

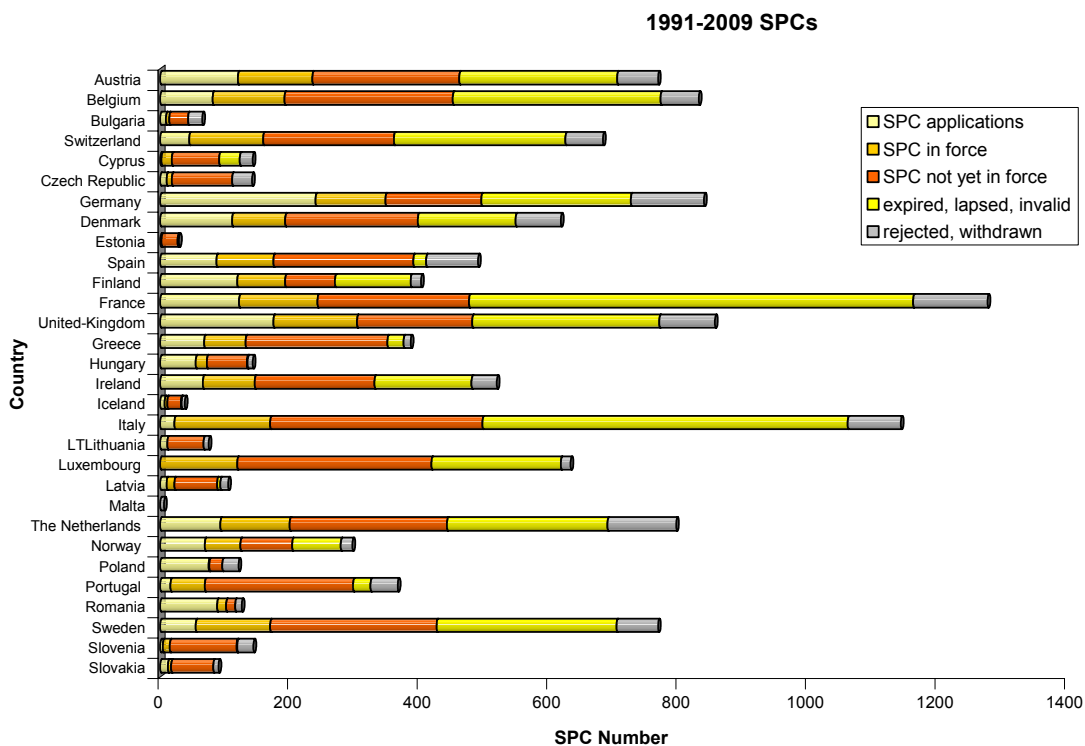
LATEST NEWS ON SPCs IN EUROPE

➤ MEDICINAL PRODUCT SPCs IN EUROPE

❖ Medicinal Product SPCs filed from 1991 to 2009

About 12920 SPC applications for medicinal products regulated by EC Regulation 469/2009 or National laws have been filed in European countries from January 1991 to December 2009, and published until the end of March 2010.

In the graph below, is shown, for each country the number of SPCs filed from 1991 to 2009, dispatched according to their status.



The situation differs from one country to another due to the importance of the markets and/or to the applicable laws and/or to the date of entry in force of the EU Regulation.

So for SPCs in force in March 2010 we noted:

- ✓ in the twelve new EU countries (SPC EU Regulation since 2004 or later) there are few SPCs in force: 0 to 17 SPCs per country

- ✓ in Spain, Greece, Portugal and Iceland (SPC EU Regulation since 1998) there are 88, 64, 53, 4 SPCs in force, respectively

- ✓ in Denmark, Finland, Ireland and Norway (SPC EU Regulation since 1993 or 1994) there are 82, 74, 80, 55 SPCs in force, respectively

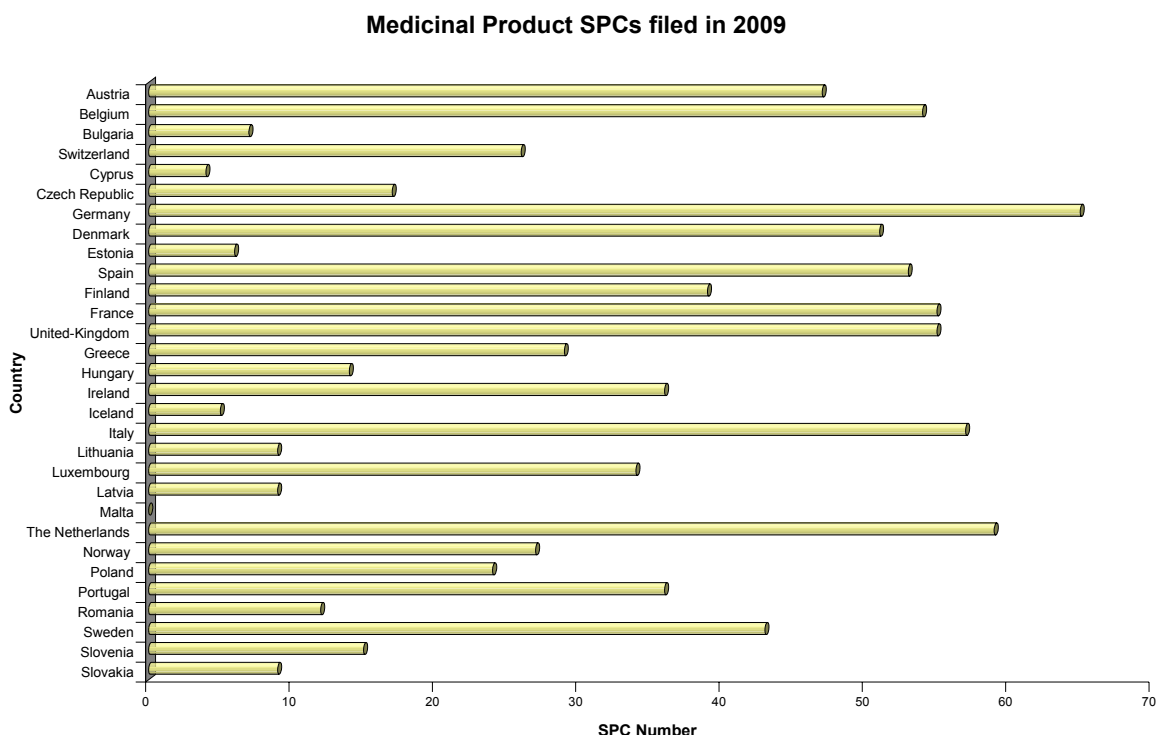
- ✓ in Austria, Belgium, Switzerland, Germany, France, United-Kingdom, Italy, Luxembourg, The Netherlands, Sweden (SPC EU Regulation since 1993 or 1994 or Swiss Law) there are 107 to 148 EU or CH SPCs in force.

