

Alert | Patent Prosecution



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Amendment to Dutch Patents Act (Rijksoctrooiwet) Allows for Extemporaneous Preparation of Medicine in Certain Circumstances

Article 53 (3) Dutch Patents Act

As of Feb. 1, 2019, the Dutch Patents Act 1995 (DPA) was amended to include a limitation of the exclusive right of the holder of a patent on a medicine. The exclusive right now includes an important exception in DPA Article 53(3):

The exclusive right...does not extend to the preparation for immediate use for individuals on the basis of a medical prescription of medicines in pharmacies, nor acts concerning the medicines so prepared.

This GT Alert examines this limitation. Under what conditions is a pharmacist allowed to prepare a patented medicine?

Community Patent Convention

This portion of DPA Article 53(3) enables pharmacists to prepare patented medicines in the above-stated circumstances, for immediate use for individuals on the basis of a medical prescription. The language originates from Europe's Community Patent Convention (CPC) Article 31, which states the rights

conferred by a community patent shall extend to neither the extemporaneous preparation of a medicine for individual cases in a pharmacy in accordance with a medical prescription nor acts concerning the medicine so prepared. Although the CPC never entered into force and the DPA was adopted in 1995 without this language, parties to the convention confirmed that they would amend the DPA at a later date to conform with this language in the CPC.

Political Context

While, as of Feb. 1, 2019, Dutch Parliament is no longer debating the above-quoted text of DPA Article 53(3), the political conversation continues, and the ramifications remain to be seen. The public interest in addressing excessively high medicine prices in the Netherlands motivated the legislature to make this language official. According to the Minister of Medical Care and Sports, Mr. Bruins, removing liability for patent violation in certain instances of extemporaneous preparation of medicines could provide a reasonable alternative for expensive medicines.

In his Explanatory Memorandum on the enforcement of the extemporaneous provision, the Minister of Economics, Mr. Wiebes, stated that to prevent abuse of extemporaneous preparation of medicines, the exception should only apply to:

- exceptional cases in which a pharmacist prepares a medicine himself;
- cases pursuant to a medical prescription; and
- the preparation of medicines for individual patients.

Scholars in the Netherlands agree this language does not allow the preparation of patented medicines on a widespread basis.

Case Law

The newly adopted exception in the DPA must be interpreted restrictively. Case law in member states where the exception entered into force earlier dictates that extemporaneous preparation of medicine is only allowed in a specific dosage or with excipients other than those making up the medicinal products available over the counter in the country.

Legal Debate

Public sentiment in the Netherlands supports extemporaneous preparation of medicine as an alternative to expensive drugs. Obviously, a broad interpretation of the new law will be opposed by stakeholders such as patent owners and the pharmaceutical industry. Regardless of whether the medicine is available on the Dutch market, it is reasonable to anticipate a legal debate on the scope of the newly effective exception of DPA Article 53(3).

Greenberg Traurig's Amsterdam office will be closely monitoring the developing case law on exactly how the exception will apply.

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