

**DECLARATION (37 CFR §1.63) FOR UTILITY OR
DESIGN PATENT APPLICATION
USING AN
APPLICATION DATA SHEET (37 C.F.R. § 1.76)**

☒ Declaration
Submitted
with Initial
Filing OR ☐ Declaration
Submitted after Initial
Filing (surcharge
(37 CFR 1.16 (e)) required)

Attorney Dock Number TPI-350C1

First Named Inventor Örn Almarsson

COMPLETE IF KNOWN

Application Number

Filing Date

September 11, 2003

Group Art Unit

Examiner Name

This declaration is directed to an application entitled: **PHARMACEUTICAL CO-CRYSTAL COMPOSITIONS**
As the below named inventor(s), I/we declare that:
This declaration is directed to:

The attached application, or
Application No. _____, filed on _____
as amended on _____ (if applicable);

I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought;

I/ we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above;

I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application.

All statements made herein of my/own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and may jeopardize the validity of the application or any patent issuing thereon.

Full Name(s) of Inventors

Inventor One: Örn Almarsson

Citizen of: IS

Signature:

Inventor Two: Magali Bourghol Hickey

Citizen of: US

Signature:

Inventor Three: Matthew L. Peterson

Citizen of: US

Signature:

Inventor Four: Michael J. Zaworotko

Citizen of: US

Signature:

☒ Additional inventors are being named on the 1 additional form(s) attached hereto.

J:\TPI\350C1\New Application Forms\DECLARATION\APPLICATION WITH ADS.doc\DNB\ssa

DECLARATION (37 CFR §1.63) FOR UTILITY OR DESIGN PATENT APPLICATION USING AN APPLICATION DATA SHEET (37 C.F.R. § 1.76)		Attorney Dock t Number	TPI-350C1												
		First Named Inventor	Örn Almarsson												
		<i>COMPLETE IF KNOWN</i>													
☒ Declaration Submitted with Initial Filing OR ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)		Application Number													
		Filing Date	September 11, 2003												
		Group Art Unit													
		Examiner Name													
This declaration is directed to an application entitled: PHARMACEUTICAL CO-CRYSTAL COMPOSITIONS As the below named inventor(s), I/we declare that: This declaration is directed to: The attached application, or Application No. _____, filed on _____ as amended on _____ (if applicable); I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought; I/ we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above; I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application. All statements made herein of my/own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and may jeopardize the validity of the application or any patent issuing thereon. Full Name(s) of Inventors <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">Inventor Five: Brain Moulton</td><td style="width: 40%;">Citizen of: US</td></tr> <tr> <td colspan="2">Signature: _____</td></tr> <tr> <td>Inventor Six: Nair Rodriguez-Hornedo</td><td>Citizen of: US</td></tr> <tr> <td colspan="2">Signature: _____</td></tr> <tr> <td>Inventor Seven:</td><td>Citizen of:</td></tr> <tr> <td colspan="2">Signature: _____</td></tr> </table>				Inventor Five: Brain Moulton	Citizen of: US	Signature: _____		Inventor Six: Nair Rodriguez-Hornedo	Citizen of: US	Signature: _____		Inventor Seven:	Citizen of:	Signature: _____	
Inventor Five: Brain Moulton	Citizen of: US														
Signature: _____															
Inventor Six: Nair Rodriguez-Hornedo	Citizen of: US														
Signature: _____															
Inventor Seven:	Citizen of:														
Signature: _____															

Please type a plus sign (+) inside this box → ☐

PTO/SB/81 (02-01)
Approved for use through 10/31/2002 OMB 0651-0035
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

POWER OF ATTORNEY OR AUTHORIZATION OF AGENT

Application Number	
Filing Date	September 11, 2003
First Named Inventor	Örn Almarsson
Title	Pharmaceutical Co-Crystal Compositio
Group Art Unit	
Examiner Name	unknown
Attorney Docket Number	TPI-350C1

I hereby appoint:

☒ Practitioners at Customer Number
OR

23557

Place Customer
Number Bar Code
Label here

☐ Practitioner(s) named below:

Name	Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Please change the correspondence address for the above-identified application to:

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☐ Firm or
☐ Individual Name

Address

Address

City

State

Zip

Country

Telephone

Fax

I am the:

☒ Applicant/Inventor.

☐ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

Name Örn Almarsson

Signature

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☐ *Total of _____ forms are submitted.

Burden Hour Statement: This form is estimated to take 3 minutes to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Alexandria, VA 22313.

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POWER OF ATTORNEY OR AUTHORIZATION OF AGENT

Application Number	
Filing Date	September 11, 2003
First Named Inventor	Örn Almarsson
Title	Pharmaceutical Co-Crystal Composition
Group Art Unit	
Examiner Name	unknown
Attorney Docket Number	TPI-350C1

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Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

Name Magali Bourghol Hickey

Signature

Date

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NPC-UNIV-000004887

NOVARTIS EXHIBIT 1023

Novartis v. Regents, IPR2023-01346

Page 509 of 1101

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POWER OF ATTORNEY OR AUTHORIZATION OF AGENT

Application Number	
Filing Date	September 11, 2003
First Named Inventor	Örn Almarsson
Title	Pharmaceutical Co-Crystal Compositio
Group Art Unit	
Examiner Name	unknown
Attorney Docket Number	TPI-350C1

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☐ Assignee of record of the entire interest. See 37 CFR 3.71.

Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

Name Brian Moulton

Signature

Date

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NPC-UNIV-000004888

NOVARTIS EXHIBIT 1023

Novartis v. Regents, IPR2023-01346

Page 510 of 1101

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Application Number	
Filing Date	September 11, 2003
First Named Inventor	Örn Almarsson
Title	Pharmaceutical Co-Crystal Composition
Group Art Unit	
Examiner Name	unknown
Attorney Docket Number	TPI-350C1

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☐ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

Name Matthew L. Peterson

Signature

Date

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Application Number	
Filing Date	September 11, 2003
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Title	Pharmaceutical Co-Crystal Composition
Group Art Unit	
Examiner Name	unknown
Attorney Docket Number	TPI-350C1

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- ☐ Assignee of record of the entire interest. See 37 CFR 3.71.
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SIGNATURE of Applicant or Assignee of Record

Name Nair Rodriguez-Hornedo

Signature

Date

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PTO/SB/81 (02-01)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Application Number	
Filing Date	September 11, 2003
First Named Inventor	Örn Almarsson
Title	Pharmaceutical Co-Crystal Compositio
Group Art Unit	
Examiner Name	unknown
Attorney Docket Number	TPI-350C1

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☐ Individual Name

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☒ Applicant/Inventor.

☐ Assignee of record of the entire interest. See 37 CFR 3.71.

Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

Name Michael J. Zaworotko

Signature

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required. see below.

☐ *Total of forms are submitted.

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NPC-UNIV-000004891

NOVARTIS EXHIBIT 1023

Novartis v. Regents, IPR2023-01346

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APPLICATION DATA SHEET

Docket No. TPI-350C1

Application Information

Application Type::	Regular
Subject Matter::	Utility
Suggested Classification::	None
Suggested Group Art Unit::	None
CD-ROMor CD-R?::	None
Number of CD disks::	None
Number of copies of CDs::	None
Sequence submission?::	None
Computer Readable Form?::	No
Number of Copies of CRF::	None
Title::	Pharmaceutical Co-Crystal Compositions
Attorney Docket Number::	TPI-350C1
Request for Early Publication::	No
Request for Non-Publication::	No
Suggested Drawing Figure::	None
Total Drawing Sheets::	66
Small Entity?::	Yes
Petition included?::	No
Petition Type::	N/A
Secrecy Order in Parent Appl.?::	No

APPLICATION DATA SHEET

Docket No. TPI-350C1

Applicant Information

Applicant Authority Type:: Inventor
Primary Citizenship Country:: Iceland
Status:: Unknown
Inventor One Given Name:: Örn
Family Name:: Almarsson
City of Residence:: Shrewsbury
State or Province of Residence:: MA
Country of Residence:: US
Street of Mailing Address:: 22 Farmington Drive
City of Mailing Address:: Shrewsbury
State or Province of mailing address:: MA
Country of Mailing Address:: US
Postal or Zip Code of Mailing Address:: 01545

Applicant Two Authority Type:: Inventor
Primary Citizenship Country:: US
Status:: Unknown
Inventor Two Given Name:: Magali
Family Name:: Bourghol Hickey
City of Residence:: Medford
State or Province of Residence:: MA
Country of Residence:: US
Street of Mailing Address:: 342 Malden Street
City of Mailing Address:: Medford
State or Province of mailing address:: MA
Country of Mailing Address:: US
Postal or Zip Code of Mailing Address:: 02155

APPLICATION DATA SHEET

Docket No. TPI-350C1

Applicant Information

Applicant Three Authority Type::	Inventor
Primary Citizenship Country::	US
Status::	Unknown
Inventor Three Given Name::	Matthew L.
Family Name::	Peterson
City of Residence::	Framingham
State or Province of Residence::	MA
Country of Residence::	US
Street of Mailing Address::	60 Linda Avenue
City of Mailing Address::	Framingham
State or Province of mailing address::	MA
Country of Mailing Address::	US
Postal or Zip Code of Mailing Address::	01701
Applicant Four Authority Type::	Inventor
Primary Citizenship Country::	US
Status::	Unknown
Inventor Four Given Name::	Michael J.
Family Name::	Zaworotko
City of Residence::	Tampa
State or Province of Residence::	FL
Country of Residence::	US
Street of Mailing Address::	4202 E. Fowler Ave.
City of Mailing Address::	Tampa
State or Province of mailing address::	FL
Country of Mailing Address::	US
Postal or Zip Code of Mailing Address::	33620

APPLICATION DATA SHEET

Docket No. TPI-350C1

Applicant Information

Applicant Five Authority Type:: Inventor
Primary Citizenship Country:: US
Status:: Unknown
Inventor Five Given Name:: Brian
Family Name:: Moulton
City of Residence:: Temple Terrace
State or Province of Residence:: FL
Country of Residence:: US
Street of Mailing Address:: 13455 Century Cove Dr. #325
City of Mailing Address:: Temple Terrace
State or Province of mailing address:: FL
Country of Mailing Address:: US
Postal or Zip Code of Mailing Address:: 33637

Applicant Six Authority Type:: Inventor
Primary Citizenship Country:: US
Status:: Unknown
Inventor Six Given Name:: Nair
Family Name:: Rodriguez-Hornedo
City of Residence:: Ann Arbor
State or Province of Residence:: MI
Country of Residence:: US
Street of Mailing Address:: 1690 Northbrook Dr.
City of Mailing Address:: Ann Arbor
State or Province of mailing address:: MI
Country of Mailing Address:: US
Postal or Zip Code of Mailing Address:: 48103

APPLICATION DATA SHEET

Docket No. TPI-350C1

Representative Information

Representative Customer Number:: 000023557

Representative Designation::	Registration Number::	Representative Name::
Primary	45,332	Frank C. Eisenschenk, Ph.D.

Correspondence Information

Name Line One::	Frank C. Eisenschenk, Ph.D.
Name Line Two::	Saliwanchik, Lloyd & Saliwanchik, A Professional Association
Street of Mailing Address::	2421 N.W. 41 st Street, Suite A-1
City of Mailing Address::	Gainesville
State or Province of Mailing Address::	FL
Postal or Zip Code of Mailing Address::	32606
Telephone Number One::	(352) 375-8100
Telephone Number Two::	
Fax Number::	(352) 372-5800
Electronic Mail Address::	fce@slspatents.com

APPLICATION DATA SHEET

Docket No. TPI-350C1

Domestic Priority Information

Each of the applications listed in this domestic priority section are hereby incorporated by reference into this patent application in their entireties (including all figures, tables, and formulae).

Application::	Continuity Type::	Parent Application::	Parent Filing Date::
This application is a	Continuation-In-Part of	PCT US03/xxxxx	September 4, 2003
which is a	Continuation-In-Part of	10/378,956	March 3, 2003
which claims the benefit of		60/360,768	March 1, 2002
Said		PCT US03/xxxxx	September 4, 2003
Also claims the benefit of		60/451,213	February 28, 2003
And		60/463,962	April 18, 2003
And		60/487,064	July 11, 2003
This application is also a	Continuation-In-Part of	10/637,829	August 8, 2003
which is a	Divisional of	10/295,995	November 18, 2002
which is a	Continuation of	10/232,589	September 3, 2002
which claims benefit of		60/406,974	August 30, 2002
And		60/380,288	May 15, 2002
And		60/356,764	February 15, 2002
This application is also a	Continuation-In-Part of	10/449,307	May 30, 2003
which claims the benefit of		60/463,962	April 18, 2003
And		60/444,315	January 31, 2003
And		60/439,282	January 10, 2003
And		60/384,152	May 31, 2002
This application is also a	Continuation-In-Part of	10/601,092	June 20, 2003
This application also		60/451,213	February 28, 2003
claims the benefit of			
And		60/463,962	April 18, 2003
And		60/487,064	July 11, 2003

Foreign Priority Information

Country::	Application Number::	Filing Date::	Priority Claimed::
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PATENT APPLICATION FEE DETERMINATION RECORD
Effective January 1, 2003

Application or Docket Number

TP2 -350 C1

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	<i>37</i>	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	<i>37</i> minus 20 =	* <i>17</i>
INDEPENDENT CLAIMS	<i>20</i> minus 3 =	* <i>17</i>
MULTIPLE DEPENDENT CLAIM PRESENT ☐		

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY TYPE ☐

OR OTHER THAN SMALL ENTITY

RATE	FEE
BASIC FEE	375.00
X\$ 9=	
X42=	
+140=	
TOTAL	

RATE	FEE
BASIC FEE	750.00
X\$18=	<i>153.00</i>
X84=	<i>1680.00</i>
+280=	
TOTAL	<i>2208.00</i>

CLAIMS AS AMENDED - PART II

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total *	Minus **	=
	Independent *	Minus ***	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐		

RATE	ADDITIONAL FEE
X\$ 9=	
X42=	
+140=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$18=	
X84=	
+280=	
TOTAL ADDIT. FEE	

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total *	Minus **	=
	Independent *	Minus ***	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐		

RATE	ADDITIONAL FEE
X\$ 9=	
X42=	
+140=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$18=	
X84=	
+280=	
TOTAL ADDIT. FEE	

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT C	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total *	Minus **	=
	Independent *	Minus ***	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐		

RATE	ADDITIONAL FEE
X\$ 9=	
X42=	
+140=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$18=	
X84=	
+280=	
TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."

