Life Sciences Commercialisation in Israel: Overview

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A Q&A guide to life sciences commercialisation in Israel.

This Q&A provides a high-level overview of key practical issues, including the life sciences sector, pricing and state funding, distribution and sale, importing, advertising, patents, trade marks, competition law, and product liability.

Life Sciences Sector Overview

1. Give a brief overview of the life sciences sector in your jurisdiction.

The Israeli life sciences industry can generally be divided into four major sub-sectors:

- Digital health.
- Medical devices.
- Biotechnology.
- Pharmaceutical therapeutics.

The industry remains heavily biased towards medical devices (representing about 40% of life science companies in 2020). Biotechnology and digital health are the next largest sub-sectors.

Israel's life sciences industry is dominated by small scale start-ups. Public institutions such as hospitals and universities utilise commercialisation companies (TTOs) to seek out, develop, and market the know-how accumulated by them to turn patents into commercial products. TTOs play a major role in the industry, as many patents, new start-ups and licensing agreements can be seen to have originated from the ten research universities and 11 research institutes and hospitals located across Israel.

2. Give a brief overview of key life sciences funding issues in your jurisdiction.

Until 2014, life science companies in Israel tended to raise capital without the use of venture capital funding. This changed in 2015, however, and since then most financing for life sciences companies has been made through venture capital investors. In 2020, venture capital contributed about USD1.3 billion (representing 51% of total investments in Israeli life sciences companies).

For more than half a decade, Nasdaq has been the main source of public funding for Israeli life sciences companies and according to public information, more than 40 of the 80+ Israeli companies listed on Nasdaq are life science companies.

The Israel Innovation Authority (that is, an independent and impartial public entity that operates for the benefit of the Israeli innovation ecosystem and Israeli economy as a whole) invests more than USD100 million annually in the life sciences sector via its various programmes.

Pricing, Government Funding, and Reimbursement

National Health Care System

> 3. What is the structure of the national health care system, and how is it funded? Briefly explain how pharmaceuticals are introduced into that system.

Structure and Funding

The Israeli national healthcare system is based on the following main characteristics:

- Mandatory membership in one of the four Israeli Sick Funds (that is, mandatory, government-funded health care schemes provided by health insurers).
- Mandatory payments of National Health Insurance by Israeli residents to the National Health Institute, which forwards the payments to the Sick Fund (however, non-payment by an individual will not impact the duty of the Sick Fund of which they are a member to provide that person with all the medical services to which they are entitled).
- National "Health Basket" which is updated yearly to include new medicinal products and technologies and which sets out the services that the Sick Funds must provide for their members. The funding for the National "Health Basket" derives from three sources:
    - National Health Insurance payments:
    - Sick Funds' "participation" payments (derived, for example, from direct payments to the Sick Funds by members for complementary health insurance programmes); and
    - complementary payments from the Ministry of Health (MOH) budget.

Any public or private entity (for example, patients, patient organisations, physicians, pharmaceutical companies) can submit a request to add new drug or medical technology to the National Health Basket.

Interaction of the Life Sciences Industry with the Health Care System

Applications can be made to include registered drugs or drugs that have been submitted for registration and are likely to be approved during the year. Submitted drugs may receive priority review if they are included in the new health basket. Therefore, this may enhance the regulatory process.

New drugs and medical technologies are added to the National Health Basket based on recommendations of the Public Committee for Expansion of the Health Services Basket. This committee issues recommendations to the MOH about the medicines and technologies that should be included in the basket (subject to budgetary constraints). Those recommendations are subject to government approval, following the approval of the Health Council and the consent of the Minister of Finance.

Pharmaceutical companies usually negotiate prices with the MOH as part of the decision process on whether to introduce a new drug or medical technology into the Basket.

Most Israelis also pay the Sick Funds for complementary health services, including drugs, which are not included in the National Health Basket. A growing number of Israelis also have private health insurance policies, offering various plans of coverage for drugs and medical services (some of which are not included in the National Health Basket or the complementary services of the Sick Funds). Patients requiring treatments or drugs not included in the National Health Basket can petition an exceptions committee of their respective Sick Fund, and the decision can be appealed to a regional labour court.

Price Regulation and Reimbursement

> 4. How are the prices of medicinal products regulated? When is the cost of a medicinal product funded by the government or reimbursed? How is a pharmacist compensated for dispensing services?

Price Regulation

The prices of prescription drugs in Israel are controlled by the Ministries of Health and Finance and determined under the Supervision of Prices of Goods and Services Act 5756-1996, the Order for the Supervision of Prices of Goods and Services (Maximum Prices for Prescription Preparations) 5761-2001 and the Order for the Supervision of Prices of Goods and Services (Application of the Act to Preparations) 5761-2001.

Under Israeli legislation, the maximum price of most medicinal products is regulated in accordance with the following principles:

- For innovative products without generic equivalents, the maximum price of the drug marketed in Israel is equal to the average of prices in the three lowest price countries among Hungary, Spain, France, Belgium, the UK, Germany and the Netherlands.

- For innovative products with generic equivalents and for their generic equivalents, an increase in the maximum price is subject to petition and approval.

Reimbursement

Medicinal products that have been included in the National "Health Basket" are subsidised by the Sick Funds, which are allowed to collect only a portion of the price of the drug from the member-patient. Drugs that have been prescribed by a Sick Fund physician are dispensed either via the Sick Funds' own pharmacies or via private pharmacies.

Pharmacist Reimbursement

Each of the four Sick Funds has different arrangements for compensating private pharmacies for dispensing drugs that have been prescribed by a physician of the Sick Fund.

Distribution and Sale

5. Who is authorised to prescribe and supply medicines to patients or consumers? Who is authorised to distribute prescription medicines and over-the-counter medicines?

Retail Dispensing

Retail dispensing of prescription medicinal products and non-prescription drugs that are not listed in the regulations (over-the-counter (OTC) drugs) must be made by a pharmacist and in a pharmacy (cumulative conditions) (Pharmacists Regulations (Sale of a product not in a pharmacy or not by a pharmacist) 2004). Only drugs that are listed in the Regulations (general sale list drugs) can be dispensed in a pharmacy by a non-pharmacist or in a non-pharmacy business with a permit from the MOH under the Regulations.

Online Retail Dispensing

Under MOH Procedure No. 128 (2014), an Israeli pharmacy can operate a website for the online retail dispensing of pharmaceutical products (including prescription products), after obtaining approval from the MOH and in accordance with the provisions of the Procedure. The pharmacy can operate its website only if it also maintains its physical premises.

Wholesale Marketing

Under the Pharmacists Ordinance, wholesale marketing of medicinal products can only be carried out by a pharmaceuticals wholesale business or a recognised institution (a health institution recognised by the MOH under the Ordinance).

6. How is the wholesale distribution of medicines regulated?

Wholesale marketing of medicines relates to the marketing of medicines to pharmacies. The distribution or repackaging of a pharmaceutical preparation at the wholesale level is considered a "manufacturing activity" and accordingly requires a manufacturer-importer authorisation (MIA). The wholesale distributor must comply with the Israeli GDP requirements, which are intended to ensure that the quality of medicines and raw materials is maintained throughout the supply chain. The Israeli GDP requirements follow the *EU GDP Guidelines*. The MOH is authorised to inspect the premises of a wholesaler. Any unauthorised wholesale distribution of pharmaceutical preparations may be subject to criminal sanctions.

7. Which regulatory authority supervises the distribution of medicines? What are the consequences of non-compliance with the medicine distribution laws?

The distribution of medicines in Israel is supervised by the MOH's Pharmacy Division.

