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"My dream is not just the $5 billion, but much more."

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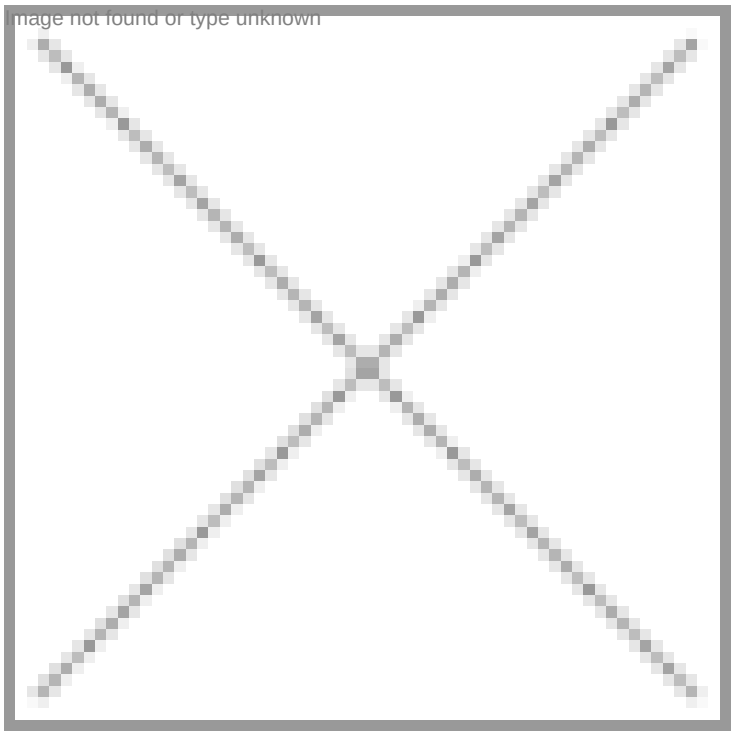
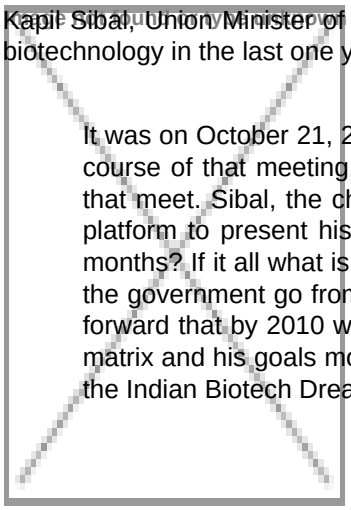


Sibal Talk

"My dream is not just $5 billion, but much more,"



Kapil Sibal, Union Minister of State for Science & Technology and Ocean development, speaks about the progress made in biotechnology in the last one year.

It was on October 21, 2004 that Sibal met some CEOs in Bangalore, who came under the aegis of ABLE. In the course of that meeting, Sibal told them what was there on his agenda. Exactly, 11 months have passed after that meet. Sibal, the chief guest for the first ever biotech CEOs summit organized by BioSpectrum, chose the platform to present his report card. "The question to be asked is have we made any progress in the last 11 months? If it all what is the progress? Where do we stand? Where does the industry go from here? Where does the government go from here? And what do we plan to do in the next one year or so to take this dream of ours forward that by 2010 we should be a $5 billion industry." Sibal was unambiguous is identifying his performance matrix and his goals moving forward. We present to you the insights of Sibal's and the government's thinking on the Indian Biotech Dream.

1. I wanted a Biotech National Policy in place.

2. I wanted India to comply with the global regime on IPRs

3. I wanted a framework for Academia-Industry interaction

4. I wanted to address procedural issues of regulation for approval of genetically engineered products

5. I wanted the biotech industry to get concessions and exemptions like the IT sector.

6. I wanted to set up of a large animal facility.

This was what Sibal stated in October 2004. So what has been the progress!

Objective 1: National Biotech Policy

Status: Likely to get Cabinet approval by December 2005

"In March 2005, we had a national biotech development strategy in place. We put it for comments on our website. And the latest news is that we are on the last leg of interactions in Chennai and Ahmedabad. After that the draft strategy will be up for the government approval which means it will go to the Cabinet. I expect this to happen in the next couple of months."

