ISRAEL

DEVELOPMENTS IN ISRAELI PATENT LAW 2000-2002

I. Amendments to the Patents Law, 5727 – 1967

Accommodation to TRIPs

On January 1, 2000 came into force an amendment to the Patents law, 5727 – 1967 ("the Law") which purpose was to bring the Law into conformity with the requirements of the TRIPs Agreement (World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights Including Trade in Counterfeit Goods). The main amendments, which were made, concerned the broadening of the definition of a "patentable invention", the reversal of the burden of proof in case of infringement of process patents and the elimination of compulsory licenses for most cases. The following is a fuller description of the amendments.

- Changes in the definition of a patented invention

Before the amendment, Section 3 of our Law, defined a patented invention as including any invention which could be used in industry or agriculture. This was at times given a narrow interpretation.

Section 3 was amended to include invention in "*any technological field and which may be used in industry*...". The law has not specified what the term "industry" means, but based on the explanations included in the blueprints of the law, as submitted to the Knesset (the Israeli Parliament) it is clear that the amendment was meant to encompass the broad requirement of Article 27 TRIPS not to discriminate between different types of inventions.

- Process Patents: shifting of burden of proof

The concept of shifting of the burden of evidence in case of process patent infringement was already stipulated in Section 50(b) of the Law. Until January 1, 2000 section 50(b) read as follows:

"50(b) A person contending that a certain product, that in the ordinary course of things is a direct product of the process subject of the patent, was not manufactured through said process – the onus of proof is on him."

The purpose of the amendment of section 50(b) was to alleviate the onus of proof imposed on the patentee, by omitting the requirement to show that that an accused product is is a direct product of the patented product in the ordinary

course of things, and thus to conform with the provisions of Article 34 of TRIPs.

The amended Section 50(b) now read as follows:

"(b) in connection with an invention that is the process for the manufacture of a product – in an action for infringement, the defendant must show that the process which he used to produce an identical product, is different from the process that is subject of the patent; for the purpose of this sub-paragraph, identical product produced without the consent of the product owner, unless proved otherwise, shall be deemed to have been obtained by the patented process if the following two conditions were met: 1. The patent owner has been unable through reasonable effort to determine the process which was actually used for the manufacture of the identical product; 2. There is a substantial likelihood that the identical product was made by the process."

However, the terminology used in the new section 50(b) of the law is different from that used in Article 34 of TRIPs, in the sense that according to TRIPs it does not matter who manufactured the product, while according to the new version of section 50(b) "the defendant must show that the process which he used to produce an identical product, is different from the process that is subject of the patent". This anomaly in the Law requires rectification.

- Compulsory licenses: limitations

The Compulsory Licenses Provisions have been amended in a manner that considerably limits the cases where compulsory licenses may be applied and further considerably limits the value of the compulsory license for the holder of such a license.

Compulsory licenses are available, in accordance with the Israeli Patent Law, in the case of abuse of monopoly (Section 119). In addition, the Law also contained provisions, which permitted the granting of a compulsory license for medicines, to ensure local supply of a medicine, even in the case of no abuse of monopoly (Section 120). Among the scenarios, which could have been regarded as an abuse of monopoly, was the provision of a product by way of import only and refusal of the patentee to grant a license to a local manufacturer. In addition, it was also possible, in the past, to obtain a compulsory license for the purpose of exporting a product outside of Israel.

Section 119 was now amended and in accordance therewith, provision of a patented product by way of import only is not considered any more as an abuse of monopoly and therefore does not constitute a ground for obtaining a compulsory license. Additionally, the specific provisions for granting a compulsory license for medicines were abolished. Furthermore, in accordance

with the amended law, the scope of the compulsory license will be "mainly for the supply of local market needs".

In all likelihood, this amendment will very much reduce the number of cases where a compulsory license may be available to or considered by the local industry.

II. Amendment to the Pharmacists Regulations: Parallel Importation of Pharmaceuticals to Israel

Since September 2000, parallel importation of a pharmaceutical became permitted in terms of the regulatory scheme applicable to pharmaceuticals.

One of the two major changes brought by the amendment is that any person or entity (and not only the manufacturer or its agent) may now apply for an Importation Permit of a registered pharmaceutical, if such applicant meets the terms prescribed by the MOH in accordance with the Regulations . The requirements for obtaining an import permit are not rigorous and can easily be met.

As yet another result of the amendment, any *Pharmaceutical Trading House* or any *Recognized Institution* may now import and market a pharmaceutical even if it is not registered in the Registered Pharmaceuticals Book, if such pharmaceutical is a *Compatible Preparation* and if, in addition, the requirements concerning transportation storage are met.

Late in 2000, several pharmaceutical companies filed a petition with the Supreme Court, asking the Court to nullify the amendment to the Pharmacists Ordinance. Among others , one of the arguments put forward by the petitioners was that the new law might be interpreted as permitting parallel importation of patented drugs. An additional argument advanced by the petitioners was that the statutory scheme described above violates Israel's TRIPS obligations, particularly in the area of data exclusivity (Article 39(3) of TRIPS) and effective enforcement measures (PART III of TRIPS; "Enforcement of Intellectual Property Rights").

