Expensive drug costs, compulsory patent licensing and the limits to compounding by pharmacists - Hanneke Later-Nijland - Axon Lawyers, Netherlands

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Accepted on December10, 2021

Abstract

Of late, the cost of medicines is a recurring subject of debate in Europe and it is anticipated that this topic will be discussed more intensely in the years to come. In this regard, the application of compulsory patent licensing and the (wider) application of the compounding exemption (formula magistralis) are seriously investigated by the Dutch Minister of Medical Care as an instrument to curb the cost of medicines. In respect to the latter, a legislative proposal is underway which would exonerate pharmacists from patent infringement when compounding medicinal products for direct use for individual cases on medical prescription in pharmacies. This presentation explores in view of the applicable legislation and case law whether these solutions have been correctly identified as the solution to the problem of expensive medicinal products. Pursuant to e.g. the TRIPS Agreement, compulsory patent licensing in view of the general interest is (at least) to be used in combination with an adequate remuneration. Nevertheless, it is worthwhile mentioning that a compulsory license in the public interest was recently granted (and upheld in appeal) in Germany for the HIV drug Isentress. The available case law with respect to compounding and the rationale thereof has demonstrated that it is solely to be utilized as an exception to the rule, which makes it unsuitable as a general solution. Patients are not guaranteed for the same quality control as authorized medicinal products and therefore a proper substantiated justification for this deviation is required. Such justification may when comparing European case law probably not be sought in financial gain leaving aside the fact that this affects the level playing field. This presentation is very relevant for parties manufacturing or marketing high-cost medicinal products.

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