



**African Regional Intellectual Property Organization**

## Regional Workshop on Human Resource Development of Patent/Trademark Agents for ARIPO Member States and Observer States.

Sufficient disclosure, Novelty, inventive step and Unity

F. Mpanju  
Patent Examiner

**ARIPO-WIPO-JPO**  
**28 October 2014.**

**Making better use of Intellectual Property for business  
competitiveness and development in Africa**

# Scope of Presentation

1. What is a patent
2. Structure of a patent document.
3. Specification
4. Novelty
5. Inventive step
6. Unity of invention
7. Conclusion



# What is a patent

- A patent is a contract between government and a 'patentee' . To be granted a patent, a person must apply to the relevant authority by submitting the patent specification
- A patent specification must be fully and accurately describe the invention, and end with one or more claims that define the extent of rights (monopoly) that the patentee is seeking.
- When granted, a patent prevents competitors from exploiting the efforts or investment the applicant has made in developing their invention for a certain number of years (the period differs from country to country). After the period has elapsed the invention can be used free by others



## What is a patent cont.

To be patentable, an invention must meet certain legal requirements. It must be novel (new) or inventive in some way and industrially applicable

It is the examiner role to determine carefully and interpreting the specification. This process of interpretation is known as 'construing'





AFRICAN REGIONAL INTELLECTUAL PROPERTY  
ORGANIZATION (ARIPO)

2190

(11)

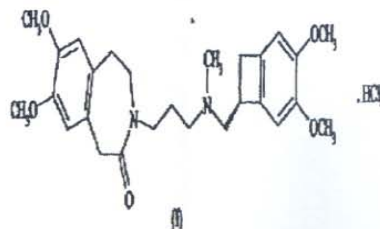
(A)

(21) Application No :	AP/P/2006/003520	(73) Applicant(s)	LES LABORATOIRES SERVIER, 12, Place de la Defense, F-92415 Courbevoie Cedex, France
(22) Filing Date :	22/02/2006	(72) Inventors	HORVATH Stéphanie, 35, route d'Orleans, 45380, La Chapelle-st-Mesmin, France AUGUSTE Marie-Noëlle, 3 bis, rue Bleue, 45000 Orleans, France DAMIEN Gérard, 31 bis Avenue du Blénois, 45130 Meung-sur-Loire, France
(24) Date of Grant & (45) Publication :	30/12/2010	(74) Representative	FISHER CORMACK & BOTHA, P O Box 74, Blantyre, MALAWI
(30) Priority Data			
(33) Country	(31) Number	(32) Date	
FR	05.01987	28/02/2005	
(84) Designated State	BW GM GH KE LS MW MZ NA SL SD SZ TZ UG ZM ZW		
(51) International Classification :	A61K 31/55 (2006.01) C07D 225/06 (2006.01)		C07D 225/00 (2006.01)

(54) Title

βδ-crystalline form of ivabradine hydrochloride, a process for its preparation and pharmaceutical compositions containing it

(57) Abstract



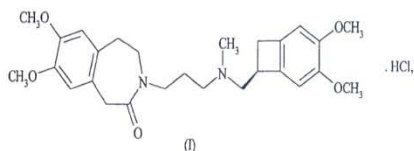
βδ-crystalline form of ivabradine hydrochloride, of ivabradine of formula (I): characterised by its powder X-ray diffraction diagram.

(56) Documents Cited : EP 0 534 859 A



**CLAIMS**

1.  $\beta$ -Crystalline form of ivabradine hydrochloride of formula (I) :



characterised by the following powder X-ray diffraction diagram measured using a PANalytical X'Pert Pro diffractometer together with an X'Celerator detector and expressed in terms of ray position (Bragg's angle 2 theta, expressed in degrees), ray height (expressed in counts), ray area (expressed in counts x degrees), ray width at half-height ("FWHM", expressed in degrees) and interplanar distance d (expressed in Å):

Ray no.	Angle 2 theta (degrees)	Height (counts)	Area (counts x degrees)	FWHM (degrees)	Interplanar distance (Å)
1	4.0	244	80	0.3346	22.139
2	5.9	377	56	0.1506	14.829
3	6.9	94	50	0.5353	12.835
4	9.2	1975	293	0.1506	9.623
5	11.8	136	27	0.2007	7.473
6	12.5	1826	241	0.1338	7.083
7	13.6	1834	303	0.1673	6.491
8	14.5	51	20	0.4015	6.119
9	16.0	1441	214	0.1506	5.525
10	17.3	4472	738	0.1673	5.134
11	18.4	546	108	0.2007	4.808
12	19.6	1025	169	0.1673	4.524

