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National Biotech Policy 2005

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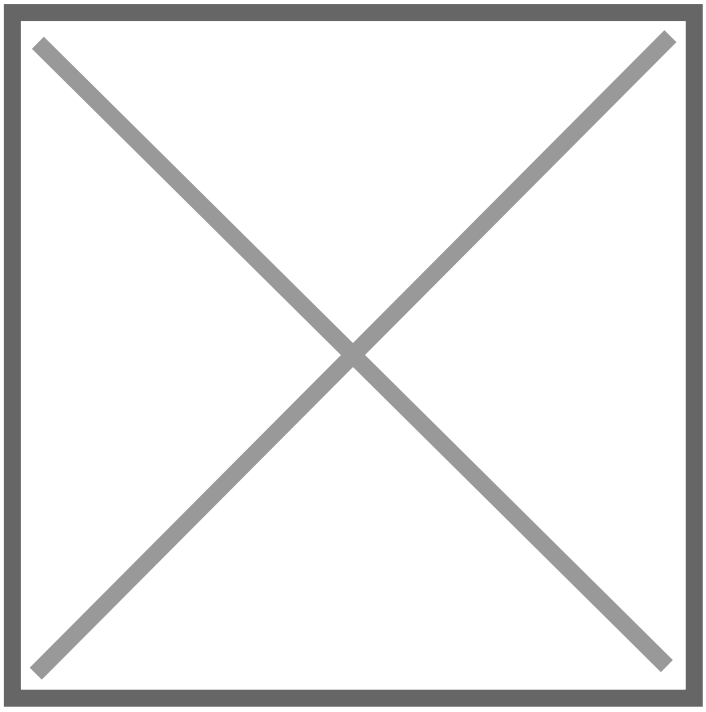

The Parleys Begin

Kapil Sibal

The biotechnology sector started to take shape in the country more than two decades ago. In the last five years, the biotechnology industry has really taken off and is about to cross the $1 billion mark. Yet, the country does not have a clearly defined policy framework for the biotech segment. The inaugural issue of BioSpectrum in March 2003 started the demand for a well-articulated National Biotechnology Policy.
A year later, now there is a lot of action related to the formulation of a national policy for biotechnology. The government is all set to announce a national biotech policy in January 2005. A report about the recent actions on this front.

The new secretary in the Department of Biotechnology, Dr M K Bhan, has been stressing the need to formulate the national policy ever since he took over in March 2004. The new Union minister for science and technology, Kapil Sibal, has been talking about the need for such a policy since assuming office in May 2004. Together, these two policy makers are set to put Indian biotechnology on a growth path. What gives hope is their public statements on the sector in recent months.

- The government clearly recognizes that it is alive to the concerns of the industry as biotechnology has tremendous potential to resolve some basic issues like poverty, hunger and diseases. It is very important to India.

- The government is going to come up with new biotech policy in January 2005. It will give all the parameters-the policy statement. Once the policy is done, then the single window clearance and other procedural issues will be addressed.

- In the BT sector, there is a need for influx of venture capitalists(VCs) in a big way. The government has to open up the sector and attract a lot of foreign direct investment(FDI).

The Union Minister for Science and Technology, Kapil Sibal met biotech CEOs in Bangalore who came together under the Association of Biotechnology-Led Entrepreneurs (ABLE) on October 21, 2004.

The Union Minister of State for Science & Technology, Kapil Sibal, has been stating these at every industry forum. These statements definitely are not mere slogans. He means business. During the last 15-20 days, there has been a lot of action. He is meeting the industry and speaking to them. He has announced that he would be accessible to listen to the issues that need to be addressed urgently. On October 21, 2004, he met biotech CEOs in Bangalore who came together under the Association of Biotechnology-Led Entrepreneurs (ABLE). During the meeting, BioSpectrum discovered that the minister was thorough with his understanding of the industry and wanted to get more in depth the industry issues. He was alive to the suggestion of the CEOs and was noting down each point that was being talked about.

He assured the captains of the industry, "In the last couple of years the government at the policy level has realized how important biotechnology is in India. There are 96 biotech companies in India. BT has tremendous potential. It is important because we can resolve basic issues like poverty, hunger and diseases, besides the potential of exports."

Sibal spelt out what was on top of his agenda. A national biotech policy by January 2005, a national bioinformatics policy by January 2005, compliance with the global regime on intellectual property rights, quadrilateral agreement between the academia, industry, laboratories and the state and addressing the procedural issues. He assured that major issues would be addressed on priority. And the government has already initiated some positive measures in that direction. For example the biotechnology parks have got the status of EoUs. He has spoken to the Finance Minister and that the minister was alive to the idea that the same concessions and exemptions like that in the IT sector be given to the BT sector. Further, he pointed out that the large animal testing is also being allowed.

