



U.S.-Israel Biotechnology Business Roundtable Summary

On May 5, 2010 the U.S.-Israel Science and Technology Foundation hosted the first U.S.-Israel Biotechnology Business Roundtable at the Hyatt Regency Chicago hotel in conjunction with the BIO 2010 International Convention. Ms. Holly Vineyard, Deputy Assistant Secretary for the Middle East, South Asia and Africa and Ms. Naomi Wiegler, Middle East Trade Specialist attended the event on behalf of the U.S. Department of Commerce. Dr. Eli Opper, Chief Scientist for the Government of Israel's Ministry of Industry, Trade and Labor, Dr. Ora Dar, Biotechnology Advisor to the Chief Scientist, and Noa Asher, Consul of Economic Affairs to the Mid-West attended the event on behalf of the Government of Israel. The well attended morning event attracted more than forty participants representing biotechnology industry, pharmaceutical industry, technology transfer offices, academic community and state economic development offices. Ann Liebschutz, Executive Director of the U.S.-Israel Science and Technology Foundation served as the meeting facilitator.

Dr. Opper commenced the roundtable by offering context for the biotechnology industry in Israel. The Office of the Chief Scientist of the Ministry of Industry, Trade, and Labor in Israel [OCS] has invested heavily in the life sciences industry and that biotechnology in particular is a preferred industry. The Office of the Chief Scientist (OCS) has established specialized incubators for life sciences and most recently is in the process of establishing a dedicated biotechnology fund in alliance with private sector fund managers to assist with the further development of the biotechnology sector in Israel.

Taking an international perspective, Dr. Opper recognized that Israel's ultimate success in this sector depends in no small part on taking advantage of international strategic alliances, particularly those with U.S. Industry. Many large U.S. companies are active in Israel and have found that Israeli companies can provide important additions to their development pipelines. The OCS runs a program that offers multinational attractive incentive packages to utilize Israel's first-class research capabilities and that he hopes that one or more leading U.S. companies will take advantage of this incentivized opportunity to establish R&D centers in Israel.

Holly Vineyard welcomed the participants to the roundtable. She pointed out that the U.S. has a new national export initiative that challenges the United States to double its exports in the next five years. She saw the growth of trade across both directions between the U.S. and Israel as a key factor to achieve that goal and to create jobs in both countries. Ms. Vineyard expressed encouragement by the recent Intellectual Property Rights (IPR) agreement between the U.S. and Israel and noted that Israel ranks very highly in biotechnology in the recent Scientific American magazine.

Clinical Trials

As Chair of the event, Marc de Garidel of Amgen offered the first industry remarks. Amgen considers Israel a first-class country in many of the aspects that count in biotechnology and is keen to expand its role in the Israeli market through its new distributor. Israel has an excellent reputation for clinical trials and Amgen would be interested in allocating more clinical trials to the region. The best aspects of clinical trials in Israel are the access to patients and the efficiency with which the trials are run. However, the downsides in his eyes lie within

the intellectual property environment and he notes that without good protection the biotechnology sector will not grow and innovation will be stifled.

Major R & D Centers in Israel

Dan Gincel of the Maryland Stem Cell Research Fund raised a question about the lack of major multinational biotechnology research and development centers in Israel. According to Gincel, major companies such as Amgen, Merck, Johnson and Johnson praise Israel as an excellent country in the biotechnology sector, but, unlike the IT sector where major companies such as Intel, IBM and Google have key R & D centers in Israel, there are few biotechnology centers. He suggests that the Israeli scientists are already working in key roles in R & D centers in the United States would return to Israel if the R & D centers opened, offering links to Israel. Mr. De Garidel offers that in the case of Amgen, it is not a particular strategy not to go to Israel, rather, that it can get complicated if R & D is located in too many places around the world for one company. Mr. Class of PhRMA notes that though the media focuses on companies that do go to China, India and Singapore, 70% of R & D has still remained in the U.S reflecting that countries continued competitiveness for biotechnology research. Further, he highlighted the recent WHO bioguidelines that were issued on April 30th and noted that Israel incorporates some of these guidelines that follow consensus of the model in the U.S., Canada, Japan, Singapore, Europe, Australia and many Asian countries, that Israel will have an even stronger policy environment for growth in Biotechnology.

Mr. Zelig also noted that Genzyme, which does have an R & D Center in Israel, that although IPR issues are definitely a key point considered by business directors, that spreading R & D too thin is also a key issue. Rather than seeing an expansion of dedicated multinational R & D centers in Israel, Mr. Zelig says that what we might see instead is a growing number of co-operative relationships which are already sprouting up with universities, hospitals and the government of Israel.