Ray no.	Angle 2 theta (degrees)	Height (counts)	Area (counts x degrees)	FWHM (degrees)	Interplanar distance (Å)
13	20.0	688	91	0.1338	4.448
14	20.4	1027	186	0.184	4.362
15	21.4	102	24	0.2342	4.143
16	22.3	1903	283	0.1506	3.990
17	22.8	674	89	0.1338	3.897
18	23.0	623	62	0.1004	3.866
19	24.4	845	56	0.0669	3.647
20	25.0	3749	557	0.1506	3.554
21	25.5	512	84	0.1673	3.497
22	26.6	289	76	0.2676	3.346
23	28.3	275	91	0.3346	3.151
24	29.1	126	21	0.1673	3.066

2. Process for the preparation of the  $\beta$ d-crystalline form of ivabradine hydrochloride according to claim 1, characterised in that a mixture of ivabradine hydrochloride and water or a mixture of ivabradine hydrochloride, isopropanol and water is heated until dissolution is complete and is then progressively cooled until crystallisation is complete, and the crystals thereby formed are collected and then dehydrated.

3. Process according to claim 2, characterised in that the solution of ivabradine hydrochloride is seeded during the cooling step.

4. Pharmaceutical composition comprising as active ingredient the  $\beta$ d-crystalline form of ivabradine hydrochloride according to claim 1, in combination with one or more pharmaceutically acceptable, inert, non-toxic carriers.

5. Use of the  $\beta$ d-crystalline form of ivabradine hydrochloride according to claim 1 in the manufacture of medicaments which are of use as bradycardics.

6. Use of the  $\beta$ d-crystalline form of ivabradine hydrochloride according to claim 1 in the manufacture of medicaments which are of use in the treatment or prevention of various clinical situations of myocardial ischaemia such as angina pectoris, myocardial infarct

and associated rhythm disturbances, and also in various pathologies involving rhythm disturbances, especially supraventricular rhythm disturbances, and in heart failure.



## Specification construction

- Description
- Who is PSA
- Is the invention fully disclosed
- Is the best method of performance explained?
- Does the description Support the claims?(Article 6)
- Is the invention Industrially applicable?

## claims

what is the scope of the claims?

Are the claims clear?

Is there unity of invention?



# Construe the specification.

- The examiner must construe the specification to determine either the words or phrases used accurately describe (or 'disclose' ) the invention and whether the claims are legitimate. The language with the patent specification is therefore extremely important (particularly when it comes to avoiding or resolving disputes about the invention).
- In most countries the interpretation for the words and phrases in a specification and claims are achieved by using recognized rules of construction.
- Construction is thus the objective of reading of a patent specification to decide what the specification says in the invention and how is it carried into effect and what monopoly it defines





# Novelty.

- ❑ An invention defined in claims is said to lack novelty if every features of the claim has been described in the prior art. It may be immediate apparent from the prior art that a feature is not novel, or it might be that a person skilled in the art would (after carefully considering the prior art) inevitably arrive at the feature.
- Claim lacks novelty if every feature is explicitly or implicitly disclosed in the prior art at the relevant date.



# Step to determine novelty

- Identify features of claimed invention.
- Determine if a written disclosure was published before the relevant date (filing/priority date).
- Identify what features of claims are disclosed by the prior art
- Determine if the prior art discloses each and every feature of the claimed invention.

- 



# Written disclosure

- For the purposes of assessing novelty, prior art is defined as everything available to the public anywhere in the world by means of written disclosure ( including drawings, illustrations, abstracts, and so on) before the relevant date.
- There is no restriction on language, location , age of material, or type of disclosure ( if cold be internet site, journal, online database, or other type of reference.



# Explicit and implicit disclosure

- Explicit- everything should be disclosed in the prior art to determine the novelty
- Implicit-an implicit arise when a document is read in the light of common general knowledge i.e the prior art disclose the bicycle may not explicitly refer to the presence of wheels, but their presence is nevertheless implied (implicit) in the light of common general knowledge.



