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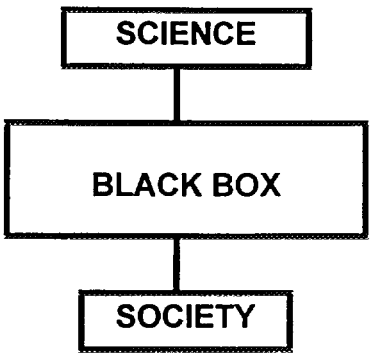
Biotechnology transfer: a matter of policy, not technology

The phenomenal rise to prominence of biotechnology in our existence has sparked a sometimes acrimonious debate on how this toolbox can and should be used for the improvement of the human condition world-wide, not just for the happy few who happen to have the resources to pay for its techniques and products. One of the many "selling points" of biotechnology has been its image as a diffuse technology, with a wide range of applications in many fields of socio-economic activity, and with (relatively) low entry barriers. This perception is caused by the fact that biotechnology, not unlike e.g. the software industry, is in the first place a knowledge based industry, much less an infrastructure based one. To carry the analogy with software further, biotechnology covers such a wide span of levels of sophistication in its applications that virtually any knowledge base, no matter how small (and we will briefly discuss a few examples later in this paper), can serve as a starting point for an industrial sector, if the available resources are used wisely. This should open the way to rapid establishment of applications of biotechnology, and a growing contribution to technology development itself, by those developing countries that are richer in well trained human resources than in capital, of which there are many.

Then why is the sector developing so unevenly, and generally much more slowly than expected, especially in developing countries? This paper will examine a number of weaknesses in present strategies for transfer of biotechnology, and offer, through the use of a number of success and failure stories, some suggestions about alternative strategies that might lead to improved success rates. It is meant as a contribution to the debate on a global framework for biotechnology transfer. The options will be very different from one country (or region) to another, they will depend on a wide range of parameters, some potentially under the control of the countries wishing to develop a national policy, others utterly beyond their control. These parameters vary with the types of applications chosen for emphasis. Therefore the best solution will be quite different from one country to another, and lessons should be learned in terms of successful approaches and strategies, not products.

The international debate on biotechnology transfer has tended to focus more or less randomly on individual components of the policy issue (e.g. biosafety, IPR). This is due to what is probably the biggest single inhibitor of the integration of technology in global development strategies: the lack of understanding at decision making level of the interactions between science, technology, the economy and society in general. Even the most diversified post industrial nations struggle with this issue. As a result of this, the highest levels of decision making tend to see the relation between science and society as in fig. 1:



A viable strategy for the use of biotechnology applications as engines for economic development requires a number of basic choices at the level of public policy, regardless of the type of economy in which it is developed, if it is eventually to transform the potential into economic development. Resources are always constrained, and socio-economic priorities are not the same in each region. In industrialised countries, the ease with which medical applications of biotechnology have been introduced, contrasts strikingly with the enormous difficulties faced by the introduction of agricultural products. Although the debate is allegedly based primarily on concerns for the environment, the underlying reason may well be that food, unlike health, is not a priority in those countries. Globally though, food is still a major priority, and will remain so for the foreseeable future. Therefore, the strategic choices made in a context of mature economies with a stable and ageing population are very different from those in developing countries.

This, together with other political considerations, has important consequences for the perception of priorities by funding sources. As the priorities of donor countries shift geographically (since the fall of the Soviet Union) and topically (with new emphasis on fields like biodiversity and conservation), aid programmes have reduced their commitment to the development of long term training and research efforts, especially in the agricultural sector, but also in the medical sector. This has led to an increasing gap in biotechnology know-how between resource poor countries and the rest of the world. It is questionable whether the currently available insufficient resources should be spread out between biotechnology and more "traditional" medical and agricultural research, as this may lead to degradation of the latter. This is a source of concern, as many biotech innovations require good "downstream" R&D capacity to reach the economy. (e.g.: no plant genetic engineering effort will ever produce a useful variety without collaboration with a good plant breeding project that can take the new genetic combinations and breed them into locally adapted varieties).