Susan Finston offers another perspective on the issue of locating R & D centers in Israel. She suggests that companies are looking for three things when they choose to locate a research center abroad, first, they are seeking an enabling environment for science and there is no other country with the high levels of spending per capita on science quite like Israel. Second, they are looking for intellectual property under rule of law, an area that is improving in Israel. Third, and most interestingly in terms of Israel, in terms of research ethics, they are looking for countries where they can not only run clinical trials and test their therapies, but where they can also sell them so as to broaden access to a new therapy. She points out that companies need to know that they will be able to have their new therapies included in the 'kupat holim' or treatment basket of the national HMO.

Further, regarding locating R & D centers in Israel, Mr. de Garidel pointed out that between health care reform and the slowed economy, companies see their margins growing smaller, especially in the U.S. market. It will be harder to justify to shareholders new big R & D spending pushes in light of shrinking margins. However, this will also be a time of great change within companies and it might just be a good time for Israeli players to make moves to for more partnerships with large companies.

Financial Issues

Another issue touched on by the participants is the difficulty of small Israeli companies of securing credit and loans in the United States to establish centers there. A participant suggested developing agreements between banks to make the process of securing references and transferring established credit histories across borders.

Patent Strength Issues

Mark Feldstein noted the importance of writing strong patents from the beginning stages for small Israeli companies, suggesting that even if IP protection is strengthened some companies may find challenges to growing in the United States or to working with large multinationals if their patents are not strong, especially as the issue of bio-similars emerges. Dr. Ora Dar, Life Science Advisor noted that the OCS has programs to help companies write strong patents.

Collaboration and the Value of Scientific Exchanges

Dr. Doina Roman of Takeda Pharmaceuticals was asked to share more about Takeda's goals in the United States by Limor Nakar-Vincent of the BIRD Foundation. Dr. Roman said that Takeda is interested in developing more co-operative connections with U.S universities and Israeli universities and even pharmaceutical companies to locate targets and therapies earlier.

Cathy Frederickson of Andro Diagnostics pointed out the benefits she sees in scientist to scientist exchanges as the level of small businesses in addition to cooperation at the multinational or university level. She has worked with Israeli scientists to bring their work to the United States for commercialization.

FDA Regulations

Ronen Tamir of Rosetta Genomics brought up the issue of FDA regulations as the U.S. tends to be the first primary market of new biotechnology products coming out of Israel. Israel companies often dedicate significant budget to making sure that they are in line with FDA regulations regarding all aspects of their product from pre-clinical stages through to marketing. Other participants also pointed out the wealth of information published online by the FDA about all aspects of approval and the contact numbers of relevant FDA staff that could be reached directly by Israeli companies. In fact, Zami Aberman of Pluristem has had studies approved by conference call from Israel.

Dan Gincel who also runs an organization, Bio Abroad, in addition to his role at the Maryland Stem Cell Research Fund, brought up an program that he has been working on to develop internships for Israelis in the FDA that will equip them to become special consultants on FDA regulatory procedure in Israel to benefit Israeli companies seeking guidance.

State Economic Development

Jessica Eads of the Missouri State Economic Development Office noted that from small communities in Missouri all the way to the state Governor Jay Nixon, Missouri recognizes the entrepreneurial spirit that lies in Israel and that Israel is incubating a number of early stage companies that are poised for growth. Missouri has tried to develop a soft-landing approach. For example, her office will try to assemble financing and facilitate logistics for those types of companies to establish bases in Missouri, a relatively low-cost state that will open access for them to the U.S. market. Further, her office also tries to identify collaborative opportunities with Missouri based research institutions to further development ties with Israel.

David Miron Wapner, Director of the U.S.-Israel Science and Technology Commission is working alongside USISTF and the OCS to develop relationships between the OCS and individual American states to support mutually beneficial R & D activities. OCS has already developed framework agreements with Maryland, Virginia, New York, Wisconsin and is in discussions with Ohio, California and Missouri.

Conclusions

Following the discussions of the U.S.-Israel Biotechnology Business Roundtable, USISTF has identified four areas for further discussion and consideration in order to grow the biotechnology relationship between the United States and Israel.

1. We should use this opportunity to continue considering technical steps that need to take place to expand R & D centers of U.S. companies in Israel.
2. We need to look at ways to build off successful clinical trials in Israel to expand this industry that is beneficial to companies in both countries.
3. We should look at ways to increase all scientific exchange from the major industry and university to the small business and individual scientist level.
4. We should consider ways to increase understanding of FDA processes in order to expedite the processes of bringing products and services from Israel companies to the U.S. market. We should also consider how this can be done in light of the coming permanent FDA representation in Amman, Jordan. We might also consider bringing deeper FDA process knowledge to Israel through Israel resident U.S. citizens participating in formal FDA regulation internships.

Participants:

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Woman – Yisum

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