## Example of novelty

- . A claim define a disposable nappy having three fastening elements.
- Prior art document discloses a disposable nappy having only two fastening elements.
- Since the document does not explicitly or implicitly disclose a third fastening element it does not deprive the claim novelty.



## inventive step

- A claimed invention is considered to involve an inventive step if it is not obvious to a person skilled in the art (PSA).
- In determining the presence of inventive step the PSA must consider the prior art base, and also the date at which the application was filed that is, was it obvious at that time.



## Example of inventive step.

- A claimed invention relates to a building structure made from aluminium. Prior art document discloses the same structure and says that it is of light-weight material but fails to mention the use of aluminium.
- Aluminium is the light weight material that is a well known in the art to be useful as a building material.
- The claims therefore lacks an inventive step.



## Inventive step cont.

- Finding of lack of inventive step may be based on either single prior art document or a combination of two or more prior art documents.
- Either case, the claimed invention as a whole is obvious only if any item (s) of prior art documents or common general knowledge would have motivated or prompted the PSA in the art to arrive at the same invention by substituting, combining or modifying one or more of those items of prior art with a reasonable like hood of success.





# Difference between novelty and inventive step

- Novelty and inventive step are different criteria. A claim lacks novelty if every element or step is explicitly or inherently disclosed within a prior art.
- The condition of inventive step is fulfilled in the invention as a whole, compared to the prior art as a whole, would not have been obvious to a person skilled in the art.



# Unity of invention

- Determining the unity of invention.
- A claim or claims must relate to a single invention only or to a group of inventions that are linked to form a single inventive concept, when viewed as a whole, the inventive concept must make an advance over the prior art.
- Determining whether the invention is actually a single entity can be difficult, especially if there are multiple categories or claim types associated with the invention.



- To determine unity of invention it is necessary to construe the claims in the specification and identify the special technical features, what is the contribution over the prior art? This is considered with respect to novelty and inventive step.
- Once the special technical features of invention has been identified, the examiner must determine whether or not there is a technical relationship between the inventions and whether or not this relationship involves the identified special technical features



# Example 1

- If the invention is a new compound A that cures a disease, the invention is that compound A . The way of making that compound A can be part of the invention.
- Also it include the way of making medicine using the compound A, and various methods of using the compound. The common feature to all the claims is the compound A, and so unity of invention exists.
- 



## Example 2 (some special technical features)

- Claim 1: a process for painting an article in which the paint contains a rust-inhibiting substance X, comprising the step...
- Claim 2: A paint containing rust-inhibiting substance X.
- Unity exists between claims 1 and 2 where the same technical feature is the paint containing substance X.



## Some special technical features cont.

Corresponding special technical features

- Claim 1: Plug characterized by feature Z
- Claim 2: Socket characterized by feature Z.
- These claims are directed to related articles –a plug and a socket, feature Z is a corresponding special technical feature which is included in both claims and therefore unity is present.
- 



## Some special technical features

- Example 2
- Claim 1: Comprise feature A and X
- Claim 2: comprise feature A and Y
- Claim 3: comprise feature X and Y
- The claims lack unity '*a priori*' because there is no element common to all claims (though it can be said that unity exists between the two claims)
  - i.e claim 1 and claim 2
  - Claim 2 and claim 3
- Unity of invention is present *a priori* because A is common to both claims and Y common to other claims.
- Unity is not usually considered in relation to dependent claims.



# Lack of unity a posterior

- Often, a special technical feature common to all can be identified, but a search reveals that the common feature is not an advance over the prior art. If lack of unity is identified in this manner it is known as 'a posterior' (meaning 'from the later' ).
- In example 2 above, unity of invention is present 'a prior' . But if the prior art reveals that A is known, there is lack of unity a posterior since A is not a technical feature that defines a contribution over the prior art.
- 







Making better use of Intellectual Property for business competitiveness and development in Africa



## African Regional Intellectual Property Organization

Address: **11 Natal Road, Belgravia, Harare, Zimbabwe**

Tel: **+263 4 794 065 /6/8/54/74**

Fax: **+263 4 794 072/3**

Email: **fmpanju@aripo.org**

**mail@aripo.org**

Website: **www.aripo.org**

**Making better use of Intellectual Property for business  
competitiveness and development in Africa**