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Patent Law – An Update On Manufacturing / Research Opportunities In Malta For The International Generics Drugs Industry

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Without doubt Malta offers significant opportunities for the generics drugs Industry and the evidence for this lies in the pharmaceutical patenting history of the country and in its legislative framework.

The following events have played a major role in the history of patenting in Malta, and have actually shaped the present scenario regarding generic drugs in the country.

1899 – The Industrial Property (Protection) Ordinance (Chapter 29 of the Laws of Malta) was enacted and this was the first piece of legislation that recognized the registration of inventions as patents in Malta. The effect of the law was territorial and the recognition, registration and protection of patents was dealt with by the law in just a few legislative provisions (the law in question catered also for trademarks and industrial designs).

1 June 2002 – The above-cited Ordinance was repealed and the Patents and Designs Act (Chapter 417 of the Laws of Malta) was brought into effect, as amended to date, and it is still the law in force in Malta which deals with patents. This Act is very detailed in nature and it provides for adequate measures which concern patentable and non-patentable inventions, the examination and grant process, the rights afforded to the owner of a patent (effects of patents), exploitation of patents, enforcement provisions concerning patents, and other provisions concerning the application and the registration process. It is to be noted here that Malta has always followed a patent registration system, rather than a patent examination system. To this end, the above-mentioned Act is supplemented by the Patent Regulations (Subsidiary legislation No. 417.01) that were adopted also on 1st June 2002 and which mostly concern rules of procedure that are to be followed in the filing of patent applications and with other formalities which could be observed during and after the patent registration process.

1 January 2003 – the Patents (Plant Protection Products) Regulations (Subsidiary Legislation No. 417.02) and the Patents (Medicinal Products) Regulations (Subsidiary Legislation No. 417.03) came into force and provided legal recognition for supplementary protection certificates (SPCs) for plant protection products and for pharmaceuticals.

1 May 2004 – Malta joins the European Union

1 March 2007 – Malta joins the European Patent Convention (EPC) and the Patent Cooperation Treaty (PCT). On this date the Patent Cooperation Treaty Regulations (Subsidiary Legislation No. 417.04) and the European Patent Convention Regulations (Subsidiary Legislation No. 417.05) came into force. Both measures mainly regulate issues of procedure such as the validation of European Patents (EP) in Malta.

The above dates are important since, to a large extent, up till 1 May 2004 when Malta joined the EU and became part of a larger and more unified economic market, Malta was never chosen by the large foreign pharmaceutical companies as a country in which to register one's own pharmaceutical patents. Until this mentioned date of 1 May 2004, the Maltese Patents Register contained only around 2,500 patents, a sizeable number of which had already expired by the said date. Between the period 1 May 2004 and 1 March 2007, Malta experienced an increase in national patent filings, the filings generally covering all the sectors of industry (engineering, manufacturing and pharmaceutical sector patents) whereby the Patents Register increased by around an additional 2,000 patents (in the region of around 3 years).

Following Malta's accession to the EPC and the PCT, national patent applications virtually came to a standstill with only a few direct national filings observed every year. However, since 1 March 2007 up to the present date (beginning of the year 2017, i.e. a period of approximately 10 years in total), the Industrial Property Registrations Directorate (IPRD) of Malta received around 4,500 applications for EP validations and for the renewal of the national counterpart of those EPs granted at European Patent Office level and which designated Malta. The outlook for these latter type of applications is that they will continue to increase over time. As far as SPCs are concerned, the information which we have from the IPRD is that there were around 70 SPC requests since the year 2003.

The above-mentioned figures lead one to understand that a substantial amount of pharmaceutical compounds were never registered in Malta, in particular those that had to be filed by the year 2003.

One may state that, to a large extent, in particular up till 2004, Malta was "forgotten" by most of the major pharmaceutical companies, probably due to its small size and population. It is true that the amount of applications increased in the period 2004 up till 2007 (i.e. the interim period between Malta's accession to the EU and Malta's accession to the EPC and PCT), however, Malta never saw substantial filings of patent applications similar to the amounts which are ordinarily seen in other larger countries.

It is also important to note that the Patents and Designs Act, as referred to above, includes certain exceptions to the patent owner's exclusive rights which are highly relevant. The said exclusive

rights and exceptions are found in Section 27 of the said Act and the relevant provisions are the ones as follows below:

"(1) Where the patent concerns a product, the proprietor of the patent shall have the right to prevent third parties from performing, without his authorisation, the following acts:
(a) the making of a product incorporating the subject matter of the patent;
(b) the offering or the putting on the market of a product incorporating the subject-matter of the patent, the use of such product, or the importation or stocking of such product for such offering or putting on the market or for such use;
(c) the inducing of third parties to perform any of the above acts.

(2) Where the patent concerns a process, the proprietor of the patent shall have the right to prevent third parties from performing without his authorisation, the following acts:
(a) the use of a process which is the subject matter of the patent;
(b) in respect of any product directly obtained by the use of the process, any of the acts referred to in subarticle (1)(b), even where a patent cannot be obtained for the said product;
(c) the inducing of third parties to perform any of the above acts."

The above-mentioned exclusive rights are subject to the following exceptions which include the 'experimental' and 'scientific research' exception, together with a 'Roche Bolar' exception:

"(6) Notwithstanding subarticles (1) and (2), the proprietor of a patent shall have no right to prevent third parties from performing the acts referred to in subarticles (1) and (2)(b) in the following circumstances:
(b) where the act consists of making or using such product for purely experimental purposes or for scientific research; …
(d) when an act is done for purposes which can reasonably be related to the development and presentation of information required by the law of Malta or any other country that regulates the production, use or sale of medicinal or phytopharmaceutical products;"

The above patenting history and legislative framework therefore have placed the country in an advantageous position in the generics field, especially when compared with other countries, since most of the international pharmaceutical inventions in the period 1990 up to 2007 were never registered in Malta.