

[TRANSLATED FROM THE HEBREW]

[Newspaper article appearing in TheMarker, November 29, 2007]

The Baxter Pharmaceutical Company is Examining the Purchase of Four Israeli Companies

In an interview with TheMarker, the chief scientist for Baxter says that the company has no problem with the intellectual property laws in Israel. Its representatives are also examining the possibility of cooperating with academic institutions.

By Ora Koren

Baxter's fields of operation: pharmaceuticals, biotechnology and medical services.

Sales: 10.4 billion dollars

Research and development costs: 614 million dollars

Number of employees: 45,000

Specialties: hemophilia, cancer, kidney diseases and immune system problems

US pharmaceutical company Baxter has decided to become active in Israel. The company, whose 2006 sales turnover exceeded the \$10 billion threshold, appointed a team headed by the company's chief scientist Dr. Norbert Riedel. The team arrived this week for its first visit to Israel, and met with 12 biotechnology companies that were selected from amongst 50 companies. The selection was made by staff at the company's headquarters in the United States, and staff at the investment promotion branch of the Ministry of Industry, Trade, and Labor. Riedel also met with representatives of the commercial arm of the Weizmann Institute of Science and Hadasit [The Technology Transfer Company of Hadassah University Hospitals].

Riedel will recommend that Baxter hold negotiations with at least four Israeli companies and, it would seem, also with academic research institutions. According to him, the company may purchase Israeli companies or offer to cooperate with them through joint licensing, marketing or development of products.

Baxter employs about 45,000 workers in 120 countries worldwide. The company was established 75 years ago and specializes in a wide range of health fields, including the development of molecular biology medication, immunization, medical instrumentation, medication transporters through the body and medical software and hardware.

“The quality of science here is high”

According to Riedel, his team came to Israel to examine the potential for technological products and platforms that are compatible with Baxter's product and strategy portfolio. “The company is involved in broad fields, and in Israel we are interested mainly in innovation and technology”, he said. “We estimate that there are

many biotechnology companies here that would be suitable as strategic partners for Baxter”.

What does strategic partnership mean?

“It could be anything, from initial technology or product licensing, co-operation in development or worldwide marketing, because we have good connections in many markets”.

Are you considering setting up a research and development center in Israel?

“Our focus at the moment is to locate a research and development partner. It could be in the centers of excellence that we have seen in the Weizmann Institute and Hadasit, or in one of your 700 biotechnology companies. I can’t, at this stage, say where it will lead. I am not ruling out the setting up of a research and development center, but I’m also not including it in our current plans. In our experience as a global company, one does not need to be present at a particular location in order to develop strategic partnerships”.

Similar to the heads of German pharmaceutical giant Merck that recently visited Israel, Riedel was also surprised to hear of criticism that US companies have with respect to pharmaceutical and intellectual property laws in Israel. According to him, Israel is effectively protecting intellectual property. “Israel has a high level of innovation and patents, and it is a world leader in the number of patents per capita”, he said. “There is excellent intellectual property here and it has strong protection. Most of the patents cover the main world markets, in the United States and Europe, which are important to us as well”.

The majority of complaints concerning intellectual property in Israel relate to the priority given to Teva’s generic product manufacturing, as opposed to that of new drugs. But according to Riedel, in any case Teva is not a direct competitor of Baxter. “Teva is primarily a generic player, and our focus is on the development of types of treatments that do not fall within the ambit of generic competition” he said. “We have rights over our products, low production costs and customer loyalty. Generic companies are not easily able to harm our strong brands”.

How does the Israeli biotechnology industry size up in comparison with the rest of the world?

“I am familiar with biotechnology companies in the United States, Germany and Britain. After a day and a half in Israel, I can say that technology here is most interesting and the focus is well-placed, particularly for incurable illnesses. The range of companies is also interesting. There are many young companies here, but also some with a product that is under development and already at the human clinical trial stage. I am leaving with the feeling that the level of science here is very high, the technology is marvelous and the number of start up and biotechnology companies is very impressive”.

[TRANSLATED FROM THE HEBREW]

[Newspaper article appearing in the TheMarker, November 20, 2007]

Chairman of Merck Germany: “I have no problem with the pharmaceutical and intellectual property laws in Israel”

This, in contrast to other international pharmaceutical companies that argued over the last few years that the Israeli law harms their rights. Yesterday the chairman of the company signed an agreement for supporting Israeli pharmaceutical companies

By Ora Koren

In an interview yesterday with TheMarker, Dr. Karl-Ludwig Kley, chairman of the German pharmaceutical and biotechnology company Merck, stated: “I have no problem with the pharmaceutical and intellectual property laws in Israel”. “These issues were not even raised when I examined our entrance into Israeli operations”, he added. Yesterday Kley signed an agreement with the Chief Scientist at the Ministry of Trade, Industry and Labor for supporting Israeli companies engaged in the development of pharmaceuticals and chemicals.