***If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

09/15/2003 WABRHAM1 00000018 190065 10660202

01 FC:2001	375.00 DA
02 FC:2202	153.00 DA
03 FC:2201	714.00 DA

PTO-1556
(5/87)

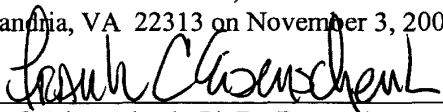
*U.S. Government Printing Office: 2002 — 489-267/69033

NPC-UNIV-000004899

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Commissioner for Patents, P.O. Box 1450
Alexandria, VA 22313 on November 3, 2003.



PRELIMINARY AMENDMENT
Patent Application
Docket No. TPI-350C1
Serial No. 10/660,202


Frank C. Eisenschenk, Ph.D., Patent Attorney

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Örn Almarsson, Magali Bourghol Hickey, Matthew L. Peterson, Michael J. Zaworotko, Brian Moulton, Nair Rodriguez-Hornedo
Serial No. : 10/660,202
Filed : September 11, 2003
For : Pharmaceutical Co-Crystal Compositions

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Sir:

Applicants respectfully request that the above-identified patent application be amended as follows:

In the Specification

Please substitute the following paragraph on page 1, beginning at line 4:

This application claims the benefit of US Provisional Patent Application No. 60/451,213 filed on February 28, 2003; U.S. Provisional Patent Application No. 60/463,962, filed on April 18, 2003; and U.S. Provisional Application No. 60/487,064, filed on July 11, 2003 each of which incorporated herein by reference in its entirety. This application is also a continuation-in-part of ~~PCT/US03/XXXXX~~ PCT/US03/27772, filed on September 4, 2003 which is a continuation-in-part of U.S. Patent Application No. 10/378,956, filed March 1, 2003, which claims the benefit of U.S. Provisional Application No. 60/360,768, filed March 1, 2002; said ~~PCT US03/XXXXX~~ PCT/US03/27772 also claims the benefit of US Provisional Patent Application No. 60/451,213 filed on February 28, 2003; U.S. Provisional Patent Application No. 60/463,962, filed on April 18, 2003; and U.S. Provisional Application No. 60/487,064, filed on July 11, 2003. This application is also a continuation-in-part of U.S. Patent Application No. 10/637,829, filed August 8, 2003, which is a divisional of U.S. Patent Application No. 10/295,995, filed November 18, 2002, which is a continuation of U.S. Patent Application No. 10/232,589, filed September 3, 2002, which claims the benefit of US Provisional Patent Application No. 60/406,974, filed August 30, 2002 and US Provisional Patent Application No. 60/380,288, filed May 15, 2002 and US Provisional Patent Application No. 60/356,764, filed February 15, 2002. This application is also a continuation-in-part of US Patent Application No. 10/449,307, filed May 30, 2003 which claims the benefit of US Provisional Patent Application No. 60/463,962 filed April 18, 2003 and US Provisional Patent Application No. 60/444,315, filed January 31, 2003 and US Provisional Patent Application No. 60/439,282 filed January 10, 2003 and US Provisional Patent Application No. 60/384,152, filed May 31, 2002. This application is also a continuation-in-part of US Patent Application No. 10/601,092, filed June 20, 2003, which claims the benefit of US Provisional Patent Application No. 60/451,213, filed February 28, 2003. Each of these applications is hereby incorporated by reference in their entireties, including all figures, tables and formulae.

Remarks

The amendments to the "Incorporation by Reference" section are being made to insert the international PCT application number which is a continuation-in-part of the subject application. Entry of the amendments presented herein is respectfully requested. Applicants respectfully assert that no new matter has been added by these amendments.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

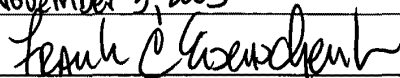
Address: 2421 N.W. 41st Street, Suite A-1
Gainesville, FL 32606-6669

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Commissioner for Patents, P.O. Box 1450
Alexandria, VA 22313-1450 on

November 3, 2003



Frank C. Eisenschenk, Ph.D., Patent Attorney



SUBMISSION OF SUPPLEMENTAL
APPLICATION DATA SHEET
UNDER 37 CFR 1.76
Patent Application
Docket No. TPI-350C1
Serial No. 10/660,202

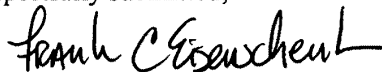
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Örn Almarsson, Magali Bourghol Hickey, Matthew L. Peterson, Michael J. Zaworotko, Brian Moulton, Nair Rodriguez-Hornedo
Serial No. : 10/660,202
Filed : September 11, 2003
For : Pharmaceutical Co-Crystal Compositions
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUBMISSION OF SUPPLEMENTAL APPLICATION DATA SHEET
UNDER 37 CFR 1.76

Attached hereto please find a Supplemental Application Data Sheet amending the Domestic Priority Information and adding the Assignee information in the above-referenced patent application. Entry of amended Application Data Sheet into the record is respectfully requested and it is respectfully requested that an indication of the entry of this paper be transmitted to the undersigned.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: Saliwanchik, Lloyd & Saliwanchik
2421 N.W. 41st Street, Suite A-1
Gainesville, FL 32606-6669

FCE/sl

Attachment: Supplemental Application Data Sheet with revised information

J:\TPI\350C1\Comm-ADS.amend.doc\DNB\dkf



SUPPLEMENTAL APPLICATION DATA SHEET

Docket No. TPI-350C1

Application Information

Application Type::	Regular
Subject Matter::	Utility
Suggested Classification::	None
Suggested Group Art Unit::	None
CD-ROM or CD-R?::	None
Number of CD disks::	None
Number of copies of CDs::	None
Sequence submission?::	None
Computer Readable Form?::	No
Number of Copies of CRF::	None
Title::	Pharmaceutical Co-Crystal Compositions
Attorney Docket Number::	TPI-350C1
Request for Early Publication::	No
Request for Non-Publication::	No
Suggested Drawing Figure::	None
Total Drawing Sheets::	66
Small Entity?::	Yes
Petition included?::	No
Petition Type::	N/A
Secrecy Order in Parent Appl.?::	No

SUPPLEMENTAL APPLICATION DATA SHEET

Docket No. TPI-350C1

Applicant Information

Applicant Authority Type:: Inventor
Primary Citizenship Country:: Iceland
Status:: Unknown
Inventor One Given Name:: Örn
Family Name:: Almarsson
City of Residence:: Shrewsbury
State or Province of Residence:: MA
Country of Residence:: US
Street of Mailing Address:: 22 Farmington Drive
City of Mailing Address:: Shrewsbury
State or Province of mailing address:: MA
Country of Mailing Address:: US
Postal or Zip Code of Mailing Address:: 01545

Applicant Two Authority Type:: Inventor
Primary Citizenship Country:: US
Status:: Unknown
Inventor Two Given Name:: Magali
Family Name:: Bourghol Hickey
City of Residence:: Medford
State or Province of Residence:: MA
Country of Residence:: US
Street of Mailing Address:: 342 Malden Street
City of Mailing Address:: Medford
State or Province of mailing address:: MA
Country of Mailing Address:: US
Postal or Zip Code of Mailing Address:: 02155

SUPPLEMENTAL APPLICATION DATA SHEET

Docket No. TPI-350C1

Applicant Information

Applicant Three Authority Type::	Inventor
Primary Citizenship Country::	US
Status::	Unknown
Inventor Three Given Name::	Matthew L.
Family Name::	Peterson
City of Residence::	Framingham
State or Province of Residence::	MA
Country of Residence::	US
Street of Mailing Address::	60 Linda Avenue
City of Mailing Address::	Framingham
State or Province of mailing address::	MA
Country of Mailing Address::	US
Postal or Zip Code of Mailing Address::	01701
Applicant Four Authority Type::	Inventor
Primary Citizenship Country::	US
Status::	Unknown
Inventor Four Given Name::	Michael J.
Family Name::	Zaworotko
City of Residence::	Tampa
State or Province of Residence::	FL
Country of Residence::	US
Street of Mailing Address::	4202 E. Fowler Ave.
City of Mailing Address::	Tampa
State or Province of mailing address::	FL
Country of Mailing Address::	US
Postal or Zip Code of Mailing Address::	33620

SUPPLEMENTAL APPLICATION DATA SHEET

Docket No. TPI-350C1

Applicant Information

Applicant Five Authority Type:: Inventor
Primary Citizenship Country:: US
Status:: Unknown
Inventor Five Given Name:: Brian
Family Name:: Moulton
City of Residence:: Temple Terrace
State or Province of Residence:: FL
Country of Residence:: US
Street of Mailing Address:: 13455 Century Cove Dr. #325
City of Mailing Address:: Temple Terrace
State or Province of mailing address:: FL
Country of Mailing Address:: US
Postal or Zip Code of Mailing Address:: 33637

Applicant Six Authority Type:: Inventor
Primary Citizenship Country:: US
Status:: Unknown
Inventor Six Given Name:: Nair
Family Name:: Rodriguez-Hornedo
City of Residence:: Ann Arbor
State or Province of Residence:: MI
Country of Residence:: US
Street of Mailing Address:: 1690 Northbrook Dr.
City of Mailing Address:: Ann Arbor
State or Province of mailing address:: MI
Country of Mailing Address:: US
Postal or Zip Code of Mailing Address:: 48103

SUPPLEMENTAL APPLICATION DATA SHEET

Docket No. TPI-350C1

Representative Information

Representative Customer Number:: 000023557

Representative Designation::	Registration Number::	Representative Name::
Primary	45,332	Frank C. Eisenschenk, Ph.D.

Correspondence Information

Name Line One::	Frank C. Eisenschenk, Ph.D.
Name Line Two::	Saliwanchik, Lloyd & Saliwanchik, A Professional Association
Street of Mailing Address::	2421 N.W. 41 st Street, Suite A-1
City of Mailing Address::	Gainesville
State or Province of Mailing Address::	FL
Postal or Zip Code of Mailing Address::	32606
Telephone Number One::	(352) 375-8100
Telephone Number Two::	
Fax Number::	(352) 372-5800
Electronic Mail Address::	fce@slspatents.com

SUPPLEMENTAL APPLICATION DATA SHEET

Docket No. TPI-350C1

Domestic Priority Information

Each of the applications listed in this domestic priority section are hereby incorporated by reference into this patent application in their entireties (including all figures, tables, and formulae).

Application::	Continuity Type::	Parent Application::	Parent Filing Date::
This application is a	Continuation-In-Part of	~~PCT-US03/xxxxx~~ <u>PCT/US03/27772</u>	September 4, 2003
which is a	Continuation-In-Part of	10/378,956	March 3, 2003
which claims the benefit of		60/360,768	March 1, 2002
Said		~~PCT-US03/xxxxx~~ <u>PCT/US03/27772</u>	September 4, 2003
Also claims the benefit of		60/451,213	February 28, 2003
And		60/463,962	April 18, 2003
And		60/487,064	July 11, 2003
This application is also a	Continuation-In-Part of	10/637,829	August 8, 2003
which is a	Divisional of	10/295,995	November 18, 2002
which is a	Continuation of	10/232,589	September 3, 2002
which claims benefit of		60/406,974	August 30, 2002
And		60/380,288	May 15, 2002
And		60/356,764	February 15, 2002
This application is also a	Continuation-In-Part of	10/449,307	May 30, 2003
which claims the benefit of		60/463,962	April 18, 2003
And		60/444,315	January 31, 2003
And		60/439,282	January 10, 2003
And		60/384,152	May 31, 2002
This application is also a	Continuation-In-Part of	10/601,092	June 20, 2003
This application also		60/451,213	February 28, 2003
claims the benefit of			
And		60/463,962	April 18, 2003
And		60/487,064	July 11, 2003

Foreign Priority Information

Country::	Application Number::	Filing Date::	Priority Claimed::
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SUPPLEMENTAL APPLICATION DATA SHEET

Docket No. TPI-350C1

Assignee Information

Assignee Name:: TransForm Pharmaceuticals, Inc.
Street of Mailing Address:: 29 Hartwell Avenue
City of Mailing Address:: Lexington
State or Province or mailing address:: Massachusetts
Country of Mailing Address:: US
Postal or Zip Code of Mailing Address:: 02421

Assignee Information

Assignee Name:: University of South Florida
Street of Mailing Address:: 4202 East Fowler Avenue, FAO 126
City of Mailing Address:: Tampa
State or Province or mailing address:: FL
Country of Mailing Address:: US
Postal or Zip Code of Mailing Address:: 33620-7900

Assignee Information

Assignee Name:: The Regents of the University of Michigan
Street of Mailing Address:: Wolverine Tower, Room 2071, 3003 S. State Street
City of Mailing Address:: Ann Arbor
State or Province or mailing address:: MI
Country of Mailing Address:: US
Postal or Zip Code of Mailing Address:: 48109-1280

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313 on November 6, 2003.


Frank C. Eisenschenk, Ph.D., Patent Attorney



INFORMATION DISCLOSURE
STATEMENT

Examining Group Unknown
Patent Application
Docket No. TPI-350C1
Serial No. 10/660,202

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : Unknown
Applicants : Örn Almarsson, Magali Bourghol Hickey, Matthew L. Peterson, Michael J. Zaworotko, Brian Moulton, Nair Rodriguez-Hornedo
Serial No. : 10/660,202
Filed : September 11, 2003
Conf. No. : Unknown
For : Pharmaceutical Co-Crystal Compositions

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§1.97 AND 1.98

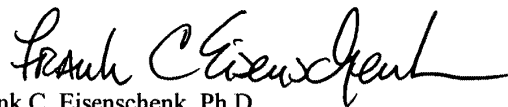
Sir:

In accordance with 37 CFR §1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. A copy of each cited reference is enclosed.

It is respectfully requested that the references cited on the attached form PTO/SB/08 be considered in the examination of the subject application and that their consideration be made of record.

Applicants respectfully assert that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,

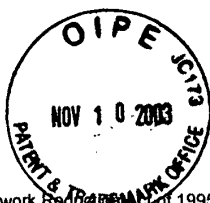


Frank C. Eisenschenk, Ph.D.
Patent Attorney
Registration No. 45,332
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: 2421 N.W. 41st Street, Suite A-1
Gainesville, FL 32606-6669

FCE/ss

Attachments: Form PTO/SB/08; copies of references cited therein.