To supervise adherence with the GDP Regulations, the Director General of the MOH (or authorised officials from the MOH GMP Oversight Unit) can conduct ad hoc inspections without prior notice at the distributor's premises. According to the GDP Regulations and MOH Procedure No. 130 if the Director General is of the view that the distributor is operating in a way that is or may be detrimental to public health or is acting in contravention of the GDP Regulations or the conditions of its MIA authorisation, they are authorised to (as applicable):

- Prohibit the sale of the medicinal products/APIs that require authorisation.
- Seize and destroy the medicinal products/APIs.
- Cancel the MIA authorisation, suspend it, or refuse to renew it.

Cross-Border Trade and Parallel Imports

8. What are the main requirements to import medicinal products into your jurisdiction? Are parallel imports of medicinal products into your jurisdiction allowed?

Import Requirements

According to both Israeli legislation and EU good manufacturing practices (GMP) laws, the import and approval of batches of medicinal products for marketing in Israel are defined as "manufacturing." Therefore, under MOH Procedure No. EX-015/02 (2018), importers are regarded as manufacturers and must obtain a manufacturer's/importer's authorisation (MIA) prior to import.

A medical preparation being imported into Israel must be registered with the Israeli Drug Registry unless its registration is exempt under one the exceptions listed in section 29(a) of the Pharmacist Regulations (Preparations) 1986.

The importation of a medical preparation into Israel requires authorisation from the MOH. An application for import authorisation must be accompanied with the following documents:

- Certificate confirming the medical preparation was stored and transported under appropriate conditions.
- Certificate of pharmaceutical product (CPP) issued in a recognised country (the US, Canada, an EU member state, Switzerland, Norway, Iceland, Australia, New Zealand and Japan) no more than two years before the application date. The CPP must indicate that the medical preparation is authorised for marketing in the recognised country.
- Label and patient leaflet of the medical preparation.
- Confirmation that the medical preparation is registered in the Israeli Drug Registry.

The MOH will not issue an import authorisation unless the following conditions are met:

- The preparation was transported into Israel by authorised dealers in recognised countries.
- The preparation was stored on its way to Israel in recognised countries only.

Parallel Imports

From a regulatory standpoint, parallel import of "matching preparations" are specifically permitted under the Pharmacists Ordinance. However, MOH procedures clarify that only a drug product from the same manufacturer as the Israeli registered drug product and that is identical to the Israeli drug product (except that it is manufactured at a different manufacturing site) is regarded as a "matching preparation" that can be a parallel import. Parallel imports only require marketing authorisation, not the full drug registration procedure. In addition, parallel imports require an import permit from the MOH Parallel Import Department.

Under well-established principles and district court case law, patents (unlike trade marks) are not internationally exhausted, therefore parallel imports of patented goods constitutes patent infringement. However, in *H.C.J. 5379/00 Bristol-Myers Squibb Company v The Minister of Health, P.D. 55(4) 447 (2001)*, the Supreme Court suggested that the principle of international exhaustion may also apply to patents. However, the Supreme Court did not reach a final conclusion in the matter.

Advertising

9. What is the main legislation and what are the regulatory authorities that control pharmaceutical advertising? Does the industry have a system of self-regulation based on industry codes of conduct? What are the main elements of that system?

The main legislation concerning the advertising of medicinal products includes the:

- Pharmacist Regulations (Preparations).
- Pharmacists Regulations (Sale of a product not in a pharmacy or not by a pharmacist).
- MOH Procedures.
- Rules of the Second Authority for Television and Radio (Ethics in TV Commercials) 1994.
- Rules of the Second Authority for Television and Radio (Ethics in Radio Commercials) 1999.

The main regulatory authority responsible for enforcing the restrictions and rules relating to advertising of medicinal products is the MOH. In addition, the Second Authority for Television and Radio regulates TV and radio commercials.

According to the Joint Ethics Covenant between the Israeli Medical Association (IMA) and Pharma Israel (that is, the representative organisation of the innovative pharmaceutical companies in Israel), the pharma companies will be subject to additional obligations in relation to the advertising and promotion of their medicinal products which are not specified in the regulations or the MOH guidelines (see *www.health.gov.il/UnitsOffice/HD/MTI/Drugs/Pages/regulations.aspx*), for example:

- Promotional materials presented by pharmaceutical companies must meet not only the requirements of the law but also the highest accepted ethical standards worldwide.
- The frequency and scope of promotional materials from pharmaceutical companies which are mailed to medical practitioners should be reasonable.

10. Is there a definition of advertising or advertisement in relation to pharmaceuticals? What kinds of activities, channels and communications meet those definitions (and are therefore subject to restrictions), and what falls outside (and is therefore permitted)?

Advertising in relation to pharmaceuticals is broadly defined as disseminating information, in writing, through the media or by any other means (Pharmacists Regulations (Medical Preparations)). Advertising of medical preparations is therefore broadly defined to encompass advertising activities in all possible media and channels. Campaigns to increase public awareness of diseases and medical conditions are also subject to various requirements and restrictions but do not require the prior approval

by the MOH. In such a campaign, the commercial or generic name of a prescription medicine must not be mentioned or even alluded to.

11. Do companies have to set up internal procedures for managing and approving their advertising of pharmaceuticals?

The pharma companies operating in Israel are required to formulate and maintain internal procedures that will ensure full implementation of the Joint Ethics Covenant, including procedures relating to the advertising and promotion of medicinal products (Joint Ethics Covenant between the IMA and Pharma Israel).

12. Does pharmaceutical advertising have to be approved by a regulator?

The advertising of any non-prescription medicine must be approved in advance by the MOH's Drug Registration Department. To apply for the advertising of a non-prescription medicine, the appointed pharmacist of the registration holder can bring a petition to the Drug Registration Department. The petition should be reviewed by the MOH within 20 days from the date of receipt. If the petition is rejected, the registration holder can submit an amended proposal within 15 days of the date of rejection. If the Drug Registration Department approves the advertising, its approval will be valid for two years, which can subsequently be renewed for an additional two-year period by notifying the MOH.

13. Are there rules on comparative advertising that apply to pharmaceutical advertising?

Comparative advertising is only permitted between products that have active pharmaceutical ingredients that are identical and where there is an adequate and uniform basis for comparison.

14. Is it possible to share information about pharmaceuticals or indications that are unlicensed and is there a risk that this could be caught by advertising rules?

In principle, subject to various restrictions, sharing information about unapproved pharmaceuticals and indications may be permissible if the information is not commercial in nature and intended for medical staff only.

15. Are there particular rules or issues with the use of the internet and social media for advertising pharmaceuticals?

Online advertising to the general public, including advertising through social media, is treated by the MOH in a similar way to advertising on any other medium. According to MOH Procedure No. 137 (2015), the registration holder can display on its website a list of the pharmaceutical products registered in its name.

A prescription medicine and a non-prescription medicine cannot be advertised on the same webpage.

Online advertising to health care professionals requires mandatory measures to ensure that access to the relevant website is limited to healthcare professionals only (for example, by requiring prior identification of the user).

16. What are the consequences of non-compliance with the rules on advertising pharmaceuticals? How are the rules enforced and by which authorities or organisations?

The MOH is the main regulatory authority responsible for enforcing the restrictions and rules relating to the advertising of medicinal products, with the Second Authority for Television and Radio responsible for regulating TV and radio commercials.

In the case of unauthorised advertising of medicines or advertising of medicines contrary to the terms of the MOH approval, the MOH can force the registration holder to do any or all of the following:

- Remove the advertisement.
- Cease the advertising activity.
- Publish a clarification to the public.

