


## Pharmacist compounding: a patent lawyer's perspective



## Patents in general

- Exclusive right 
- Quid pro quo:
  - Patentee has to disclose the invention to the public
  - Exclusivity in return
  - Limited territorial scope and time
  - Purpose: to stimulate innovation

*“ingenuity should receive a liberal encouragement”*

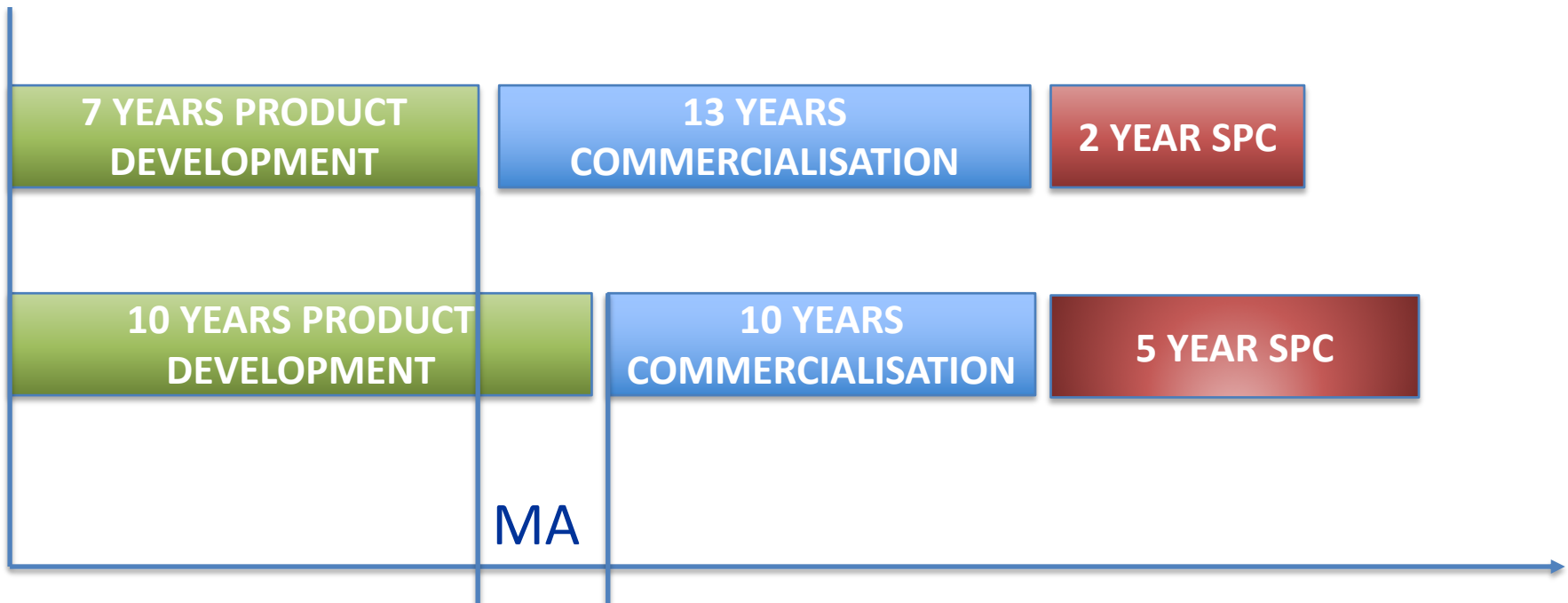
(T. Jefferson, 1807)