The lack of interest at the policy making level in the interaction between education, technology development and socio-economic development is one of the most important problems facing biotechnology transfer policies. It leads to disintegrated approaches to the different, related parts of the debate (training, biodiversity protection and utilisation, industrial base development, risk assessment and safety regulations, ...). Policy makers in developing

countries constantly face the dilemma of choosing between long term solutions through technology and capacity transfer, and short term solutions utilising conventional methods and improvements of their information and management practices.

In the following sections we will briefly touch upon a number of parameters to consider in the development of biotechnology transfer strategies adapted to the particular circumstances and needs of different countries or regions.

STRATEGIES CAN BE DESIGNED AROUND:

- MARKETS:
  - Local
  - International
    - south-south (go for growth)
    - south-north (go for size)
- PRODUCT RANGES:
  - Agriculture and/or livestock
  - Food industry
    - processing
    - additives
  - Pharmaceuticals
  - Chemical processing
  - Environment (bioremediation, conservation)
- TECHNOLOGY RANGES:
  - Traditional (e.g.)
    - breeding
    - fermentation
  - "Modern" (e.g.)
    - biochemistry
    - cell biology
    - rDNA technology

Development of long term ventures such as the introduction of biotechnology in a national development strategy requires integrated thinking about this central strategy as well. This is in sharp contrast with existing situations world-wide, where priorities for biotechnology industrial programmes are usually the result of the emergence of a centre of excellence in biotechnology related research, often linked to the work of a strong personality, but without previous thought of its relevance for local economic development.

CHOICE CAN BE DETERMINED BY CENTRAL NEED.

- use biotech to improve existing strong sectors

or

- develop new sectors using newly accessible biological resources (biodiversity)

or

- use biotech to develop new physical resources, either by developing new species (aquaculture/ arid land/ waterlogged land), or by adapting existing species (breeding for stress tolerance)

or

- develop generic technologies (e.g.)
  - diagnostics (AB and/or DNA based)
  - screening technology (biochemical)

or

- develop biotech around public health priorities
  - vaccines
  - screening (epidemiology)

Of course, the choice for each particular country, region, institution will also depend on limiting resources: manpower, financial resources, infrastructure, biological diversity, etc... . Thus, part of a long range planning exercise is to find a good fit between the national socio-economic priorities (which can, as stated before, be to promote export industries!) and the existing resources.

There is scope for regional co-operation between countries with different priority needs. In several developing regions of the world, large differences exist between neighbouring countries in terms of population density, trained manpower availability, food production and productivity. Regional co-operation would seem to be one promising way to ensure equitable spread of development around biotechnology in such regions.

THE QUESTION OF COMPETING TECHNOLOGIES

In the biotechnology debate, remarkably little attention is given to the issue of how other technologies might solve some of the big development problems addressed by biotech. The spectacular development of information technology and of combinatorial chemistry, linked to the most recent developments in rDNA technology, are working towards a major shift in the requirements for natural biodiversity as a source of material for biotechnology to work on. It has been one of the central tenets of the Biodiversity Convention that genetic and organic chemical resources from biodiversity are a key requirement for further development of biotechnology, and therefore

constitute both a major potential source of wealth for tropical countries and a priority target for protection. This hypothesis is eroding fast, and the consequences should be considered carefully, as they do not apply equally on all types of applications of biotech.

THE QUESTION OF COMPETING TECHNOLOGIES

- Where are the most dynamic competing technologies interacting with the hopes and aspirations of biotechnology?

➳ information technology vs. rDNA technology
➳ combinatorial chemistry vs. secondary metabolites

Common characteristic: high end/ upstream

- Which sectors have least to fear from this?