So we are going to have a national biotech development strategy, which offers huge concessions to the industry and gives a road map as to what's going to happen in the years to come. How will the human resource be developed? How are industry and academia going to interact with each other? What kind of support system will be put in place? What kind of tax, excise duty, and other concessions are to be put in place? How will the biotech parks be set up? How will we train academia to start looking at multi-disciplinary courses to teach individuals? All that is set out in the Biotech Development strategy. This objective is well on the road to be accomplished and we will probably have the Cabinet approval in the next two months.

Objective 2: Comply with the global regime on IPRs

Status: Product patents regime in place

"As far as the second objective, namely complying with global regime is concerned, the product patents are in place. In fact, there was an article in The New York Times stating that the Indian government is sold out to multinationals. An article like that and that too in the The New York Times indicates we are doing the right things. That problem is behind us."

Objective 3: Framework for Academia-Industry interaction

Status: Legislation on the lines of the Bayh Dole Act is expected

"As far as the policy framework for Academia-Industry interaction is considered, we are all at the moment working for a legislation on the lines of the Bayh Dole Act, in which we want to ensure that the academia, the national labs, and industry collaborate with each other and the IP generated pursuant to that is shared by those who contribute to the generation of the IP. Of course, we will not do everything that the Bayh Dole Act does. We will try and improve upon this. I do believe that those in academia and industry to whom the funds are given must own the IP and unless they have ownership rights or believe that they have the ownership rights, they will not be able to create globally competitive products."

"We are not sure if that framework will come in the form of a legislation or an executive guideline. But my personal preference would be to legislate so that there would be no discretion left in any collaboration that takes place between academia, industry, national labs and the
government."

"Funding will be provided by us. But the question that arises next is who owns that R&D? That should depend on the nature of the product, the nature of partnership and the nature of the R&D. This is done best by partners who are partnering in the

enterprise rather than intervention from the outside. The government should not have any part in it. That's going to happen soon. I assume that by the Budget session of 2006, we should have the kind of legislation based on the Bayh-Dole Act passed."

Objective 4: Procedural issues of regulation and genetically engineered products

Status: Mashelkar Committee recommendations to be in place by November

"As far as the procedural issues on regulation and approval of genetically engineered products are concerned, we have the Mashelkar Committee Report now and the Report clearly points to a single window kind of clearance. The multi-approval approach, the kind of GEAC approach, has been rejected. We will soon have the support of Ministry of Environment and Forests for the Mashelkar Committee recommendations. And you will have that in place by November. That is a huge step forward. We also believe that the issue of approval should be decided in the Department of Biotechnology (DBT) rather than anywhere else. Hopefully we should be able to do that."

"One of the concerns that the industry has and rightly so is the availability of cell lines. That is a matter of great concern and of vital importance to the industry. I understand that the cell lines that are available in India will not serve the next generation R&D that the industry wishes to do. Therefore most of the industry will have to rely upon the cell lines that are imported and with the present GEAC kind of procedures, it is very difficult to do that. The delays are so large that it is uneconomical to go through that procedure. We have now decided, and that is again the recommendation of the Mashelkar Committee Report, that 90 percent of all cell lines will be imported without any problems. That is you can import them directly. There will be no questions asked and the permission will be given by the DBT. It's only the 10 percent, which are complicated, that would need to go through the approval system because of biosafety considerations. That approval system will be far more streamlined than it is at the moment. These two would happen by November."

Objective 5: Concessions and exemptions like that in the IT sector for the BT sector

Status: Mostly in place

"As far as the exemptions like the tax and other exemptions are concerned, we do have most of them in place. We are going to set up biotech parks in 20 states in the country. We have already granted 150 percent weightage deduction on R&D expenditure. We have a single window application-processing proposal. The biotech industry got benefits under the budget this time for export oriented units. These have now been extended to the biotech parks. We now have 100 percent FDI permitted through the automatic route and biotech units are exempted from income tax and export proceeds have to be realized within 10-12 months. And biotech parks are allowed to retain 100 percent export earnings in the EEFC (Exchange Earners Foreign Current) amount. So all those concessions, which are by and large necessary for the BT industry, are already in place."