The MOH is also authorised in such cases to impose monetary sanctions and to take disciplinary and criminal actions.

Advertising to the Public

17. Which pharmaceuticals can and cannot be advertised to the public? What information must and must not be included in advertising of pharmaceuticals to the public?

The advertising of prescription-only medicines to the general public is prohibited. However, the advertising of non-prescription medicines to the general public can be approved under strict conditions, including the information appearing in the advertisement being correct, accurate, clear and in accordance with the indication that was approved for the product.

18. Is it permitted to provide free samples to the public? Are there restrictions on special offers and other types of inducements?

According to MOH Guidelines (Circular No. 13/2018), which apply to any medical institution operating under an MOH permit, along with its affiliated bodies and employees, a medical practitioner cannot accept samples of medicines from a medical representative unless the samples are received for demonstration purposes only and their receipt is co-ordinated in advance with the management of the medical institution.

Similarly, the employees of a medical institution are not permitted to request or receive any reward or incentive or personal benefit (which includes travel expenses for conventions, office equipment and food/drink) from a medical representative.

According to the Joint Ethics Covenant between the IMA and Pharma Israel, physicians can receive gifts of nominal value from pharmaceutical companies if these are intended to directly serve their work, or symbolic gifts that are part of socially-accepted culture or courteous behaviour.

Pharmacists are also not permitted to receive rewards or commission for promoting the sale of pharmaceutical products within a pharmacy.

Engagement with Patient Organisations

19.What activities are permitted (or required) in relation to engagement with patient organisations? What restrictions apply?

The funding of patient organisations by pharmaceutical companies (including providing donations to such organisations) is essentially permissible but subject to various transparency rules. For example, the information presented by a patient organisation must be independent and not influenced by the funding or donating pharmaceutical company.

However, the advertising of prescription drugs by or through patient organisations is strictly prohibited.

Advertising to Health Care Professionals and Organisations

20. What are the definitions of a health care professional and a health care organisation? What information must be included in advertising to them?

The terms "health care professional" and "health care organisation" are not defined in the relevant legislation and MOH's guidelines but pharmacists are clearly considered health care professionals in the context of pharmaceutical advertising.

Advertisements directed at health care professionals (physicians and pharmacists) are permitted if they emphasise the approved indications. For example, when advertising prescription and non-prescription medicines to health care professionals, the leaflets must be approved by the MOH, must be sent only to physicians and pharmacists in Israel, or can be published on the website of the MOH's Pharmacy Division. The leaflet or advertisement can also be published in the professional journals intended for physicians and pharmacists.

If the information being communicated is highly important (for example, communicating information relating to changes in the composition of the medical preparation, its method of administration or dosage form, use instructions and so on), this should be communicated, subject to the MOH's approval, to all medical staff (that is, physicians, pharmacists, medical managers and chief pharmacists of Sick Funds, directors of hospitals, managers of pharmacy services in hospitals, the relevant professional associations, the pharmacists' associations, the district pharmacists and the Institute for Standardisation and Control of Pharmaceuticals at the MOH's Pharmacy Division).

Gifts and Incentives

21. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for health care establishments or individual medical practitioners?

Legal Restrictions

Under the Penal Act 1977, providing or accepting a benefit to/by a civil servant in consideration for an action by the civil servant related to their duties, constitutes the criminal offence of bribery. Medical practitioners who are employees of government hospitals or of Sick Funds are subject to these provisions. Common marketing practices are unlikely to fall under the ambit of criminal legislation.

Under the Public Service (Gifts) Law 1979, a civil servant (including medical practitioners employed by the state or the Sick Funds) cannot accept benefits while performing duties (more specifically, the law provides that the employee must either refuse

to receive the benefit or immediately give notice of receiving the benefit. In the latter case, the benefit will generally become the property of the state. Failure to give notice is a criminal offence). However, the law exempts from its application "a low value and reasonable benefit that was given according to what is customary under the circumstances."

Under the MOH Guidelines (Circular No. 13/2018), which apply to any healthcare institutions operating under a licence from the MOH, their affiliated bodies and employees, a medical practitioner cannot accept any rewards or benefits whatsoever from a medical representative. In addition, a medical practitioner employed by a public health care institution must obtain approval from the management of the healthcare institution for any external work, which must be denied if there is risk of a conflict of interest. Sponsoring of conventions and similar activities may be permitted, subject to various limitations and conditions.

Ethical Restrictions

In accordance with the Joint Ethics Covenant between the IMA and Pharma Israel, consultancy agreements between physicians and pharmaceutical companies are regarded in principle as legitimate, subject to the following conditions:

- Any consultancy agreement must be in writing.
- If the physician is employed at a hospital, medical institution or other public institution, they will undertake under the consultancy agreement to report the engagement with the company to the employer and to obtain the employer's advance approval if required under any law.
- Physicians must ensure that any engagement with the pharmaceutical company does not put them in conflict of interest with their position at the institution where they are employed or with their ethical and professional obligations towards their patients.

The funding by pharmaceutical companies of the participation (including travel expenses) of physicians in scientific conferences and continuing education programmes (including abroad) is regarded in principle as legitimate under the Joint Ethics Covenant. However, certain conditions must be fulfilled, including:

- The invitation to the physician must be made via the relevant scientific union or by the physician's employer and not directly by the pharmaceutical company.
- Physicians invited to a scientific conference should be selected in accordance with agreed transparent criteria.

A pharmaceutical company cannot give, and a physician cannot accept, any personal benefits unless these are "gifts of nominal value which are intended to directly serve the physician's work, or symbolic gifts which are part of an acceptable social culture or etiquette" (Joint Ethics Covenant between the IMA and Pharma Israel).

Transparency and Disclosure

22. Do pharmaceutical companies have to disclose details of transfers of value to health care professionals or health care organisations?

If an Israeli-resident individual or corporation registered in Israel is the registration holder, manufacturer, importer or marketer of a medicinal product (or corporation that controls or is controlled by them) donates any amount to a health institution, or makes an annual donation to a medical practitioner of more than ILS2,500, they must provide an annual report to the MOH, detailing:

- Each donation.
- The identity of the recipient.
- The sum or value of the donation.
- The purpose the donation.
- A description of the donation if it is non-monetary (for example, shares/stock, artworks or household items).,

(Section 40A(a), National Insurance Act 1994.)

Corresponding reporting obligations apply directly to any health institution or medical practitioner receiving a donation from one of the entities listed above, even if that entity is a foreign resident or corporation.

Each year, the MOH publishes a list of all reported donations on its website (*www.gov.il/he/Departments/DynamicCollectors/db-donation-reports?skip=50*).

23. What are the consequences of non-compliance with the rules on marketing to health care professionals?

Violating the rules on marketing to health care professionals may lead to the imposition of various possible sanctions, depending on the nature and severity of the violation. These sanctions may include monetary, administrative and criminal sanctions.

Patents

Conditions for Patentability

24. Provide a brief definition of a patent, the key legal requirements to obtain it and the law that applies.

Conditions and Legislation

The Israeli patent system is governed by the Patents Act 5727-1967 (*www.wipo.int/wipolex/en/text/341499*). It is a first-to-file system (section 9, Patents Act). The person entitled to apply for the patent must be the owner or a co-owner of the invention

(sections 2 and 77, Patents Act). Under the Patents Act, a patentable invention is "an invention, whether a product or a process in any field of technology, which is new and useful, can be used industrially and involves an inventive step" (section 3, Patents Act). However, the following inventions cannot be the subject matter of patent protection:

- A method of therapeutic treatment of the human body.
- New varieties of plants or animals, except microbiological organisms not derived from nature.