➳ food production
➳ first line health care

Common characteristic: close to market sectors of the economy

ATTITUDES TOWARDS INTELLECTUAL PROPERTY PROTECTION:

Possibly the most contentious issue in the international debate on biotechnology is that of ownership rights on living material and its derivatives. While much of this discussion is on ethical issues in industrialised countries, in the international arena the main issue is that of equitable compensation of especially developing countries for their contribution to the field. The debate has seemingly gone astray over ideological and philosophical questions. The question is not if or what should be protected, but how. As with any other industry with a high technology component, no entity, be it a country, a corporation or another type of institution, can participate at the cutting edge of the field if it does not respect the results of the efforts of other entities, and thereby gain legal recognition, respectability and protection for its own work. The question then is not philosophical, but practical: how can developing countries achieve protection for their production of biological resources? One of the key factors missing in most developing countries' training programmes is expertise in IPR. Not surprisingly, countries who do not have access to their own experts in patenting and intellectual rights protection, have a significant handicap at the negotiating table. The best tactic then is usually to say "no" to everything, to avoid giving anything away without proper compensation. It

might be that one of the most productive ways to make progress in this area is training of intellectual property rights experts from developing countries.

ATTITUDE TO INTELLECTUAL PROPERTY PROTECTION:

- need dependent on expected markets
- different strategies possible:
  - no patents (go for local markets, not protected ones, this is most of the future growth markets)
  - patents (go for all markets, including the present biggest ones)

Strategy will depend on the type of product, on existing and available technologies, on business strategy envisaged, and on international treaties (WTO)

CONSEQUENCES OF STRATEGIC CHOICES FOR TRAINING PROGRAMMES

Since biotechnology is essentially a knowledge based sector of the economy, a key component of any strategy is definition and implementation of a multidisciplinary training programme. This is at present one of the most neglected parts of the international debate. Amazingly, training strategies almost generally seem to start from the idea that a biotechnology industry needs highly trained molecular biologists, period. In practice, they are a useful (not an essential!) part of the range of competencies required. More important are engineers, patenting and licensing experts, business analysts, etc...

TRAINING PRIORITIES

- molecular biologists/biochemists?
- business and associated ? (legal, IPR, ...)
- downstream strengths? (agro/health/food industry)

One of the key policy messages on biotechnology therefore must be that its positive socio-economic effects can only be obtained in the context of a broad range of trained staff. Training for excellence in biotechnology alone will not generate any perceptible economic benefit. This is a particularly important

notion to get accepted by the large donors of funding for advanced training of developing country experts. The table below lists some of the fields of expertise required to do more than create finance starved academic research laboratories in molecular biology.

CAPACITY REQUIREMENTS:

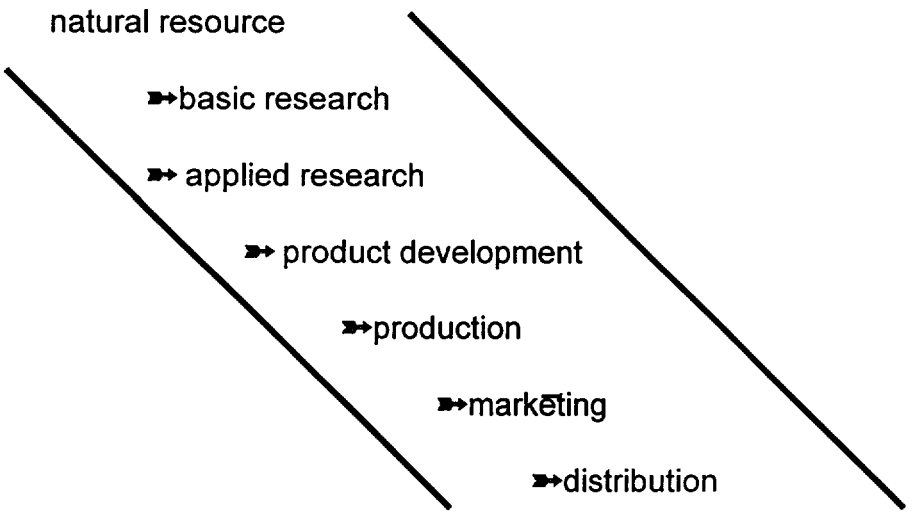
- legal
- business
- engineering
- human resources
    - cheap
    - trained
- finance
- transport and communications
- risk assessment and regulation