❖ Medicinal Product SPCs filed in 2009

How many SPCs?

898 SPCs filed in 2009 were published at the end of April 2009.

In the graph below, is shown the number of SPCs for each country.



* No data for Malta

Which medicinal products?

The 898 SPCs filed in 2009 and published at the end of April 2009 cover about 95 different products (active ingredients, combinations of active ingredients, or formulations).

► Among these 898 SPCs, about 24.0% relate to antineoplastic agents, 2.1% to antibacterials, 2.3% to antivirals, 14.0% to vaccines, 11.0% to sex hormones, 5.9% to angiotensin antagonists, 3.1% to cholesterol and triglyceride reducers, 5.6% to glucose lowering agents.

► We noted products, for which were lodged at least 18 SPCs. These products can be roughly sorted according to their therapeutic category:

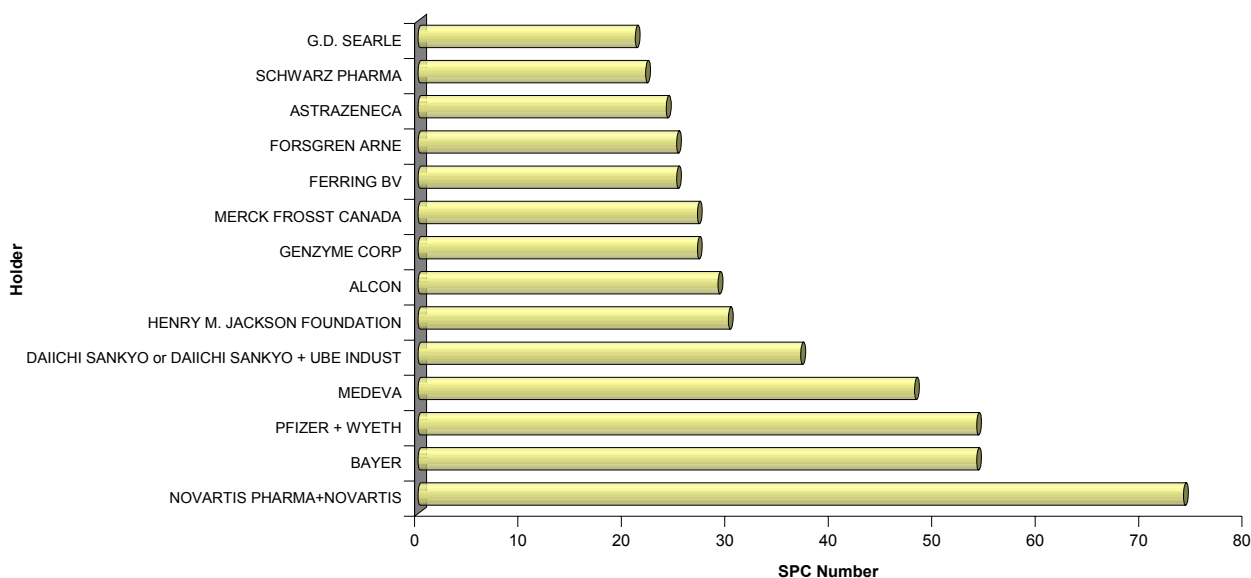
- **Antineoplastic agents:** catumoxamab (34; 15 referring to Trion Pharma, 10 to GSF-Forschungszentrum für Umwelt und Gesundheit GmbH, 9 to Ascenion GmbH patents), gefitinib (23), degarelix (25), certolizumab pegol (18), ustekinumab (19), tocilizumab (30)
- **Platelet aggregation inhibitors:** prasugrel (18)
- **Antihemorrhagics:** romiplostim (19)
- **Angiotensin antagonists:** combination of amlodipine besylate and olmesartan medoxomil (19), combination of aliskiren and hydrochlorothiazide (34)
- **Cholesterol and triglyceride reducers:** combination of laropiprant and nicotinic acid (26)
- **Sex hormones:** combination of dienogest and estradiol valerate (21), lasofoxifene (22), bazedoxifene (22)
- **Vaccines:** Pneumococcal polysaccharide vaccines (69; 25 referring to Forsgren Arne, 14 to GlaxoSmithKline Biologicals, 30 to Henry M. Jackson Foundation for the Advancement of Military Medicine patents)
- **Antiepileptics:** eslicarbazepine acetate (18), lacosamide (37)
- **Antiglaucoma:** combination of brinzolamide and timolol (29).

Who filed Medicinal product SPCs and for which products?

Out of the 897 SPCs filed in 2009 and published at the end of March 2009, we noted 14 holders which lodged at least 20 SPCs (497 SPCs).

