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The Rise of Teva: A Pharmaceutical Giant

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Production of the Copaxone drug, a revolutionary treatment for Multiple Sclerosis, by Teva Pharmaceuticals. Photo: Teva.

Teva Pharmaceutical Industries Ltd. has a nose for drug development—beyond its country of origin.

In March, the Israeli company announced that the U.S. Food and Drug Administration (FDA) approved QNASL™, its new nasal spray to treat allergy symptoms. The product is just the latest in the repertoire of medications that have made Teva a worldwide success. The company is also growing in influence financially and politically as it continues to produce both generic and brand name drugs in the U.S. pharmaceutical market.

“Today, one in seven prescriptions filled in the U.S. are filled with a Teva drug,” Denise Bradley, Vice President, Corporate Communications, Teva Pharmaceuticals-Americas, told JointMedia News Service.

However, with an upcoming leadership change, will Teva’s rapid growth slow down? According to a recent *Haaretz* report, Jeremy Levin, who takes over as Teva’s global CEO May 9, has set up a team to re-examine the company’s brand drugs under development. It is unclear whether this means Teva will halt or scale back research and development, and which of its products will be affected.

Teva boasts a presence in 60 countries, employs about 40,000 employees, and had \$16 billion in sales in 2010. Eli Hurvitz, Teva’s former CEO who was widely regarded as responsible for turning the company into a global pharmaceutical powerhouse, died in November 2011. Levin will take over for current CEO Shlomo Yanai, who is retiring.

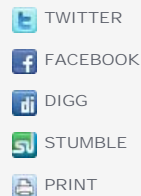
The company has also entered the national contraception debate. Teva had spent several years conducting trials in collaboration with the FDA over its Plan B One-Step, a one-pill emergency contraceptive. The FDA then decided to approve the pill for over-the-counter sale without an age restriction and chose to grant Teva three years of exclusive rights to sell the brand. The FDA had also concluded that generic versions of Plan B do not meet the same standards.

In December 2011, Health and Human Services (HHS) Secretary Kathleen Sebelius blocked the FDA motion, a first for the HHS. Since then the Center for Reproductive Rights has reopened a federal lawsuit seeking to overturn this action, and make the sale of Plan B One-Step, and any generic drugs equivalent to it, be unrestricted and over-the-counter. Teva has intervened in the lawsuit in an effort to defend the three years of exclusive marketing rights it was originally granted by the FDA.

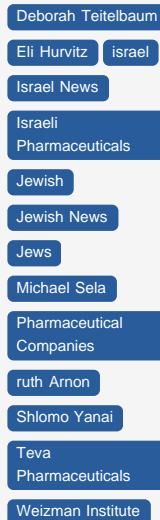
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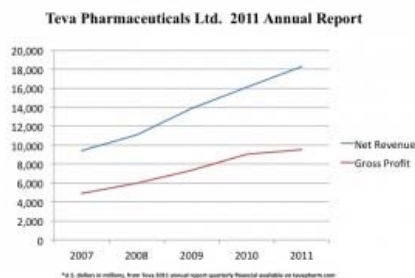
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From a small business to a global player

The story of how Teva grew from a small business to a company with global financial success and political impact begins in the 1930s. Elsa Kuver and Dr. Gunter Friedlander founded Teva (meaning “nature” in Hebrew) in Jerusalem. According to the Israel Ministry of Foreign Affairs, Teva initially sold imported medications, especially from Germany, until the supply dwindled with the rise of the Nazis. During this time, the Arab League still boycotted Israeli-manufactured products and goods, including pharmaceutical drugs. According to a *Wall Street Journal* report in 2004, the enactment of a patent act in 1967 allowed Israeli companies to make generic versions of foreign patent-protected drugs as long as they were not being marketed in Israel.



A chart indicating the growth of Teva Pharmaceuticals from 2007-2011. Photo: Illustration by JointMedia News Service.

Teva's entrance into the generic drug business, as well as years of aggressive mergers and acquisitions, catapulted the company to global success. But a few other factors were at play. During the 1980s, Teva expanded its activity in the field of medical devices by acquiring two companies that allowed it to produce both Penicillin and non-Penicillin drugs. “The separation, an essential requirement of the health authorities, paved the way for Teva's entry into the U.S. market, thus establishing its position as an international company,” Bradley said.

Teva also introduced Copaxone to the commercial drug market. A revolutionary drug treatment for Multiple Sclerosis, Copaxone was the first Israeli drug approved by the FDA, in 1996. It was

developed by Professor Michael Sela, Ruth Arnon, and Deborah Teitelbaum of the Weizman Institute of Science in Rehovot, Israel.

