



österreichisches  
patentamt

# Decision C-471/14

Seattle Genetics Inc.

versus

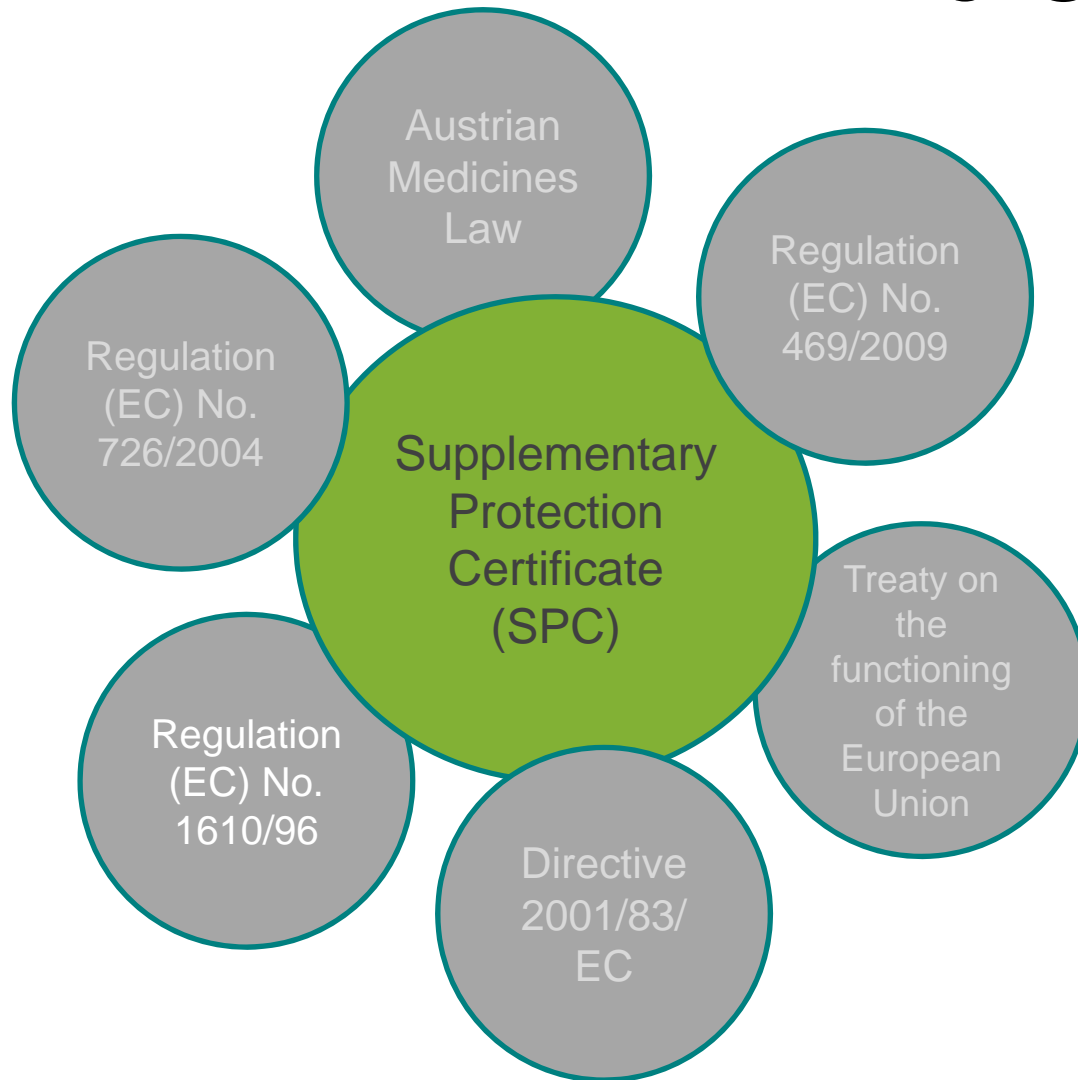
Austrian Patent Office

March 6, 2019





# The Complexity of the System





# Why all these rules?

## Article 13 (1) of Reg.(EC) 469/09

### *Article 13*

#### **Duration of the certificate**

1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years.