For these 497 SPCs, the figure below represents the number of SPCs sorted by holder.

Medicinal Product SPCs – Main Holders



Medicinal products for which SPCs were filed by the first 14 SPC holders in 2009:

► *Novartis or Novartis Pharma*: 34 SPCs for aliskiren and hydrochlorothiazide combinations, 14 for canakinumab, 19 for robenacoxib and pimecrolimus (2), metformin and vildagliptin combinations (2), vildagliptin (2), rufinamide (1).

► *Bayer Schering Pharma, Bayer Healthcare, Bayer Corp or Bayer Animal Health*: 20 SPCs for dienogest and estradiol valerate combination, 12 for drospirenone and ethinylestradiol combinations, 9 for rivaroxaban, 9 for golimumab and drospirenone and estradiol combinations (1), gadobutrol (1), imidacloprid and moxidectin combinations (1), sorafenib (1).

► *Daiichi Sankyo or Daiichi Sankyo and UBE Industries*: 19 for amlodipine besylate and olmesartan medoxomil combinations, 18 for prasugrel.

► *Pfizer or Wyeth*: 22 SPCs for lasofoxifene or lasofoxifene tartrate, 23 SPCs for bazedoxifene or bazedoxifene acetate, 3 for latanoprost, 2 for maraviroc and fesoterodine (1), gonadotropin releasing factor (1), varenicline (1).

► *Medeva*: 48 SPCs for DTPa-HB-IPV vaccine, DTPa-HB-IPV-Hib vaccine or DTPa-IPV vaccine.

► *Henry M. Jackson Foundation for the Advancement of Military Medicine*: 30 SPCs for Pneumococcal Polysaccharide vaccines.

► *Alcon Laboratories or Alcon Research*: 29 SPCs for combinations of brinzolamide and timolol or timolol maleate.

► *Genzyme Corp*: 16 SPCs for alglucosidase alfa, 11 for sevelamer carbonate or sevelamer carbonate or bicarbonate.

► *Merck Frost Canada*: 26 SPCs for combinations of laropiprant and nicotinic acid, 1 for etoricoxib.

► *Ferring BV*: 25 SPCs for degarelix or degarelix acetate.

► *Forsgren Arne*: 25 SPCs for Pneumococcal Polysaccharide vaccines.

► *AstraZeneca*: 23 SPCs for gefitinib, 1 for rosuvastatin.

► *Schwarz Pharma*: 20 SPCs for lacosamide, 2 for fesoterodine.

► *G.D. Searle*: 21 SPCs for mavacoxib.

❖ SPCs in Europe relating to vaccines

More than 800 SPC or SPCs applications relating to vaccines for human use were lodged from 1995 to 2009.

The protection conferred by the patent claims is not always sufficient to fully protect vaccines object of the AMM. To overcome this failure, the holders file multiple SPC applications referring to a single marketing authorization either for different products or by referring to different patents.

According to their interpretation of the Regulation 469/2009, the examiners of patent offices drastically limit the number of SPC granted. This results in a lengthening procedure and/or appeal procedure versus examiner decisions.

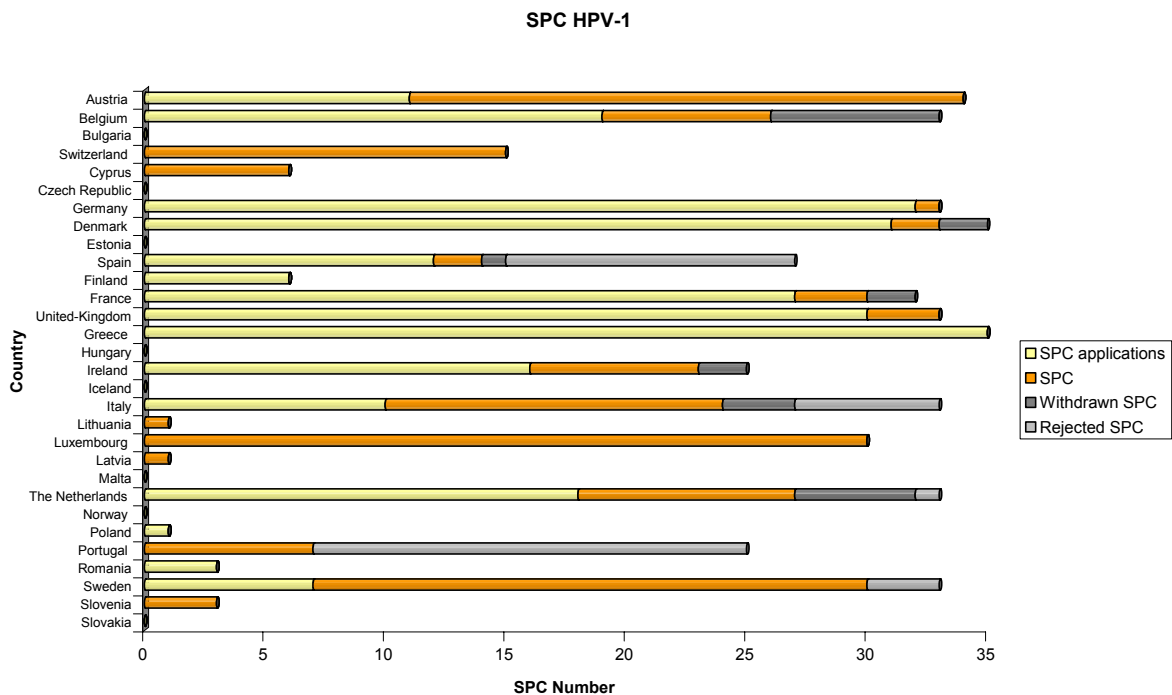
To illustrate the situation on the SPC for vaccines we present below some statistics for HPV vaccines, H5N1 vaccines and DTPa vaccines.