(Section 7, Patents Act.)

Local practice with respect to biotechnological inventions closely follows the European Patent Convention 1973 (EPC).

According to local practice, a claim set for an invention in the biotechnological field is usually confined to one or more original proteins, sharing a certain common activity, their use and processes for their production. Among the claims that can be included are claims for:

- Nucleic acids.
- Vectors encoding and expressing the active proteins.
- Plasmids in transformed micro-organism or other transgenic organism, such as plant or animal which carries such DNA/RNA (unless the genome of the transgenic organism has been changed other than by inserting and carrying the DNA/RNA).

Only components that directly relate to the original protein (its structure, use, application, function, activity and process for its production) and the DNA capable of encoding the protein (in a free or bound form or carried by a vector) are considered elements of the same invention. Claims relating to other proteins of different biological activity (for example, an antibody to the original protein), or claims relating to DNA or nucleotide sequences incapable of encoding the original protein (for example, a hybridised nucleic acid such as cDNA or a sense sequence), are considered separate inventions.

Isolated stem cells for further differentiating or isolating into specialised cells or tissues can also be claimed.

Types of Patent Available

Protection under an Israeli patent can cover the entire life cycle of pharmaceutical research and development. The following relating to a "therapeutic treatment of the human body" are protected:

- Products or compositions used for the treatment of the human body (*CA 244/72 Plantex Ltd v The Wellcome Foundation Ltd ILR 27(2) 29*).
- Purpose-limited product or composition claims (formerly, Swiss-type claims). Such claims provide adequate protection and are also recognised for primary, secondary and any subsequent medical indications of an active ingredient.
- Diagnostic or detection methods.
- Cosmetic (non-therapeutic) treatment.

Main Categories Excluded from Patent Protection

The exclusion from patentability relating to plant or animal varieties only applies to naturally occurring organisms. Therefore:

- Mutants of naturally occurring organisms are patentable.
- Non-mutant micro-organisms that are derived from non-natural environments are patentable. For example, new adaptable strains isolated from man-made waste or pollution areas are also patentable.
- A claim for a micro-organism (natural or mutant) for use as an active component in a composition for producing a novel product (such as antibiotics, sugars, proteins, and so on) by the micro-organism is acceptable.
- Natural products (newly discovered genes, proteins, polysaccharides, and so on) are patentable for use in treating a medical condition or in a particular process. The US Supreme Court decision in *AMP v Myriad Genetics 569 US 12-398 (2013),* in which it was held that isolated, naturally-occurring DNA is not patent eligible, has not had an impact on Israeli practice.

Specific Provisions for the Life Sciences Industry

Local practice with respect to biotechnological inventions closely follows the European Patent Convention 1973 (EPC).

The decisive feature for the patentability of biotechnological inventions is whether the material is naturally occurring. Therefore, naturally occurring organisms, such as plants, animals and micro-organisms, cannot be patented. However, mutants of naturally-occurring organisms can be afforded patent protection. Non-mutant micro-organisms derived from non-natural environments (for example, adaptable strains isolated from man-made waste or pollution areas) are patentable. It is also acceptable to claim the micro-organism (natural or mutant) for use as an active component in a composition for producing a novel product (such as antibiotics, sugars, proteins and so on) by the micro-organism.

Natural products (for example, newly-discovered genes, proteins, polysaccharides and so on) can be patented, for use in treating a medical condition or in a particular process. At the time of writing, the US Supreme Court decision in AMP v Myriad Genetics 569 US 12-398 (2013), in which it was held that isolated naturally occurring DNA is not patent eligible, has not had any impact on local practice in Israel.

To obtain gene patents, the applicant must identify a specific utility. According to ILPTO practice, *in vitro* studies showing increased biological activity constitute sufficient support. It is expected that this practice will survive judicial scrutiny in the future and that Israeli courts will not impose unrealistic requirements on patentees for the proof of *in vivo* therapeutic applications at the date of filing.

Purpose-limited product or composition claims (formerly, Swiss-type claims) are patentable in Israel. Such claims provide adequate protection and are also recognised for primary, secondary and any subsequent medical indications of an active ingredient.

Registering a Patent

25. Which authority registers patents? Briefly outline the key stages and timing in obtaining a patent.

Patent Registration Authority

Patent applications are filed with the Israeli Patent Office (ILPTO). The ILPTO provides guidance on the application procedure and fees.

A patent application filed in Israel must describe the invention in a manner which enables it to be performed by a person skilled in the art. It must also summarise the state of the prior art in the technical field relating to the invention. The following must be disclosed to the ILPTO:

- Prior art publications cited against corresponding applications in other jurisdictions.
- Prior art publications known to the applicant and directly related to the invention.

Changes in the list of prior art publications must be reported to the ILPTO up until the allowance of the application.

Patent Office filing fees are NIS 2,077. For each 50 pages after the first 100 pages, there are additional fees of NIS 260. For each claim exceeding 50 claims, there is an additional fee of NIS 533.

Process and Timing

Israel is a member of the WIPO Paris Convention for the Protection of Industrial Property 1883 (Paris Convention) and of the Patent Cooperation Treaty 1970 (PCT). A national phase entry of the PCT into Israel must be submitted within 30 months of the earliest priority date. A Paris Convention application must be filed in Israel within 12 months from the priority date.

Israel is a strict examining country. The ILPTO relies on the examination results, particularly for prior art citations, of parallel applications in the leading examination jurisdictions (Europe and the US). In addition, the ILPTO conducts an independent prior art search and examines the application on various other grounds (for example, unity of invention, sufficient support for the claimed invention, and so on).

Before examination, the applicant must file with the ILPTO all information concerning prior art references, particularly those cited against the parallel applications in other jurisdictions. Third parties can supplement that information within two months after the applicant submits its disclosure statement to the ILPTO. Israeli law does not enable third parties to submit written arguments in addition to prior art references. Until the application is allowed, the applicant is under an ongoing obligation to update the ILPTO of any additional references relied on by foreign patent offices.

Modified examination. Under the Patents Act, the applicant can base the Israeli application on a corresponding granted patent in one or several specified examining countries (that is, Austria, Australia, the US, Germany, Denmark, the UK, the Russian Federation, Japan, the European Patent Office (EPO), Norway, Canada and Sweden) (section 17). In a modified examination, the claims of the Israeli application must be rendered identical to the granted claims of the foreign patent on which it is based. In such a case, the application will be deemed to have complied with the requirements of novelty, inventive step, enablement and support. The period of modified examination is much shorter than for regular examination, and it mainly concerns formal issues specific to Israeli patent practice.

Expedited examination. Examination is automatic and no formal request is required. In special circumstances (for example, pending infringement), it is possible to petition for an early initiation of examination and expedited examination. Third parties can also petition for expedited examination in special circumstances (for example, business interests of the third party). When examination is expedited, the ILPTO will deny extensions to respond to office actions (other than in circumstances of *force majeure*).

The ILPTO is also involved in bilateral Patent Prosecution Highway (PPH) arrangements with several countries/organisations including, among others, the US and the EPO, and is also implementing a pilot under the *Global Patent Prosecution Highway (GPPH) Programme*. Patent applications under the PPH and GPPH programme can be granted special status and qualify for accelerated examination.

Pre-grant opposition. Following allowance by the ILPTO, there is a three-month non-extendable opposition period. If an opposition is filed, the patent will only be granted if the opposition is denied by the Patent Registrar. This pre-grant opposition procedure is very similar in nature and length to court litigation procedures. It includes cross-examination of experts and witnesses and, in appropriate circumstances, limited discovery. It will often last for two to three years and sometimes longer. In view of the contentious nature of opposition proceedings, in most cases they are conducted by patent litigation lawyers who are more capable of handling such complex proceedings than patent agents.