THE ROLE OF INTERNATIONAL ORGANISATIONS

International organisations, particularly the UN agencies, are in a unique position to evaluate broad strategies for long term industrial development world-wide. In the case of biotechnology, and with special emphasis on developing countries, this is particularly relevant, because of the diffuse nature of biotechnology, its pervasiveness across an unequalled diversity of industrial sectors, and its direct impact on human life and the environment.

The criteria for preferring one of these strategies over another are different according to the situation of each country. This can to some extent be generalised to the level of entire regional blocs. At its most basic level, the choice is between programmes and projects, between a centralised and a diversified approach. Much current thinking about biotech appears to happen along lines similar to those used for other types of technologies. It is not obvious that a centralised approach to R&D and industrial development in this area will give the results that a similar approach has given some developing countries in developing a capacity for other complex technologies. The applications of biotech do not come in billion dollar chunks, like e.g. mining, or chemical industry, or nuclear capacity. Much of the value is, and is likely to remain, created by a myriad of relatively small incremental value products. There will be exceptions (some drugs), but the reasons why these products carry such huge potential rewards are that they require enormous investments over long periods of time, and that they have a very high risk of failure, in which case the investment is lost.

Whatever the sector chosen for development, and the strategy adopted, the end products will always reach the economy through variations of the following sequence:



Different types of industry require radically different types of approach. The key parameter to consider is where in the process of technology and product development the heaviest investments in human and financial capita are needed.

- For example, in drug development, the most complex parts are basic studies on diseases, and clinical testing of potential drugs. Primary screening of molecules is often (relatively) cheap and technologically within easier reach. A country that wishes to stimulate the development of a national capacity in drug development, could adopt a capacity development model starting with primary screening to acquire property on molecules, and access to know-how in advanced screening, testing and clinical trials at a later stage.

- For the use of genetically engineered crop plants, the bulk of the costs and risks are in the pre-field stages. Field breeding is relatively much cheaper. Moreover, there are already many good breeding programmes in resource poor countries. Also, no successful crop genetic engineering programme will benefit local farmers, unless its products are made available through locally adapted crop varieties. In this context, it is particularly worrying that a number of poor countries are neglecting their small breeding and agricultural research programmes in favour of undirected investments in advanced biotechnology research capacity. This is a good example of how a drive into

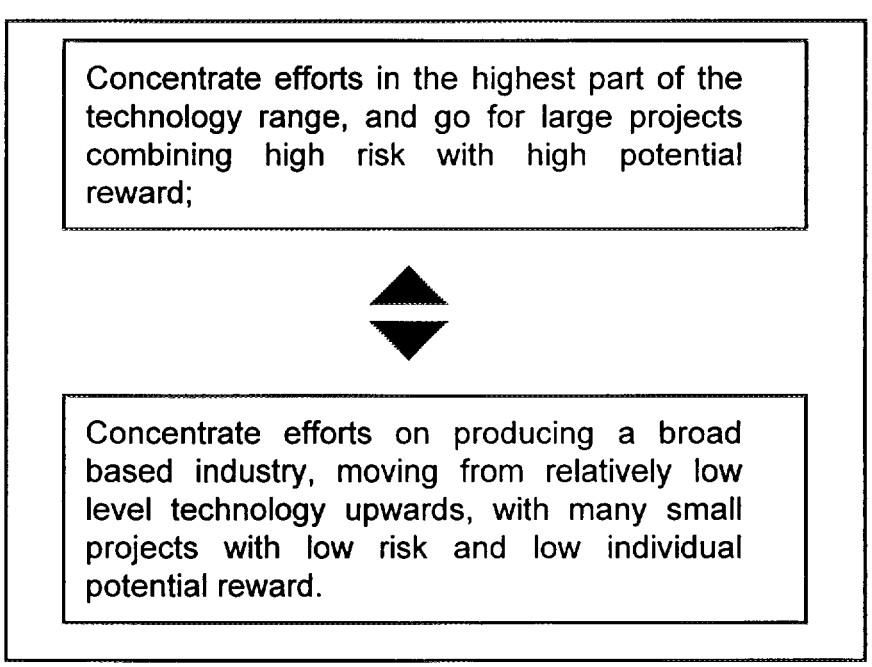
biotechnology without proper policy can actually lead to a loss of development.