✓ Human Papilloma virus vaccines

477 SPC applications relating to HPV vaccines (Cervarix® or Silgard® and/or Gardasil®) were lodged in Europe: 449 in 2007, 27 in 2008 and 1 in 2009.

They refer to 9 patent families filed in July 1992, June 1993, September 1993, March 1994, October 1995, March 1996, August 1998, October 1999 or March 2000.

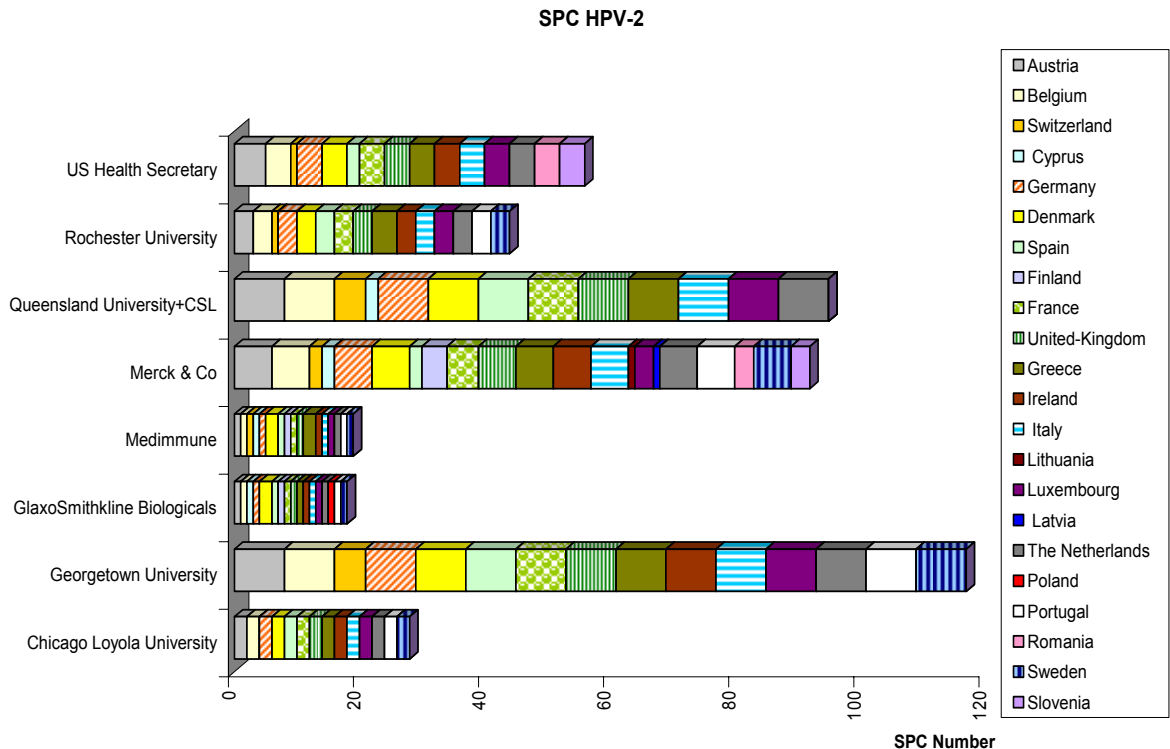
- The figure SPC HPV-1 below represents the number of SPCs sorted by country and dispatched according to their status.



We noted

- no SPC application published in Bulgaria, Czech Republic, Estonia, Hungary, Iceland, Malta, Norway and Slovakia
- very few SPC granted in Germany, France and United-Kingdom: respectively 1 and 3.

- The figure SPC HPV-2 below represents the number of SPCs for each holder sorted by country.



✓ **H5N1 vaccines**

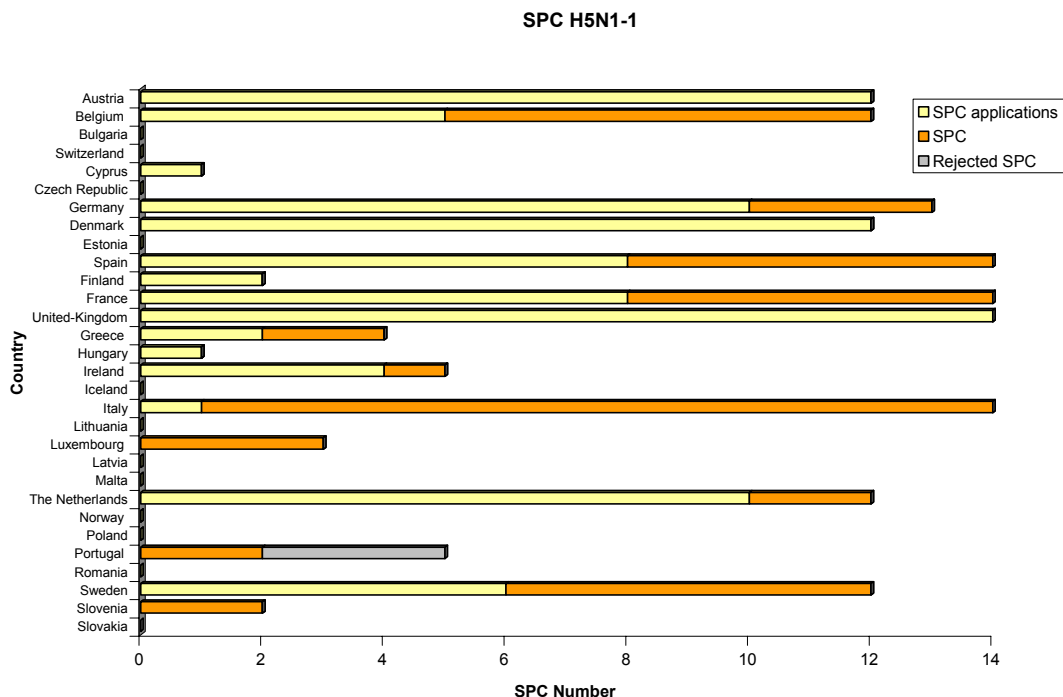
152 SPC applications relating to H5N1 vaccines (Cervarix® or Silgard® and/or Gardasil®) were lodged in Europe: 52 in 2007 and 100 in 2008.

