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AIPPI approves Resolution aimed at helping rescue claims on second medical uses from the Valley of Death

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As readers well know, over the years many patent offices around the world have opened the door to the patentability of so-called “second medical uses” to foster research on possible solutions to unmet medical needs based on the use of already known compounds. Although the most developed patent offices such as the European Patent Office (“EPO”) and the United States Patent Office (“USPO”) have a relatively long history of accepting these types of claims, their effective protection may be distorted by existing regulatory regimes. For example, in countries where electronic-prescribing (“e-prescribing”) software cause an active principle to be prescribed for all possible uses regardless of the fact that some uses may be patented, such active principle may end up being prescribed and dispensed to treat patented indications, notwithstanding the existence of a patent in force.

This distorted playing field entails risks both for innovators and for manufacturers of generics. The current environment is so unsatisfactory that it has been described as “The Valley of Death” by Harvard Law School professor Benjamin N. Roin in a forthcoming article entitled, “Solving the Problem of New Uses.” To give readers a “sneak preview” of the solutions that he puts forward in his 66-page article, it may suffice to quote the first paragraph of his conclusions: “With these two simple changes, we can address one of the most critical problems facing biomedical research. The government only needs to modify the specifications for qualifying e-prescribing software and establish privacy rules allowing pharmaceutical companies restricted access to patients’ health records. Pharmaceutical companies would then have the necessary information to enforce new-use patents.”

Prof. Roin’s article illustrates that the effective protection of second medical use claims must cut into the domains of intellectual property, unfair competition and regulatory law. In an increasing complex regulatory environment, patent law, alone, does not seem to be sufficiently equipped to cope with the wide spectrum of challenges presented by the enforcement of these types of claims in some cases. Against this background, one must congratulate the AIPPI for having approved a Resolution in Toronto on 15 September 2014 (Question Q 238) highlighting, among other aspects, that the regulatory frameworks should facilitate transparency as to whether pharmaceuticals are being dispensed for patented medical uses, and, while not preventing the legitimate commercialization of pharmaceuticals for non-patented medical uses, facilitate enforcement of patent protection for second medical uses. The approved Resolution ends with a paragraph urging “[…] the relevant authorities to implement the necessary measures so that effective protection of second medical uses is not jeopardized by regulatory frameworks.”

No doubt this is a positive step towards a more transparent playing field, which should benefit all stakeholders concerned.

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