Over the past few years international pharmaceutical companies have argued that the Israeli pharmaceutical law harms their copyrights [*sic*]. They claim that multinational pharmaceutical companies will not open research and development centers in Israel until the laws are changed. These companies, including Johnson & Johnson and Pfizer, even convinced the Office of the US Trade Representative to place Israel on a critical list of countries infringing copyrights [*sic*], as a means of exerting pressure to change the law. An economic interest lies behind their position: to restrict Teva’s steps, which develops copycat (generic) drugs which are eating away at their market share.

Will the level of intellectual property protection in Israel harm cooperation between Merck and Israeli companies?

Kley: “I’m not aware of any problem which would make our cooperation with Israeli companies difficult”.

What are your expectations from the new operations in Israel?

Kley: “Israel is well-known for its very high quality of scientific research, as well as for its creativity and innovation in those fields which interest us. I therefore expect to find in Israel new technologies, new products and approaches to treatment which we can develop jointly. It would be a win-win situation for both parties.”

Do you intend to establish in the future a research and development center in Israel?

Kley: “The first step will be to see how the cooperation works between the companies. During the merger process between Merck Pharmaceuticals and Serono we reduced the number of research and development centers to three. In Israel we will concentrate for the time being on the success of the cooperation – and this means that we will invest money in companies and people”.

What is the scope of the planned investment in Israel?

Kley: “The investment will depend on the number of projects, and it will increase as cooperation progresses. The key here will be defining appropriate projects and locating scientists. In our meetings here over the past two days we learned that there are many Israeli companies that are interested in cooperating with us in developing projects. I assume that the amount which will be invested will be significant”.

More companies are on the way to Israel

During the agreement’s signing ceremony Kley expressed his personal commitment to the success of the cooperation. The Chief Scientist at the Ministry of Industry, Trade and Labor, Eli Ofer, said that the agreement with Merck constitutes a significant development for the biotechnology industry and a further step in implementing the national program for prioritizing biotechnology which his office announced.

Merck operates in about 60 countries worldwide. The company’s turnover amounts to more than € billion and employs around 30,000 employees.

Lately pharmaceutical and biotechnology companies have expressed interest in entering into operations in Israel. Some of them have in the past expressed criticism of the pharmaceutical and intellectual property laws in Israel which, they believe, harm their rights. This matter was raised in meetings which the Minister of Industry, Trade and Labor, Eli Yishai, recently held with the heads of the Office of the US Trade Representative. At the end of those talks Yishai announced that he would examine the United States arguments on this matter. However, the Ministry of Industry, Trade and Labor stated that Yishai did not promise to change the law.

Congress of the United States
Washington, DC 20515

April 20, 2007

The Honorable Susan Schwab
United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear Ambassador Schwab:

We write with regard to Israel's status on the United States Trade Representative (USTR) Special 301 Report for 2007. It is our understanding that the USTR has been encouraged to designate Israel on the "Priority Watch List". While we recognize that concerns may exist with regards to Israel's Intellectual Property Rights (IPR) laws, we strongly feel that this recommendation is unwarranted and we urge you to remove Israel from the list.

First, in recent years, Israel has made great strides – working closely with the United States – to update and improve their intellectual property laws relating to data exclusivity and patent term restoration. Data exclusivity is allotted for 5 ½ years from the date an innovative drug is first approved for use in a recognized country¹, or five years from the date of approval for use in Israel, whichever is earlier. This model is adapted from the North American Free Trade Agreement (NAFTA). Patent term restoration is allotted for up to five years beyond the twenty-year patent term required under the most comprehensive multilateral agreement on intellectual property, the World Trade Organization (WTO) TRIPS agreement.

Israel's protections far exceed the current level of protection with regard to both data exclusivity and patent term restoration provided by many other countries on the "Priority Watch List" or the "Watch List". In fact, at least eight countries on the 2006 Priority Watch List lacked data exclusivity protections. Furthermore, at least 26 of the countries on the 2006 Watch List and at least eight Priority Watch List countries provide no patent term restoration protections.

Second, as you are well aware, trade relations are an integral component of our strategic partnership with Israel. The United States entered into its first ever free trade agreement with Israel in 1985, and since then trade has been key to maintaining a mutually beneficial and strong U.S.-Israel relationship. We are concerned that Israel's designation on the Special 301 list impairs this trade relationship, and is ultimately detrimental to our relations with our most important ally in the Middle East.