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PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Project of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	10/378,956		
		Filing Date	September 11, 2003		
		First Named Inventor	Örn Almarsson		
		Art Unit			
		Examiner Name			
Sheet	1	of	2	Attorney Docket Number	TPI-350C1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U1	US-			
	U2	US-			
	U3	US-			
	U4	US-			
	U5	US-			
	U6	US-			
	U7	US-			
	U8	US-			
	U9	US-			

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	- Number ⁴ - Kind Code ⁵ (if known)				
	F1	GB 1 297 261 A		11-22-1972 (22 Nov 1972)	E.R. Squibb & Sons, Inc.	whole document	
	F2						
	F3						
	F4						
	F5						
	F6						
	F7						

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard T.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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PTO/SB/08B (08-03)
Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known		
			Application Number	10/378,956	
			Filing Date	September 11, 2003	
			First Named Inventor	Örn Almarsson	
			Group Art Unit		
			Examiner Name		
Sheet	2	of	2	Attorney Docket Number	TPI-350C1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	R1	BRADER, M.L. <i>et al. Nature Biotechnol.</i> , 2002, 20 :800-804.	
	R2	EL-NAHHAS, S.A. <i>Pharmazie</i> , 1996, 51(12):960-963.	
	R3	FLEISCHMAN, S.G. <i>et al. Crystal Growth & Design.</i> , 2003, 3(6): 909-919.	
	R4	OSWALD, I.D.H. <i>et al. Acta Cryst.</i> , 2002, B58:1057-1066.	
	R5	REYNOLDS, J.E.F. (ed). Martindale, The Extra Pharmacopoeia, 1993, The Pharmaceutical Press, London, England, 13 th Edition, pp. 1431 (e.g., Acetaminophen, Aspirin, and Caffeine Tablets), 1465 (e.g., Aspirin plus C), 1521 (Codafen Continus), 1610 (Gaboril Complex).	
	R6	WALSH, R.D. Bailey <i>et al. Chem. Commun.</i> , 2003, 2003:186-187.	
	R7		
	R8		
	R9		
	R10		
	R11		
	R12		
	R13		

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

J:\TPI\350C1\NDS\DS-PTO-SB-08-1449_refs from PCT-ISR&USF.doc/DNB/ssa

NPC-UNIV-000004917

NOVARTIS EXHIBIT 1023

Novartis v. Regents, IPR2023-01346

Page 535 of 1101



I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Commissioner for Patents, P.O. Box 1450
Alexandria, VA 22313 on April 1, 2004.

Frank C. Eisenschenk
Frank C. Eisenschenk, Ph.D., Patent Attorney

SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

Patent Application
Docket No. TPI-350C1
Serial No. 10/660,202

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Örn Almarsson, Magali Bourghol Hickey, Matthew L. Peterson, Michael J. Zaworotko, Brian Moulton, Nair Rodriguez-Hornedo
Serial No. : 10/660,202
Filed : September 11, 2003
For : Pharmaceutical Co-Crystal Compositions

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 CFR §1.97 and §1.98, the references listed on the attached Forms PTO/SB/08A and PTO/SB/08B are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. Copies of the cited documents and the Search Report are enclosed. It is respectfully requested that the references listed on the attached Forms PTO/SB/08A and PTO/SB/08B be considered and made of record in the examination of the subject application.

J:\TPI\350C1\IDS\IDS.doc/DNB/ehm

The undersigned hereby certifies that the items of information contained in this statement were cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.

Applicants respectfully assert that the requirements of 37 CFR §§1.97 and 1.98 are met by the foregoing.

Though no fees are believed to be required for this paper, the Patent Office is hereby authorized to charge any fees required by this paper to Deposit Account No. 19-0065.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: 2421 N.W. 41st Street, Suite A-1
Gainesville, FL 32606-6669

FCE/ehm

Attachments: Forms PTO/SB/08A and PTO/SB/08B
Copies of Listed References

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Complete if Known			
		Application Number	10/660,202		
		Filing Date	September 11, 2003		
		First Named Inventor	Orn Almarsson		
		Art Unit			
		Examiner Name			
Sheet	2	of	2	Attorney Docket Number	TPI-350C1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	5	WEISSBUCH, I. et al., "Understanding and Control of Nucleation, Growth, Habit, Dissolution and Structure...", Acta Cryst. (1995), pp. 115-148, vol. B51	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Substitute for form 1449/PTO

Sheet	1	of	2
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Application Number	10/660,202
Filing Date	September 11, 2003
First Named Inventor	Orn Almarsson
Art Unit	
Examiner Name	
Attorney Docket Number	TPI-350C1

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ²
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	1	WO 03/074474 A2	09-12-2003	Zaworotko et al	Pls review all	
	2	WO 03/033462 A2	04-24-2003	Matzger et al.	Pls review all	
	3	WO 01/51919 A2	07-19-2001	Levinson et al.	Pls review all	
	4	WO 01/42222 A1	06-14-2001	Ferro et al.	Pls review all	

**Examiner
Signature**

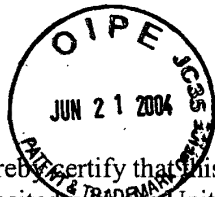
Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Page 539 of 1101



17W

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Commissioner for Patents, P.O. Box 1450
Alexandria, VA 22313 on June 18, 2004.

Frank C. Eisenschenk

Frank C. Eisenschenk, Ph.D., Patent Attorney

SECOND SUPPLEMENTAL
INFORMATION DISCLOSURE
STATEMENT
Patent Application
Docket No. TPI-350C1
Serial No. 10/660,202

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Örn Almarsson, Magali Bourghol Hickey, Matthew L. Peterson, Michael J. Zaworotko, Brian Moulton, Nair Rodriguez-Hornedo
Serial No. : 10/660,202
Filed : September 11, 2003
For : Pharmaceutical Co-Crystal Compositions

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 CFR §1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. A copy of each cited reference is enclosed.

It is respectfully requested that the references cited on the attached form PTO/SB/08 be considered in the examination of the subject application and that their consideration be made of record.

J:\TPI\350C1\IDS\2nd.SIDS.doc/DNB/amh

Applicants respectfully assert that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

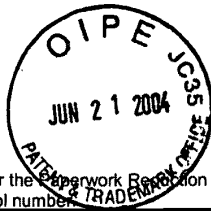
Fax No.: 352-372-5800

Address: 2421 N.W. 41st Street, Suite A-1
Gainesville, FL 32606-6669

FCE/amh

Attachments: Forms PTO/SB/08

Copies of Listed References



PTO/SB/08A (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	10/660,202		
		Filing Date	September 11, 2003		
		First Named Inventor	Örn Almarsson		
		Art Unit			
		Examiner Name			
Sheet	1	of	1	Attorney Docket Number	TPI-350C1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U1	US-			
	U2	US-			
	U3	US-			
	U4	US-			
	U5	US-			
	U6	US-			
	U7	US-			
	U8	US-			
	U9	US-			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³	- Number ⁴ - Kind Code ⁵ (if known)			
	F1	WO	02/056878 A2	07-25-2002	Pharmacia Corp.	All
	F2	WO	01/41536 A2	06-14-2001	Pharmacia Corp.	All
	F3	EP	1167355 A1	01-02-2002	Fako Ilaclari A.S.	All
	F4					
	F5					
	F6					
	F7					

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard T.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

J:\TPI\350C1\IDS\2nd.SIDS.form.doc\DNB/amh



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
10/660,202	09/11/2003	Om Almarsson	TPI-350C1

Frank C. Eisenschenk, Ph.D.
 Saliwanchik, Lloyd & Saliwanchik
 A Professional Association
 2421 N.W. 41st Street, Suite A-1
 Gainesville, FL 32606

CONFIRMATION NO. 6536

FORMALITIES LETTER



OC000000013290007

Date Mailed: 07/21/2004

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

*Filing Date Granted***Items Required To Avoid Abandonment:**

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is unsigned.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

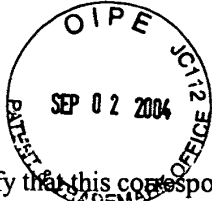
Total additional fee(s) required for this application is **\$65** for a Small Entity

- **\$65** Late oath or declaration Surcharge.

Replies should be mailed to: Mail Stop Missing Parts
 Commissioner for Patents
 P.O. Box 1450
 Alexandria VA 22313-1450

*A copy of this notice **MUST** be returned with the reply.*

T.TU
Customer Service Center
Initial Patent Examination Division (703) 308-1202
PART 3 - OFFICE COPY



TFW

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Commissioner for Patents, P.O. Box 1450
Alexandria, VA 22313 on August 25, 2004

Frank C. Eisenschenk

Frank C. Eisenschenk, Ph.D., Patent Attorney

**THIRD SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT**

Examining Group 1653
Patent Application
Docket No. TPI-350C1
Serial No. 10/660,202

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : 1653
Applicants : Örn Almarsson, Magali Bourghol Hickey, Matthew L. Peterson, Michael J. Zaworotko, Brian Moulton, Nair Rodriguez-Hornedo
Serial No. : 10/660,202
Filed : September 11, 2003
Conf. No. : 6536
For : Pharmaceutical Co-Crystal Compositions

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 CFR §1.56, the reference listed on the attached form PTO/SB/08 is being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. A copy of the cited reference and the Partial International Search Report is enclosed.

It is respectfully requested that the reference cited on the attached form PTO/SB/08 be considered in the examination of the subject application and that its consideration be made of record.

J:\TPI\350C1\IDS\3d.SIDS.doc/DNB/sl

Applicants respectfully assert that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

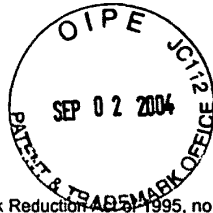
Address: 2421 N.W. 41st Street, Suite A-1
Gainesville, FL 32606-6669

FCE/sl

Attachments: Form PTO/SB/08

Copy of WO 0142221

Copy of Partial International Search Report



PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Complete if Known

Application Number	10/606,202
Filing Date	September 11, 2003
First Named Inventor	Orn Almarsson
Art Unit	1653
Examiner Name	
Attorney Docket Number	TPI-350C1

Sheet 1 of 1

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U1	US-			
	U2	US-			
	U3	US-			
	U4	US-			
	U5	US-			
	U6	US-			
	U7	US-			
	U8	US-			
	U9	US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	F1	WO 01/42221 A1	06-14-2001	Pharmacia Corp.	All	
	F2					
	F3					
	F4					
	F5					
	F6					
	F7					

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard T.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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NPC-UNIV-000005366

NOVARTIS EXHIBIT 1023

Novartis v. Regents, IPR2023-01346

Page 547 of 1101



I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313 on November 1, 2004.

Examining Group 1653
Patent Application
Docket No. TPI-350C1
Serial No. 10/660,202

Frank C. Eisenschenk

Frank C. Eisenschenk, Ph.D., Patent Attorney

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : 1653
Applicants : Örn Almarsson, Magali Bourghol Hickey, Matthew L. Peterson, Michael J. Zaworotko, Brian Moulton, Nair Rodriguez-Hornedo
Serial No. : 10/660,202
Filed : September 11, 2003
Conf. No. : 6536
For : Pharmaceutical Co-Crystal Compositions

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Sir:

A Petition and Fee for a two-month Extension of Time through and including November 22, 2004, accompanies this Transmittal Letter.

The above-referenced patent application was filed with unsigned Declaration (37 CFR 1.63) for Utility Application Using an Application Data Sheet and Power of Attorney forms. Transmitted herewith is a fully executed Declaration (37 CFR § 1.63) for Utility or Design Application Using an Application Data Sheet form and Power of Attorney forms for the subject application.

Attached hereto please find a Supplemental Application Data Sheet which amends the Application Information and Applicant Information in the subject application. Entry of the Supplemental Application Data Sheet into the record is respectfully requested and it is respectfully

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requested that an indication of the entry be transmitted to the undersigned by way of an Updated Filing Receipt.

A Notice to File Missing Parts of Nonprovisional Application was received from the Patent and Trademark Office, and a copy of that Notice is attached hereto.

Please charge the surcharge of \$65.00 to Deposit Account No. 19-0065. The Commissioner is hereby authorized to charge any additional fees which may be required to Deposit Account No. 19-0065. Two copies of this transmittal letter are enclosed.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.
Patent Attorney
Registration No. 45,332
Telephone No.: (352) 375-8100
Facsimile No.: (352) 372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

FCE/sl

Enclosures: Executed Declaration form; Executed Power of Attorney forms; Supplemental Application Data Sheet; Copy of Notice to File Missing Parts of Nonprovisional Application



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
10/660,202	09/11/2003	Orn Almarsson	TPI-350C1

Frank C. Eisenschenk, Ph.D.
 Saliwanchik, Lloyd & Saliwanchik
 A Professional Association
 2421 N.W. 41st Street, Suite A-1
 Gainesville, FL 32606



CONFIRMATION NO. 6536

FORMALITIES LETTER



OC000000013290007

Date Mailed: 07/21/2004

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

*Filing Date Granted***Items Required To Avoid Abandonment:**

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is unsigned.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **\$65** for a Small Entity

- **\$65** Late oath or declaration Surcharge.

Replies should be mailed to: Mail Stop Missing Parts
 Commissioner for Patents
 P.O. Box 1450
 Alexandria VA 22313-1450

11/04/2004 BABRAHA1 00000058 190065 10660202

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*A copy of this notice **MUST** be returned with the reply.*

NPC-UNIV-000005412

NOVARTIS EXHIBIT 1023

Novartis v. Regents, IPR2023-01346

Page 550 of 1101

T.TU
Customer Service Center
Initial Patent Examination Division (703) 308-1202
PART 2 - COPY TO BE RETURNED WITH RESPONSE

**DECLARATION (37 CFR §1.63) FOR UTILITY OR
DESIGN PATENT APPLICATION
USING AN
APPLICATION DATA SHEET (37 C.F.R. §1.76) E**

☐ Declaration
Submitted
with Initial
Filing

OR

☒ Declaration
Submitted after Initial
Filing (surcharge
(37 CFR 1.16 (e)) required)

Attorney Docket Number TPI-350C1

First Named Inventor Örn Almarsson

COMPLETE IF KNOWN

Application Number 10/660,202

Filing Date September 11, 2003

Group Art Unit

Examiner Name

This declaration is directed to an application entitled: **PHARMACEUTICAL CO-CRYSTAL COMPOSITIONS**
As the below named inventor(s), I/we declare that:
This declaration is directed to:

The attached application, or

Application No. 10/660,202, filed on September 11, 2003
as amended on November 3, 2003 (if applicable);

I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought;

I/ we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above;

I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application.

All statements made herein of my/own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and may jeopardize the validity of the application or any patent issuing thereon.

Full Name(s) of Inventors

Inventor One: Örn Almarsson

Citizen of: IS

Signature: *Örn Almarsson*

Inventor Two: Magali Bourghol Hickey

Citizen of: US

Signature: *Magali B. Hickey*

Inventor Three: Matthew L. Peterson

Citizen of: US

Signature: *Matthew L. Peterson*

Inventor Four: Michael J. Zaworotko

Citizen of: US

Signature:

☒ Additional inventors are being named on the 1 additional form(s) attached hereto.