## Geographical scope NL:

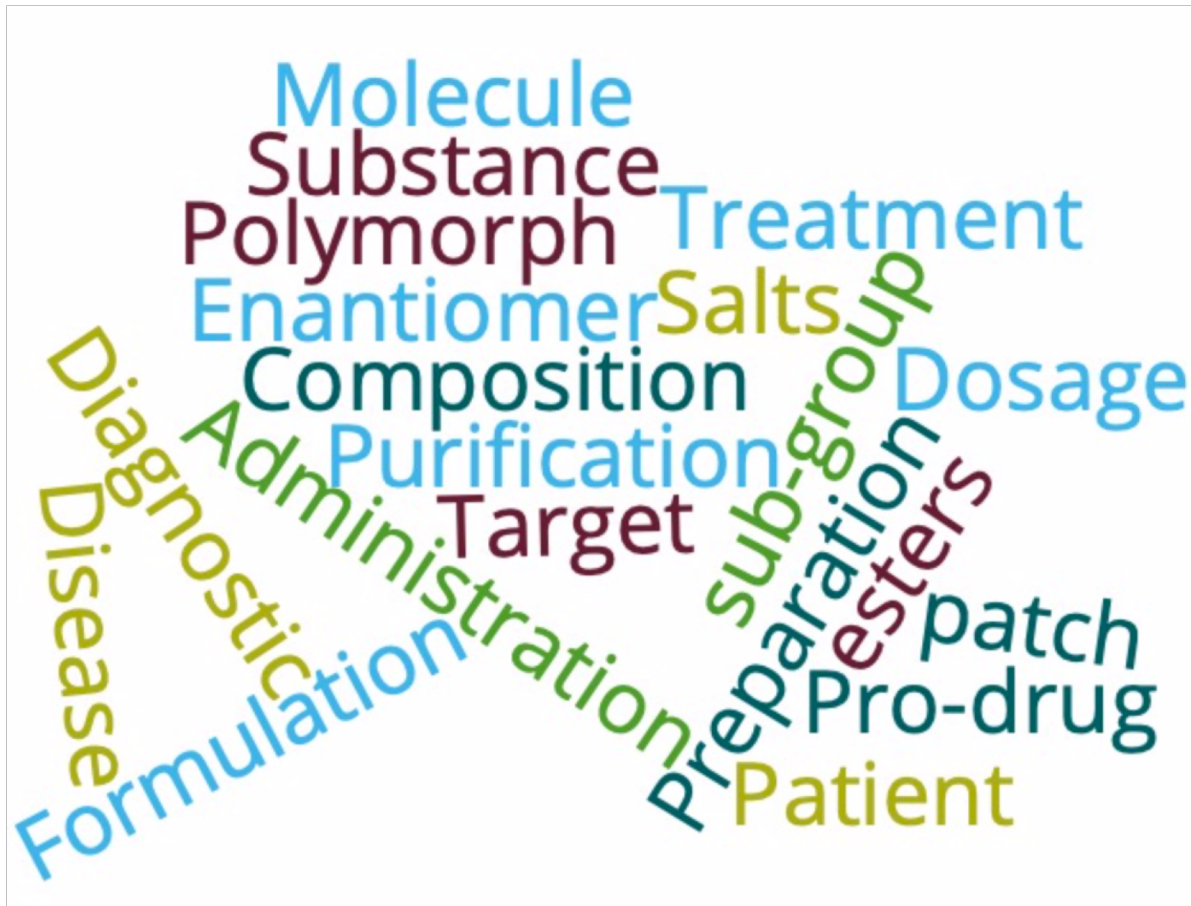


Patent lifetime 20 years, but for pharmaceutical products:



Max 5 years SPC extension depending on date of first MA

## Types of pharmaceutical patents:



## Patent exclusivity – the rule



■ Art. 53 Dutch Patent Act:

A patent shall confer on its proprietor the exclusive right

*a. to manufacture, use, market or resell, rent, deliver or otherwise trade the patented product in or for his business, or to offer, import or hold in stock for any purpose;*

*b. to use the patented process in or for his business or to use, market or resell, rent, deliver or otherwise trade in the product obtained directly by using that process in or for his business, or to offer, import or hold in stock for any purpose.*

## Patent exclusivity – the exceptions

### ■ Exemptions in the Patents Act:

The exclusive right does not extend to acts which serve:

- **Research exemption:** exclusively to acts of research of the patented subject matter
- **Bolar exemption:** necessary studies and trials for generic approval
- **Pharmacists exemption:** nor does the exclusive right extend to the preparation for direct use for individual cases on medical prescription of medicinal products in pharmacies, or to acts relating to medicinal products so prepared.

## Patent exclusivity – pharmacists exemption

- preparation
- for direct use
- for individual cases
- on medical prescription
- of medicinal products in pharmacies, or to acts relating to medicinal products so prepared



Introduced 1 Feb 2019  
But old law (1980s)

## Patent exclusivity – pharmacists exemption

- Explanatory note (EAC Min. Wiebes, Dec. 2018):

*“This exemption is intended for the preparation of medicines for direct use for individual patients and on medical prescription in pharmacies. This makes it possible for a pharmacist in individual cases to prepare the patented medicine himself (the so-called **magistral preparation**), for example **when a suitable dosage or method of administration for an individual patient is not available**. The purpose of the exception is **not to prepare a patented medicine on a structural scale without the patent holder's permission**; after all, this would **erode** the patent holder's **right**.” (emphasis AK)*

## Patent exclusivity – pharmacists exemption

- Explanatory memorandum (approval CPC):

*In order to prevent any abuse of this exemption, it is expressly stipulated that the preparation must be on prescription for direct use in individual cases of medicinal products in pharmacies, not in companies, and that there must therefore be a medical prescription before the medicinal product is prepared for this particular case. This also means that the preparation of larger quantities of medicines for more patients, as is the case in hospital pharmacies, is not permitted. (emphasis, AK)*

## Conclusions – pharmacists exemption

- Patent law exemptions in general **narrow scope**
- **Objective** of the exemption is to allow medical professionals to help patients in need
- Supplier of essential means not free of **indirect infringement**
- Risk in **civil court**:
  - Injunction (backed by penalty)
  - Damages
  - PI (“kort geding”)
  - Other enforcement measures

Min. Bruins April '19:  
*The relationship between patent holder and pharmacist is a **civil law** relationship that is **not** governed by the Medicines Directive or Act.*

## Patent exclusivity – Compulsory license

### ■ Art 57 Patents Act:

*“Our Minister may, if in his opinion the general interest so requires, grant a licence under a patent to a person designated by Our Minister for subject matter that is precisely described by Our Minister. Before issuing its decision, Our Minister shall, unless the urgency required for this purpose dictates otherwise, examine whether the patent holder is prepared to grant the licence voluntarily under reasonable conditions. To this end, he shall give the patent proprietor the opportunity to express his feelings in writing and, if the latter so requests, also orally. The decision shall be communicated to the patent proprietor and to the licensee. By means of his decision, Our Minister may impose the provision of security on the licensee within a certain period of time. The lodging of objections and appeals shall have suspensive effect, unless Our Minister's decision provides otherwise on the grounds of the urgency required in this respect.”*

## Patent exclusivity – Compulsory license

### ■ Art 57 Patents Act:

- The Minister of EAC (*Economische Zaken en Klimaat*)
- In the public interest
- First investigate if patentee is willing to license
- Reasonable conditions
- Negotiate a reasonable compensation (or the court will decide)
- No obligation to supply when there is a compulsory license

## Compulsory license - conclusion

- Minister Bruins (July 2018):

*“There is hardly any experience with compulsory licences in the Netherlands; it is also not a widespread practice at a global level. As a result, there is a lack of consistent case law. It is therefore difficult to predict whether a decision to grant a compulsory licence will stand up.”*

- Designed for emergency situations of public interest.

- In sum:

- procedurally and substantively complex,
- uncertain outcome and
- still reasonable compensation required

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