**Clear?**

# The case at issue (I)

- Seattle Genetics = holder of EP 1545613 B1
- Applied for on 31 July 2003
- Granted on 20 July 2011
- On 31 May 2011: Application for a MA under the centralised procedure for Brenduximab vedotin by the Takeda Global
- Grant of the MA by decision dated 25 October 2012
- Notification date: 30 October 2012
- Official publication of the grant on 30 November 2012



## The case at issue (II)

- On 2 November 2012: Seattle Genetics filed an application for a SPC based on EP 1545613 B1
- APO fixed the expiry date as 25 October 2027

Filing date of EP 1545613 B1: 31 July 2003

Grant of the first MA: 25 October 2012  
(Date of Decision)

Expiry of the basic patent: 31 July 2023

Expiry date for the SPC: 25 October 2027

## The case at issue (III)

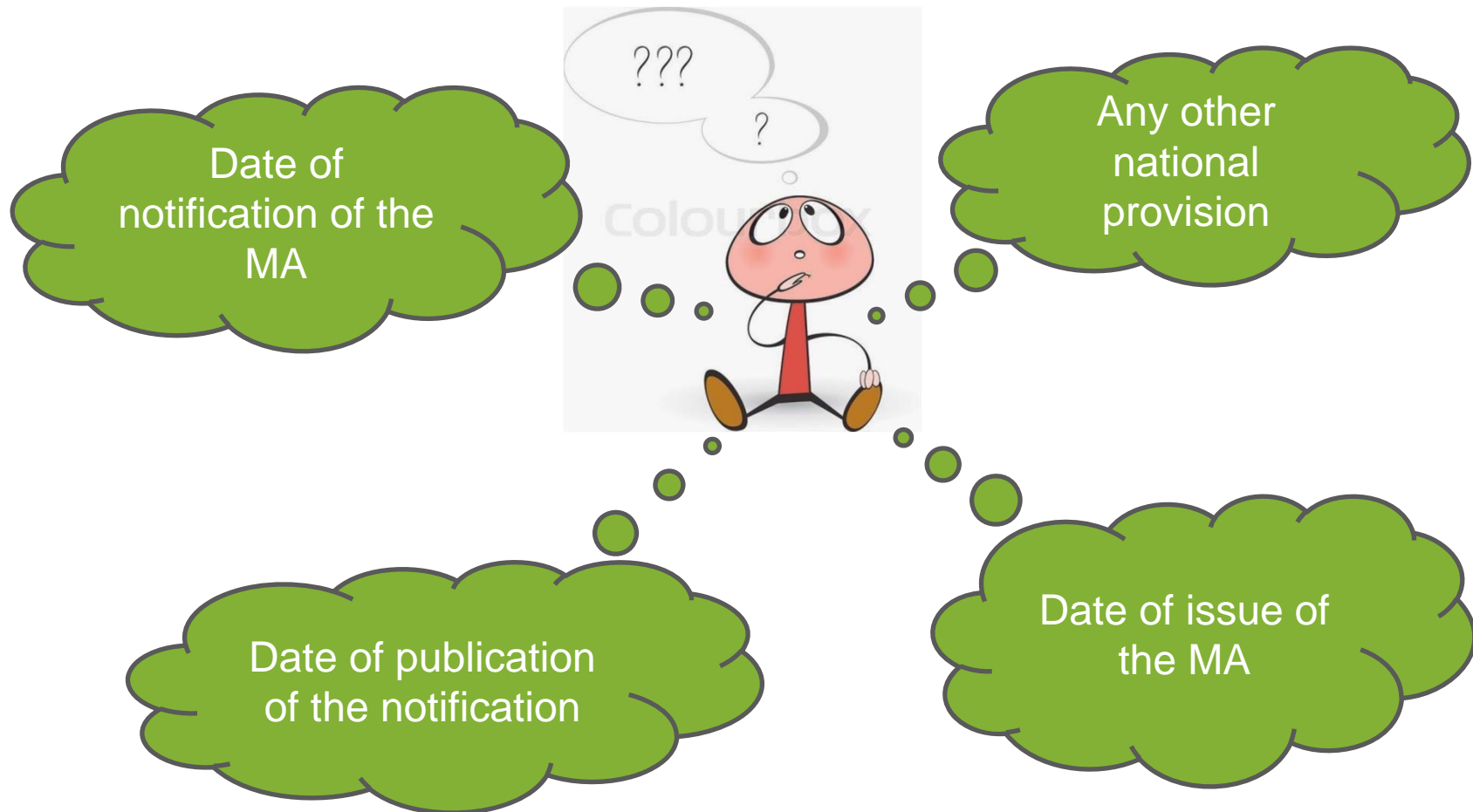
- On October 2014, Seattle Genetics made an appeal against the decision of the APO before the Higher Regional Court claiming for the rectification of the SPC expiry date
- Seattle Genetics: The date of the first MA within the meaning of Art 13(1) of Reg No 469/2009 must be the date on which the applicant was given notification.
- Higher Regional Court stated that the NPOs of MS differ in their practice.
- Decision to stay the proceedings and referral to the CJEU