S:\Legal\PATENTS\Patent Applications\TPI\035+ (1039) C6-Xa\TPI\035X1\DECLARATION\APPLICATION WITH ADS.doc\DNB\SSA

NPC-UNIV-000005414

NOVARTIS EXHIBIT 1023

Novartis v. Regents, IPR2023-01346

Page 552 of 1101

DECLARATION (37 CFR §1.63) FOR UTILITY OR DESIGN PATENT APPLICATION USING AN APPLICATION DATA SHEET (37 C.F.R. § 1.76)		Attorney Docket Number	TPI-350C1
		First Named Inventor	Örn Almarsson
		COMPLETE IF KNOWN	
☐ Declaration Submitted with Initial Filing OR ☒ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)	Application Number	10/660,202	
	Filing Date	September 11, 2003	
	Group Art Unit		
	Examiner Name		

This declaration is directed to an application entitled: **PHARMACEUTICAL CO-CRYSTAL COMPOSITIONS**

As the below named inventor(s), I/we declare that:

This declaration is directed to:

The attached application, or
 Application No. 10/660,202, filed on September 11, 2003
 as amended on November 3, 2003 (if applicable);

I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought;

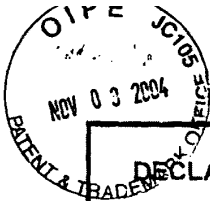
I/ we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above;

I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application.

All statements made herein of my/own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and may jeopardize the validity of the application or any patent issuing thereon.

Full Name(s) of Inventors

Inventor Five: Brian Moulton	Citizen of: US
Signature:	
Inventor Six: Nair Rodriguez-Hornedo	Citizen of: US
Signature:	
Inventor Seven:	Citizen of:
Signature:	



**DECLARATION (37 CFR §1.63) FOR UTILITY OR
DESIGN PATENT APPLICATION
USING AN
APPLICATION DATA SHEET (37 C.F.R. § 1.76)**

☒ Declaration Submitted with Initial Filing OR ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number TPI-350C1

First Named Inventor Örn Almarsson

COMPLETE IF KNOWN

Application Number 10/660,202

Filing Date September 11, 2003

Group Art Unit

Examiner Name

This declaration is directed to an application entitled: **PHARMACEUTICAL CO-CRYSTAL COMPOSITIONS**
As the below named inventor(s), I/we declare that:
This declaration is directed to:

The attached application, or
Application No. 10/660,202, filed on September 11, 2003
as amended on November 3, 2003 (if applicable);

I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought;

I/ we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above;

I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application.

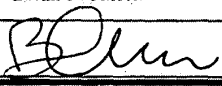
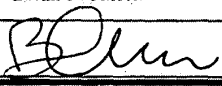
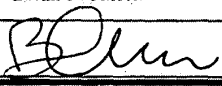
All statements made herein of my/own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and may jeopardize the validity of the application or any patent issuing thereon.

Full Name(s) of Inventors

Inventor One: Örn Almarsson	Citizen of: IS
Signature:	
Inventor Two: Magali Bourghol Hickey	Citizen of: US
Signature:	
Inventor Three: Matthew L. Peterson	Citizen of: US
Signature:	
Inventor Four: Michael J. Zaworotko	Citizen of: ~~US~~ CANADA
Signature: <i>Michael J. Zaworotko</i>	

☒ Additional inventors are being named on the 1 additional form(s) attached hereto.

J:\TPI350C1\New Application Forms\DECLARATION\APPLICATION WITH ADS.doc\DNB\ssa

DECLARATION (37 CFR §1.63) FOR UTILITY OR DESIGN PATENT APPLICATION USING AN APPLICATION DATA SHEET (37 C.F.R. § 1.76)		Attorney Docket Number	TPI-350C1												
		First Named Inventor	Örn Almarsson												
		<i>COMPLETE IF KNOWN</i>													
☒ Declaration Submitted with Initial Filing OR ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)		Application Number	10/660,202												
		Filing Date	September 11, 2003												
		Group Art Unit													
		Examiner Name													
This declaration is directed to an application entitled: PHARMACEUTICAL CO-CRYSTAL COMPOSITIONS As the below named inventor(s), I/we declare that: This declaration is directed to: The attached application, or Application No. <u>10/660,202</u>, filed on <u>September 11, 2003</u> as amended on <u>November 3, 2003</u> (if applicable); I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought; I/ we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above; I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application. All statements made herein of my/own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and may jeopardize the validity of the application or any patent issuing thereon. Full Name(s) of Inventors <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">Inventor Five: Brian Moulton</td> <td>Citizen of: <u>US CANADA</u></td> </tr> <tr> <td colspan="2">Signature: </td> </tr> <tr> <td>Inventor Six: Nair Rodriguez-Hornedo</td> <td>Citizen of: US</td> </tr> <tr> <td colspan="2">Signature:</td> </tr> <tr> <td>Inventor Seven:</td> <td>Citizen of:</td> </tr> <tr> <td colspan="2">Signature:</td> </tr> </table>				Inventor Five: Brian Moulton	Citizen of: <u>US CANADA</u>	Signature: 		Inventor Six: Nair Rodriguez-Hornedo	Citizen of: US	Signature:		Inventor Seven:	Citizen of:	Signature:	
Inventor Five: Brian Moulton	Citizen of: <u>US CANADA</u>														
Signature: 															
Inventor Six: Nair Rodriguez-Hornedo	Citizen of: US														
Signature:															
Inventor Seven:	Citizen of:														
Signature:															

**DECLARATION (37 CFR §1.63) FOR UTILITY OR
DESIGN PATENT APPLICATION
USING AN
APPLICATION DATA SHEET (37 C.F.R. § 1.76)**

☒ Declaration
Submitted
with Initial
Filing

OR

☐ Declaration
Submitted after Initial
Filing (surcharge
(37 CFR 1.16 (e)) required)

Attorney Docket Number

TPI-350C1

First Named Inventor

Örn Almarsson

COMPLETE IF KNOWN

Application Number

10/660,202

Filing Date

September 11, 2003

Group Art Unit

Examiner Name

This declaration is directed to an application entitled: **PHARMACEUTICAL CO-CRYSTAL COMPOSITIONS**
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This declaration is directed to:

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Full Name(s) of Inventors

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Citizen of: IS

Signature:

Inventor Two: Magali Bourghol Hickey

Citizen of: US

Signature:

Inventor Three: Matthew L. Peterson

Citizen of: US

Signature:

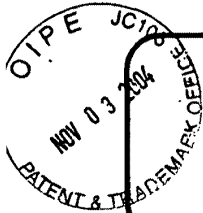
Inventor Four: Michael J. Zaworotko

Citizen of: US

Signature:

☒ Additional inventors are being named on the 1 additional form(s) attached hereto.

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☒ Declaration Submitted with Initial Filing OR ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)		COMPLETE IF KNOWN													
		Application Number	10/660,202												
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Inventor Five: Brian Moulton	Citizen of: US														
Signature: _____															
Inventor Six: Nair Rodriguez-Hornedo	Citizen of: US														
Signature: <i>Nair Rodriguez-Hornedo</i>															
Inventor Seven:	Citizen of:														
Signature: _____															



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POWER OF ATTORNEY OR AUTHORIZATION OF AGENT

Application Number	10/660,202
Filing Date	September 11, 2003
First Named Inventor	Örn Almarsson
Title	Pharmaceutical Co-Crystal Compositions
Group Art Unit	
Examiner Name	unknown
Attorney Docket Number	TPI-305C1

I hereby appoint:

- ☒ Practitioners at Customer Number
OR
☐ Practitioner(s) named below:

23557

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as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

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☐ Individual Name

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State

Zip

Country

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Fax

I am the:

- ☒ Applicant/Inventor.

- ☐ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

Name	Örn Almarsson
Signature	
Date	25 th October 2004

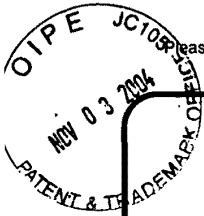
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☒ Total of 6 forms are submitted.

Burden Hour Statement: This form is estimated to take 3 minutes to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Alexandria, VA 22313.

NPC-UNIV-000005420

NOVARTIS EXHIBIT 1023
Novartis v. Regents, IPR2023-01346
Page 558 of 1101



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First Named Inventor	Örn Almarsson
Title	Pharmaceutical Co-Crystal Compositions
Group Art Unit	
Examiner Name	unknown
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Name Magali Bourghol Hickey

Signature

Magali B. Hickey

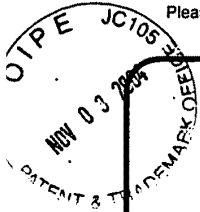
Date

10/18/04

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Filing Date	September 11, 2003
First Named Inventor	Örn Almarsson
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Name Matthew L. Peterson

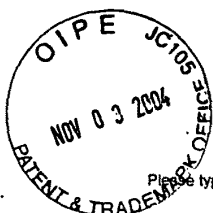
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Group Art Unit	
Examiner Name	unknown
Attorney Docket Number	TPI-350C1

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SIGNATURE of Applicant or Assignee of Record

Name Michael J. Zawortko

Signature

Date

October 29th 2003

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Application Number	10/660,202
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First Named Inventor	Örn Almarsson
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Group Art Unit	
Examiner Name	unknown
Attorney Docket Number	TPI-350C1

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Name Brian Moulton

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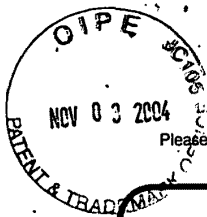
Date

21 October 2003

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Examiner Name	unknown
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Name Nair Rodriguez-Hornedo

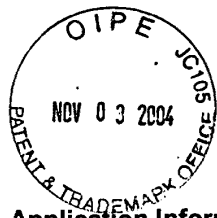
Signature *Nair Rodriguez-Hornedo*

Date Dec 12, 2003

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☒ *Total of 1 forms are submitted.

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SUPPLEMENTAL APPLICATION DATA SHEET

Docket No. TPI-350C1

Application Information

<u>Application number::</u>	<u>10/660,202</u>
<u>Filing Date::</u>	<u>09/11/2003</u>
Application Type::	Regular
Subject Matter::	Utility
Suggested Classification::	None
Suggested Group Art Unit::	None
CD-ROM or CD-R?::	None
Number of CD disks::	None
Number of copies of CDs::	None
Sequence submission?::	None
Computer Readable Form?::	No
Number of Copies of CRF::	None
Title::	Pharmaceutical Co-Crystal Compositions
Attorney Docket Number::	TPI-350C1
Request for Early Publication::	No
Request for Non-Publication::	No
Suggested Drawing Figure::	None
Total Drawing Sheets::	66
Small Entity?::	Yes
Petition included?::	No
Petition Type::	N/A
Secrecy Order in Parent Appl.?::	No

SUPPLEMENTAL APPLICATION DATA SHEET

Docket No. TPI-350C1

Applicant Information

Applicant Authority Type:: Inventor
Primary Citizenship Country:: Iceland
Status:: Unknown
Inventor One Given Name:: Örn
Family Name:: Almarsson
City of Residence:: Shrewsbury
State or Province of Residence:: MA
Country of Residence:: US
Street of Mailing Address:: 22 Farmington Drive
City of Mailing Address:: Shrewsbury
State or Province of mailing address:: MA
Country of Mailing Address:: US
Postal or Zip Code of Mailing Address:: 01545

Applicant Two Authority Type:: Inventor
Primary Citizenship Country:: US
Status:: Unknown
Inventor Two Given Name:: Magali
Family Name:: Bourghol Hickey
City of Residence:: Medford
State or Province of Residence:: MA
Country of Residence:: US
Street of Mailing Address:: 342 Malden Street
City of Mailing Address:: Medford
State or Province of mailing address:: MA
Country of Mailing Address:: US
Postal or Zip Code of Mailing Address:: 02155

SUPPLEMENTAL APPLICATION DATA SHEET

Docket No. TPI-350C1

Applicant Information

Applicant Three Authority Type:: Inventor
Primary Citizenship Country:: US
Status:: Unknown
Inventor Three Given Name:: Matthew L.
Family Name:: Peterson
City of Residence:: Framingham
State or Province of Residence:: MA
Country of Residence:: US
Street of Mailing Address:: ~~60 Linda Avenue~~ 25 Downey Street
City of Mailing Address:: ~~Framingham~~ Hopkinton
State or Province of mailing address:: MA
Country of Mailing Address:: US
Postal or Zip Code of Mailing Address:: ~~01704~~ 01748

Applicant Four Authority Type:: Inventor
Primary Citizenship Country:: ~~US~~ Canada
Status:: Unknown
Inventor Four Given Name:: Michael J.
Family Name:: Zaworotko
City of Residence:: Tampa
State or Province of Residence:: FL
Country of Residence:: US
Street of Mailing Address:: 4202 E. Fowler Ave.
City of Mailing Address:: Tampa
State or Province of mailing address:: FL
Country of Mailing Address:: US
Postal or Zip Code of Mailing Address:: 33620

SUPPLEMENTAL APPLICATION DATA SHEET

Docket No. TPI-350C1

Applicant Information

Applicant Five Authority Type::	Inventor
Primary Citizenship Country::	~~US~~ <u>Canada</u>
Status::	Unknown
Inventor Five Given Name::	Brian
Family Name::	Moulton
City of Residence::	~~Temple Terrace~~ <u>Providence</u>
State or Province of Residence::	~~FL~~ <u>RI</u>
Country of Residence::	US
Street of Mailing Address::	~~13455 Century Cove Dr. #325~~ <u>324 Brook Street, Box H</u>
City of Mailing Address::	~~Temple Terrace~~ <u>Providence</u>
State or Province of mailing address::	~~FL~~ <u>RI</u>
Country of Mailing Address::	US
Postal or Zip Code of Mailing Address::	~~33637~~ <u>02912</u>
Applicant Six Authority Type::	Inventor
Primary Citizenship Country::	US
Status::	Unknown
Inventor Six Given Name::	Nair
Family Name::	Rodriguez-Hornedo
City of Residence::	Ann Arbor
State or Province of Residence::	MI
Country of Residence::	US
Street of Mailing Address::	1690 Northbrook Dr.
City of Mailing Address::	Ann Arbor
State or Province of mailing address::	MI
Country of Mailing Address::	US
Postal or Zip Code of Mailing Address::	48103

SUPPLEMENTAL APPLICATION DATA SHEET

Docket No. TPI-350C1

Representative Information

Representative Customer Number:: 000023557

Representative Designation::	Registration Number::	Representative Name::
Primary	45,332	Frank C. Eisenschenk, Ph.D.

Correspondence Information

Name Line One::	Frank C. Eisenschenk, Ph.D.
Name Line Two::	Saliwanchik, Lloyd & Saliwanchik, A Professional Association
Street of Mailing Address::	~~2421 N.W. 41st Street, Suite A-1~~ <u>P.O. Box 142950</u>
City of Mailing Address::	Gainesville
State or Province of Mailing Address::	FL
Postal or Zip Code of Mailing Address::	~~32606~~ <u>32614-2950</u>
Telephone Number One::	(352) 375-8100
Telephone Number Two::	
Fax Number::	(352) 372-5800
Electronic Mail Address::	fce@slspatents.com

SUPPLEMENTAL APPLICATION DATA SHEET

Docket No. TPI-350C1

Domestic Priority Information

Each of the applications listed in this domestic priority section are hereby incorporated by reference into this patent application in their entireties (including all figures, tables, and formulae).