Patent linkage. There is currently no patent linkage system in place in Israel. The existence of a patent dispute in Israel therefore has no implications on the regulatory review of an application to register a pharmaceutical product in Israel.

Length of Patent Protection

26. When does patent protection start and how long does it last? Can monopoly rights be extended by other means?

Duration

Patents are granted for 20 years counted from the patent application date, subject to renewal. Renewal fees are payable in one instalment for the entire duration of the patent. The patent can also be renewed for shorter periods (six years plus three extensions of four years, plus two years) throughout the patent's life.

Extending Protection

It is possible to petition the Patent Office to grant a patent term extension (PTE) of up to five years for patents covering pharmaceutical drugs and medical devices. The unique Israeli PTE system links the entitlement, duration and validity of Israeli PTEs to marketing authorisations, reference patents and PTEs or supplementary protection certificates (SPCs) in other selected recognised countries (the US and five EU member states). The exact conditions and procedure for obtaining PTEs and calculating their duration are complex. An additional period of exclusivity due to paediatric studies is not available and there is no exclusivity for orphan medicines under Israeli law.

Products comprising a new chemical entity may qualify for marketing exclusivity of up to six and a half years from the first registration of the product in recognised countries (the US, EU member states, and several other countries).

Patent Infringement

27. What rights does a patent grant to its owner? On what grounds can a patent infringement action be brought? What are the main defences to a patent infringement action? How is a claim for patent infringement made and what remedies are available?

Rights Granted by a Patent

A patent grants its owner the right to prevent unauthorised exploitation of the patented invention during a period of 20-years commencing on the effective filing date of the patent application.

Grounds for Patent Infringement

Under the Patents Act, the patentee can prevent any other person from exploiting the patented invention either in the manner defined in the claims or in a similar manner that, in light of what is defined in the claims, constitutes the essence of the patented invention. Exploitation includes manufacturing, use or offering for sale, and selling or importing for manufacture, use or sale (section 1, Patents Act). The patentee's rights to prevent unauthorised exploitation of the patented invention are broadly interpreted by the courts. Among others, it was held that export of patented goods from Israel also amounts to infringement although it is not specifically listed as one of the acts exclusive to the patentee (*MCM (Jerusalem) 814/05 Orbotech Ltd v Camtech Ltd, Tak-Dist 2005(2) 2893*). Importation of patented goods into Israel for transit into the areas of the Palestinian Authority was also held to be infringing although the goods were not destined for use in Israel (*CF 1141/03 Merck Frosst Canada & Co v The Birzeit Pharmaceutical Company (published in Nevo)*).

If the invention is a process, the patent also applies to the direct product of that process (*section 50(a), Patents Act*). When the defendant's product is identical to the direct product of the process, the burden lies on the defendant to prove that it did not use the patented process (section 50(b), Patents Act). In addition, a presumption of infringement of the patented process exists if the following two conditions are met:

- The patentee cannot determine, using reasonable efforts, which process was actually used for the manufacture of the defendant's product.
- There is high likelihood that the defendant's product was manufactured using the patented process (*CA 7614/96 Zehori and Sons Industries Ltd v 'REGBA' Ltd, PD 54(3) 721*).

(Section 50(b), Patents Act.)

Bolar exemption. There is a Bolar exemption that applies to experimental acts carried out during the patent term for the purpose of obtaining an approval for marketing the product after the expiration of the patent in Israel or in another country where a Bolar exemption applies (section 54A, Patents Act). The experimental act is not an exploitation of the invention if:

- It is part of an effort to obtain a marketing approval in Israel or another country where an experimental act is permitted for the purpose of obtaining a marketing approval before the expiration of the patent.
- The resulting product must only be used for the purposes of applying for a marketing approval.

There has not been much litigation in relation to this exemption, and there is still uncertainty regarding its scope. Running bioequivalence studies for obtaining a marketing approval for a generic drug are clearly exempt from infringement. Stockpiling products for marketing after the patent expiration, or offers to supply the patented product, are certainly not exempt. However, there is still a considerable grey area, such as the manufacture of pilot batches or the upscaling of manufacturing processes.

In August 2022 the Knesset (Israeli Parliament), at first reading, approved a bill to amend the Patents Act, which would introduce manufacturing and stockpiling waivers during the post-termination exercise period. The bill is still pending at the Knesset.

Experimental use exemptions. Any act that "is not on a commercial scale and is not commercial in character" is exempt. To qualify for the exemption, both conditions must be satisfied. The exemption has also been interpreted as a de minimis exemption and is mainly relevant to provide protection for non-commercial academic research.

The Patents Act provides that "an experimental act in connection with the invention, the objective of which is to improve the invention or to develop another invention" is not an infringement. This experimental-use exemption apparently applies to experimental acts with a commercial purpose. Comparative clinical trials between drugs assessing the efficacy and safety profiles of the drugs are also covered.

To qualify for an experimental-use exemption, the experiment's object must be the patented invention itself and it must be aimed at the testing of the essential features of the patented invention. The experimental-use exemption is therefore not intended to undermine the protection for diagnostic kits or research tools in biotechnology. In the same way, a person who wishes to test a new cure for cancer by applying it to a patented genetically modified mouse cannot rely on the exemption.

Claim and Remedies

Patent infringement proceedings are initiated by submitting a statement of claim to the district court having local jurisdiction over the matter. In practice, most patent infringement proceedings are heard by the Tel Aviv District Court or the Jerusalem District Court. Appeals on decisions of the district courts are heard by the Supreme Court of Israel. There are no specialised patent courts or patent sections in any of the district courts. However, in practice, patent cases will, in many cases, be assigned to judges with previous experience in patent matters.

Patent infringement proceedings can be brought by the patentee or its recorded exclusive licensee. In case of co-ownership, each owner can sue for infringement. It is not necessary to name all owners as co-plaintiffs or obtain their consent for the filing of the claim. However, if some of the co-owners are not plaintiffs, they must be joined to the proceedings as defendants (section 178, Patents Act).

Interim remedies. In patent cases, the provisional measures commonly invoked are preliminary injunctions restraining the infringing activity. However, a wide range of conservatory measures are available under the Israeli Civil Procedure Regulations and practice. In addition to preliminary injunctions, it is possible to obtain attachment orders, Mareva injunctions and Anton Piller orders to seize the infringing goods as well as documents attesting to the infringing activity, the identity of suppliers and customers, and so on. Whether or not such measures will be applicable to a particular patent case will depend on the particular circumstances of the case.

Permanent remedies. When the patent is valid and infringed, the court will grant an injunction restraining further infringement of the patent. This is the first and foremost remedy to which the patentee is entitled. In addition, in appropriate circumstances, the court will also grant injunctions restraining the use of the "poisoned fruit" of the infringement, such as data accumulated in violating the patent. Moreover, the use of the poisoned fruit of the infringement can probably also be enjoined after the expiration of the patent (*CF (Tel Aviv) 881/94 Eli Lilly and Company v Teva Pharmaceutical Industries Ltd, Tak-Dist 98(3) 1586, (n 44)*). Orders requiring the recall of patent infringing goods, destruction of the goods and so on, are also available.

A patentee prevailing in the infringement proceedings will also be entitled to monetary compensation. In awarding compensation, the court may take into consideration the direct damages caused to the patentee, the extent of the infringement, the profits derived by the infringer from the act of infringement and reasonable royalties that the infringer would have had to pay in consideration for a licence (section 183(b), Patents Act). In practice, the patentee can either claim the actual damages that it sustained as a result of the infringement or the profits that the defendant derived from the infringement.