In June 2001, the Supreme Court dismissed the petition, holding that IP issues are not the concern of the Ministry of Health ("**MOH**") and that the amended Pharmacists Regulations was neutral, as regards the issue of Intellectual Property protection. The court left it to patentees to challenge at court the permissibility of parallel importation. under patent law, and the applicability of international exhaustion doctrine. The final position of Israeli law regarding international exhaustion is yet to be resolved.

One of the arguments made by the petitioners was that the Amendment contravenes Israel's obligation under Article 39(3) of TRIPS to prevent unfair commercial use of the data contained on the registration file. The issue of Data Exclusivity was not the crux of the petition but the Supreme Court's position has serve as reinforcement to the position of the government, which, until now, was reluctant to promote data exclusivity legislation.

III. Contibutory Infringement

In the matter of C.A. 1636/98 *Rav Bariach v. Havshush Car Accessories Trading House* Ltd. PD 55(5), 337, the Supreme Court introduced by way of judicial legislation, the concept of Contributory Infringement into the Israeli patent laws.

The Court ruled that in order to establish liability on the basis of contributory infringement, the following three conditions need to be met:

(i) the components sold constitute a material part of the invention;
(ii) the seller knows (or ought to have known, having regard to the circumstances of the case) that the product sold by him is especially adapted for the infringing combination and is actually intended therefore.
(iii) The item sold is not a staple product that is suitable for substantial non-infringing use.

The above conditions are essentially a mixture of U.S.C. 35§271(c) and of Section 60(2) of the British Patents Act, 1977 (which follows Article 26(1) of the EPC).

In yet another case, CA. 7614/96 *Zhori & Sons Industries Ltd., vs. Regba*, the Supreme Court stated that the contributory infringement doctrine could not be invoked where the patent is a process patent, and the onus of proof is shifted to the "contributor" to show that direct infringement did not occur.

IV. Testimony by Video Conference Permissible

In view of the violence in the Middle East in the past two years, some witnesses were reluctant to attend cross examination hearings in Israel. On one occasion the Israeli Supreme Court handed down one decision in the matter of ALA 3005/02 *SmithKline Beecham, PLC vs. Unipharm and others* that permited witnesses to testify by video conference, as an alternative to a personal appearance in court.

The Court stated that it was to be favored that witnesses be heard by video conference rather than not be heard at all, given their refusal to travel to Israel:

"In view of the fact that Applicants [namely, SmithKline] cannot compel witnesses on their behalf to travel to Israel to testify, and in view of Applicants' submission that the witnesses' testimony is crucial and substantial to its case, I arrived at the conclusion that under the present circumstances it is necessary to strike an appropriate balance between the different interests of those involved in the matter, which favors hearing the testimony and the cross-examination of the witnesses by video conference as this is preferred over not hearing these testimonies at all."

This decision set a precedent and accordingly, on another occasion the Deputy Registrar of Patents allowed cross examination by video-conference. However, a contadicting judgement was issued this year by another Judge of the Supreme court, which lead to a series of refusals of petitions for cross examination via video. It remains to be seen how this trend will develop.

V. Expanding Scope of Drugs that Can Be Subject of Patent Term Extension

The Israeli Patents Law was amended in 1998, when provisions were introduced for patent term extension in order to permit ethical drug manufacturers to extend the life of their patent.

The Amendment of the Law includes a number of ambiguities, some of which will no doubt be tested in the future. One such ambiguity that came to test in 2002, concerns the definition of who is entitled to file an application for patent term extension. The section of the Law that was at issue is Section 64C(a) that reads as follows:

"The holder of a basic patent and the holder of an exclusive license may apply for an extension order."

In view of said wording, the Patent Office held that in the event of a patent that has not yet issued, the right to patent term extension will be lost.

In a decision issued by the Deputy Registrar on January 2, 2002 it was ruled that in cases where the drug received marketing approval before that patent had issued, the Registrar may prolong the term to file an application for an extension order, until 60 days after the patent issued.

VI. Term for PCT Chapter I National Entry of International Applications in Israel Extended to Thirty (30) Months

In 2002 Israel has amended its Patent Rules to define the term of 30 month under PCT Article 22(1). By making this amendment, Israel has joined the many PCT Contracting States which have already amended their national laws in order to make them compatible with the recent modification of PCT Article 22(1).

Thus, the National Phase in Israel (whether under PCT Chapter I or Chapter II) can now be entered within the 30-month term from the priority date (or filing date, where no priority has been claimed) of the international application.

The amendment is effective as of October 4, 2002. It applies to those international applications for which on that date the period of 20 months from the priority date (or from the filing date if no priority has been claimed), has not yet expired.

This Report is provided by David Gilat, Adv., Patent Attorney of Reinhold Cohn Group in Israel

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