Application::	Continuity Type::	Parent Application::	Parent Filing Date::
This application is a	Continuation-In-Part of	PCT/US03/27772	September 4, 2003
which is a	Continuation-In-Part of	10/378,956	March 3, 2003
which claims the benefit of		60/360,768	March 1, 2002
Said		PCT/US03/27772	September 4, 2003
Also claims the benefit of		60/451,213	February 28, 2003
And		60/463,962	April 18, 2003
And		60/487,064	July 11, 2003
This application is also a	Continuation-In-Part of	10/637,829	August 8, 2003
which is a	Divisional of	10/295,995	November 18, 2002
which is a	Continuation of	10/232,589	September 3, 2002
which claims benefit of		60/406,974	August 30, 2002
And		60/380,288	May 15, 2002
And		60/356,764	February 15, 2002
This application is also a	Continuation-In-Part of	10/449,307	May 30, 2003
which claims the benefit of		60/463,962	April 18, 2003
And		60/444,315	January 31, 2003
And		60/439,282	January 10, 2003
And		60/384,152	May 31, 2002
This application is also a	Continuation-In-Part of	10/601,092	June 20, 2003
This application also		60/451,213	February 28, 2003
claims the benefit of			
And		60/463,962	April 18, 2003
And		60/487,064	July 11, 2003

Foreign Priority Information

Country::	Application Number::	Filing Date::	Priority Claimed::
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SUPPLEMENTAL APPLICATION DATA SHEET

Docket No. TPI-350C1

Assignee Information

Assignee Name:: TransForm Pharmaceuticals, Inc.
Street of Mailing Address:: 29 Hartwell Avenue
City of Mailing Address:: Lexington
State or Province or mailing address:: Massachusetts
Country of Mailing Address:: US
Postal or Zip Code of Mailing Address:: 02421

Assignee Information

Assignee Name:: University of South Florida
Street of Mailing Address:: 4202 East Fowler Avenue, FAO 126
City of Mailing Address:: Tampa
State or Province or mailing address:: FL
Country of Mailing Address:: US
Postal or Zip Code of Mailing Address:: 33620-7900

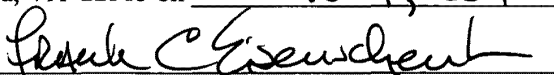
Assignee Information

Assignee Name:: The Regents of the University of Michigan
Street of Mailing Address:: Wolverine Tower, Room 2071, 3003 S. State Street
City of Mailing Address:: Ann Arbor
State or Province or mailing address:: MI
Country of Mailing Address:: US
Postal or Zip Code of Mailing Address:: 48109-1280

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Commissioner for Patents, P.O. Box 1450

Alexandria, VA 22313 on November 1, 2004



Frank C. Eisenschenk, Ph.D., Patent Attorney



PETITION AND FEE FOR EXTENSION OF TIME UNDER 37 CFR §1.136(a)

Examining Group 1653

Patent Application

Docket No. TPI-350C1

Serial No. 10/660,202

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : 1653
Applicants : Örn Almarsson, Magali Bourghol Hickey, Matthew L. Peterson, Michael J. Zaworotko, Brian Moulton, Nair Rodriguez-Hornedo
Serial No. : 10/660,202
Filed : September 11, 2003
Conf. No. : 6536
For : Pharmaceutical Co-Crystal Compositions

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

PETITION AND FEE FOR EXTENSION OF TIME UNDER 37 CFR §1.136(a)

Sir:

Applicants request that the period for response to the Notice to File Missing Parts of Nonprovisional Application be extended two months through and including November 22, 2004. A Transmittal Letter accompanies this Petition. Please charge the fee of \$215.00 to Deposit Account No. 19-0065.

Any additional fees as required by 37 CFR §§1.16 or 1.17 should be charged to Deposit Account No. 19-0065. Two additional copies of this Petition are enclosed.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: P.O. Box 142950

Gainesville, FL 32614-2950

11/04/2004 BABRAH1 00000059 190065 10660202

01 FC:2252 215.00 DA

FCE/sl

Attachment: Transmittal Letter

J:\TPI\350C1\PTO\Pet&Fee.1mth.dec-poa.doc\DNB/sl

NPC-UNIV-000005433

NOVARTIS EXHIBIT 1023

Novartis v. Regents, IPR2023-01346

Page 571 of 1101



1617 Ifw
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Commissioner for Patents, P.O. Box 1450
Alexandria, VA 22313 on August 28, 2006

Frank C. Eisenschenk, Ph.D., Patent Attorney

SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

Patent Application
Docket No. TPI-350C1
Serial No. 10/660,202

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Örn Almarsson, Magali Bourghol Hickey, Matthew L. Peterson, Michael J. Zaworotko, Brian Moulton, Nair Rodriguez-Hornedo
Serial No. : 10/660,202
Filed : September 11, 2003
For : Pharmaceutical Co-Crystal Compositions

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 CFR §§1.97 and 1.98, Applicants would like to bring to the attention of the Examiner, the references cited in the following patent applications:

U.S. Serial No. 10/378,956, filed March 3, 2003;
U.S. Serial No. 10/637,829, filed August 8, 2003;
U.S. Serial No. 10/295,995, filed November 18, 2002, now U.S. Patent No. 6,699,840;
U.S. Serial No. 10/232,589, filed September 3, 2002, now U.S. Patent No. 6,559,293;
U.S. Serial No. 10/449,307, filed March 30, 2003, now U.S. Patent No. 7,078,526; and
U.S. Serial No. 10/601,092, filed June 20, 2003.

The subject application, Serial No. 10/660,202, claims the benefit under 35 USC §120 of the filing date of patent applications referred to above. Applicants respectfully request that the copies of references supplied in the Information Disclosure Statements of the application referred to above, as

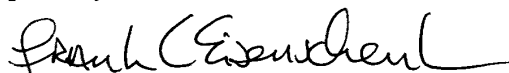
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well as any references cited during the prosecution thereof, be made of record in the 10/660,202 application. As copies of the references made of record in the applications referred to above, and cited on the attached form PTO/SB/08, can be found in the casefiles referred to above, copies of those references are not provided herewith.

It is respectfully requested that the references cited on the attached form PTO/SB/08 be considered in the examination of the subject application and that their consideration be made of record.

Applicants respectfully assert that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statements.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.
Patent Attorney
Registration No. 45,332
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

FCE/sl

Attachment: Form PTO/SB/08



PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	10/660,202
				Filing Date	September 11, 2003
				First Named Inventor	Örn Almarsson
				Art Unit	1617
				Examiner Name	Leonard Williams
Sheet	1	of	36	Attorney Docket Number	TPI-350C1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
	U1	US-2,711,411	06-21-1955	Holbert, <i>et al.</i>	All
	U2	US-4,198,507	04-15-1980	Barry, <i>et al.</i>	All
	U3	US-4,368,197	01-11-1983	Shefter, <i>et al.</i>	All
	U4	US-4,994,604	02-19-1991	Tung, <i>et al.</i>	All
	U5	US-5,177,262	01-15-1993	Taylor, <i>et al.</i>	All
	U6	US-5,332,834	07-26-1994	Bhattacharya, <i>et al.</i>	All
	U7	US-5,338,644	08-16-1994	Taylor, <i>et al.</i>	All
	U8	US-5,380,867	01-10-1995	Bhattacharya, <i>et al.</i>	All
	U9	US-5,412,094	05-02-1995	Amos, <i>et al.</i>	All
	U10	US-5,523,090	06-04-1996	Znaiden, <i>et al.</i>	All
	U11	US-5,614,342	03-25-1997	Molai, <i>et al.</i>	All
	U12	US-5,998,413	12-07-1999	Heeres, <i>et al.</i>	All
	U13	US-6,001,996	12-14-1999	Amos, <i>et al.</i>	All
	U14	US-6,268,385	07-31-2001	Whittle, <i>et al.</i>	All
	U15	US-6,570,036	05-27-2003	Reuter	All
	U16	US-2003/0162226	08-28-2003	Cima, <i>et al.</i>	All
	U17	US-2003/0166581	09-04-2003	Almarsson, <i>et al.</i>	All
	U18	US-2003/0224006	12-04-2003	Zaworotko, <i>et al.</i>	All
	U19	US-2004/0019211	01-29-2004	Remenar, <i>et al.</i>	All
	U20	US-2004/0106052	06-03-2004	Molai	All

Examiner Signature	Date Considered
-----------------------	--------------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard T.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	10/660,202
				Filing Date	September 11, 2003
				First Named Inventor	Örn Almarsson
				Art Unit	1617
				Examiner Name	Leonard Williams
Sheet	2	of	36	Attorney Docket Number	TPI-350C1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
	U21	US-2004/0106053	06-03-2004	Molaire, <i>et al.</i>	All
	U22	US-2004/0106055	06-03-2004	Molaire, <i>et al.</i>	All
	U23	US-2004/0171062	09-02-2004	Hirth, <i>et al.</i>	All
	U24	US-2004/0176335	09-09-2004	Childs	All
	U25	US-2005/0070551	03-31-1995	Remenar, <i>et al.</i>	All
	U26	US-2005/0181041	08-18-2005	Goldman	All
	U27	US-2005/0169982	08-04-2005	Almarsson, <i>et al.</i>	All
	U28	US-2005/0252649	11-17-2005	Chiu, <i>et al.</i>	All
	U29	US-2005/0256127	11-17-2005	Ku, <i>et al.</i>	All
	U30	US-6,559,293	05-06-2003	Almarsson, <i>et al.</i>	All
	U31	US-6,699,840	03-02-2004	Almarsson, <i>et al.</i>	All
	U32	US-2004-0053853	03-18-2004	Almarsson, <i>et al.</i>	All
	U33	US-2005/0070551 A1	03-31-2005	Remenar, <i>et al.</i>	All
	U34	US-2003/00224006	12-04-2003	Zaworotko <i>et al.</i>	All
	U35	US-3,536,809	04-09-1991	Schaller <i>et al.</i>	All
	U36	US-3,598,123	08-10-1971	Zaffaroni	All
	U37	US-3,845,770	11-05-1974	Theeuwes <i>et al.</i>	All
	U38	US-3,916,899	11-04-1975	Theeuwes <i>et al.</i>	All
	U39	US-4,008,719	02-22-1977	Theeuwes <i>et al.</i>	All
	U40	US-4,267,179	05-12-1981	Heeres <i>et al.</i>	All
	U41	US-4,764,604	08-16-1988	Muller	All

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard T.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	10/660,202
				Filing Date	September 11, 2003
				First Named Inventor	Örn Almarsson
				Art Unit	1617
				Examiner Name	Leonard Williams
Sheet	3	of	36	Attorney Docket Number	TPI-350C1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U42	US-4,916,134	04-10-1990	Heeres <i>et al.</i>	All
	U43	US-5,006,513	04-09-1991	Hector <i>et al.</i>	All
	U44	US-5,059,595	10-22-1991	Le Grazie	All
	U45	US-5,073,543	12-17-1991	Marshall <i>et al.</i>	All
	U46	US-5,120,548	06-09-1992	McClelland <i>et al.</i>	All
	U47	US-5,354,556	10-11-1994	Sparks <i>et al.</i>	All
	U48	US-5,414,997	05-16-1995	Tailer	All
	U49	US-5,474,997	12-12-1995	Gray <i>et al.</i>	All
	U50	US-5,591,767	01-07-1997	Mohr <i>et al.</i>	All
	U51	US-5,633,015	05-27-1997	Gilis <i>et al.</i>	All
	U52	US-5,639,476	06-17-1997	Oshlack <i>et al.</i>	All
	U53	US-5,661,151	08-26-1997	Saksena <i>et al.</i>	All
	U54	US-5,674,533	10-07-1997	Santus <i>et al.</i>	All
	U55	US-5,707,975	01-13-1998	Francois <i>et al.</i>	All
	U56	US-5,733,566	03-31-1998	Lewis	All
	U57	US-2003/0096014	05-22-2003	Sherman	All
	U58	US-4,513,006	04-23-1995	Maryanoff <i>et al.</i>	All
	U59	US-6,191,117	02-20-2001	Kozachuk	All
	U60	US-6,201,010	03-13-2001	Cottrell	All
	U61	US-5,753,693	05-19-1998	Shank	All

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard T.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	10/660,202		
		Filing Date	September 11, 2003		
		First Named Inventor	Örn Almarsson		
		Art Unit	1617		
		Examiner Name	Leonard Williams		
Sheet	4	of	36	Attorney Docket Number	TPI-350C1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U62	US-5,998,380	12-07-1999	Ehrenberg <i>et al.</i>	All
	U63	US-6,319,903	11-20-2001	Carrazana <i>et al.</i>	All
	U64	US-5,935,933	08-10-1999	Shank <i>et al.</i>	All
	U65	US-5,760,007	06-02-1999	Shank <i>et al.</i>	All
	U66	US-5,952,187	09-14-1999	Stenglein <i>et al.</i>	All
	U67	US-5,242,942	09-07-1993	Costanzo <i>et al.</i>	All
	U68	US-5,384,327	01-24-1995	Costanzo <i>et al.</i>	All
	U69	US-6,071,537	06-06-2000	Shank	All
	U70	US-6,503,884	01-07-2003	Ehrenberg <i>et al.</i>	All
	U71	US-2003/0069190	04-10-2003	Abdel-Magid <i>et al.</i>	All
	U72	US-2002/0042446	04-11-2002	Dewey <i>et al.</i>	All
	U73	US-2002/0037925	03-28-2002	Dewey <i>et al.</i>	All
	U74	US-2003/0072802	04-17-2003	Cutler	All
	U75	US-6,488,962	12-03-2002	Berner <i>et al.</i>	All
	U76	US- 7,078,526	07-18-2006	Remenar <i>et al.</i>	All
	U77	US-6,294,192	9-25-2001	Patel <i>et al.</i>	All
	U78	US-5,466,823	11-14-1995	Talley <i>et al.</i>	All
	U79	US-4,008,321	02-15-1977	Kamishita <i>et al.</i>	All
	U80	US-4,853,379	08-01-1989	Shroot <i>et al.</i>	All
	U81	US-5,641,512	06-24-1997	Cimitluca	All