Punitive damages are available but only rarely imposed (*CA 3400/03 Rohama Rubinstein v Ain Tal (1983) Ltd Tak-Sup 2005(6) 490*). If an infringement was committed after the patentee or its exclusive licensee warned the infringer, the court may order the infringer to pay punitive damages in an amount that will not exceed the amount of damages ruled by the court (section 183(c), Patents Act).

The patentee may be entitled to recover full retroactive compensation for infringing exploitation of the invention, which is the subject matter of the patent application, after it was allowed by the Patent Office (section 179, Patents Act). Therefore, the patentee's right to compensation materialises on grant of the patent. However, it also applies retrospectively starting from the date of publication of allowance of the application. In addition, the patentee can recover retroactive compensation limited to reasonable royalties for infringing exploitation of the invention in the period between the first publication of the patent application and its allowance. Such compensation is only available if the unauthorised use also infringes the issued patent and the patent is essentially identical to the application as first published.

Defences to a Patent Infringement Action

Research exemption. The main research defences to a patent infringement action in Israel are experimental use exemptions and the Bolar exemption (see above, *Grounds for Patent Infringement*).

IP exhaustion. According to well-established principles and district court case law, patents (unlike trade marks) are not internationally exhausted. Therefore, the parallel import of genuine patented goods constitutes patent infringement. However, in *H.C.J. 5379/00 Bristol-Myers Squibb Company v The Minister of Health, P.D. 55(4) 447 (2001)*, the Supreme Court suggested that the principle of international exhaustion may also apply to patents. However, the Supreme Court did not provide a final conclusion on the matter.

Stockpiling. The stockpiling of products for marketing after the expiration of a patent would not be exempt from an infringement action. However, if the latest bill to amend the Patents Act is approved in a final reading, stockpiling will be allowed during the last six months of the post-termination exercise period. The bill is still pending at the Knesset.

Manufacturing for export. The export of patented goods from Israel would amount to infringement even though this is not specifically listed as one of the acts exclusive to the patentee (*MCM (Jerusalem) 814/05 Orbotech Ltd v Camtech Ltd, Tak-Dist 2005(2) 2893*). However, if the latest bill to amend the Patents Act is approved in a final reading, manufacturing for export will be allowed in Israel throughout the entire post-termination exercise period.

Regulatory activity. Regulatory activity may qualify for an exemption if the activity constitutes a Bolar-type exemption (see above, *Grounds for Patent Infringement*, *Bolar exemption*).

International IP Treaties

28. Is your jurisdiction party to international treaties that facilitate the recognition of foreign IPRs in your jurisdiction?

General

Israel is party to all major international IP treaties (for example, *WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)* and so on).

Patents

Israel is party to the following international patent treaties:

- *WIPO Paris Convention for the Protection of Industrial Property 1883 (Paris Convention).*
- The *Patent Cooperation Treaty 1970 (PCT).*
- *WIPO Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure 1977.*

Trade Marks

Israel is party to the following international trade mark treaties:

- *Paris Convention.*
- *WIPO Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks 1989 (Madrid Protocol).*
- Nice Agreement concerning the International Classification of Goods and Service.

Trade Marks

Legal Requirements to Obtain a Trade Mark

29. Provide a brief definition of a trade mark, the key legal requirements to obtain it, and the law that applies.

Legislation and Scope of Protection

The main laws governing registration of trade marks governing the protection and enforcement of trade mark rights in Israel are the:

- Trade Marks Ordinance (New Version) 5732-1972.
- Trade Marks Regulations (Implementation of the Madrid Protocol) 5767-2007.

Other relevant legislation relevant to trade mark matters in Israel includes the:

- Commercial Torts Law 5759-1999.
- Merchandise Marks Ordinance 1929.

A "trade mark" is defined in the Israel Trade Mark Ordinance (New Version) as a mark that is used, or intended to be used, by a person in relation to goods they manufacture or deal in. The term "mark" means letters, numerals, words, devices or other signs, or combinations thereof, whether two-dimensional or three-dimensional. Under this definition, a broad range of marks (including unconventional marks such as three-dimensional marks constituting the shape of a product, colours and sounds) are registrable as a trade mark in Israel.

A registered trade mark gives its owner the right for exclusive use of the mark in respect of the goods for which it is registered, and goods of the same description. An unregistered well-known mark is entitled to the same scope of protection.

A well-known mark that is registered in Israel gives its owner the right for exclusive use of the mark in respect of goods which are not of the same description, if the use of the mark by a third party is likely to point to a connection between those goods and the owner of the registered trademark, and the owner of the registered trade mark is liable to be adversely affected as a result of such use.

Israeli law also provides protection to common law rights in unregistered trade marks based on the doctrines of passing off, unfair competition and unjust enrichment.

Under the current Israeli Trade Mark Office (ILTMO) policy (Trade Marks Registrar Circular No. 033-2016), pharmaceutical trade marks can be registered with a generic specification (that is, without a specific medical indication) if the drug for which the mark is intended is still under development and it is not possible to characterise its specific indications. In such a case, the trade mark applicant must submit a declaration confirming that the drug for which the mark is intended is still under development.

General Conditions and Specific Rules for Naming Medicines

A trade mark must be either inherently distinctive or possess acquired distinctiveness by virtue of extensive use (Article 8, Trade Marks Ordinance (New Version) 1972). It is possible to base the Israeli application on a corresponding registration in applicant's country of origin (section 16, Trade Marks Ordinance). Invoking the Israeli *telle quelle* provision may allow registration under a significantly lower threshold of distinctiveness. Under the *telle quelle* provision, a mark registered as a trade mark in applicant's country of origin will be allowed for registration in Israel, unless it is found that the mark does not have even a slight degree of distinctive character.

Pharmaceutical trade marks are not considered as a separate category of marks that requires its own distinct rules. It is generally assumed that the same likelihood of confusion tests are applied to pharmaceutical trade marks as they are to trade marks associated with other products but not when confusion could result in fatal consequences.

International non-proprietary names are not registrable as trade marks as they are devoid of any distinctive character and should remain open for public use.

In addition to traditional word marks, all aspects of a pharmaceutical product can be registered as trade marks in Israel. For example, the trade dress of packaging and the shape of a pill or tablet may be eligible for registration as a trademark. The qualification is that, for features such as the three-dimensional configuration of a pill/tablet or the colour of a pill/tablet or packaging, registration is dependent on proof of acquired distinctiveness (*CA 11487/03 August Storck KG v Alfa Intuit Foodstuffs Ltd (published in Nevo database); CF 1242/08 Dexon Ltd v Agis Commercial Agencies (1989) Ltd (published in Nevo database)*). In addition, the threshold for establishing acquired distinctiveness will be especially high for a single colour as a feature of the pharmaceutical product, and will be somewhat lower for a colour combination (*Dexon Ltd v Agis Commercial Agencies (1989) Ltd*). However, the combination of several non-traditional aspects in a single trade mark may overcome the higher thresholds for obtaining registration. For instance, the 3D shape of a pill/tablet limited to a single color and combined with applicant's house mark engraved on the pill/tablet may be eligible for registration.

Registering a Trade Mark

30. Which authority registers trade marks? Briefly outline the key stages and timing to obtain a registered trade mark.

Trade Mark Registration Authority

Trade mark applications are filed with the Israeli Trade Mark Office (ILTMO). The ILTMO website provides guidance on the application procedure along with a breakdown of the fees involved in the trade mark application and the maintenance process. The MOH does not review the pharmaceutical trade mark and is not involved in the trade mark registration process. However, during the regulatory process, the MOH will refuse to register a medical preparation if its commercial name is misleading and likely to harm public health.

