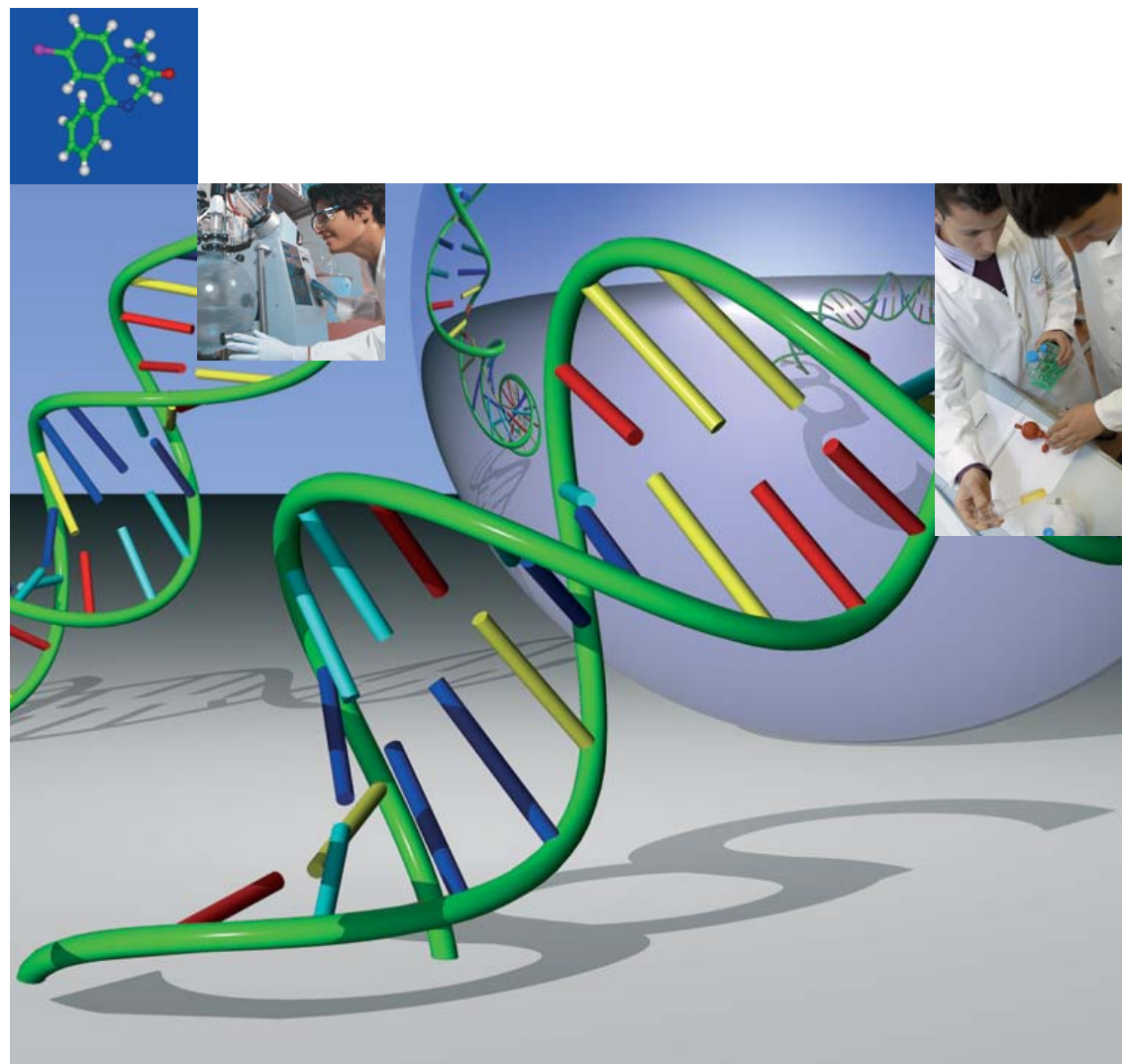


## Short Insight into the World of Patents

*Roche Global Patent Function*

*We take care of your Inventions*



## Introduction

Patents are the lifeblood of pharmaceutical companies like Roche. Large sums of money must be invested to develop new medicines in a particularly difficult and lengthy process. Once a new medicine has been successfully developed it would be fairly easy for third parties to copy the product within short and without large investments. That's where patents come into play! Patents are the most effective and efficient tool to protect products and innovations. They are used to prevent competitors from copying and thus provide an incentive to invest into costly and risky research and development of new healthcare products and therapies.