Discussions begin

At the inaugural conference of the Bangalore Bio 2004 in July, Dr MK Bhan, secretary, Department of Biotechnology, announced that a comprehensive National Biotechnology Policy would be put in place in the next six to seven months. Concurrently, the Union Science and Technology minister Kapil Sibal opined that the Biotech Policy would be ready by January 2005-when India embraces the product-patent
regime.

It may be recalled that in its inaugural issue in March 2003, BioSpectrum had initiated an informed national debate on the framing of a National Biotechnology Policy. Now that the ball has been set rolling and the government machinery is working to draft the policy, BioSpectrum too is following up with the trials and tribulations of evolving a biotech policy for the country.

At the Bangalore Bio event Dr Bhan elaborated on the agenda of the policy and said, "The policy would outline clearly the government's thrust in the field including attracting investment and enforcing regulations. A commission would be set up to frame the national biotech policy that would include crucial elements from the Mashelkar Committee on pharma biotech and MS Swaminathan Committee on Agri biotech". "A group would frame guidelines and advise the biotechnology department on the model to be adopted in public private partnership in this segment", he added.

The Indian government had announced a Science and Technology (S&T) policy in January 2003, which gives a broad open-ended framework for application of S&T for the benefit of the society. The proposed biotech policy, keeping this S&T policy as a base, would address specific policy issues in relation to biotechnology and also outline the future strategy and road map.

The Task Force

The government has set up a task force under the chairmanship of DBT secretary Dr MK Bhan. The Union minister for science and technology, Kapil Sibal is keen to formulate a national policy on biotechnology and put in place a single window system of clearance of transgenic products by January 2005.

The Bhan Task Force will use the suggestions of the M S Swaminathan Task Force Report on agricultural biotechnology and the forthcoming report of the Mashelkar Task Force on recombinant pharma products.The government also plans another panel to recommend the use of transgenic products and crops in food and processed foods.

The Bhan Task Force is also expected to recommend "strategies for translation of the biotech policy towards full utilization of the potential of the technology for human welfare and economic development." It would also recommend setting up of sub-committees in different sub-sectors and draw a roadmap for these sub-sectors for the next 10 years. It would propose modifications to the existing laws and procedures in involved in regulation of transgenic products, suggest incentives for promotion of trade and investment in biotechnology and measures for creating awareness of the overall status and new initiatives.

The other members are :

1. Dr M.K Bhan, Secretary, DBT-Chairman

2. Dr Mangala Rai, DG, Indian Council of Agricultural Research (ICAR)

3. Dr N K Ganguly, DG, Indian Council for Medical Research (ICMR)

4. Prof G Padmanabhan, Professor Emeritus, Indian Institute of Science, Bangalore

5. Dr Suman Sahai, Convenor, Gene Campaign, New Delhi

6. Prof P N Tandon, Chairman, National Brain Research Center, New Delhi

7. Dr D Balasubramanian, Director(Research), LV Prasad Eye Institute, Hyderabad

8. Prof C R Babu, University of Delhi

9. Dr P N Bhatt, former DDG, ICAR

10. Dr M Vidyasagar, Sr VP (Advanced Technology), TCS, Hyderabad

11. Prof A S Kolaskar, Vice Chancellor, University of Pune, Pune

12. Mrs Kiran Mazumdar-Shaw, CMD, Biocon & President, ABLE, Bangalore

13. Dr Swati Piramal, Director, Nicholas Piramal, Mumbai

14. Mr Rakesh Rewari, CEO, SIDBI Venture Capital Ltd, Mumbai

15. Mr Raju Barwale, CEO, Mahyco-Monsanto, Mumbai

16. Dr Rama Mukherjee, Dabur Research Foundation, New Delhi

The central aim of the Biotechnology Policy and Strategy would be towards full utilization of the potential of biotechnology for human welfare and economic development. For this, the policy would contain specific proposals and action points, incentives and programs. In addition to being a policy document, it would give a strategic direction to different sectors to accelerate the pace of development of biotechnology for the next ten years in the country. New models of center-state, private-public, R&D-industry partnership, inter ministerial, inter institutional/agency coordination would be worked on to exploit the full potential of the country in this sector.

A high level main committee for drafting the Biotech Policy and Strategic Action Plan consisting of 30 experts has been constituted. Since biotechnology involves various sectors, 12 sub committees consisting of 5-8 specialist members have been created, each headed by a group leader. The various sectoral or subcommittees include: medical biotechnology, agricultural biotechnology, bioresources including sericulture, food biotechnology, animal and dairy sectors, marine biotechnology, environmental biotechnology, bioinformatics, industrial biotechnology, investment and trade, traditional including biofertilizers and biopesticides, human resource development.

Each sectoral committee will identify the thrust areas, prepare an action plan and status paper in their respective sub sector. This is aimed at developing a knowledge base in that sectoral area and will outline a strategy map for the future. The sub committees will provide this information to the main Biotechnology Policy Framework Committee (BPFC). After further deliberations, the final recommendations of the main committee will be put on the Internet for public comments.