Examiner Signature		Date Considered	
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			Application Number	10/660,202	
			Filing Date	September 11, 2003	
			First Named Inventor	Örn Almarsson	
			Art Unit	1617	
			Examiner Name	Leonard Williams	
Sheet	5	of	36	Attorney Docket Number	TPI-350C1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U82	US-6,420,394 B1	07-16-2002	Supersaxo	All
	U83	US-2003/0224006 A1	12-04-2003	Zaworotko <i>et al.</i>	All
	U84	US-			
	U85	US-			
	U86	US-			
	U87	US-			
	U88	US-			
	U89	US-			
	U90	US-			
	U91	US-			
	U92	US-			
	U93	US-			
	U94	US-			
	U95	US-			
	U96	US-			
	U97	US-			
	U98	US-			
	U99	US-			
	U100	US-			
	U101	US-			

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		Filing Date	September 11, 2003		
		First Named Inventor	Örn Almarsson		
		Art Unit	1617		
		Examiner Name	Leonard Williams		
Sheet	6	of	36	Attorney Docket Number	TPI-350C1

FOREIGN PATENT DOCUMENTS						
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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
	F1	EP 413528 B1	11-15-1995	Yu, R. <i>et al.</i>	All	
	F2	EP 1364649 A1	11-26-2003	Cilag AG	All	
	F3	WO 94/16733 A1	08-04-1994	Chiesi Farmaceutici S.P.A.	All	
	F4	WO 96/07331 A1	03-14-1996	Xyrofin Oy	All	
	F5	WO 98/57967 A1	12-23-1998	Dong-A Pharmaceutical Co., Ltd.	All	
	F6	WO 2000/53283 A1	09-14-2000	Reuter Chemische Apparatebau KG	All	
	F7	WO 2001/13904 A2	03-01-2001	Ortho-McNeil Pharmaceutical, Inc.	All	
	F8	JP 54-16494	02-07-1979	Yamanouchi Pharmaceutical Co., Ltd.	All	X
	F9	WO 00/50020 A2	08-31-2000	University of Cincinnati	All	
	F10	FR 769,586	06-11-1934	Chemische Fabrik von Heyden	All	X
	F11	IT 01303251	11-06-2000	Industriale Chimica, S.R.L.	All	X
	F12	WO 2001/97853 A1	12-27-2001	Biochemie Gesellschaft MBH	All	
	F13	EP 0310122 B1	04-05-1989	Kaken Pharma	All	
	F14	WO 2002/062318 A2	08-15-2002	DSM N.V.	All	
	F15	EP 0283992 B1	09-16-1992	Janssen Pharma	All	
	F16	WO 2003/101392 A2	12-11-2003	Transform Pharmaceuticals, Inc.	All	
	F17	WO 2004/054571 A1	07-01-2004	Cilag AG	All	
	F18	WO 2004/078161 A1 (CD-ROM)	09-16-2004	Transform Pharmaceuticals, Inc.	All	
	F19	WO 2004/078163 A2 (CD-ROM)	09-16-2004	Transform Pharmaceuticals, Inc.	All	

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				Application Number	10/660,202
				Filing Date	September 11, 2003
				First Named Inventor	Örn Almarsson
				Group Art Unit	1617
				Examiner Name	Leonard Williams
Sheet	7	of	36	Attorney Docket Number	TPI-350C1

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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
	F20	WO 2004/089313 A2	10-21-2004	Transform Pharmaceuticals, Inc.	All	
	F21	WO 2005/023198 A2 (CD-ROM)	03-17-2005	Transform Pharmaceuticals, Inc.	All	
	F22	WO 2005/037424 A1	04-28-2005	Salvias AG	All	
	F23	WO 2005/055983 A2	06-23-2005	Medcrystalforms, LCC	All	
	F24	WO 2005/060968 A1 (CD-ROM)	07-07-2005	Sepracor, Inc.	All	
	F25	WO 2005/089375 A2 (CD-ROM)	09-29-2005	S.S.C.I., Inc.	All	
	F26	WO 2005/094804 A1	10-13-2005	The Regents of the University of Michigan	All	
	F27	WO 2006/024930 A1	03-09-2006	Pharmacia and Upjohn Co., LCC	All	
	F28	WO 03/070738 A2	08-28-2003	Transform Pharmaceuticals, Inc.	All	
	F29	WO 03/074474 A2	09-12-2003	Univ. South Fl	All	
	F30	WO 95/17407 A1	06-29-1995	Schering Corp	All	
	F31	WO 00/07583 A2	02-17-2000	Brookhaven Science Associates	All	
	F32	WO 00/72841 A1	12-07-2000	Berlant, Jeffrey	All	
	F33	WO 03 033462 A2	04-23-2003	Regents of Univ. Mich.	All	
	F34	WO 01 51919 A2	07-19-2001	Transform Pharm. Inc.	All	
	F35	WO 01 42222 A1	06-14-2001	Pharmacia Corp.	All	
	F36	WO 95/23596 A1	09-08-1995	The Boots Co.	All	
	F37	WO 00/32189 A1	06-08-2000	G. D. Searle & Co.	All	
	F38	WO 01/41760 A3	06-14-2001	Pharmacia Corporation	All	
	F39	WO 01/78724 A1	10/25/2001	Pharmacia Corporation	All	
	F40	WO 01/91750 A1	12/06/2001	Pharmacia Corporation	All	
	F41	WO 02/00627 A1	01/03/2002	Fako Ilacilari A.S.	All	
	F42	IN 182620	12-24-1994	Bajaj et al.	All	

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		Filing Date	September 11, 2003		
		First Named Inventor	Örn Almarsson		
		Group Art Unit	1617		
		Examiner Name	Leonard Williams		
Sheet	8	of	36	Attorney Docket Number	TPI-350C1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	R1	AAKERÖY, C. <i>et al.</i> "Crystal engineering of hydrogen-bonded assemblies- a progress report" <i>Aust. J. Chem.</i> , 2001, pp. 409-421, Vol. 54.	
	R2	BINGHAM, A. <i>et al.</i> "Over one hundred solvates of sulfathiazole" <i>Chem. Commun.</i> , 2001, pp. 603-604.	
	R3	BYRIEL, K., <i>et al.</i> "Molecular cocrystals of carboxylic acids. IX Carboxylic acid interactions with organic heterocyclic bases. The crystal structures of the adducts of (2,4-dichlorophenoxy) acetic acid with 3-hydroxypyridine, 2,4,6-trinitrobenzoic acid with 2-aminopyrimidine, and 4-nitrobenzoic acid with 3-amino-1,2,4-triazole" <i>Aust. J. Chem.</i> , 1992, pp. 969-981, Vol. 45, No. 6.	
	R4	SALMON, J. <i>et al.</i> "Supramolecular chemistry of boronic acids (Abstract)" 38 th Midwest Regional Meeting of the American Chemical Society in Columbia, MO., November 5-7, 2003, published by the American Chemical Society, Washington, D.C.	
	R5	URBINA, J. <i>et al.</i> "Supramolecular design of inorganic/organic networks using flexible ligands with self-complementary hydrogen bonds (Abstract)" 38 th Midwest Regional Meeting of the American Chemical Society in Columbia, MO., November 5-7, 2003, published by the American Chemical Society, Washington, D.C.	

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	R6	SMITH, D. <i>et al.</i> "Structure confirmation by single crystal X-ray diffraction of a series of new schiff bases and theoretical computations on 3-(N-2- α , α , α -trifluorotoluidylidene amino) tetrahydrothiophene-1, 1-dioxide (Abstract)" 216 th ACS National Meeting in Boston, MA., August 23-27, 1998, published by the American Chemical Society, Washington, D.C.	
	R7	DESIRAJU, G. "Supramolecular synthons in crystal engineering- A new organic synthesis" <i>Angew. Chem. Int. Ed. Engl.</i> , 1995, pp. 2311-2327, Vol. 34.	
	R8	FRITCHIE, C. <i>et al.</i> "The configuration of phenothiazine in various molecular complexes" <i>Chem. Commun.</i> , 1968, pp. 833-834.	
	R9	HUANG, C.-M. <i>et al.</i> "Molecular packing modes. Part XI. Crystal structures of the 2:1 complexes of benzamide with succinic acid and furamide with oxalic acid" <i>J. Chem. Soc. Perkins Trans. 2: Physical Organic Chemistry</i> , 1973, pp. 503-508, Vol. 5.	
	R10	JACKISCH, M. <i>et al.</i> "Structures of three related biphenyl compounds: 4,4'-biphenyldiol, 3, 3',5,5'-tetra- <i>tert</i> -butyl-4,4'-biphenyldiol, and 3,3',5,5'- tetra- <i>tert</i> -butyl-1,1'-bicyclohexa-2,5-dienylidene-4,4'-dione" <i>Acta Cryst.</i> , 1990, pp. 919-922, Vol. C46.	
	R11	KIM, S. <i>et al.</i> "The structure of a crystalline complex containing one phenobarbital molecule and two adenine derivatives" <i>Proc. Natl. Acad. Sci. USA</i> , 1968, pp. 402-408, Vol. 60.	
	R12	KOBAYASHI, H. <i>et al.</i> "Sinusoidal structure of the 1:1 complex of phenothiazine and 7,7,8,8-tetracyanoquinodimethane, PTZ-TCNQ" <i>Acta Cryst.</i> , 1974, pp. 1010-1017, Vol. B30.	
	R13	ERMER, O. <i>et al.</i> "Molecular recognition among alcohols and amines: super-tetrahedral crystal architectures of linear diphenol-diamine complexes and aminophenols" <i>J. Chem. Soc. Perkins Trans. 2</i> , 1994, pp. 925-944.	
	R14	MARTIN, R. <i>et al.</i> "Polyphenal-caffeine complexation" <i>J. Chem. Soc., Chem. Commun.</i> , 1986, pp. 105-106.	
	R15	LEHN, J.-M. <i>et al.</i> "Molecular recognition directed self-assembly of ordered supramolecular strands by cocrystallization of complementary molecular components" <i>Chem. Soc., Chem. Commun.</i> , 1990, pp. 479-481.	

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	R16	LYNCH, D. <i>et al.</i> "Molecular cocrystals of carboxylic acids. XV Preparation and characterization of heterocyclic base adducts with a series of carboxylic acids, and the crystal structures of the adducts of 2-aminopyrimidine with 2,6-dihydroxybenzoic acid, 4-aminobenzoic acid, phenoxyacetic acid, (2,4-dichlorophenoxy) acetic acid, (3,4-dichlorophenoxy)- acetic acid and salicylic acid, and 2-aminopyridine with 2,6-dihydroxybenzoic acid" <i>Aust. J. Chem.</i> , 1994, pp. 1097-1115, Vol. 47.	
	R17	MCINTOSH, J. <i>et al.</i> "Chemotherapeutic drugs in anaerobic infections of wounds" <i>The Lancet</i> , June 26, 1943, pp. 793-795.	
	R18	MCINTOSH, J. <i>et al.</i> "Zinc peroxide, proflavine and penicillin in experimental <i>cl. welchii</i> infections" <i>The Lancet</i> , December 26, 1942, pp. 750-752.	
	R19	SMITH, G. <i>et al.</i> "Molecular cocrystals of carboxylic acids. XXI The role of secondary group interactions in adduct formation between 2-aminopyrimidine and substituted benzoic acids: the crystal structures of the adducts with <i>o</i> -phthalic acid, <i>o</i> -nitrobenzoic acid, <i>o</i> -aminobenzoic acid and <i>m</i> -aminobenzoic acid" <i>Aust. J. Chem.</i> , 1995, pp. 1151-1166, Vol. 48.	
	R20	WEISSBUCH, I. <i>et al.</i> "Crystal morphology control with tailor-made additives; a stereochemical approach" <i>Advances in Crystal Growth Research</i> , 2001, pp. 381-400.	
	R21	MCAHON, J. <i>et al.</i> "Crystal engineering of the composition of pharmaceutical phases. 3 ¹ . Primary amide supramolecular heterosynthons and their role in the design of pharmaceutical co-crystals" <i>Z. Kristallogr.</i> , 2005, pp. 340-350, Vol. 220.	
	R22	MEEJOO, S. <i>et al.</i> "The interplay of aryl-perfluoroaryl stacking interactions and interstack hydrogen bonding in controlling the structure of a molecular cocrystal" <i>Chemphyschem</i> , 2003, pp. 766-769, Vol. 4.	
	R23	MIRMEHRABI, M. <i>et al.</i> "Improving the filterability and solid density of ranitidine hydrochloride form 1" <i>Journal of Pharmaceutical Sciences</i> , July 2004, pp. 1692-1700, Vol. 93, No. 7.	
	R24	MORRIS, K. <i>et al.</i> "Theoretical approaches to physical transformations of active pharmaceutical ingredients during manufacturing processes" <i>Advanced Drug Delivery Reviews</i> , 2001, pp. 91-114, Vol. 48.	

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		Filing Date	September 11, 2003		
		First Named Inventor	Örn Almarsson		
		Group Art Unit	1617		
		Examiner Name	Leonard Williams		
Sheet	11	of	36	Attorney Docket Number	TPI-350C1

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	R25	NAKANISHI, I. <i>et al.</i> "X-ray structural studies on two forms of β -cyclodextrin barbital complexes" <i>Journal of Inclusion Phenomena</i> , 1984, pp. 689-699, Vol. 2.	
	R26	NAKAO, S. <i>et al.</i> "The crystal and molecular structure of the 2:1 molecular complex of theophylline with phenobarbital" <i>Acta Cryst.</i> , 1977, pp. 1373-1378, Vol. B33.	
	R27	NATARAJAN, S. <i>et al.</i> "Reinvestigation of the crystal structure of diglycine hydrochloride" <i>Zeitschrift für Kristallographie</i> , 1992, pp. 265-270, Vol. 198.	
	R28	OLENIK, B. <i>et al.</i> "Cooperative and anticooperative effects in the cocrystals of mono- and diazanaphthalenes with meso-1, 2-diphenyl-1,2-ethanediol" <i>Crystal Growth & Design</i> , 2003, pp. 175-181, Vol. 3, No. 2.	
	R29	OLENIK, B. <i>et al.</i> "Supramolecular synthesis by cocrystallization of oxalic and fumaric acid with diazanaphthalenes" <i>Crystal Growth & Design</i> , 2003, pp. 183-188, Vol. 3, No. 2.	
	R30	GROTH, P. "d-Glucose-sodium chloride-monohydrate (glucose-sodium chloride) = $2C_6H_{12}O_6 \cdot NaCl \cdot H_2O$ " <i>Chemische Kristallographie</i> , 1910, pp. 438-439.	X
	R31	OSWALD, I. <i>et al.</i> "Rationalisation of co-crystal formation through knowledge-mining" <i>Crystallography Reviews</i> , 2004, pp. 57-66, Vol. 10, No. 1.	
	R32	OUYANG, X. <i>et al.</i> "Single-crystal-to-single-crystal topochemical polymerizations of a terminal diacetylene: two remarkable transformations give the same conjugated polymer" <i>J. Am. Chem. Soc.</i> , 2003, pp. 12400-12401, Vol. 125.	
	R33	PATEL, U. <i>et al.</i> "Structure of the 1:1 complex between 4-amino-N-(4,6-dimethyl-2-pyrimidinyl)- benzenesulfonamide (sulfadimidine) and 2-hydroxybenzoic acid (salicylic acid)" <i>Acta Cryst.</i> , 1988, pp. 1264-1267, Vol. C44.	
	R34	REDDY, L. <i>et al.</i> "Phenyl-perfluorophenyl synthon mediated cocrystallization of carboxylic acids and amides" <i>Crystal Growth & Design</i> , 2004, pp. 89-94, Vol. 4., No. 1.	
	R35	REMENAR, J. <i>et al.</i> "Crystal engineering of novel cocrystals of a triazole drug with 1,4-dicarboxylic acids" <i>J. Am. Chem. Soc.</i> , 2003, pp. 8456-8457, Vol. 125.	