They refer to 4 patent families filed in August 1990, December 1994, April 2000 or July 2000.

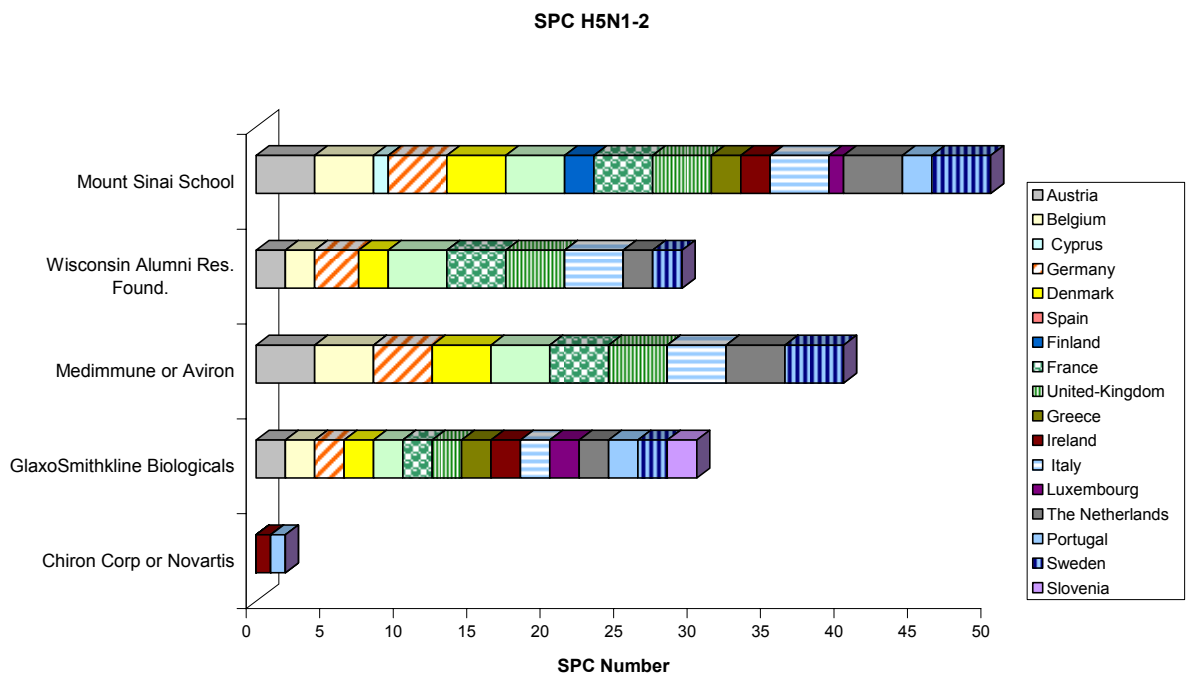
We noted

- no SPC application published in Bulgaria, Switzerland, Czech Republic, Estonia, Iceland, Lithuania, Latvia, Malta, Norway, Poland, Romania and Slovakia
- no SPC granted in the United Kingdom, 3 SPCs granted in Germany.

- The figure SPC H5N1-1 below represents the number of SPCs sorted by country and dispatched according to their status.



- The figure SPC H5N1-2 below represents the number of SPCs for each holder sorted by country.



✓ **DTPa vaccines**

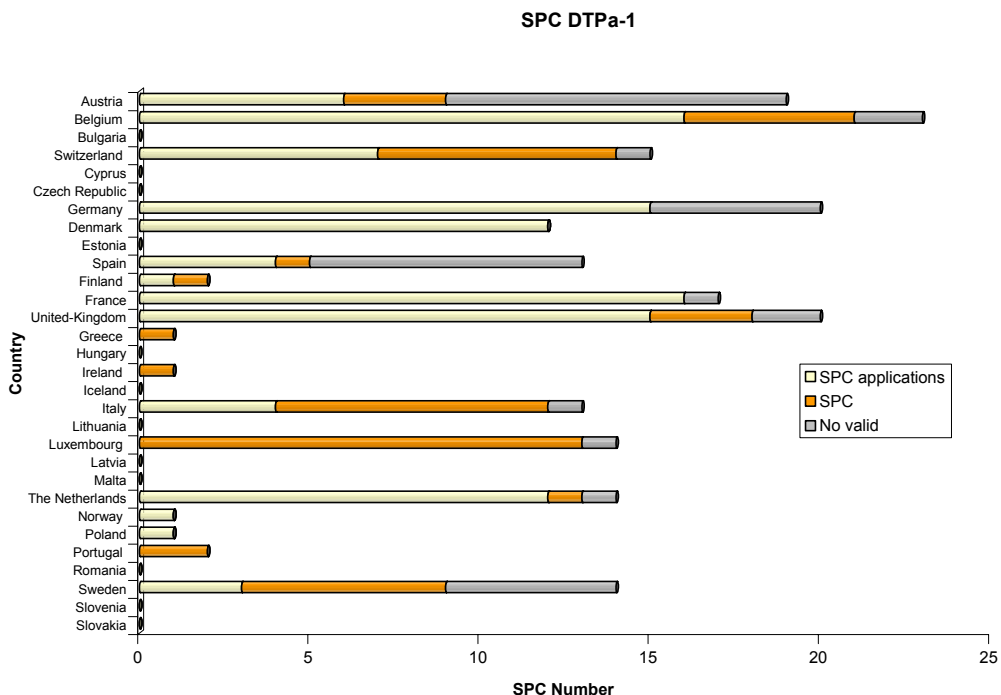
202 SPC applications relating to DTPa, DTPa-Hib, DTPa-HB, DTPa-HB-IPV, DTPa-HB-IPV-Hib, vaccines (Infanrix®, Tracellar®, Boostrix®, Tetravac®, Pentavac®, Pediacel®) were lodged in Europe: 53 from 1995 to 1999, 99 from 2004 to 2006 and 50 in 2009 or 2010.