The vision of the Roche Global Patent Function is to be

"A global team of pro-active, result-oriented patent experts dedicated to supporting Roche business objectives; delivering tangible results which create value; and earning recognition and respect throughout the Organization." **Our vision**

All our activities are carried out in close collaboration with our colleagues from Research, Development, Business Development, Licensing and Legal. Needless to say that it is essential that everybody in Roche has a basic understanding of the patent system. This brochure provides a short insight into the world of patents and outlines the Roche patent policies and strategies. Enjoy reading!

Dr Eric A. Notegen

Head of Roche Global Corporate Patent Function



## What is a Patent?

The patent system is an indispensable element of economic development and growth. Patents provide limited **exclusive rights** to exploit the protected invention on a commercial basis in exchange for a complete and early public disclosure.

A patent confers on its owner the **right to prevent third parties** from making, using, offering for sale, selling, or importing the patented invention, but is **not an affirmative right** to use the protected invention.

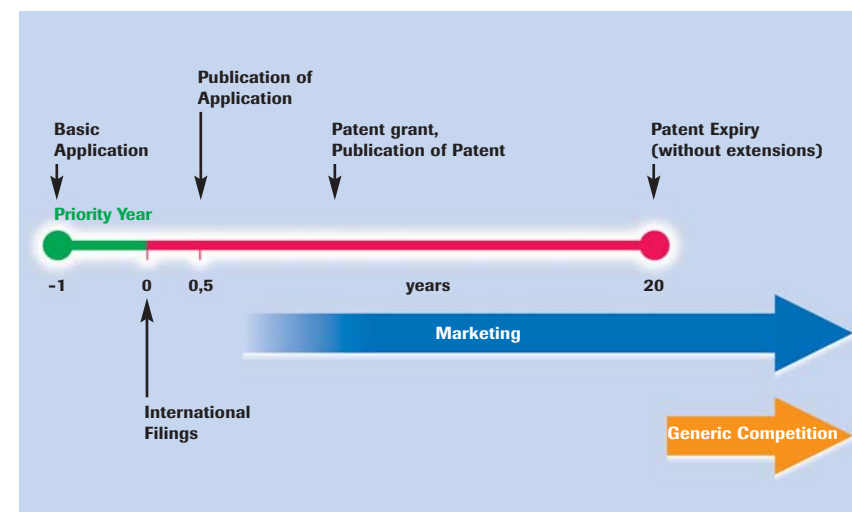
Patents are **limited in time**. In general, patents are granted for a term of twenty years starting with the date of filing of the patent application. However, in case of delays in obtaining market approval for pharmaceutical products, the term of the basic patents relating to such products may be **extended** in almost all important countries by up to five years by way of Patent Term Extensions (PTE) or Supplementary Protection Certificates (SPC).

Patents have a **limited territorial effect**. Consequently they have to be applied for in all countries where protection is desired. The first filing, the so-called priority or basic application, is generally submitted in one country only and is followed by applications in all countries where protection is desired (international filings). Such applications have to be filed within the non-extendible time period of one year (priority year).

Patent applications are **published** by the various Patent Offices 18 months after the basic patent application has been filed.

Patents are **not effective before grant**. Patent applications are examined by Patent Offices and a patent is granted if the invention meets all the criteria for patentability.

Patents are normally **respected by competitors**. However, if they are infringed, they have to be enforced through **court proceedings**. In such proceedings the **validity** of patents may be challenged.



Stages of Patent Life



## What are the Requirements for obtaining a Patent?

Patents are granted for inventions which are new, involve an inventive step (i.e. are not obvious) and meet the requirement of industrial applicability, i.e. can be used in any kind of industry.

