‘Debate in The Netherlands about medicine prices is too polarized’

Kluwer Patent Blog
June 13, 2019

Kluwer Patent blogger

Please refer to this post as: Kluwer Patent blogger, ‘‘Debate in The Netherlands about medicine prices is too polarized’’, Kluwer Patent Blog, June 13 2019, http://patentblog.kluweriplaw.com/2019/06/13/debate-in-the-netherlands-about-medicine-prices-is-too-polarized/

The focus in The Netherlands on the option of compounding medicines as a means to circumvent the use of (expensive) authorised medicinal products of pharmaceutical companies and to pressurize them into lowering their prices, is confusing and possibly misleading and not necessarily good for patients. Attorney-at-law Hanneke Later-Nijland, also a trained pharmacist and a former Inspector for Healthcare, has said this in an interview with Kluwer IP Law.
In the Netherlands, a new provision of the Dutch Patent Act 1995 came into force on 1 February 2019, allowing pharmacists to prepare patented medicines, on a small scale, for patients. This attracted quite a lot of attention. Can you explain why?

“The new provision* is not remarkable or exceptional in itself. It is based on European legislation and surrounding countries have had this option for many years. But in The Netherlands it was never implemented, it didn’t have any priority. This probably changed due to the report Development of new medicines – Better, faster, cheaper of the Council on Public Health and Society (November 2017), in which compounding of medicinal products was proposed as an efficient instrument to curb the cost of medicines.”

What is your opinion about that?

“To begin with: compounding is not that simple and not always possible. Last week, I listened to a Dutch parliamentary debate on medicines, in which minister Bruins of Health Care announced that Spinraza, an expensive drug for Spinal Muscular Atrophy (SMA), shall most likely be reimbursed for all patients, instead of for a limited patient group. Of course, this was very good news, but I was flabbergasted to hear an MP of the Socialist Party suggest the Minister to investigate whether compounding of Spinraza would be a good alternative.

That is completely unrealistic because (1) Spinraza is a very complex product (antisense therapy) and (2) it is infused intrathecally (it will reach the cerebrospinal fluid), which entails many risks.

More importantly, under European legislation and case law (from a regulatory perspective), compounding is not allowed on a large scale. That’s why using the pharmacy exemption is unsuitable as a means to curbing the prices of medicinal products.”

At a seminar earlier this year in Amsterdam on compounding pharmacists, you discussed what pharmaceutical companies can do in case they are challenged, and suggested to: 1) Prepare enforcement request with IGJ (incl. recall at patient level); 2) Try to obtain the product (“second sample”); 3) Trace the suppliers of APIs; 4) Collect all communication re the compounded product (advertising?) Discuss quality risks of compounded products with prescribers; 5) Do not overlook product liability of pharmacists; 6) Use media, with help of PR experts; 7) Lobby.
This list seems to indicate you think the consequences of the new pharmacists exemption should be restricted and counteracted as much as possible.

“This was my advice on how to act when you, as a company, are confronted with this issue. More generally spoken, I think and regret that the climate in The Netherlands is too polarized. On the one hand, the pharmaceutical industry is criticised publicly in a very outspoken way, connected to the pricings discussion, on the other hand the industry is irritated because it is framed as if the medicines prices are eating up our national healthcare budget, while the real numbers show a modest chunk for pharmaceutical care. Just look it up: 7% of the state budget for healthcare (€73 billion for 2017).There is little understanding of each other’s point of view. That isn’t very helpful and has led to unrest. From what I’ve heard, some companies are even reconsidering whether they still want to invest in The Netherlands.”

The pharmaceutical industry and the Association Innovative Medicines among others, have voiced concerns about safety of compounded medicines. Do they have a point?

“I think so. Minister Bruins has created the impression that compounded products are a viable alternative for the original products, that they are interchangeable and just as good. But this is wrong. Pursuant to European legislation, we have competent authorities, the European Medicines Agency (EMA) or national medicines evaluation board (MEB), seriously assessing the efficacy and safety of medicinal products before they enter the market. Compounding means that this system is circumvented. In the US, which also has a system of marketing authorizations in place, we’ve seen tens (over 40) of patients dying of compounded drugs which turned out to be contaminated, which led to an outbreak of fungal meningitis.

In The Netherlands, the Amsterdam Medical Center (AMC) started compounding CDCA for 44 patients with cerebrotendinous xanthomatosis (CTX) last year, after Leadiant had obtained orphan medicine designation for this drug and raised the price to about 160.000 euro per patient per year. CDCA had earlier been on the market at a far lower price for the treatment of gallstones. The AMC had to stop compounding however, when a test by the Dutch Health Inspectorate (IGJ) showed the hospital had used active pharmaceutical ingredients which were not complaint with the applicable standards and contained unidentified impurities. “In the meantime, 44 patients have used these drugs.”

Does the Dutch government have too liberal a view of the scale at which compounding is acceptable?

“As I said before, according to European legislation and case law, compounding is the exception to the rule. In a recent letter, minister Bruins wrote compounding is allowed for up to 50 patients with long-term use, or up to 150 patients for short-term use. In case of orphan diseases, this could be the whole market! However, in the explanatory notes of the new provision of the Dutch Patent Act, his colleague minister of Economic Affairs Wiebes, wrote that compounding is only possible under strict conditions, and certainly not in a structural way.”

An important question is whether pharmaceutical companies are abusing the EU’s orphan drug regulation, as critics say. Due to this regulation Leadiant could raise its price for CDCA exorbitantly. In a similar case, earlier this year Minister Bruins clashed with Novartis about lutetium-octreotaat, after the Swiss pharma company had fivefolded the price of this cancer drug, an orphan medicine for patients with neuroendocrine tumors. What’s your opinion?

“In a period that many important block buster medicines lost their patents, the industry has clearly discovered the benefits of the orphan drug regulation. We, as in the EU, followed the US in that respect, they have had an Orphan Act since 1983. We decided to have those rules to prevent that our biotech industry would have remained behind with a significant impact on patients. Anyone can have an opinion on the way this works and whether that is appropriate or well, socially acceptable in this sector, but as far as I know the orphan designation was granted according to the rules.”

What do you think of the proposal of minister Bruins to reduce the EU market exclusivity for orphan drugs from 10 to 5 years and his insistency on more transparency about costs of the pharmaceutical companies?

“Well, I am looking forward to a less polarised debate between government officials and industry allowing collaboration with the purpose of a balanced health care system. One thing is sure: change of policy yields a change in practice. Such changes should be decided upon light-headedly. Long-term estimates should be made in order to anticipate on (1) whether this change will indeed lead to the desirable effect, but also (2) what side effects such change may have for our healthcare system.”

**Article 53, third paragraph, second sentence Dutch Patent Act, reads: “The exclusive [patent holder’s] right shall neither extend to the preparation for direct use for individual cases on medical prescription of medicines in pharmacies, nor to acts concerning the medicines thus prepared.”*