Process and Timing

Obtaining a trade mark registration in a straightforward case takes about ten to 12 months. Applications are examined in four to seven months from the application date, unless expedited examination is requested. If the application is allowed by the

examiner, it is automatically published for opposition purposes in the *Israeli Trademarks Journal* at the end of the month during which the application is allowed. If within three months after publication no oppositions are filed against an application, the registration certificate will be issued.

Since Israel is a member of the Paris Convention, a trade mark application in Israel can claim priority from a first filed application (the priority application) if the application in Israel is filed within six months from the filing date of the priority application.

During examination of a trade mark application in Israel, the application may be challenged on the basis of absolute grounds (for example, a lack of distinctive character, geographical indication, surname and so on) or relative grounds (confusing similarity to previously registered trade marks).

Pharmaceutical trade marks are not allowed for registration in Israel in respect of broad specifications of goods in class 5 unless the medical preparation, for which the mark is intended, is under development and it is not yet possible to characterise its specific indications.

Competition Law Issues

Competition Authorities and Legislation

31. Briefly outline the competition law framework in your jurisdiction and how it impacts on the pharmaceutical sector.

Competition Law and Main Provisions

Under the Economic Competition Act 1988, arrangements involving restrictions likely to prevent or reduce competition are prohibited, unless they are cleared in advance by the Israel Competition Authority (ICA) (sections 2 and 4, Economic Competition Act). Under well-established Israeli Supreme Court case law, unapproved restrictive arrangements are generally unenforceable (*FA 4465/98 Tivol Ltd v Chef Hayam Ltd, PDI 56(1) 56*).

In addition, Israeli competition laws prohibit an undertaking with a monopolistic position (which from January 2019 also includes an undertaking with a market share of or less than 50% but with significant market power) from abusing its position in the market "in a manner which might reduce business competition or injure the public" (section 29A(a), Economic Competition Act). Without derogating from the generality of this prohibition, the following practices by a monopolist will be deemed an abuse of its position:

- Setting unfair buying or selling prices for assets or services produced/provided under a monopoly.
- Increasing or decreasing the quantity of assets or scope of services offered, not within the context of fair competitive activity.

- Setting different contractual conditions for similar transactions in a manner that may grant certain customers or suppliers an unfair advantage in relation to their competitors.
- Including in a contract regarding assets or services conditions that, by their nature or according to accepted trading practices, are unrelated to the subject matter of the contract.

(Section 29A(b), Economic Competition Act.)

Under the Patents Act, the Patent Registrar can grant a compulsory licence if the patentee abuses its patent monopoly rights (section 117(a), Patents Act). The exploitation by the patentee of patent monopoly rights will be deemed as abusive if one or more of the following circumstances exists and the patentee does not provide a reasonable justification for their existence:

- Total demand for the product is not satisfied in Israel on reasonable terms.
- The conditions the patentee attaches to the supply of the product, or to the grant of a licence for its production or use, are unfair under the circumstances, do not take public interest into account and these conditions basically arise due to the existence of the patent.

(Section 119, Patents Act.)

In practice, compulsory licences will only be available in the most extreme circumstances of abuse of patent rights.

Competition Authority

The ICA is the main authority responsible for maintaining and promoting competition within the Israeli economy. The ICA has vast powers to impose substantial administrative fines, initiate criminal proceedings, and conduct its own investigations.

Until recently, enforcement of competition law in the Israeli pharmaceutical sector was fairly rare. However, on 23 November 2021, the ICA's acting Commissioner laid down their intention, subject to a hearing, of imposing a fine of INS8 million on MBI Pharma Ltd and personal sanctions of about INS600,000 on two of the company's officers. MBI Pharma was accused of setting a high and unfair price for the drug Leadiant, a life-saving drug for patients with Cerebrotendinous Xanthomatosis. This is the first time an ICA Commissioner has initiated enforcement proceedings against a monopolistic undertaking for abusing its position by charging an unfairly high price.

In conformity with the Commissioner's decision to initiate proceedings, the Supreme Court recently ruled that the part of section 29A(b) of the Economic Competition Act which prohibits an undertaking with a monopolistic position from charging unfair prices for products or services, also applies to cases where the undertaking charges "exorbitant prices" rather than "predatory prices" (*LCA 1248/19 Gefniel v Central Company for Manufacture of Soft Drinks Ltd*). The Supreme Court further held that this prohibition can be enforced through a class action. This landmark ruling is likely to have a far-reaching impact on all business sectors, including the pharmaceutical sector.

32. Has pharmaceutical competition case law in your jurisdiction focused on any key areas?

In *CF (Central) 33666-07-11 Unipharm Ltd v Sanofi (Plavix),*an Israeli company sued the pharmaceutical company Sanofi. The facts of the case are complex, but in essence, the District Court held that Sanofi abused its monopolistic position in connection with the drug Plavix by misleading the Patent Office (ILPTO) in connection with a patent application claiming a crystalline form of the active ingredient. The application was eventually abandoned following opposition and never matured to registration. However, the court held that Sanofi's acts amounted to an abuse of its position because the pending application deterred generic competition for about two years. The court held that under such circumstances, the appropriate remedy is to order the patentee to pay the generic claimant the profits it derived from sales of the product during the period of delay of generic entry on the basis of the law of unjust enrichment.

The Supreme Court rejected Sanofi's appeal against the Judgment of the District Court in the *Plavix* case but reversed District Court's ruling that by misleading the ILPTO, Sanofi abused its monopolistic position in connection with the drug Plavix. The Supreme Court held in this regard that, although the submission of misleading information by Sanofi violated the provisions of the Patent Act and harmed competition, in submitting this information Sanofi did not use its monopolistic power and position, because the ILPTO could have been misled by Sanofi even if it did not enjoy a monopolistic position.

The Supreme Court agreed to hold a rehearing on its judgment before an expanded panel of five judges, with judgment from the rehearing expected in about a year.

Given that it is rare for the Supreme Court to hold a rehearing on one of its judgments, its willingness to do so in the *Plavix* case illustrates the precedential and problematic nature of its judgment (in the interests of full disclosure: the undersigned was not involved in the District Court proceedings but is representing Sanofi in the appeal and the rehearing).

As mentioned above, under well-established district court case law, patents (unlike trade marks) are not internationally exhausted and therefore parallel importation of genuine patented goods constitutes patent infringement. The Supreme Court suggested that the principle of international exhaustion may also apply to patents (*HCJ 5379/00 Bristol-Myers Squibb Company v The Minister of Health, PD 55(4) 447 (2001)*) but did not reach a final conclusion on this matter.

See *Question 31, Competition Authority*.

Commercial Contracts and Competition Law

33. Briefly outline the competition issues that can arise in relation to commercial contracts and other business arrangements relating to medicinal products.

Under the Economic Competition Act, an arrangement involving restraints that all relate to the use of registered patent rights (and other listed IP rights), entered into directly by the patent owner and the party receiving the rights, will not be deemed a restrictive arrangement (section 3(2), Economic Competition Act). The exact scope of the exemption has not been sufficiently analysed in Israeli case law. However, Israeli competition laws generally follow the substantive framework of competition laws in Europe. Therefore, patent and know-how licence agreements involving restraints that are white-listed in the respective EU block exemptions are likely to be permitted in Israel and, conversely, black-listed restraints are likely to turn the licence into an anti-competitive practice. Vertical price fixing and no-challenge clauses, among others, will not be permitted. Information sharing among competitors may also constitute, under certain circumstances, a restrictive arrangement. However, clauses permitting the licensor to terminate the agreement if the licensee challenges the validity of the licensed rights are likely to

be regarded as legitimate. In addition, the Israeli Competition Authority issued certain block exemptions regarding franchise agreements, distribution agreements, research and development agreements and joint ventures, which apply depending on several conditions (including whether the parties are competitors in the relevant product market, the market share of the respective parties, and so on).