An invention is **new** if it is not anticipated in the state of the art (or the prior art). The state of the art comprises everything made available to the public by means of a written or oral description, by use or in any other way (including electronic means such as the internet), before the date of filing of the patent application. Novelty is an objective element.

An invention involves an **inventive step** if it is not an obvious improvement of something described in the prior art. Inventive step requires some type of creative contribution to the state of the art. Consequently, inventive step/non-obviousness has objective and subjective elements.

The requirement of **industrial applicability** is met if the invention can be used in any kind of industry. To meet such requirement, the patent application must contain a description of how the invention can be made and used (e.g. synthetic processes, therapeutic indication, formulation and/or dosing).

The invention must be disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. In other words, the **disclosure must enable** skilled persons to work the invention without undue burden. Further, the applicant is requested to disclose the so-called **best mode**, i.e. the best way to practice the invention.

## What can be patented?

In the area of pharmaceuticals, patents can be applied for inventions of the following categories:

- New **products**, e.g. chemical or biochemical compounds, biological materials, intermediates
- New **compositions** or **formulations**
- New **uses** of a product, e.g. new therapeutic indications, new dosage regimens
- New **processes** for manufacturing a product
- New **research tools**, e.g. assays, targets, biomarkers
- New **objects**, e.g. machines, dosing dispensers
- New **business methods** and **software**





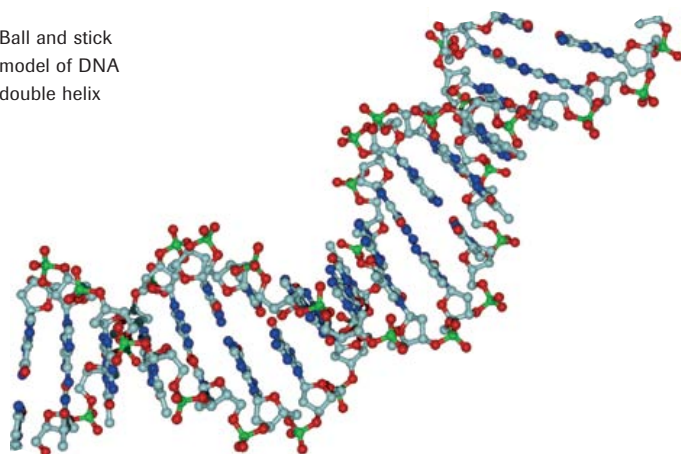
## Main Tasks of the Patent Function

- Secure, maintain and defend **patent protection** for all commercially valuable results of R&D.
- Help securing **freedom-to-operate** for our research activities and securing **market access** for products that otherwise may be blocked from being marketed, used or manufactured due to third party patents, i.e. assist the Company in helping design around the patents, challenging those patents, or obtaining a license under reasonable conditions.
- Contribute to the LifeCycle process with the aim to maximize **market exclusivity** for all important Roche products.
- Ensure that **Roche patents are respected** by third parties, if necessary by way of litigation.

Secure market access and maximize market exclusivity for Roche products and innovations for as long as possible using all types of intellectual property rights.

**Mission statement**

Ball and stick model of DNA double helix



**1474**

World's first Patent Law introduced in Venice

**1623/24**

Regulations for the protection of Intellectual Property in England

**1768**

James Watt gets a patent for steam engine

**1791**

Patent Law introduced in France

**1873**

Louis Pasteur gets a patent for living organism (purified yeast) in the USA

**1877**

Introduction of first nationwide Patent Law for Germany

**1887**

First Patent Law established in Switzerland

**1896**

Fritz Hoffmann-La Roche founds F. Hoffmann-La Roche & Co.