- (1) Is the date of the first MA pursuant to Art 13(1) of Regulation determined according to EU law or does that provision refer to the date on which the authorisation takes effect under the law of the MS?*
- (2) If the Court's answer is that the date referred to in Question 1 is determined by EU law, which date must be taken into account – the date of authorisation or the date of notification?*



# Good Question







# Motives of the decision

- Remedy of the shortcomings of national patent schemes
- Uniform application of EU law
- Art 13 (1) does not define the date of the first authorisation nor does it contain any reference to national law.
- Purpose of the Regulation justifies an autonomous and uniform interpretation



# Decision C-471/14

## Date of the first authorisation

### (1) determination by EU law

### (2)

CONSOLIDATED VERSION  
OF  
THE TREATY ON THE FUNCTIONING OF THE  
EUROPEAN UNION  
*Article 297*

2. Non-legislative acts adopted in the form of regulations, directives or decisions, when the latter do not specify to whom they are addressed, shall be signed by the President of the institution which adopted them.

Regulations and directives which are addressed to all Member States, as well as decisions which do not specify to whom they are addressed, shall be published in the *Official Journal of the European Union*. They shall enter into force on the date specified in them or, in the absence thereof, on the twentieth day following that of their publication.

Other directives, and decisions which specify to whom they are addressed, shall be notified to those to whom they are addressed and shall take effect upon such notification.



Date of the notification

# Uniformity achieved?

- Reg No 469/09 lays down that an SPC can also be granted on the basis of national MA
- Interpretation of the concept „the first authorisation to place the product on the market“ by national law
- National courts decide upon the notification date
- No guidelines for determining the notification date of national MAs. How can it be audited?

# Aftermath of Decision C-471/14

C-492/16 („Incyte“)

Many SPCs were granted before the Seattle Genetics interpretation, resulting in shorter terms, and many of them already ran out of the national appeal terms.

➔ Divergent practices in the MS:

Refusal of a recalculation vs. rectification of the duration based on national or EU legal reasons



## Decision C-492/16

- Incyte has an SPC granted well before Seattle Genetics
- Right to appeal was not anymore given
- Request to the HIPO for correction of the SPC term
- Rejection of the request because SPC granting decision did not contain any error



## Decision C-492/16

- Appeal to the Metropolitan Court referring to Art 17(2) PPP Regulation as basis for the rectification
- Budapest High Court stayed the proceeding and asked CJEU for clarification.
- The Court reasoned with reference to its interpretation of the date of first MA in Seattle Genetics and the *ex tunc* effect of that judgement, that any other date than the date of notification must be regarded as incorrect, why its rectification should be allowed.

# Outcome of C-471/14 and C-492/16

in Austria:

- Pending SPC applications will be corrected
- Irrespective of the nature of the first MA
- No correction of granted SPCs of IP office's own motion
- Correction of granted SPCs upon request