They refer to 7 patent families filed in March 1984, May 1985, March or April 1987, April 1990, May 1993, May 1996 or November 1997.

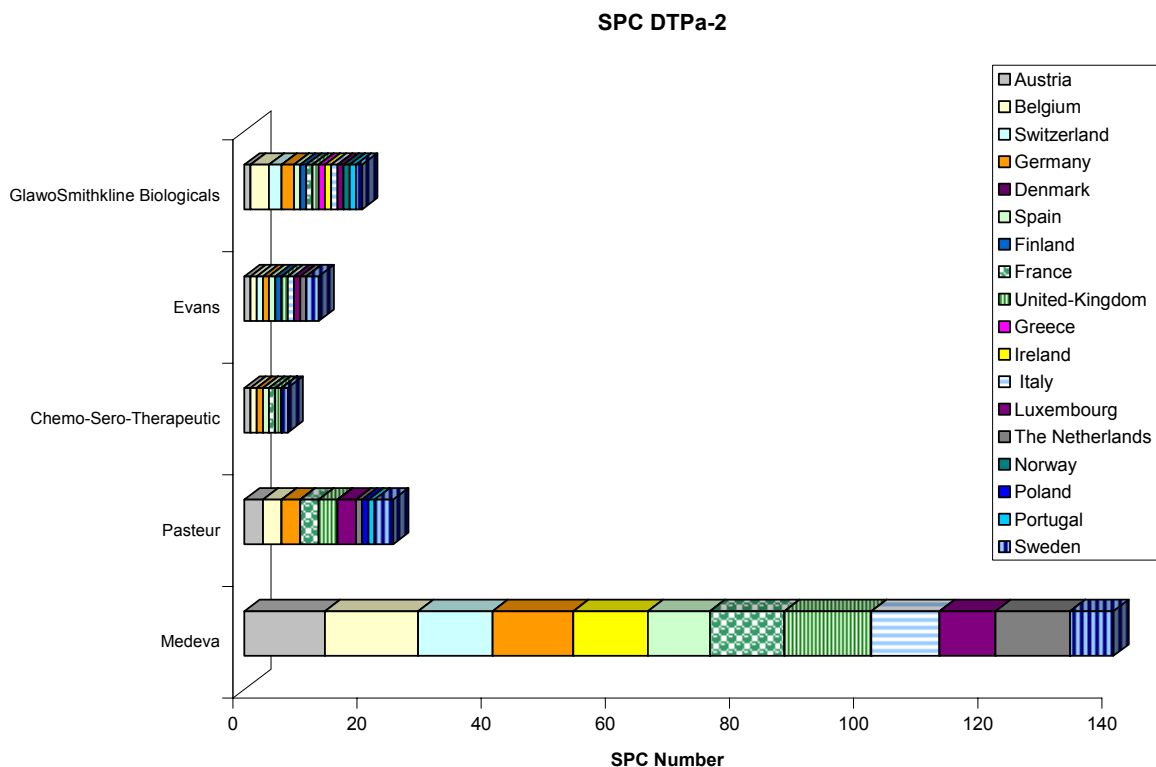
- The figure SPC DTPa-1 below represents the number of SPCs sorted by country and dispatched according to their status.

We noted

- no SPC application published in Bulgaria, Cyprus, Czech Republic, Estonia, Hungary, Iceland, Lithuania, Latvia, Malta, Romania, Slovenia and Slovakia
- no SPC granted in Germany and France, 3 SPCs granted in The United Kingdom.



- The figure SPC DTPa-2 below represents the number of SPCs for each holder sorted by country.



❖ Paediatric SPC extensions

On 5 May 2010 we noticed

- ✓ **Losartan**
 - SPCs with paediatric extension lapsed on 1 or 2 March 2010 in Austria, Belgium, Germany, Denmark, Finland, France, The United Kingdom, Ireland, Italy, The Netherlands and Sweden
 - Paediatric extension until 1 December 2010 in Latvia.
- ✓ **Anastrozole** (extension until 10 or 11 February 2011)
 - Paediatric extension granted in Finland and Sweden
 - Paediatric extension applications published in Austria, Belgium, Germany, Denmark, France, The United Kingdom, Ireland, Italy and The Netherlands.
- ✓ **Caspofungin** (extension until April 2017 in most countries but September 2017 in Czech Republic)
 - Paediatric extension granted in Germany, Denmark, France, The United Kingdom, Ireland, The Netherlands and Sweden
 - Paediatric extension applications published in Austria, Belgium, Czech Republic, Finland and Slovenia.
- ✓ **Zoledronic acid** (extension until May 2013 in most countries but October 2013 in Slovenia)
 - Paediatric extension granted in Denmark, Sweden and Slovenia
 - Paediatric extension application published in Austria, Germany, Finland, France, The United Kingdom, Ireland, The Netherlands, and Slovenia.

