues to be examined would be· (1) What has India actually agreed to in the area of commercial exploitation of biotechnology under to GATT/WTO agreements? (2) What are its implications on exploiting gene technology for medicine in the country? (3) How best to utilize the grace period available to implement the agreement fully to the country's advantage? (4) What steps are to be taken to create infrastructural facilities for drug design and clinical trials in the country at par with international standards? (5) Initiate mechanism for certification of biologicals. recombinant DNA products. etc , both short-term and long-term measures (6) Reexamine the drug licensing regulations (certification patents, etc.) in the context of developments in science, global competition and demands of the country

Above all, there has to be a sincere political commitment to indigenize, and bureaucracy should help to interpret rules to India's advantage All the efforts which DBT has put in to foster research in biotechnology in the country will be of no consequence if user agencies do not facilitate commercialization If international pressures of different sorts let the powers that be to stifle indigenous initiatives at commercialization, either due to ignorance, indifference or design, the country would miss the biotech revolution as well. We can then all be blaming each other for missing the boat, a familiar scenario all along! Let us hope that it will be a different story this time and the country really means business with a human face

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