Given the level of protections provided by Israel, and the importance of the U.S.-Israel relationship, it is extremely concerning that the USTR in 2005 elevated Israel from

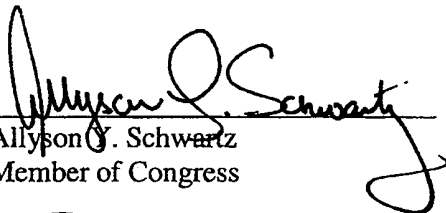
¹ A "recognized country", as defined in the Pharmacists Regulations (Pharmaceutical Products), 1986, includes any one of the following countries: United States, Canada, the EU member states, Norway, Switzerland, Iceland, Japan, Australia and New Zealand.


"Watch List" status to "Priority Watch List" status, and in 2006 maintained Israel on the "Priority Watch List". Israel has made substantial efforts to provide adequate intellectual property protection while ensuring access to medicines for its citizens. Therefore, we respectfully request that Israel be removed from the USTR Special 301 Report.

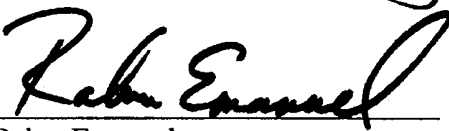
We would also like to take this opportunity to ask the USTR to provide Congress a rationale for its development of Special 301 standards and designations for determining the adequacy and effectiveness of the intellectual property protections enforced by U.S. trading partners. Given our concerns over Israel's placement on the list, we are interested in ensuring that the development of the Special 301 Report is more transparent and fair -- providing an understanding of how information is collected among various U.S. agencies and how submissions from private stakeholders are assessed in formulating each annual Special 301 Report.


We appreciate your consideration of our concerns and requests and look forward to working with you to ensure that the development of the Special 301 Report is a transparent and fair process and the report itself serves as a useful and balanced guide to intellectual property protections around the world.