**1933**

Tadeusz Reichstein invents an industrial method of synthesizing Vitamin C

**1954**

Switzerland passes national Patent Law

**1957**

Leo Sternbach chances upon the benzodiazepines (Librium, Valium Roche)

**1962**

Fluoro-uracil Roche is the first anticancer drug of the company





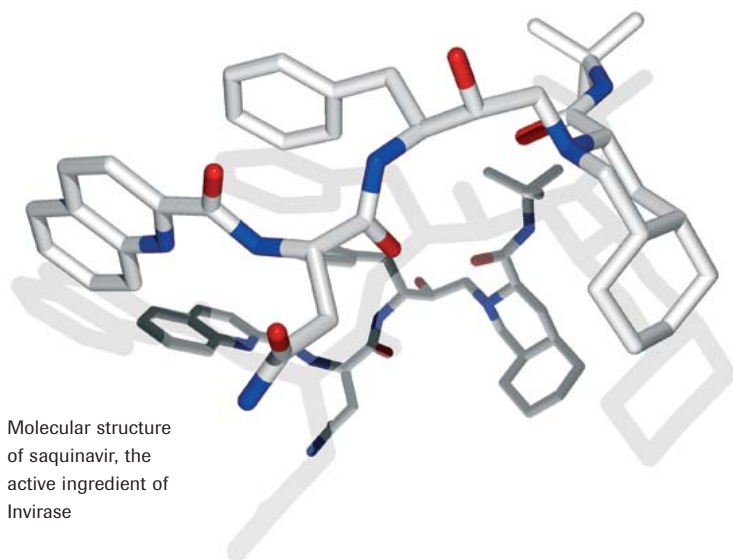
## The Roche Patent Function at your Service

There are local Patent Departments located **at any Roche Pharma site**, i.e. in Basel, Penzberg, Nutley, Palo Alto and Boulder.

Within the Roche Global Patent Function, all R&D projects, pipeline products and marketed products are assigned to individual patent attorneys.

You can identify the **patent attorney** responsible for your area of interest at <http://groupnet.roche.com> under the link Corporate Patents

Please do not hesitate to contact your patent attorney whenever you have research results to be protected by a patent or if you have any inquiry concerning Roche or third party patents.  
We are looking forward to being at your service!



Molecular structure of saquinavir, the active ingredient of Invirase

**1963**

Valium Roche is launched

**1968**

United States Valium patent issues (US 3,371,088)

**1973**

Signing of European Patent Convention (Switzerland joins as a member in 1978)

**1975**

First production of monoclonal antibodies by Köhler and Milstein

**1984**

Swiss Rocephin patent issues (CH 641 468)

Grant of a patent directed to genetically engineered Insulin

**1988**

A patent directed to a genetically modified mouse (Harvard mouse) issues in the USA

