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Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

(88) Date of publication of the international search report:

21 April 2011

(54) Title: IMPROVED METHOD FOR SYNTHESIZING PIRFENIDONE

(57) Abstract: A process for synthesizing pirfenidone from bromobenzene having less than about 0.15% by weight dibromobenzene is disclosed. Also disclosed are processes of synthesizing pirfenidone without using ethyl acetate or n-butanol, and pirfenidone having controlled levels of ethyl acetate, n-butanol, di(5-methyl-2-pyridinone)benzenes, and other impurities having specified retention times. Also disclosed are formulated dosage forms including the disclosed pirfenidone.



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A. CLASSIFICATION OF SUBJECT MATTER*C07D 401/10(2006.01)i, C07D 213/64(2006.01)i, A61K 31/4412(2006.01)i, A61P 9/00(2006.01)i*

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

C07D 401/10; C07D 213/64

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

CAPLUS, eKOMPASS(KIPO internal)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	KR 10-2004-0022232 A (ASAHI GLASS COMPANY, LTD.) 11 March 2004 See examples 1-4, page 3 line 3-7, page 2 line 3-4	1-5, 23-29
A	CN 1817862 A (ZHEJIANG ACADEMY OF MEDICAL SCIENCES) 16 August 2006 See entire document	1-5, 23-29

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

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Name and mailing address of the ISA/KR

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INTERNATIONAL SEARCH REPORTInternational application No.
PCT/US2010/037090**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 7, 9-11, 14-16, 20-22
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Claims 7, 9-11, 14-16, 20-22 refer to claims which are not searchable due to not being drafted in accordance with the third sentence of Rule 6.4(a).
3. ☒ Claims Nos.: 6, 8, 12, 13, 17-19
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2010/037090

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
KR 10-2004-0022232 A	11.03.2004	AU 2002323904 A1 JP 4342940 B2 WO 03-014087 A1	24.02.2003 17.07.2009 20.02.2003
CN 1817862 A	16.08.2006	CN 100396669 C	24.02.2003