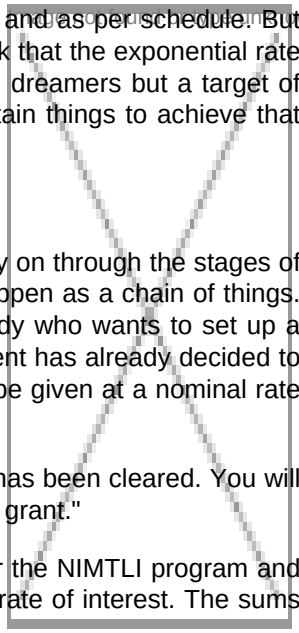
Objective 6: A large animal facility.

Status: Feasibility study on

"As far as the large animal testing facility is concerned, it will be set up in Hyderabad. The feasibility study of this facility has started."

The Road Ahead Sibal's Five Point Action Plan

The government, by and large, has been working according to the promises that have been made and as per schedule. But the question is how do we take $1 billion industry to a $5 billion industry by 2010? "I personally think that the exponential rate of growth of the biotech sector in the country (the target of $5 billion) is a target not of doers and dreamers but a target of those who think conservatively. I believe we can do much more than that. But we have to do certain things to achieve that target."



A system to promote public private partnership

"We have to put in place a system that can support R&D at the pre-proof-of concept stage and carry on through the stages of manufacture and sale of the products. We need continuous public-private partnership. It should happen as a chain of things. For example, there should be pre-proof-of-concept stage funding in the nature of grants to anybody who wants to set up a business incubator or a start-up company. There the government of India and the biotech department has already decided to give up to Rs 50 lakh as grants, free of any strings attached. Anything more than that amount will be given at a nominal rate of interest, which will not affect the company."

"Once the proof-of-concept is shown, similar concessions need to be further extended. That policy has been cleared. You will soon see advertisements in the newspapers on this so that you can apply for that facility and get the grant."

"Once the proof-of-concept stage has been reached, we move to another kind of partnership under the NIMTLI program and that partnership allows any department or a CSIR lab or anybody else to get money at a very low rate of interest. The sums are much larger. So that public-private partnership will continue to be operated."

"Once you reach a stage where the product would be manufactured, you can go to the Technology Development Board (TDB) within the Department of Science and Technology. TDB will then partner with you to actually do the pilot project and set you off to the market place. You should realize that we have in our mind the zeal to partner with you at every stage of your requirement-pre-concept through the pilot project and up to sale of the product. If we achieve that we are then on the road to the kind of $5 billion hopes we have for 2010."

Evolve best practices

"We need the best practices in place to carry out clinical trials. DBT is planning to set up a Translational Center for Clinical Research Organizations (CROs). This is to facilitate the link between lab research and CROs. A Translational Center is a scientific link between laboratory research (clinical trials) and human trials (actual clinical trials). It is not enough for all of us to become familiar with the best practices, but do trials, which are acceptable to the international community, as world class. This in turn will attract FDI to India. A large number of trials are already taking place in India, but these trials are taking place because MNCs believe these trials are far cheaper in India and we have the human resources and capabilities to actually go through those trials, though we do not have the best practices in place in India at this point of time. This institute (the Center) that we are going to set up is going to partner with you to establish the best protocols and practices for trials, which will be acceptable throughout the world. I think that's an area where huge investments are going to come in. That's a strategy that we need to evolve."

Industry also needs to gear up

"The Indian biotech sector is a nascent, but is on the course of being mature. There are huge possibilities. There are 280 companies and the turnover of $1 billion is done by 20 of them or 60 percent of that turnover is by 20 companies. Now that means 260 companies, which are small, have huge potential for growth and this potential ultimately has to be tapped. And if we are able to partner with them in the manner that I suggested, then perhaps we can generate the kind of growth that you are hoping. And if that growth spreads beyond the 20 to 100 or 120 companies, then the $5 billion target is really conservative."

