Patent protection in regulated markets

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A regulated market is an organized market that is supervised by one or more "supervisory authorities" or "market regulators."

For example, in the USA, the *Federal Aviation Administration (F.A.A.)* regulates the aviation market and the *Food and Drug Administration (F.D.A.)* organizes the pharmaceutical market. These administrative authorities define all the rules, from general guidelines to detailed technical specifications, to market regulated products and services. Given the globalization of trade, US requirements generally extend worldwide.

Applicable market regulations can significantly influence technical inventions and thus patents. Drafting patent applications and, more specifically, patent claims requires special attention due to the involvement of these third-party regulators. The certainties and uncertainties that can lead to adapting how a patent application is drafted can be technical, market-related, or regulatory.

Several specific problems can effectively arise regarding this articulation between patent matters and regulatory affairs. Some examples are now discussed (this article does not address other aspects such as competition law or mechanisms of protectionism, e.g. privileged or anticipated access to information, interactions if not collusions between national industries and national regulators).

With regard to the content of technical inventions, the guidelines issued by the supervisory authorities can sometimes severely limit the range of possibilities: all inventions are not equal. Some inventions, although novel and inventive, cannot be marketed if they do not meet the regulator's requirements. It is therefore essential to anticipate these rules. In practice, product development requires the skills of staff from the company’s various departments.

Regulations may also have temporal repercussions for the protection of inventions. The regulator's guidelines or specifications may be available late on and can either confirm or invalidate technical choices (e.g. inventions) made very early on by manufacturers. As the industrial development cycles of products and services have their own requirements, there may be little residual room for maneuver. Where appropriate, the regulator's publication of guidelines or specifications can be an opportunity to facilitate and accelerate the emergence of inventions in a reactive or even opportunistic manner.

Regulations may also pose specific confidentiality issues. With regard to document exchanges between manufacturers and supervisory authorities (e.g. certification, accreditation, etc.), confidentiality should be ensured, in particular, to avoid accidental disclosure which could prevent the patent's issuance.

"Official" publications of supervisory authorities can constitute records of prior art in the same manner as any other published document. The patentability of inventions should be considered carefully. The "direct" application of specifications as published will generally not be new. With regard to inventive step, the regulator's publications can contain perspectives or technological horizons constituting "incentives" which limit patentability.

The involvement of a third-party regulator therefore limits the realm of what is possible. If an invention is too different from formal requirements, it cannot be implemented and will remain speculative. If an invention is directly related to them, it will not be patentable.

Consider the example of a regulated market for medical devices for diabetes management. Devices for the subcutaneous administration of insulin all follow a "semi-open" loop paradigm. In practice, all insulin administration should be performed by either the patient themselves or a medical practitioner. A closed loop device, where the machine decides whether or not to administer the insulin, is prohibited. Therefore, almost all patent claims filed by manufacturers provide for the patient's response either explicitly or implicitly through the use of the passive form in the text of the claim. However, projects relating to the so-called "artificial pancreas" have led the regulator to seriously consider “closing” the interaction loop (e.g. by taking peripheral safety devices into account). In this case, pending applications or granted patents could become obsolete almost overnight. It is therefore advisable and advantageous to provide for, at least in the description of applications, embodiments describing a total automation of processes. Alongside technological developments, which are interlinked with the regulations, there are a number of other examples justifying the adaptation of how patent applications are drafted to varying extents. Still with regard to diabetes management, the intimate understanding of safety rules can lead to innovative solutions that are (presumably) acceptable to the regulator. As observed in recent years, the exponential growth of smartphones and other connected watches has led to a number of promising perspectives (but conversely to certain technical bottlenecks, especially due to computer security). Experience in dealing with market authorities is acquired over time: the medical diagnostics industry has the experience in healthcare regulatory affairs which IT giants lack (but conversely, they have unmatched technical agility in computer science).

In another area, that of avionics, Flight Management Systems certified by the F.A.A. ("Federal Aviation Administration") have been supplemented in recent years by "Electronic Flight Bags" implemented in conventional consumer tablets or laptop computers. Powerful and flexible tools are developing around a digital core whose certification is a lengthy, expensive, and complex operation. Almost by definition, innovations are increasingly focused on peripheral systems and processes that supplement this digital certified avionics core. Systemic risk analysis remains central but, in certain conditions, more flexibility to change the peripheral systems and processes at the heart of the F.M.S. helps develop innovative man-machine interface systems for the cockpit. It remains difficult to decide between incremental innovations, which can be accepted by the regulator but whose patentability is questionable, and patentable inventions for which there remains some doubt about whether they can be accepted by regulatory authorities *in fine.*

As illustrated by the foregoing examples, the specific risks associated with the involvement of a regulator also represent opportunities for manufacturers. In general, this involvement tends to complicate the drafting of claims which already take into consideration a subtle

compromise between generally increasing technical possibilities and legal reasoning, which is also becoming more complex (e.g. patentability, detectability, exercise of rights). By appropriately anticipating the regulator's requirements it is possible to improve the text of patent applications and, more generally, the portfolio of patents held. The texts of patent applications can be adapted to varying degrees. "Rich" patent descriptions which include numerous detailed fallback embodiments are recommended in consideration of these regulatory certainties and / or uncertainties.

In conclusion, it is generally relevant and effective to closely monitor publications by supervisory authorities in view of filing patent applications in a reactive or even opportunistic manner. We recommend that inventors work closely with regulatory affairs managers and patent attorneys.