Sincerely,

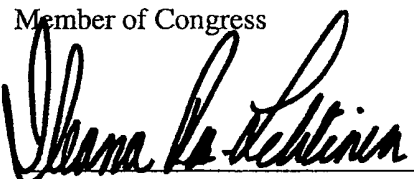

Allyson G. Schwartz
Member of Congress

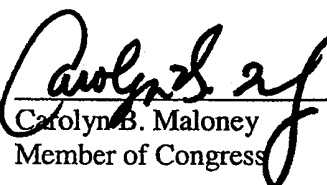

Henry A. Waxman
Member of Congress

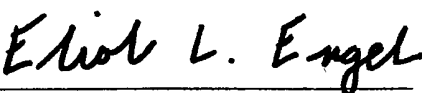

Rahm Emanuel
Member of Congress


Eric Cantor
Member of Congress


Tom Lantos
Member of Congress


Heana Ros-Lehtinen
Member of Congress


Carolyn B. Maloney
Member of Congress


Eliot L. Engel
Member of Congress



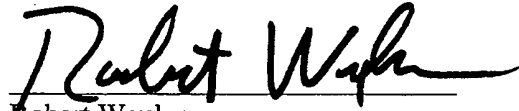
Steve Israel
Member of Congress



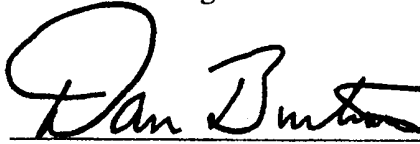
Ron Klein
Member of Congress



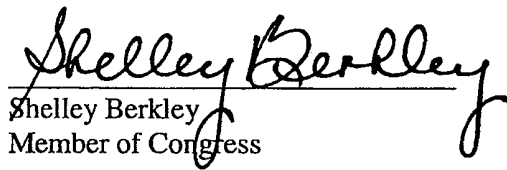
Michael R. McNulty
Member of Congress



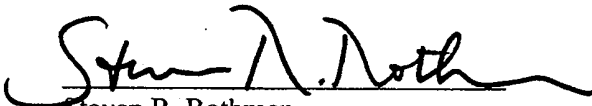
Robert Wexler
Member of Congress



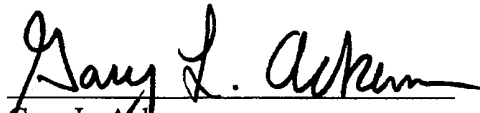
Dan Burton
Member of Congress



Shelley Berkley
Member of Congress



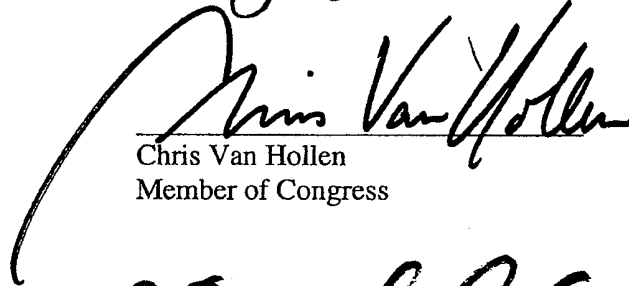
Steven R. Rothman
Member of Congress



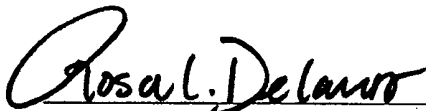
Gary L. Ackerman
Member of Congress



Jane Harman
Member of Congress



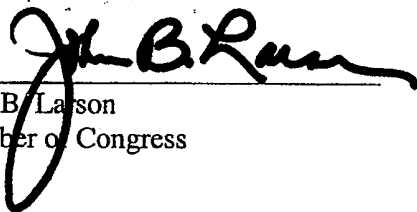
Chris Van Hollen
Member of Congress



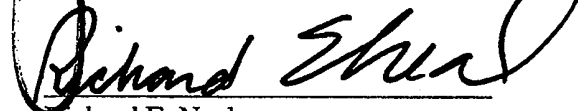
Rosa L. DeLauro
Member of Congress



Janice D. Schakowsky
Member of Congress



John B. Larson
Member of Congress



Richard E. Neal
Member of Congress

United States Senate

WASHINGTON, DC 20510

April 23, 2007

The Honorable Susan Schwab
United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear Ambassador Schwab:

We would like to take this opportunity to write to you regarding Israel and the United States Trade Representative (USTR) Special 301 Report for 2007.

Like you, we support the protection of intellectual property and the promotion of fair market access for U.S. products. We also believe that these important aims should be realized in an honest and impartial fashion. As you conduct your annual review of intellectual property laws in various countries, we therefore urge you to present a fair and balanced report with respect to Israel.

It is our understanding that USTR has been encouraged to once again place Israel on the Priority Watch List. We urge you to reject this recommendation because Israel has provided industry with strong intellectual property protections, including strong data exclusivity and patent term restoration protections, which exceed internationally-agreed upon standards.

For example, in Israel, data exclusivity is allotted for 5½ years from the date that an innovative drug is first approved for use in a recognized country,¹ or five years from the date of approval for use in Israel, whichever is earlier. This rule was adopted from the North American Free Trade Agreement (NAFTA). Furthermore, the rule exceeds the data protections afforded by Article 39.3 of the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), which does not establish any period of exclusivity.

Similarly, Israel's patent term restoration rules exceed the standards set forth in both TRIPS and NAFTA. In fact, patent term restoration is available in Israel for up to five years beyond the twenty-year minimum term required under TRIPS. NAFTA does not require parties to grant patent restoration; Article 1709.12 simply states that parties *may*

¹ A "recognized country," as defined in the Pharmacists Regulations (Pharmaceutical Products), 1986, includes any one of the following countries: United States, Canada, the EU member states, Norway, Switzerland, Iceland, Japan, Australia and New Zealand.

extend the term of patent protection, in appropriate cases, to compensate for delays caused by regulatory approval processes.

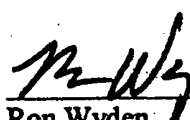
It is our understanding that Israel's intellectual property protections far exceed the levels of protection in many, if not most, of the other countries on USTR's Priority Watch List and Watch List. In fact, at least eight countries on the 2006 Priority Watch List lacked data exclusivity protections and patent term restoration protections. Additionally, at least twenty-six of the countries on the 2006 Watch List failed to provide patent term restoration.

Given its intellectual property protections, it is extremely concerning that USTR placed Israel on the Priority Watch List in 2005 and 2006. The repeated listing of Israel on the Priority Watch List in the Special 301 Report raises questions about USTR's development of the report. In order to fully understand the process and ensure fairness, we ask you to provide answers to the following questions:

- What factors does USTR consider when deciding whether to place a foreign country on the Special 301 Watch List or Priority Watch List?
- How are these factors weighted?
- What information does USTR rely upon in making its Special 301 determinations?
- Are the views of US industry given special consideration and if so, what amount of special consideration are they afforded?

We urge you to reconsider the strength of Israel's intellectual property laws and remove it from the Priority Watch List. We look forward to working with you to ensure that the development of the Special 301 Report is a transparent and fair process and that the report itself serves as a useful and balanced guide to intellectual property protections around the world.