Some of the sectoral committee meetings have taken place while others are in progress. The first meeting of the main committee took place on October 27. There are some questions like what should be the rationale behind selecting or rather leaving sectors out of preview of the policy? A bioinformatics policy is already in place and is put on the Internet. So should each sector have a separate policy? Will the biotechnology policy prompt to the creation of some legislations as was the case with other policies like the Drug policy, Seed policy and Exim policy?

Dr KK Tripathi, advisor on regulatory affairs and policy matters in DBT, has suggested that the policy document may address specific issues related to: promotion of research and development, technology transfer and commercialization, public-private partnership, capacity building, human resources development, infrastructure strengthening, international cooperation regulatory framework, biosafety, IPR, trade and investment, social and ethical issues and communication and public awareness.

Dr Manju Sharma, former secretary DBT, commented, "My perspective is that biotechnology is a part and parcel of India's science and technology policy. What is needed is to implement the first vision document (2003 Science and Technology policy) for five years. This would help to create a knowledge based society, thrust on institutional development, poverty alleviation, large projects of societal upliftment, intensify research, convert leads to products, processes and technology and benefit the poorest of the poor, for whom this technology is meant. I look at biotechnology in a very broad perspective. For example if a vaccine is developed through a biotech-based technique, then the prices will crash and the poor, deprived section of the society will benefit the most."

The first few suggestions

Sibal has been thinking laterally and the industry too needs to become proactive to help the framers of the policy. The Minister has asked the industry to be realistic in its expectations and approach. For instance, the proposal for a national biotech fund with Rs 200 crore corpus. He said he would be going to the Finance Minister with the proposal, but opines that arriving at a solution which is within the purview of his ministry, will be a more realistic one. He cites the case of Pharmaceutical Research and Development Support Fund (PRDSF). The initial discussions started for Rs 150 crore as grant every year and ultimately it ended up with Rs 25 crore. That too as a corpus and spending is out of the interest earned.

"I do not see realistically any BT fund coming out. So it is better to address the issue ourselves. We realize by and large that no movement can take forward without public, private partnering. The level of funding in the budgetary allocation can be asked to be increased so that the government can partner with private players through the DBT for project finance. A model has to be put in place. Everybody is ready to do this. The model that can be in place is we give the knowledge for equity. We are risking the transfer of knowledge for free of cost. That is a model I know can work and can be conceived," Sibal reportedly told the industry gathering in Bangalore.

Sibal also stressed on public-private partnership. In fact he stresses on a four-way partnership- Lab-Academia-Public-Private (LAPP). "We have to move forward with industry support in this field by way of public-private partnerships. We cannot do R&D in isolation, we have to collaborate with the industry and come out with products. The key to move forward is a quadrilateral agreement between the academia, industry, lab and the state. There should be synergy amongst all four of them. The academia and lab have to come up with the ideas and the supporting R&D work. While the industry and the State have to

support them with the funding. Presently our R&D centers are like little oases of knowledge and since any science should not surpass the common good of people so we have to turn the entire country into a big oasis. The National Biotechnology Policy being drafted is taking care of these issues."

Also the minister understands that the biotechnology sector needs the influx of VCs in a big way. "We have to open up FDI to the sector. Induct a lot of FDI," said Sibal. He is also open to the idea of incentivising the VCs. Addressing the issue of compliance to WTO norms, Sibal assured that that will be taken care of. The industry may not see the third amendment bill of IPR passed in the Parliament passed by January 2005 owing to the short time of the Winter Session starting in December. But industry sources are hopeful that an ordinance to that effect can take care of the concerns. The issue of data exclusivity has not been dealt with in the Third Amendment Bill to the Patents Act and is likely to be addressed in the biotech policy.

One of the important things that the minister has set out is setting up an inter-ministerial group accommodating representatives from other ministries like the social welfare and health. The objective is to facilitate clearances in one go.

How will the policy bolster the small entrepreneur? Take for example, the diagnostics sector, according to Dr Ravi Kumar, managing director, xCyton, the finished products from companies are imported at a much lower duty structure, while the entrepreneur has to pay higher import duties on every raw material. In a way, it is penalizing the entrepreneur. Sibal is keen on looking into such issues and as this is an export import issue and he will talk to the relevant people. Further, he wants the industry to give a list of such discrepancies so that he could convince the ministries concerned.

There is a need for international accrediting institutions for both and clinical and other facilities. And guidelines for clinical trials will be taken up, which is not avoidable. He assured the setting up of Center for Public and World Class Biotech. He also believes that as the minister for Science & technology, there is a need for at least 20 institutions like IISc to build significant human resources.

Dr Bhan sums up: "The Biotechnology Policy of India is continuously evolving but its basic concepts have been settled for creating a vibrant industry, wealth generation and for whatever biotechnology has to offer to the country. The whole policy framework has been structured in a way on how to use biotechnology in a pragmatic and sensible way for the betterment of the masses."

Action has started at last on the policy front. The industry will wait with bated breath the unveiling of the promised policy come January 2005.

Ch. Srinivas Rao and Rolly Dureha