"But the fact is that the industry also needs to gear up. It's true that we are going to partner with you and also fund you, but the expectations from us are also huge. We expect the industry to invest in R&D in a big way. At the moment they are not investing in R&D as they have a lot of constraints. Most of them are very small enterprises and in times to come they will invest in R&D. For example, in Israel, there are about 3,000 companies, which are newly set up. That has been done in the last 10 years. All those 3,000 companies are doing fabulous R&D. But Israel has a disadvantage. Though they are doing R&D, they do not have any manufacturing facilities nor do they have the human resource or the capital. We have a great

advantage of being distinctly strong in manufacturing and on the pharma side. So what we need to do is to strengthen our innovation of new companies."

"That innovation will be strengthened only if one, we partner with you and two, some venture capital comes into the market. Today companies in the US are looking to India to actually invest through the venture capital. You ought to take advantage of that, but please don't ask us to fund you for your travel abroad. We can fund you for your R&D. We cannot fund you for your 'Bloody Marys'. So by and large this is the road ahead of us."

Environment for global partnerships

"I know for the fact that nobody outside the country can even think of doing Phaseâ€“III trials in India. A lot of companies have told me that protocols need to be set up in the country. When I went to the US, one of the things that I told the US government was that we want the FDA to collaborate with the drug controller in India to set up those protocols for the purpose of world class clinical trials, which will even be accepted in the US. We should formulate procedures, which will not make the processes equally complicated or expensive in India. We will have to accept the protocols in principle and devise our own methodologies to actually implement that. The US in principle has agreed to that."

"A lot of the private companies in both the countries are unwilling to part with the biological material at this point of time. I spoke to US government on the issue of import of biological material. I stressed on the need for setting up of protocols on bringing the biological material into India and in turn this can be licensed to who ever wants it subject to conditions that take care of the concerns of the companies in both the countries. This has also been agreed upon in principle. I wish to inform you that I am going to the US on October 17, 2005 to sign an umbrella science and technology agreement and I am going to carry forward the biotech and nanotech dialogue with the US administration to ensure that most of the things that I talked about are actually put in place in India so that the industry here is helped in the process of the growth."

Industry needs to be proactive

"I am delighted to be here. But you need not wait till the next summit to give me your agenda. You should set up a day to meet me in Delhi every two months or so. So that we sit across the table and find out how the problems enunciated by you have been dealt with and see what we are lacking and how we can go forward. That is a far more effective way of doing things than coming and making a statement and going back without having on table what you exactly want. I would therefore suggest you to give me on a piece of paper the points on which action needs to be taken."

"I know for example people are talking about exemptions on diagnostics kits. They say kits manufactured here are not yet given concessions. The government of India perhaps wants from you the list of reagents that can be exempted. But if you give a whole volume of reagents, you are not going to get the exemptions. So talk within you fraternity, limit the number of reagents on which you want the exemptions, give the exact list. We will move forward. So you too have to work at your end and help us in
helping you.

"I took this as an example as that was the thought that came into my mind because this issue was raised by me. I talked to the finance minister. Nobody from the industry got in touch with me since October 2004. I am myself raising the issue telling you all what the problem is. Now if you people (two-three) were to meet me saying this is what we need and this is the new problem that has come up. This interaction five-six times a year will also help us deal with the problems that emerge while moving forward. That is a better way of dealing with the issue."

"Come to me every two months or so with an agenda telling me in advance what the previous agenda was and what were some of the decisions taken. I can then tell you what was implemented and what was not or at what stage it is in. We want the government to be completely transparent. We want to tell you where the difficulties are and where we can help you and where we cannot or where to approach for somebody else's help. All these things are important. And I think this kind of a system is important for the industry and government to work together."

But my dream is not just the $5 billion, but much more. You are the sunrise industry of the country in the early part of this century and I think you will make it possible to take this country forward and achieve the growth rate of 8 percent of GDP that we have
been talking.