❖ *French decisions affecting SPCs*

As usual, there are very few French decisions relating to patents. We mention three decisions relating to SPCs.

✓ Cour d'appel de Paris dismissed on 6/11/2009 **Daiichi Sankyo** appeal against the decision of the Director-General of the French Patent Office (INPI) on 13 February 2009 to reject French SPC 06C0019 for an olmesartan medoxomil and hydrochlorothiazide combination, referring to EP0503785 patent.

The Cour d'appel de Paris dismissed Daiichi Sankyo's appeal because it was not possible to get an SPC for the Olmesartan Medoxomil and Hydrochlorothiazide combination, as this combination was not protected by the patent.

✓ TGI Paris 3rd chambre, 3rd section (07/10/2009) Société **ALKABELLO AS/ S.A. STALLERGENES**

According to this decision, the Court revoked French SPC FR07C0033 for Extrait allergénique de pollen de fléole des prés (Phleum pratense) referring to EP0278877 and to French MA 378011-6 of 08/02/2007 (Grazax®), the French MA for Grazax® not being the first marketing authorization granted for this product as a medicinal. Indeed, an MA for Alutard® drug based on the same active ingredient has been issued on 03/05/2006.

There is no mention of revocation in the French Patent Register (probably appeal).

✓ TGI Paris, 3rd chambre, 1st section (06/10/2009) **TEVA CLASSICS, TEVA SANTE, TEVA PHARMACEUTICAL Industries Ltd/ SEPRACOR**

According to this decision, the Court revoked, for insufficiency, the French part of all claims of Sepracor patent EP0663828 relating to use of levocetirizine for the treatment of allergic rhinitis and asthma.

The specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art: it contains no technical information supporting the statements in the application, including experiments or plausible explanations that can demonstrate the real effects involving alleged invention. The absence of any mention of research and results is the demonstration of the speculative nature of the patent application and effect of concealing the lack of inventive step.

There is no mention of revocation in the French Patent Register (probably appeal).

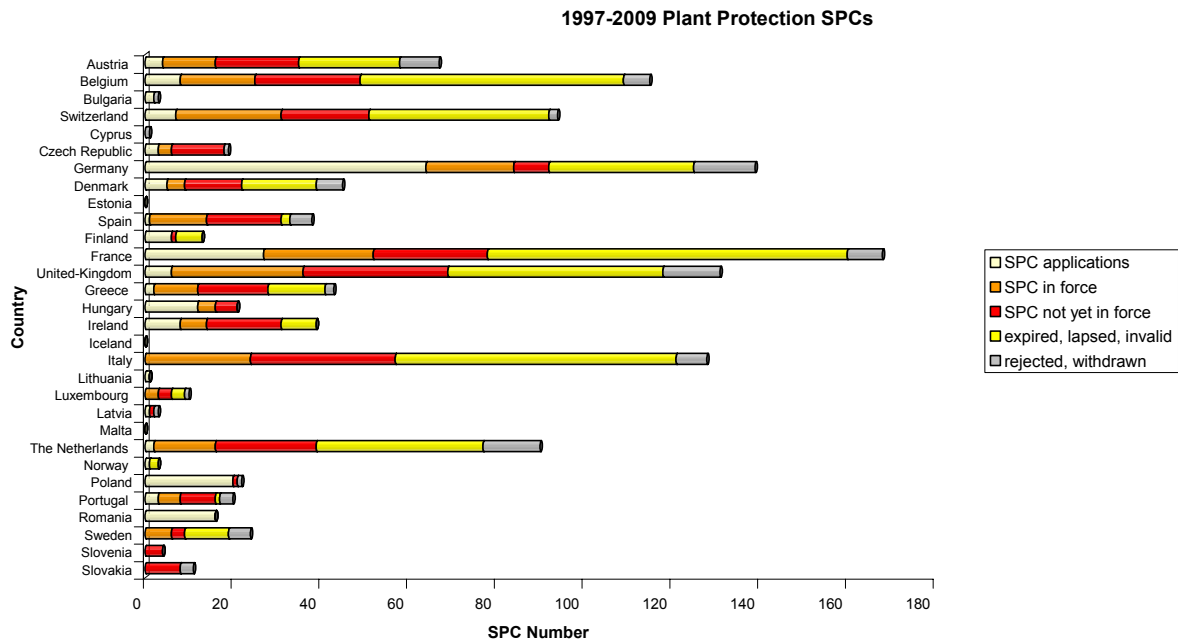
French SPC **FR02C0024** for levocetirizine dihydrochloride referring to Sepracor patent will be no more valid if the decision is confirmed.

➤ PLANT PROTECTION PRODUCT SPCs IN EUROPE

❖ Plant Protection Product SPCs filed from 1997 to 2009

About 1268 SPC applications for plant protection products regulated by EC Regulation 1768/96 or National laws have been filed in European countries from February 1997 to December 2009.

The figure below represents the number of SPCs sorted by country. For each country, is shown the number of SPCs dispatched according to their status