**1991**

Acquisition of the rights to Polymerase Chain Reaction (PCR) from Cetus

**1995**

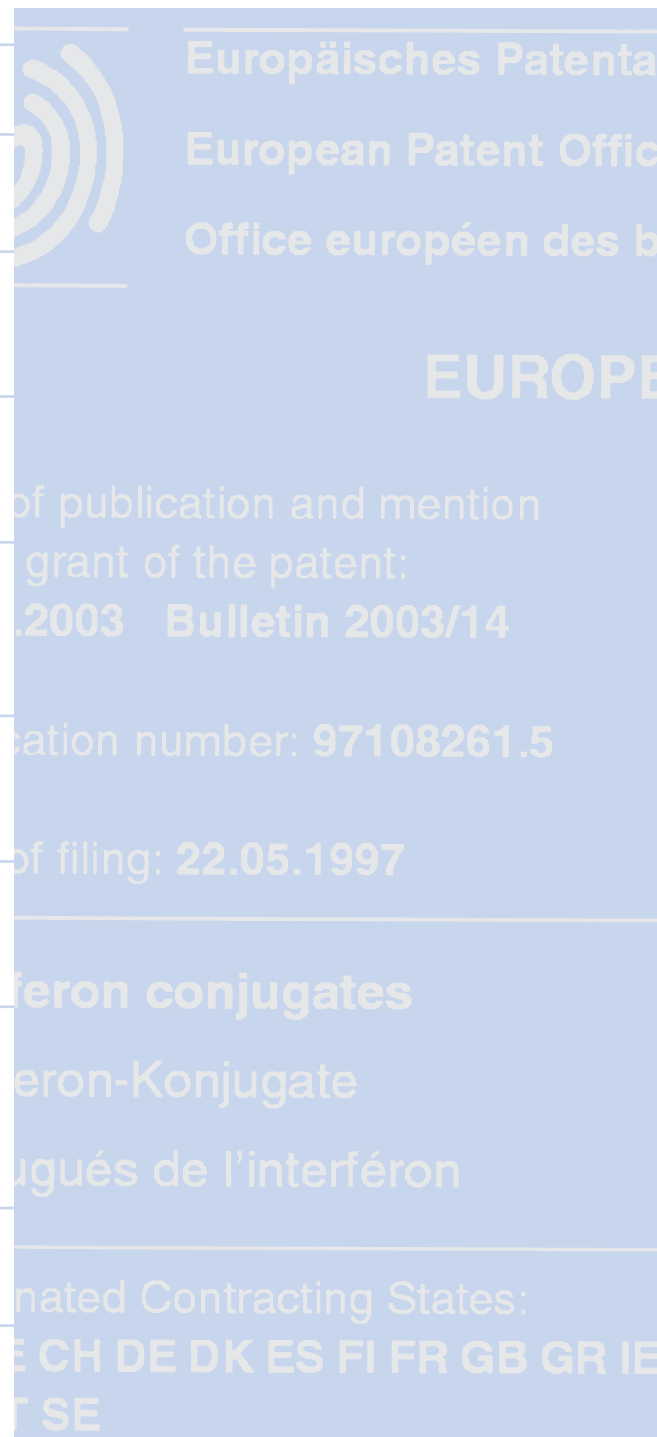
Switzerland joins World Trade Organization, which defines minimal standards for all fields of Intellectual Property (patents, trademarks, copyright)

**1996**

European patent for MabThera issues (EP 0 669 836)

**2003**

European patent for Pegasys issues (EP 0 809 996)

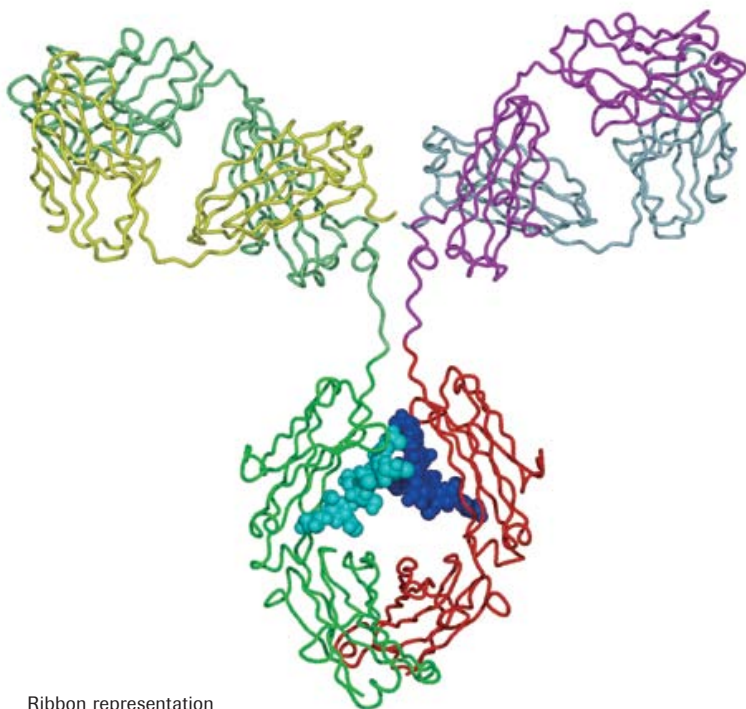




## Sense of Urgency

Patents must be **applied for as quickly as possible!**  
 With regard to new molecular entities with therapeutic utility or pharmaceutical compositions, it is of utmost importance to apply for patent protection as early as any pre-clinical experimental results indicating therapeutic utility become available.

It is important to understand that Roche risks a complete loss of protection for its research results if patent applications are not promptly filed or get published before the invention is filed for patent.