Whatever the field of activity, and the choice of prime actors in the development scheme, the major element for success is a multidisciplinary approach. This has important consequences for the one area in which public initiative is solely responsible: training. Too often, high technology as a tool for development is equated with the production of enough PhDs. In some niche areas (e.g. software development) this might be appropriate. But if the objective is to develop an entire new sector of the economy, with businesses of a kind not existing before, a much broader body of expertise is needed.

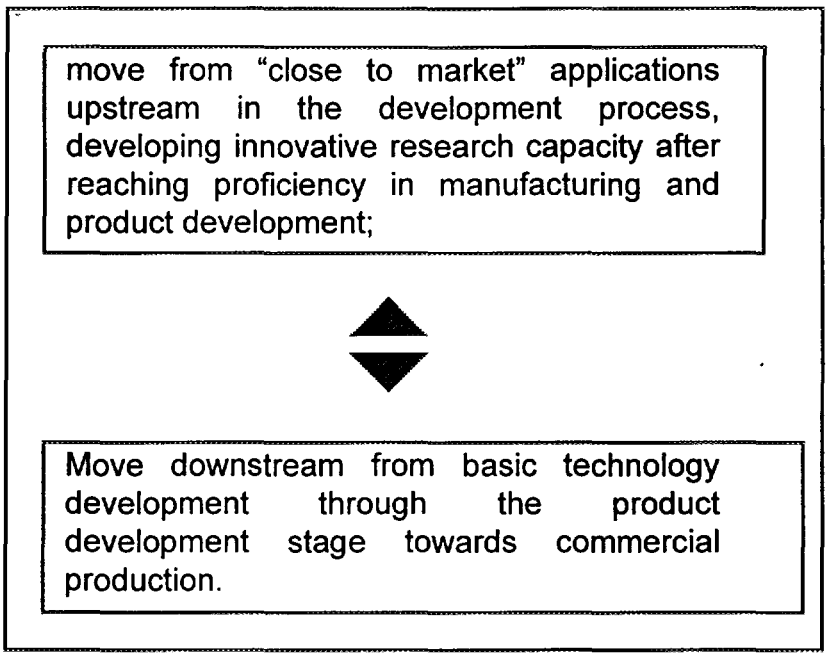
Moreover, on top of the training policy needed, public authorities face hard choices in other fields: legislation and regulations on safety, IPR capacity development, public information.
Finally, if a national or regional strategy for biotechnology related economic development is to have a chance to succeed, it requires efficient access to financing sources for long term programmes as much as training and a legal framework.

Basically, strategic choices have to be made along 2 main axes of thinking:

TECHNOLOGY SPECTRUM



DEVELOPMENT STRATEGY



It is suggested that international organisations would concentrate efforts near the second alternative in terms of the technology spectrum, and near the first alternative in terms of development strategy. This approach seems to offer the best opportunities to build on existing strengths in almost any country. It might also help resisting the temptation to build up unsustainable prestige projects insufficiently linked to existing and expected industrial realities.