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		Examiner Name	Leonard Williams		
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	R36	SCHMIDT, G. "Photodimerization in the solid state" <i>Pure Appl. Chem.</i> , 1971, pp. 647-678, Vol. 27.	
	R37	SHAN, N. <i>et al.</i> "Co-crystal of 4,7-phenanthroline and carboxylic acids: synthon competition and prediction" <i>Tetrahedron Letters</i> , 2002, pp. 8721-8725, Vol. 43.	
	R38	SHAN, N. <i>et al.</i> "Crystal engineering using 4,4'-bipyridyl with di- and tricarboxylic acids" <i>Crystal Engineering</i> , 2002, pp. 9-24, Vol. 5.	
	R39	SHAN, N. <i>et al.</i> "Supramolecular synthons in the co-crystal structures of 2-aminopyrimidine with diols and carboxylic acids" <i>Tetrahedron Letters</i> , 2002, pp. 3101-3104, Vol. 43.	
	R40	MCINTOSH, J. <i>et al.</i> "Further observations on the chemotherapy of experimental gas gangrene: flavazole, marfanil, V187 and V335" <i>British Journal of Experimental Pathology</i> , 1946, pp. 46-54, Vol. 27.	
	R41	SHAVIV, R. <i>et al.</i> "Magnetochemistry of the tetrahaloferrate (III) ions 6. Crystal structure and magnetic ordering in [(pyH) ₃ Cl] [FeCl ₄] ₂ " <i>Inorganica Chimica Acta</i> , 1992, pp. 613-621, Vol. 198-200.	
	R42	SHEFTER, E. "Structural studies on complexes IV: Crystal structure of a 1:1 5-chlorosalicylic acid and theophylline complex" <i>Journal of Pharmaceutical Sciences</i> , 1969, pp. 710-714, Vol. 58.	
	R43	SHIMIZU, N. <i>et al.</i> "Structure of 2,4-diamino-5-(3,4,5-trimethoxybenzyl) pyrimidine-5,5-diethylbarbituric acid (1:1)" <i>Acta Cryst.</i> , 1982, pp. 2309- 2311, Vol. B38.	
	R44	SINGH, N. B. <i>et al.</i> "Solid state reaction between 8-hydroxyquinoline and <i>p</i> -nitrobenzoic acid" <i>Indian Journal of Chemistry</i> , May 1988, pp. 429-432, Vol. 37B.	
	R45	SMITH, G. <i>et al.</i> "The 1:1 adduct of 4-aminobenzoic acid with 4-aminobenzonitrile" <i>Acta Cryst.</i> , 2000, pp. 1155-1156, Vol. C56.	

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		Filing Date	September 11, 2003		
		First Named Inventor	Örn Almarsson		
		Group Art Unit	1617		
		Examiner Name	Leonard Williams		
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	R46	STEINER, T. "Donor and acceptor strengths in C-H...O hydrogen bonds quantified from crystallographic data of small solvent molecules" <i>New. J. Chem.</i> , 1998, pp. 1099-1103.	
	R47	STOREY, R. et al. "Automation of solid form screening procedures in the pharmaceutical industry- how to avoid the bottlenecks" <i>Crystallography Reviews</i> , 2004, pp. 45-56, Vol. 10, No. 1.	
	R48	SZAFRAN, M. et al. "Molecular structures and hydrogen bonding in the 1:1 and 1:2 complexes of pyridine betaine with 2,6-dichloro-4-nitrophenol; an example of strongly coupled hydrogen bonds, O-H...O=C-O-H...O-" <i>Journal of Molecular Structure</i> , 1997, pp. 145-160, Vol. 416.	
	R49	TAKEUCHI, M. et al. "Synchrotron radiation SAXS/WAXS study of polymorph-dependent phase behavior of binary mixtures of saturated monoacid triacylglycerols" <i>Crystal Growth & Design</i> , 2003, pp. 369-374, Vol. 3, No. 3.	
	R50	TANG, C. P. et al. "Reaction pathways in crystalline host-guest inclusion complexes: rotation by a net 180° of the acetyl group on photoaddition of guest- acetophenone and -m-Chloroacetophenone to the atom C5 of host deoxycholic acid" <i>J. Am. Chem. Soc.</i> , 1985, pp. 4058-4070, Vol. 107.	
	R51	TAYLOR, R. et al. "Rules governing the crystal packing of mono- and dialcohols" <i>Acta Crystallographica Section B, Structural Science</i> , 2001, pp. 815-827, Vol. B57.	
	R52	THALLAPALLY, P. et al. "Polymorphism of 1,3,5-trinitrobenzene induced by a trisindane additive" <i>Angew. Chem. Int. Ed.</i> , 2004, pp. 1149-1155, Vol. 43.	
	R53	TIMMERMAN, P. et al. "Noncovalent Assembly of functional groups on calix[4]arene molecular boxes" <i>Chem. Eur. J.</i> , 1997, pp. 1823-1832, Vol. 3., No. 11.	
	R54	SHAN, N. et al. "Mechanochemistry and co-crystal formation: effect of solvent on reaction kinetics" <i>Chem. Commun.</i> , 2002, pp. 2372-2373.	
	R55	CAIRA, M. et al. "X-ray structure and thermal analysis of a 1:1 complex between (S)-naproxen and heptakis (2,3,6-tri-O-methyl)-β-cyclodextrin" <i>Journal of Inclusion Phenomena and Molecular Recognition in Chemistry</i> , 1995, pp. 277-290, Vol. 20.	

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	R56	TRASK, A. <i>et al.</i> "Crystal engineering of organic cocrystals by the solid-state grinding approach" <i>Top Curr. Chem.</i> , 2005, pp. 41-70, Vol. 254.	
	R57	TRASK, A. <i>et al.</i> "Pharmaceutical cocrystallization: engineering a remedy for caffeine hydration" <i>Crystal Growth & Design</i> , 2005, pp. 1013-1021, Vol. 5, No. 3.	
	R58	TRASK, A. <i>et al.</i> "Solvent-drop grinding: green polymorph control of cocrystallisation" <i>Chem. Commun.</i> , 2004, pp. 890-891 in addition to supplemental materials.	
	R59	TROWBRIDGE, L. <i>et al.</i> "Composites for nonlinear optics: Crystal growth and polymorphism" <i>University of Sussex, Falmer Brighton UK, School of Chemistry and Molecular Sciences</i> , pp. 272.	
	R60	UNO, T. <i>et al.</i> "Structure of 5,5-diphenylhydantoin-1- (4-bromophenyl)-4-dimethylamino-2,3-dimethyl-3-pyrazolin-5-one (1:1)" <i>Acta Cryst.</i> , 1980, pp. 2794-2796, Vol. B36.	
	R61	VAN ROEY, P. <i>et al.</i> "Structure-activity studies of non-steroidal aromatase inhibitors: the crystal and molecular structures of CGS 16949A and CGS 18320B" <i>J. Enzyme Inhibition</i> , 1991, pp. 119-132, Vol. 5.	
	R62	VAN ROEY, P. <i>et al.</i> "Structure of <i>cis</i> -1-[[4-(1-imidazolylmethyl) cyclohexyl] methyl] imidazole- succinic acid complex" <i>Acta Cryst.</i> , 1991, pp. 1015-1018, Vol. C47.	
	R63	VISHWESHWAR, P. <i>et al.</i> "Crystal engineering of pharmaceutical co-crystals from polymorphic active pharmaceutical ingredients" <i>Chem. Commun.</i> , 2005, pp. 4601-4603.	
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	R65	VISHWESHWAR, P. <i>et al.</i> "Supramolecular synthons based on N-H...N and C-H...O hydrogen bonds. Crystal engineering of a helical structure with 5,5-diethylbarbituric acid" <i>Chem. Commun.</i> , 2002, pp. 1830-1831.	
	R66	VISHWESHWAR, P. <i>et al.</i> "Supramolecular synthons in phenol-isonicotinamide adducts" <i>Cryst. Eng. Comm.</i> 2003, pp. 164-168, Vol. 5, No. 31.	

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	R67	VOET, D. <i>et al.</i> "The crystal and molecular structure of the intermolecular complex 9-ethyladenine-5, 5-diethylbarbituric acid" <i>Journal of the American Chemical Society</i> , November 15, 1972, pp. 8213-8222, Vol. 94, No. 23.	
	R68	VOET, D. <i>et al.</i> "The structure of an intermolecular complex between cytosine and 5-fluorouracil" <i>Journal of the American Chemical Society</i> , May 21, 1969, pp. 3069-3075, Vol. 91, No. 11.	
	R69	STEZOWSKI, J. J. <i>et al.</i> "Characterization of a 1:1 complex of an unusual structure in the phenothiazine/phenazine binary phase diagram" <i>Zeitschrift für Kristallographie in International Journal for Structural, Physical, Chemical Aspects of Crystalline Materials</i> , 1983, pp. 213-215, Vol. 162, No. 1-4.	X
	R70	WANG, A. <i>et al.</i> "Crystal structure of 1:1 complex of barbitol with 1-methylimidazole" <i>Journal of Pharmaceutical Sciences</i> , March 1979, pp. 361-363, Vol. 68, No. 3.	
	R71	ALBEROLA, S. <i>et al.</i> "Crystalline and Molecular Structure of Sulfanilimide-Antipyrine" <i>Acta Cryst.</i> , 1977, pp. 3337-3341, Vol. B33.	X
	R72	WOOD, R. A. <i>et al.</i> "2,5-O-methylene-D-mannitol sodium-chloride, C ₇ H ₁₄ O ₆ . NaCl" <i>Cryst. Struct. Comm.</i> , 1976, 207-210, Vol. 5.	
	R73	XU, J. <i>et al.</i> "Effect of composition distribution on miscibility and co-crystallization phenomena in the blends of low density polyethylene with conventional and metallocene-based ethylene-butene copolymers" <i>Polymer</i> , 2001, pp. 3867-3874, Vol. 42.	
	R74	YOO, J. <i>et al.</i> "Cocrystallization of a dinuclear platinum complex as a monomer and a one-dimensional polymer" <i>Polyhedron</i> , 2002, pp. 715-719, Vol. 21.	
	R75	ZAITU, S. <i>et al.</i> "A 2:1 molecular complex of theophylline and 5-fluorouracil as the monohydrate" <i>Acta Cryst.</i> , 1995, pp. 1857-1859, Vol. C51.	
	R76	ZAMAN, M. B. <i>et al.</i> "Linear hydrogen-bonded molecular tapes in the cocrystals of squaric acid with 4,4'-dipyridylacetylene and 1,2-bis(4-pyridyl) ethylene" <i>Acta Cryst.</i> , 2001, pp. 621-624, Vol. C57.	
	R77	ZERKOWSKI, J. <i>et al.</i> "Design of organic structures in the solid state: hydrogen-bonded molecular "tapes" ¹ " <i>J. Am. Chem. Soc.</i> , 1990, pp. 9025-9026, Vol. 112.	
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NOVARTIS EXHIBIT 1023

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known	
		Application Number	10/660,202
		Filing Date	September 11, 2003
		First Named Inventor	Örn Almarsson
		Group Art Unit	1617
		Examiner Name	Leonard Williams
Sheet	16	of	36
		Attorney Docket Number	TPI-350C1

NON PATENT LITERATURE DOCUMENTS			
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	R78	ZERKOWSKI, J. <i>et al.</i> "Investigations into the robustness of secondary and tertiary architecture of hydrogen-bonded crystalline tapes" <i>Chem. Mater.</i> , 1994, pp. 1250-1257, Vol. 6.	
	R79	ZERKOWSKI, J. <i>et al.</i> "New varieties of crystalline architecture produced by small changes in molecular structure in tape complexes of melamines and barbiturates" <i>J. Am. Chem. Soc.</i> , 1994, pp. 4305-4315, Vol. 116.	
	R80	ZERKOWSKI, J. <i>et al.</i> "Polymorphic packing arrangements in a class of engineered organic crystals" <i>Chem. Mater.</i> , 1997, pp. 1933-1941, Vol. 9.	
	R81	ZERKOWSKI, J. <i>et al.</i> "Solid-state structures of "Rosette" and "Crinkled Tape" motifs derived from the cyanuric acid-melamine lattice" <i>J. Am. Chem. Soc.</i> , 1992, pp. 5473-5475, Vol. 114.	
	R82	ZHANG, R. <i>et al.</i> "Atmospheric new particle formation enhanced by organic acids" <i>Science</i> , June 4, 2004, pp. 1487-1490 with additional supporting online material, Vol. 304.	
	R83	ZHU, H. <i>et al.</i> "Influence of water activity in organic solvent + water mixtures on the nature of the crystallizing drug phase. 1. theophylline" <i>International Journal of Pharmaceutics</i> , 1996, pp. 151-160, Vol. 135.	
	R84	AAKERÖY, C. <i>et al.</i> "Aromatic dicarboxylic acids as building blocks of extended hydrogen-bonded architectures" <i>Supramolecular Chemistry</i> , 1998, pp. 127-135, Vol. 9.	
	R85	AAKERÖY, C. <i>et al.</i> "Assembly of 2-D inorganic/organic lamellar structures through a combination of copper (I) coordination polymers and self-complimentary hydrogen bonds" <i>J. Chem. Soc., Dalton Trans.</i> , 2000, pp. 3869-3872.	
	R86	AAKERÖY, C. <i>et al.</i> "Building organic assemblies with 2-pyridone and dicarboxylic acids: relating molecular conformation and synthon stability to crystal structure" <i>Crystal Engineering</i> , 1998, pp. 225-241, Vol. 1, No. 3-4.	
	R87	AAKERÖY, C. <i>et al.</i> "The C-H...C1 hydrogen bond: does it exist?" <i>New J. Chem.</i> , 1999, pp. 145-152.	
	R88	AAKERÖY, C. <i>et al.</i> "Crystal engineering of ionic solids" <i>Modular Chemistry</i> (ed. by Michl, J.), 1997, pp. 153-162, Kluwer Academic Publishers, The Netherlands.	