Ribbon representation of an IgG antibody

## Patent first, publish later

Patents must be applied for **before the invention is published or disclosed** to a third party who is not under a confidentiality obligation.

Therefore, all intended scientific publications, including oral presentations, have to be **reviewed by the Patent Department** in order to be able to take the necessary steps to protect important developments by a patent application before they are disseminated to the public.

The Roche **Publication Policy** and the forms for Publication Clearance can be found at <http://groupnet.roche.com> under the link Corporate Patents

 Europäisches Patentamt European Patent Office Office européen des brevets		 (11) EP 0 809 996 B1
(12) EUROPEAN PATENT SPECIFICATION		
(45) Date of publication and mention of the grant of the patent: 02.04.2003 Bulletin 2003/14	(51) Int. Cl. <sup>7</sup> A61K 47/48	
(21) Application number: 97106261.5		
(22) Date of filing: 22.08.1997		
(54) Interferon conjugates Interferon-Konjugate Conjugats de l'interféron		
(84) Designated Contracting States: AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE Designated Extension States: LT LV RO SI	(56) References cited: EP-A- 0 400 472 EP-A- 0 510 356 EP-A- 0 593 868 WO-A-95/13095 WO-A-95/21629 WO-A-96/11953 WO-A-97/18892 US-A- 5 281 698	
(30) Priority: 31.05.1996 US 18834	* MONKARSH SP ET AL.: "Positional isomers of monoglycylated interferon alpha-2a: isolation, characterization, and biological activity." ANAL BIOCHEM. MAY 1 1997, 247 (2) P434-40, XP00292202 UNITED STATES	
(43) Date of publication of application: 03.12.1997 Bulletin 1997/49	* TRUITT GA ET AL.: "Pharmacodynamic and preliminary pharmacokinetic evaluation of pegylated derivatives of interferon-alpha 2a (Meeting abstract)." PROC ANNU MEET AM ASSOC. CANCER RES. 26-A1445 1994, XP00292204	
(73) Proprietor: F. HOFFMANN-LA ROCHE AG 4070 Basel (CH)	* BALLERON AV ET AL.: "In vivo fate of PEG-interferon alpha-2a (Ro 25-3038) in tumor bearing mice (Meeting abstract)." PROC ANNU MEET AM ASSOC. CANCER RES. 26-A1445 1994, XP00292205	
(72) Inventors: * Balion, Pascal Sebastian Floham Park, New Jersey 07932 (US) * Pallares, Alicia Valiso North Caldwell, New Jersey 07006 (US)	* MONKARSH SP ET AL.: "A BRANCHED MONOMETHOXYPOLY(ETHYLENE GLYCOL) FOR PROTEIN MODIFICATION" BIOCONJUGATE CHEMISTRY, vol. 6, no. 1, 1 January 1995, pages 62-69, XP00494804	
Remarks: The file contains technical information submitted after the application was filed and not included in the specification		
Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).		
EP 0 809 996 B1	Printed on June 10, 2003 (PAIS) (PT)	

Title page of European Patent for Pegasys



## LifeCycle Management and Patents

By applying the right strategy in innovating and patenting improvements, it is possible to **optimize the overall patent protection** of pharmaceutical products. For example, patents can be applied for

- alternative **salts, prodrugs**, different **morphologic forms**
- different **mode of application** of the active ingredient
- new **formulations** or new **galenical forms**
- new **dosage regimens**
- new **therapeutic indications** of the active ingredient
- **combinations** of the active ingredient with other therapeutically active substances
- alternative **manufacturing processes** and **intermediates**

Timely filing of abovementioned lifecycle patent applications may provide additional protection for marketed products after expiration of the basic compound patent.

LifeCycle Management by using patents is an ongoing process and must start as early as possible! It is therefore imperative that the respective patent attorneys are members of the LifeCycle Teams and that they are consulted as lifecycle strategies are developed, implemented and revised.



European Patent Office  
in Munich

### Interested in more details?

A detailed introduction to the world of patents can be found in our publication *Patents – Detailed Introduction to the World of Patents* which is available at <http://groupnet.roche.com> under the link Corporate Patents.

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