

# Intellectual property law in Israel, and US and European objections: Market exclusivity vs. data exclusivity

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Can Israel balance the rights of multinational drug companies with its own generic pharmaceutical industry?

Intellectual property (IP) rights to pharmaceuticals have recently been at the center of public debate and controversy in Israel. The debate focuses on some aspects relating to the proper balance between rights provided to innovators on the one hand, and freedom of operation of others, primarily generic pharmaceutical companies on the other hand.

In 1998, the Israeli Patents Law was amended by introducing patent term extension (PTE) provisions that permit extending the life of a patent beyond the normal 20-year term, to compensate for the regulatory delays in obtaining marketing approval<sup>1</sup>. As a balance, the legislators also introduced provisions exempting from infringement any act taken for the purpose of developing a generic substitute of a patented pharmaceutical, to be marketed after the patent expires. By this amendment Israel followed in the footsteps of many industrialized countries, including the United States and European countries, among others<sup>2</sup>.

Israel has a very strong generic pharmaceutical industry, including Teva Pharmaceutical Industries (Petach Tikva)—which is today one of the world's leading generic drug companies—and others. Clearly, given the relatively small size of the Israeli market, the main mar-

kets for the generic pharmaceutical industry are other countries, primarily the US. To cater to the needs of this industry, and unlike the laws in other countries, the infringement exemption in Israel applies not only for developing a generic substitute of a patented drug for marketing locally after the patent expires, but also for the purpose of marketing it in another country that has PTE provisions, on the one hand, and a similar exemption, on the other hand. Not surprisingly, this broad exemption was met with criticism and concern among multinational pharma companies and other pharma patent holders, and was also a topic of debate on the diplomatic level between Israel and the US. These concerns have heightened also in view of some recent voices calling for amendment of the PTE provisions to the detriment of innovators.

Other than by way of patents, the pharma industry has traditionally relied on market exclusivity and data exclusivity in maintaining its exclusivity in new drugs. Market exclusivity is a time period after approval to market a drug and may be granted in some instances to a first company by regulatory agencies, such as the Food and Drug Administration in the US. There is no market exclusivity in Israel yet. Within the market exclusivity period the regulatory agency will not grant approval to a second company to market the same drug. Data exclusivity is the confidentiality of the regulatory file submitted to regulatory authorities.

The 'catch-22' is that to be able to proceed with an abbreviated (and hence much shorter and less costly) drug approval process, the generic pharmaceutical developer needs to show equivalence to an existing drug. However, without having access to the regulatory file, this is, of course, not possible.

Most industrial countries have provisions ensuring data exclusivity for several years, but no such provisions exist in the law that governs the regulation of pharmaceuticals in Israel<sup>3</sup>. Thus, generic drug developers are currently allowed to exploit the files to manufacture and register drugs for marketing in Israel (subject to other rights, e.g., patent rights) and for export, such as to a developing country where especially reasonably priced pharmaceuticals are desperately needed. However, this freedom to operate that has hitherto helped Israel build its pharmaceutical industry has precipitated concern in the US and Europe.

The Israeli government decided recently to grant a 5-year pharmaceutical marketing exclusivity for new products marketed within Israel. Although a period of market exclusivity should be welcomed, it nonetheless raised concerns as it pertains to products only and not data<sup>4</sup>. That is, the 5-year pharmaceutical marketing exclusivity in Israel does not provide confidentiality as to the regulatory data, and would permit access to drug registration files for the purpose of producing generic drugs in Israel for export. As a result, the US and European Union have been pressuring Israel to introduce data exclusivity provisions into the applicable law in Israel.

In May 2004, the US stated that it perceived "serious shortcomings" in Israel's proposed legislation. The US then announced that it may put Israel back on its "priority watch list" of countries that violate IP rights (it had been removed from that list in 2003). However, the US ultimately reversed its decision to downgrade Israel to its priority watch list<sup>5</sup>.

Further, in September 2004, commercial representatives of Germany, France, Denmark and Switzerland voiced concern, believing that

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Israel may be unwilling to honor European trade agreements. Denmark's representative, Daniel Shemi, was quoted as saying, "The damage caused to the Israeli drug and medical industries and the terrible blow to Israel's international image as a result of its intellectual property policy hurt its economic and medical interests"<sup>6</sup>.

The pressure peaked in October 2004, with the visit to Israel by the US Trade Representative, Robert Zoellick. The issue of data exclusivity for ethical pharmaceuticals was one of the main topics of his visit. It appears that the Israeli government may be yielding to the pressure, declaring its intention to change the law and introduce data exclusivity. Indeed it has been publicly stated there has been progress between Israel and the US on IP rights in the pharmaceutical sector, and that the issues have been narrowed<sup>5</sup>. However, no law to this effect has been passed to date, and there is no deadline for Israel to come up with a revised proposal that would satisfy the US. Moreover,

there is strong lobbying against it by the generic drug industry.

Thus, the issue is still being heavily debated within Israel. How the debate is resolved is yet to unfold, but eventually, a balance will probably be struck between the interests of those who first market a drug to have exclusivity, and the need of generic pharmaceutical developers to not be burdened by an undue period of exclusivity.

Israel's past record of defending and respecting IP rights has led major companies around the world to file patent applications in Israel, and seek Israeli patents. Because Israel seems to be further debating the issue of data exclusivity, with a view towards reaching some sort of accommodation with the US, the US appears to applying less pressure.

However, with the recent reelection of US President George W. Bush, as well as an increase in the Republican majority in Congress, Israel may not yet be in a position to breathe a sigh of relief. The current dispute

intensified under President George W. Bush, and it is worth mentioning that major drug manufacturers are on a list of the 30 leading contributors to the Republican, but not the Democratic party<sup>7</sup>. The spotlight may remain on Israel to have a data exclusivity provision in its law. Therefore, it seems that Israel may need to reach an accommodation with the US and Europe sooner, rather than later, on the issue of data exclusivity to avoid being put back on the priority watch list.

1. Amendment to *The Patents Law*, 5727-1967 (1998 Amendment).
2. See 35 USC 155, 155A, 156, 271(e); Proposed directive amending directive 2001/83/EC, Article 10.4.
3. *The Pharmacists Ordinance*, New Version (1981). Laws of the state of Israel, State of Israel.
4. US, Israeli officials to tackle dispute over drug data exclusivity. *IP Law Bulletin* (October 11, 2004).
5. US, Israeli negotiators make progress in talks on drug IP rights. *IP Law Bulletin* (October 17, 2004).
6. Intellectual property bill risks US censure. *Jerusalem Post* (September 9, 2004).
7. Drugs vote Republican, which may be why the US is pressing Israel so hard on IP. *Globes Online* (September 26, 2004).