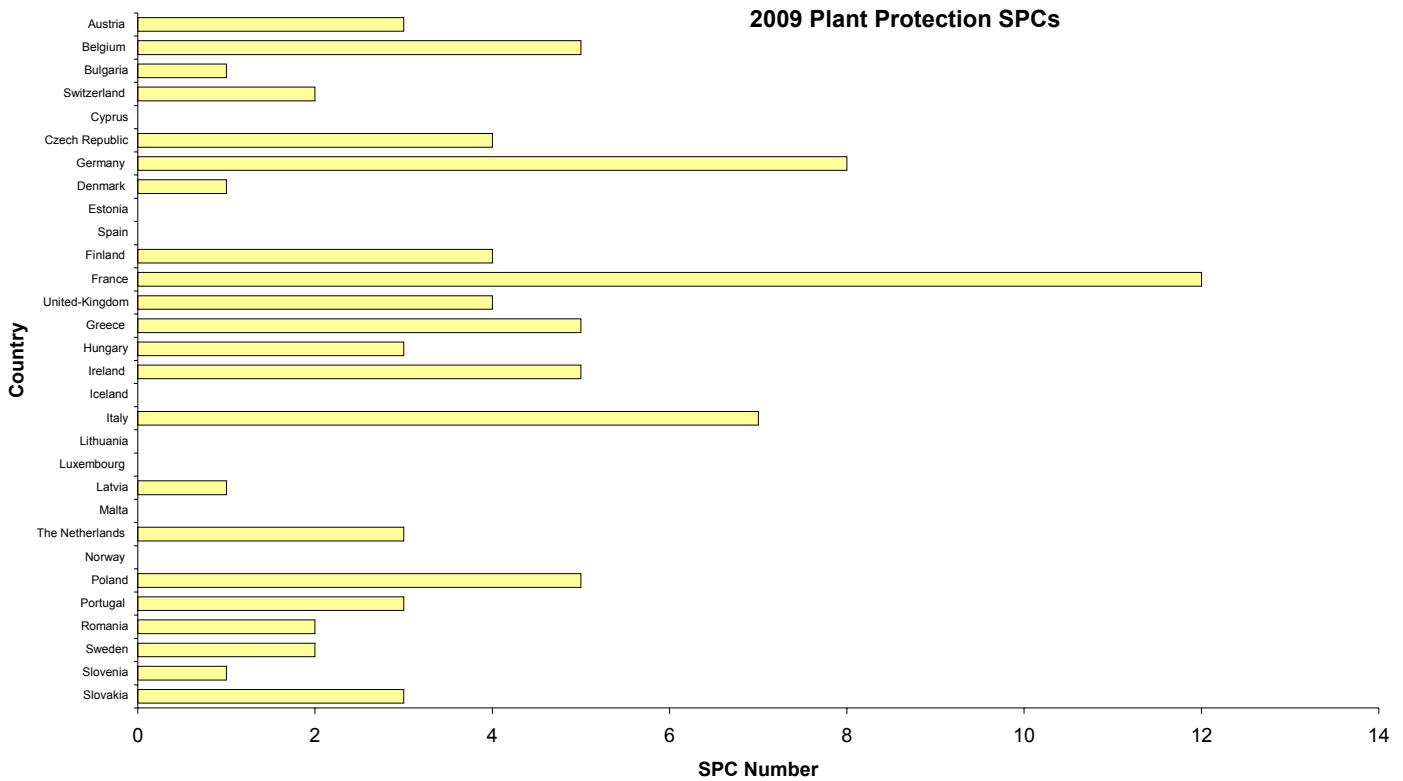
We can rank countries by number of SPCs, which are an indication of the importance of the market:

- ✓ 0 to 13 SPCs in Bulgaria, Cyprus, Estonia, Finland, Iceland, Lithuania, Luxembourg, Latvia, Malta, Norway, Slovenia and Slovakia
- ✓ 19 to 45 SPCs: Czech Republic, Denmark, Spain, Greece, Hungary, Ireland, Poland, Portugal, Romania and Sweden
- ✓ 67 to 94 SPCs: Austria, Switzerland and The Netherlands
- ✓ 115 to 168 SPCs: Belgium, Germany, France, The United-Kingdom and Italy.

❖ *Plant Protection Product SPCs filed in 2009*

84 Plant protection SPCs filed in 2009 were published at the end of April 2009.

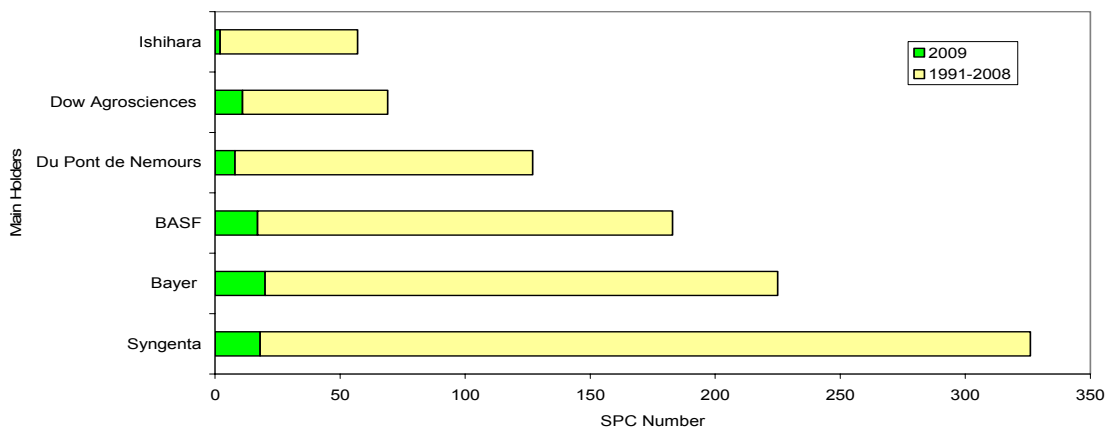
In the graph below, is shown the number of SPCs for each country.



❖ *Who filed Plant Protection SPCs?*

987 SPCs out of the 1270 filed from 1997 to 2009 and 76 out of the 84 filed in 2009

In the graph below, is shown, the number of SPCs filed in 2009 or from 1991 to 2008 dispatched according to the main holders.



Syngenta is by far the largest applicant followed by Bayer and BASF.

They filed respectively 25.7%, 17.7%, 14% of all SPCs filed from 1997 to 2009 and 21.4%, 17.7%, 14.4% of all SPCs filed in 2009.