Field of research: Intellectual Property – Life sciences- Patents- Access to Health Technologies and Innovation.

Title: Changes in the Medical Devices Regulatory framework and its impact on the Medical Device Industry: From the Medical Devices Directives to the Medical Devices Regulations.

Abstract

Medical devices play an increasingly important role in healthcare worldwide by contributing substantially to the prevention, diagnosis and treatment of diseases. At a European level, enhancing competitiveness while ensuring public health and safety is one of the key objectives of the European Commission.

With the aim of pursuing such objectives, medical devices within Europe have been regulated since 1990 by means of three Directives, namely Directive 90/385/ECC concerning the Active Implantable medical devices (AIMDD), Directive 93/42/ECC concerning medical devices (MDD), and Directive 98/79/ECC concerning in vitro diagnostic medical devices (IVDD). Over the past years, the system has been subject to amendments and has been complemented by several non-binding guidance documents reflecting the consensus of stakeholders.

In 2008 the European Commission launched a public consultation concerning the revision of the Medical Device Directive and, in 2010, regarding the revision of the in Vitro Diagnostic Medical Device Directive. A process for reviewing the Medical Devices Regulatory Legislation followed these consultations in 2012. The aim of the reform was to provide a more harmonized framework, as well as to modernize the legislation in view of the technological developments of the sector.

As a result, on the 5th April 2017, two new regulations on medical devices were adopted (Regulation EU 2017/745 and Regulation EU 2017/ 746), and they entered into force on 25 May 2017. These new regulations contain a series of extremely important improvements to modernize the current system, which will apply 3 years after the publication, as regards MD and 5 years after publication as regards IVDD.

If, on the one hand, a new regulatory system was deemed necessary to properly address the gaps of the past, it is on the other hand likely to result in a major overhaul of the present regulatory framework, with risk that the tougher requirements for the industry will lead to late access to medical technologies.

The incoming changes have raised the question of whether medical devices manufacturers and patentees should be entitled to seek compensation for their loss of patent protection by way of the so called "SPCs" (supplementary protection certificates), originally introduced by Regulation No. 469/2009 for pharmaceutical products. The current SPCs legislation does not expressly foresee it and judicial decisions have been inconsistent on this issue among the EU jurisdictions.

This article analyses the current and incoming regulatory framework governing medical devices, with the aim of highlighting how these major changes would affect the industry at issue. This has the ultimate aim of determining whether or not SPCs are needed for the Medical Devices Industry.

Methodology

Comparative approach.

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