“Copaxone is a polimer of four amino-acids” used to treat multiple sclerosis patients who experience periods of heavy symptoms followed by periods of lighter symptoms, Sela told JointMedia News Service. The drug can dramatically decrease the number of heavy symptom periods. Teva also markets another major branded drug, Azilect, the first once-daily treatment for Parkinson's disease.

Sela and Hurvitz, Teva's former CEO, had been friends long before Copaxone entered the picture. Hurvitz immediately decided to produce the drug after a dinner with Sela, where the scientist presented him slides about the invention. Today, Copaxone “is responsible for 30 to 50 percent of Teva's net income,” Sela said, and he has remained on the company's board of directors for nearly two decades.

Producing both generic and original medications, the company is always either defending the patents it holds on its own brand medications, or challenging the patents of other companies so that it can produce generic versions of the drugs. The patent on Copaxone will run out in 2014, but other drug companies are already challenging the validity of the patent. This month Teva sued Synthon BV for trying to sell a generic version of Copaxone before the expiration of the patent owned by Teva.

Furthermore, Yanai, Teva's current Global CEO, has claimed that “a generic version of Copaxone is not possible because of its complex chemical identity,” meaning that elaborate clinical trials will be necessary for the drug to gain FDA approval. That will not happen by 2014, he told the *Jerusalem Post* in 2010.

As for Plan B, Teva representatives refused to comment on the issue, but the Center for Reproductive Rights provided a statement from Suzanne Novak, senior staff attorney for the organization. “An intervention by Teva Pharmaceuticals would distract from the issue at hand — that FDA has placed politics over science time and time again. The agency has continued to treat women's reproductive health differently without justification, repeatedly failing to give emergency contraception a fair review,” Novak said. A hearing is scheduled for April 27 to discuss Teva's motion to intervene in the lawsuit, the center told JointMedia News Service.

In addition to the issue of contraception, last year a U.S. court dismissed Teva's challenge to the patent for Viagra by Pfizer Inc., blocking Teva from marketing a generic version until 2019. Recently, another company — AstraZeneca — lost a battle in a U.S. court to extend a patent on Seroquel XR, a Schizophrenia and Bipolar Disorder medication.

Sure enough, according to reports, Teva is launching the sale of a generic version.

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THEATER



Olympia Dukakis Performs One Woman Monologue Show at Theater Festival

Ynet – American actress Olympia Dukakis on Thursday arrived in Israel as a guest of the annual international theatre festival held at the Cameri Theatre. Dukakis will perform “Rose” – a one-woman play by Martin Sherman. “Rose” is a monologue of a Jewish Holocaust survivor, who lost her daughter in World War II and sits shiva for a Palestinian girl who was shot by her grandson. Read full story

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He’s already been inducted into the National Jewish Sports Hall of Fame, but don’t tell Virginia Tech men’s basketball coach Seth Greenberg that his Jewish sports legacy is complete. Greenberg was recently appointed as head coach for the U.S. Maccabiah Games men’s basketball team. The 19th Maccabiah Games will be held in Israel in July 2013, when the U.S. hoops team hopes to duplicate the 2009 squad’s feat of winning the gold medal. That team was led by then University [...]

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Eighteen violins from European Jewish communities destroyed during the Holocaust are now being heard nearly 70 years later in North Carolina. Amnon Weinstein began collecting the instruments in 1996, some of which were played by Jews inside Nazi concentration camps while others “belonged to the Klezmer musical culture”, according to the “Violins of Hope” website. “When I play one of these instruments, I go through that same process of discovering what makes this instrument sound the best,” University of North [...]

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15th Century Jewish Prayer Book Expected to Fetch Over Half a Million Dollars (PHOTOS)

Christie’s New York will be unveiling to the public for the first time since it’s creation in Tuscany during the late 15th century, an extremely rare Jewish prayer book believed to be the only work of its kind by Giovanni di Giuliano Boccardi. The 400 page Hebrew book was purchased in Frankfurt in the early 20th Century and covers an entire year’s worth of prayer, from Passover to Yom Kippur. A coat of arms on the front of the book [...]

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“Entry to Jews is Forbidden” T-Shirts on Sale at Polish Soccer Games

Israel National News – Tee shirts with anti-Semitic slogans are being sold outside the Polish football club, Widzew Lodz, Polskie Radio reported on Thursday. The items have been on sale in a pavilion next to the club’s official shop. “This is Widzew terrain, entry to Jews is forbidden,” reads the slogan on one Tee shirt. Read full story.

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