Sincerely,


Ron Wyden
United States Senator


Sam Brownback
United States Senator


Chuck Schumer
United States Senator

Saums, Edmund

From: Groves, Jennifer C.
Sent: Friday, April 27, 2007 12:34 PM
To: Saums, Edmund
Subject: FW: Senate finance 301 call/general ip briefing

See Israel and 301 readout from Hill briefing today.

-----Original Message-----

From: McCoy, Stanford
Sent: Friday, April 27, 2007 12:31 PM
To: Espinel, Victoria; Wilson, Christopher S.; Groves, Jennifer C.; Ellis, Sarah E.
Subject: RE: Senate finance 301 call/general ip briefing

Brazil did not come up. We had only 2 people, Amber + Alex (Wyden). Amber's questions were on Thailand, and I gave her the Q&A answer emphasizing CL was not the main concern. She asked if we had drawn any conclusions re TRIPS consistency of what Thailand did; I said no, and we acknowledged CL was possible under TRIPS, our concerns were mainly process. She said do we normally criticize countries for doing things that are consistent with TRIPS? And I said we hadn't concluded it was consistent either, but we did have concerns about the process and climate implications and as to TRIPS we do not limit ourselves to the TRIPS minimum in our concerns, as seen for example with China.

Wyden staffer questions were all on Israel. He asked do we set out a set of PWL criteria in this year's report, and I said no we have not had a scorecard like that in the past and do not have one now. He asked if we limit our criticisms to TRIPS, I said no we do not limit our concerns to the TRIPS minimum, and our expectations about Israel are shaped by its advanced level of development; disappointing that Israel has done little to work with us to resolve those concerns. He said they are concerned about our lack of USTR transparency of criteria on Israel, said we'll be hearing more from them about this. Sarah suggested we do a separate Israel call.

We need a Q&A for Monday on Israel.

[TRANSLATED FROM THE HEBREW]

[PRINTED ON THE LETTERHEAD OF]
THE MINISTER OF HEALTH

With God's help

October 30, 2007
Our reference: 12-52589/100(m)
(In your response, please cite our reference number)
File - Pharmaceuticals 52

To
MK Eli Yishai
Deputy Prime Minister and
Minister of Industry, Trade and Labor
Ministry of Industry, Trade and Labor
5 Bank of Israel St.
Jerusalem

Dear Sir,

Re: Intellectual Property in Pharmaceuticals

Lately we have learned of your intention to alter the intellectual property laws in the field of pharmaceuticals, in order to apparently draw further investments by multinational pharmaceutical companies to the State of Israel.

We were surprised to learn from the attached article that the Ministry of Industry, Trade and Labor believes that Israel's intellectual property laws do not meet the accepted international norms; and this, contrary to the position of the Justice, Treasury and Health Ministries.

The handling of issues concerning intellectual property in pharmaceuticals has been ongoing for a number of years now, and has been successfully carried out by the inter-ministerial committee headed by the Ministry of Industry Trade and Labor, thus for example, in 2005 the Knesset legislated an amendment to the Pharmacists Ordinance which for the first time offers protection over information in the registration files for a period of five years from the date of registration, or five and a half years from the date of registration in a recognized country. Despite the provision of this protection and raising the intellectual property environment in Israel to a level which does not fall below that of Western countries or OECD member countries, some of the countries continue, with the encouragement of the international pharmaceutical industry, to argue without justification that there is insufficient protection. Unfortunately, we have learned that based upon this argument, these companies refuse to invest in Israel despite the fact that they are investing in other countries where intellectual property protection falls far below that of Israel, such as India, China and Russia. After Israel took significant steps in the field of intellectual property, the burden of proof is upon the multinational companies to operate and invest in the State of Israel, not only in clinical marketing trials but through investments in developing and manufacturing new pharmaceuticals.

Those issues which are in dispute are well known, as are their budgetary costs. Any change in the balance which was achieved would cost the health system tens of millions of shekels and would harm the availability to patients of essential and cheap drugs.

At a time when the health basket budget does not meet the entire demand for novel technologies, and scientific surveys indicate that greater numbers of people from the lower socioeconomic levels of society (among them the ultra-Orthodox sector and the pensioner sector) are forgoing the taking of drugs as a result of their high prices, I hereby inform you that I will not agree to any change of intellectual property laws that would come at the expense of the infirm and the health system budget, without full monetary compensation to the health budgets and the promise of continued availability of essential and cheap drugs to patients.

Sincerely yours

(signed)

MK Yacov Ben Yizri
Minister of Health