Licensing Approvals and Formalities

34.Does a patent or trade mark licence and payment of royalties under it to a foreign licensor have to be approved by a government or regulatory body? Are there any formalities or other requirements to make the licence enforceable?

There are no restrictions on the licensing or transferring of patent or trade mark rights to foreign parties. However, there is one important requirement under the Encouragement of Research, Development and Technological Innovation in the Industry Act that technology or IP funded by the Israel Innovation Authority can only be transferred to a foreign party with the prior approval of a research committee of the Innovation Authority. Patent and trade mark licences are valid and enforceable in relation to third parties if they are recoded at the Register of Patents/Trade Marks.

Product Liability

Regulators

35. Outline the key regulators and their powers in relation to medicinal product safety.

The key regulator responsible for medicinal product safety is the MOH, which can order a recall of medicinal products.

Medicinal Product Liability Law

36. Outline the key areas of law applicable to medicinal product liability, including key legislation and recent case law.

Medicinal product liability mainly arises under the:

- Liability for Defective Products Act 1980.
- Tort Ordinance (New Version).
- Consumer Protection Act 1981.

In addition, medicinal product liability can, in principle, arise under contractual claims or claims arising under laws regulating the sale of products.

Under the Liability for Defective Products Act, the substantive test for liability is bodily injury resulting from a defect in the product, regardless of fault on the part of the manufacturer. A product is considered defective under the Act in any of the following situations:

- A defect in the product may cause bodily injury.
- Under the circumstances, warnings or care and use instructions are required and were not provided or are inadequate considering the risk associated with the product.

Under the Tort Ordinance, the substantive test for liability is negligence. For negligence to be established, the following elements must be present:

- A duty of care (both conceptual and concrete).
- Breach of the duty of care.
- A causal connection (factual and legal) between breach and the damage that occurred.

Under the Consumer Protection Act, the substantive test for liability is primarily the misleading of consumers with respect to the risks involved in the use of a product, and failure to disclose to consumers any feature of the product that requires special care to prevent injury.

There is not much case law addressing medicinal product liability. In the *Eltroxin (Levothyroxine)* case *(CA (Central) 16584-10-11 Peleg v Perigo Israel Pharmaceuticals Ltd (published in Nevo, 2015))* the Central District Court approved a class action against the Israeli registration holder based on a claim for violation of the Consumer Protection Act, for failing to adequately inform the MOH and patients that a change in the formulation of the drug required monitoring of the patients switching to the new formulation. In November 2018, the Court approved a settlement according to which the Israeli registration holder paid a total sum of around ILS46 million.

Disputes over medicinal product liability can be resolved in a settlement agreement. If a settlement is reached between parties to court proceedings, it is usually approved by the court and given the force of a judgement. The terms of a settlement agreement need not necessarily be made public.

Legal disputes over medicinal product liability can also be resolved in ADR proceedings, such as mediation or arbitration.

Liable Parties

37.Who is potentially liable for defective medicinal products?

Under the Liability for Defective Products Act, the manufacturer or the importer of a medicinal product that was manufactured outside of Israel can be liable for defective medicinal products.

Under the Tort Ordinance, any entity involved in the chain of production or distribution of a medicinal product may, in principle, be found liable.

Under the Consumer Protection Act, the manufacturer or marketer are among the entities that can be found liable for defective medicinal products. In the *Eltroxin (Levothyroxine) case*, the Central District Court held that the Israeli registration holder of the drug was considered a manufacturer of the drug for the purposes of the Consumer Protection Act.

Any prudent company involved in the production and supply chains of a medicinal product should have a product liability insurance policy. It is important for marketers to ensure that their contracts with suppliers/manufacturers include indemnity provisions enabling them to recover any loss which may result from the marketing of a defective medicinal product.

Defences

38. What defences are available to product liability claims? Is it possible to limit liability for defective medicinal products?

Under the Liability for Defective Products Act, the liability is strict and only the following defences are available for a manufacturer/importer:

- The defect that caused the bodily injury was formed after the product left the control of the manufacturer/importer. Where the manufacturer/importer proves that the particular product concerned underwent reasonable safety inspections before leaving its control, it will be presumed that the injury was caused by a defect that was formed after the product left their control.
- According to the state of scientific and technological development at the time the product left the control of the manufacturer/importer, the manufacturer/importer could not have known that the product did not meet reasonable safety standards.

- The product left the control of the manufacturer/importer unwillingly despite reasonable precautions by the manufacturer/importer who took steps to warn the relevant public of the risk associated with the product.
- The injured person was at least 12 years old and knew of the defect in the product and the risk associated with the product, and willingly exposed themself to that risk.

In addition, while contributory negligence by the injured person will not constitute a defence, gross contributory negligence (by an injured person who is at least 12 years of age) can result in a reduction of the amount of compensation awarded by the court.

Any limitation of liability for defective products is void (section 7, Liability for Defective Products Act).

With respect to the Consumer Protection Act, the Central District Court in the *Eltroxin (Levothyroxine)* case held that the standard of liability for consumer deception is generally strict (similar to the standard of liability under the Liability for Defective Products Act). However, the Central District Court did not reach a definitive conclusion on this point and it has not yet been considered by the Supreme Court.

Product Liability Claims

39. How can a product liability claim be brought?

Limitation Periods

The limitation period for bringing a product liability claim under the Liability for Defective Products Act is earlier of three years from the occurrence of the bodily injury or ten years from the end of the year in which the product left the control of the manufacturer/importer. The limitation period for bringing a product liability claim under the Tort Ordinance or the Consumer Protection Act is normally seven years from the date on which the damage occurred.

Class Actions

Product liability class actions are allowed if based on:

- Violations of the Liability for Defective Products Act.
- A consumer deception under the Consumer Protection Act.
- Tortious liability under the Torts Ordinance.

Remedies

40. What remedies are available to the claimant? Are punitive or exemplary damages allowed for product liability claims?

Under the Liability for Defective Products Act, damages (which can be awarded only for bodily injury) are capped. However, damages for tortious acts under the Torts Ordinance and for violations of the Consumer Protection Act are not capped. In principle, an Israeli court can also award punitive damages in product liability claims that are not based on the Liability for Defective Products Act. However, the court can consider awarding punitive damages only in the most extreme cases involving wilful misconduct.

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Recent transactions

- Advising on some of the most complex and widely publicised patent, trade mark and copyright disputes.
- Litigating on cases for the most innovative pharmaceutical companies in connection with many blockbuster drugs. Supervising complex experiments and working extensively with some of the world's leading experts.
- Patent prosecution work and leveraging unrivalled litigation experience to obtain enforceable patents and develop creative prosecution strategies.

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Professional associations/memberships. International Association for the Protection of Intellectual Property (AIPPI); International Trademark Association (INTA); Licensing Executives Society International (LESI).

Publications

- *IP in Life Sciences* (Globe Business Publishing, 2015).
- *Global Patent Litigation* (Kluwer Law International, 2015).
- *Patent Transactions in the Life Sciences* (Globe Business Publishing, 2014).
- *E-Discovery and Data Privacy: A Practical Guide* (Wolters Kluwer, 2010).
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