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		Group Art Unit	1617		
		Examiner Name	Leonard Williams		
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	R89	AAKERÖY, C. <i>et al.</i> "Crystal engineering: strategies and architectures" <i>Acta Cryst.</i> , 1997, pp. 569-586, Vol. B53.	
	R90	AAKERÖY, C. <i>et al.</i> "Crystal engineering using intermolecular hydrogen-bonded connectors and classic coordination chemistry" <i>Transactions ACA</i> , 1998, pp. 97-103, Vol. 33.	
	R91	AAKERÖY, C. <i>et al.</i> "The crystal structure of the molecular cocrystal L-malic acid L-tartaric acid (1/1)" <i>Supramolecular Chemistry</i> , 1996, pp. 153-156, Vol. 7.	
	R92	AAKERÖY, C. <i>et al.</i> "Deliberate combination of coordination polymers and hydrogen bonds in a supramolecular design strategy for inorganic/organic hybrid networks" <i>Chem. Commun.</i> , 2000, pp. 935-936.	
	R93	AAKERÖY, C. <i>et al.</i> "Di-hydroxy malonic acid as a building block of hydrogen-bonded 3-dimensional architectures" <i>Journal of Chemical Crystallography</i> , 1998, pp. 111-117, Vol. 28, No. 2.	
	R94	AAKERÖY, C. <i>et al.</i> "Do polymorphic compounds make good cocrystallizing agents? A structural case study that demonstrates the importance of synthon flexibility" <i>Crystal Growth & Design</i> , 2003, 159-165, Vol. 3, No. 2.	
	R95	AAKERÖY, C. <i>et al.</i> "Heteromeric intermolecular interactions as synthetic tools for the formation of binary co-crystals" <i>Cryst. Eng. Comm.</i> , 2004, pp. 19-24, Vol. 6, No. 5.	
	R96	AAKERÖY, C. <i>et al.</i> "A high-yielding supramolecular reaction" <i>J. Am. Chem. Soc.</i> , 2002, 14425-14432, Vol. 124.	
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	R98	AAKERÖY, C. <i>et al.</i> "Hydrogen-bond assisted assembly of organic and organic-inorganic solids" <i>Crystal Engineering: From Molecules and Crystals to Materials</i> , 1999, pp. 89-106, Kluwer Academic Publishers, The Netherlands.	
	R99	AAKERÖY, C. <i>et al.</i> "Hydrogen-bonding in solids" <i>Crystal Engineering</i> (ed. by Seddon, K. R. <i>et al.</i>), 1999, pp. 303-324, Kluwer Academic Publishers, The Netherlands.	
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	R100	AAKERÖY, C. <i>et al.</i> "Low-dimensional architectures of silver coordination compounds assembled via amide-amide hydrogen bonds" <i>Crystal Engineering</i> , 1998, pp. 39-49, Vol. 1, No. 1.	
	R101	AAKERÖY, C. <i>et al.</i> "Molecular mechanics and crystal engineering" <i>Crystal Engineering</i> (ed. by Seddon, K. R. <i>et al.</i>), 1999, pp. 69-82, Kluwer Academic Publishers, The Netherlands.	
	R102	AAKERÖY, C. <i>et al.</i> "New building blocks for crystal engineering. Syntheses and crystal structures of oxime-substituted pyridines" <i>Cryst. Eng. Comm.</i> , 2000, pp. 1-6, Vol. 27.	
	R103	AAKERÖY, C. <i>et al.</i> "Novel colorless composite materials for nonlinear optics" <i>Adv. Mater.</i> , 1993, pp. 364-367, Vol. 5, No. 5.	
	R104	AAKERÖY, C. <i>et al.</i> "Organic assemblies of 2-pyridones with dicarboxylic acids" <i>Tetrahedron</i> , 2000, pp. 6693-6699, Vol. 56.	
	R105	AAKERÖY, C. <i>et al.</i> "Pitfalls in the supramolecular assembly of silver(I) coordination compounds" <i>Journal of Molecular Structure</i> , 1999, pp. 91-101, Vol. 474.	
	R106	AAKERÖY, C. <i>et al.</i> "A structural study of 2-amino-5-nitropyridine and 2-amino-3-nitropyridine: intermolecular forces and polymorphism" <i>J. Mater. Chem.</i> , 1998, pp. 1385-1389, Vol. 8, No. 6.	
	R107	AAKERÖY, C. <i>et al.</i> "Supramolecular assembly of low-dimensional silver (I) architectures via amide-amide hydrogen bonds" <i>Chem. Commun.</i> , 1998, pp. 1067-1068.	
	R108	AAKERÖY, C. <i>et al.</i> "'Total synthesis' supramolecular style: design and hydrogen-bond-directed assembly of ternary supermolecules" <i>Angew. Chem. Int. Ed.</i> , 2001, pp. 3240-3242, Vol. 40, No. 17.	
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	R110	AHN, S. <i>et al.</i> "Polymorphs of a 1:1 cocrystal with tunnel and layer structures: <i>p,p'</i> -biphenol/dimethyl sulfoxide" <i>Crystal Growth & Design</i> , 2001, pp. 107-111, Vol. 1, No. 2.	
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	R111	AKAZOME, M. <i>et al.</i> "Enantioselective inclusion of methyl phenyl sulfoxides and benzyl methyl sulfoxides by (R)-phenylglycyl-(R)-phenylglycine and the crystal structures of the inclusion cavities" <i>J. Org. Chem.</i> , 2000, pp. 68-76, Vol. 65.	
	R112	AKHTARUZZAMAN, M.D. <i>et al.</i> "One-dimensional hydrogen-bonded molecular tapes in 1, 4-bis[(4-pyridinio) ethynyl]benzene chloranilate" <i>Acta. Cryst.</i> , 2001, pp. o353-o355, Vol. E57.	
	R113	ALLEN, F. <i>et al.</i> "Systematic analysis of structural data as a research technique in organic chemistry" <i>Acc. Chem. Res.</i> , 1983, pp. 146-153, Vol. 16.	
	R114	ALMARSSON, Ö. <i>et al.</i> "Crystal engineering of the composition of pharmaceutical phases. Do pharmaceutical co-crystals represent a new path to improved medicines?" <i>Chem. Commun.</i> , 2004, pp. 1889-1896.	
	R115	AMAI, M. <i>et al.</i> "1:1 complex of octadecanoic acid and 3-pyridinecarboxamide" <i>Acta Cryst.</i> , 1998, pp. 1367-1369, Vol. C54.	
	R116	ANDERSON, N. <i>et al.</i> "Sulfonation with inversion by mitsunobu reaction: an improvement on the original conditions" <i>J. Org. Chem.</i> , 1996, pp. 7955-7958, Vol. 61.	
	R117	AOKI, K. <i>et al.</i> "A 1:1 complex of theophylline and <i>p</i> -nitrophenol" <i>Acta Cryst.</i> , 1978, pp. 2333-2336, Vol. B34.	
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	R122	BERL, V. <i>et al.</i> "Induced fit selection of a barbiturate receptor from a dynamic structural and conformational/configurational library" <i>Eur. J. Org. Chem.</i> , 1999, pp. 3089-3094.	
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	R123	BERTOLASI, V. <i>et al.</i> "Competition between hydrogen bonding and donor-acceptor interactions in co-crystals of 1,3-dimethylbarbituric acid with aromatic amines" <i>New J. Chem.</i> , 2001, pp. 408-415, Vol. 25.	
	R124	BERTOLASI, V. <i>et al.</i> "General rules for the packing of hydrogen-bonded crystals as derived from the analysis of squaric acid anions: aminoaromatic nitrogen base co-crystals" <i>Acta Cryst.</i> , 2001, pp. 591-598, Vol. B57.	
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	R126	BETTINETTI, G. <i>et al.</i> "Thermal analysis of binary systems of the pharmaceuticals trimethoprim and benzoic acid" <i>Journal of Thermal Analysis</i> , 1983, pp. 285-294, Vol. 28.	
	R127	BETTIS, J. <i>et al.</i> "Biopharmaceutics and dosage form design" <i>Amer. J. Hosp. Pharm.</i> , March 1973, pp. 240-243, Vol. 30.	
	R128	BOLTON, S. <i>et al.</i> "Complexes formed in solution by homologs of caffeine" <i>Journal of the American Pharmaceutical Association</i> , January 1957, pp. 38-41, Vol. XLVI, No. 1.	
	R129	BOND, A. "In situ co-crystallisation as a tool for low-temperature crystal engineering" <i>Chem. Commun.</i> , 2003, pp. 250-251, Vol. 2.	
	R130	BONIN, M. <i>et al.</i> "Urotropin azelate: a rather unwilling co-crystal" <i>Acta Cryst.</i> , 2003, pp. 72-86, Vol. B59.	
	R131	BOSSHARD, C. <i>et al.</i> "Microscopic nonlinearities of two-component organic crystals" <i>J. Opt. Soc. Am. B</i> , November 2001, pp. 1620-1626, Vol. 18, No. 11.	
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	R133	BRAGA, D. <i>et al.</i> "Hydrogen bonding interactions between ions: a powerful tool in molecular crystal engineering" <i>Structure and Bonding</i> , 2004, pp. 1-32, Vol. 111.	
	R134	BRIERLEY, C. <i>et al.</i> "Preparation and structure of the 1:2 π -molecular complex of phenothiazine with pyromellitic dianhydride" <i>J. Chem. Phys.</i> , February 1, 1985, pp. 1522-1528, Vol. 82, No. 1.	
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	R135	BURGI, H. <i>et al.</i> "Crystallisation of supramolecular materials" <i>Current Opinion in Solid State & Materials Science</i> , 1998, pp. 425-430, Vol. 3.	
	R136	BYRN, S. R. <i>et al.</i> "Solid-state pharmaceutical chemistry" <i>Chem. Mater.</i> , 1994, pp. 1148-1158, Vol. 6.	
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		Group Art Unit	1617		
		Examiner Name	Leonard Williams		
Sheet	22	of	36	Attorney Docket Number	TPI-350C1

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	R146	CHINNAKALI, K. <i>et al.</i> "2-aminopyrimidine and <i>p</i> -phenylene-diacetic acid (1:1) co-crystal" <i>Acta Cryst.</i> , 1999, pp. 399-401, Vol. C55.	
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	R179	GAO, X. <i>et al.</i> "Supramolecular construction of molecular ladders in the solid state" <i>Angew. Chem. Int. Ed.</i> , 2004, pp. 232-236, Vol. 43.	
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	R198	HSU, I. <i>et al.</i> "Hydrogen bonding NH...N of barbiturates: The 1:1 crystal complex of imidazole and 5,5-diethylbarbituric acid (barbital)" <i>Acta Cryst.</i> , 1974, pp. 988-993, Vol. B30.	
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		Filing Date	September 11, 2003		
		First Named Inventor	Örn Almarsson		
		Group Art Unit	1617		
		Examiner Name	Leonard Williams		
Sheet	27	of	36	Attorney Docket Number	TPI-350C1

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	R200	ISHIDA, T. <i>et al.</i> "Structural study of histamine H ₂ -receptor antagonists. Five 3-[2-(diamino-methyleneamino)-4-thiazolymethylthio] propionamidine and -amide derivatives" <i>Acta Cryst.</i> , 1989, pp. 505-512, Vol. B45.	
	R201	KATAKAI, R. <i>et al.</i> "Stepwise synthesis of oligopeptides with N-carboxy-α-amino acid anhydrides. IV. Glycine NCA" <i>J. Org. Chem.</i> , 1972, pp. 327-329, Vol. 37, No. 2.	
	R202	KAWAKAMI, Y. <i>et al.</i> "The rationale for E2020 as a potent acetylcholinesterase inhibitor" <i>Bioorganic & Medicinal Chemistry</i> , 1996, pp. 1429-1446, Vol. 4, No. 9.	
	R203	KELDERS, H. <i>et al.</i> "Automated protein crystallization and a new crystal form of a subtilisin: eglin complex" <i>Protein Engineering</i> , 1987, pp. 301-303, Vol. 1, No. 4.	
	R204	KHALIL, R. M. "Complexation of paracetamol with xanthine derivatives" <i>Egypt. J. Pharm. Sci.</i> , 1992, pp. 757-769, Vol. 33, No. 5-6.	
	R205	KIM, S. "Crystal structure of the 1:1 complex of 5-fluorouracil and 9-ethylhypoxanthine" <i>Science</i> , November 24, 1967, pp. 1046-1048, Vol. 158, No. 3804.	
	R206	KIRYU, S. <i>et al.</i> "Crystal structure of a 1:1 aminopyrine-barbital complex" <i>Journal of Pharmaceutical Sciences</i> , May 1971, pp. 699-703, Vol. 60, No. 5.	
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	R208	KLEIN, C. <i>et al.</i> "Molecular structure of two conformationally restrained fentanyl analogues: cis- and trans-isomers of N-{3-methyl-1-[1,2,3,4-tetrahydro naphthyl]-4-piperidinyll}-N-phenylpropanamide" <i>Journal of Pharmaceutical Sciences</i> , November 1985, pp. 1147-1151, Vol. 74, No. 11.	
	R209	KOSHIMA, H. <i>et al.</i> "Photoreactivities of two kinds of bimolecular crystals formed from acridine and phenothiazine" <i>J. Chem. Soc., Perkins Trans. 2</i> , 1997, pp. 2033-2038.	
	R210	KOSHIMA, H. <i>et al.</i> "Polymorphs of a cocrystal with achiral and chiral structures prepared by pseudoseeding: tryptamine/hydrocinnamic acid" <i>Crystal Growth & Design</i> , 2001, pp. 355-357, Vol. 1, No. 5.	
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	R211	KRISHNAMOHAN SHARMA, C. V. <i>et al.</i> "X-ray crystal structure of C ₆ H ₃ (CO ₂ H) ₃ -1,3,5-1.5(4,4'-bipy): a 'super trimesic acid' chicken-wire grid" <i>Chem. Commun.</i> , 1996, pp. 2655-2656.	
	R212	KURODA, R. <i>et al.</i> "Generation of a co-crystal phase with coloristic properties <i>via</i> solid state grinding procedures" <i>Chem. Commun.</i> , 2002, pp. 2848-2849.	
	R213	LEISEROWITZ, L. <i>et al.</i> "The molecular packing modes and hydrogen-bonding properties of amide: dicarboxylic acid complexes" <i>Acta Cryst.</i> , 1977, pp. 2719-2733, Vol. B33.	
	R214	LEISEROWITZ, L. "Molecular packing modes. Carboxylic acids" <i>Acta Cryst.</i> , 1976, pp. 775-802, Vol. B32.	
	R215	LYNCH, D. <i>et al.</i> "Molecular cocrystals of carboxylic acids. XXXI ³ adducts of 2-aminopyrimidine and 3-amino-1,2,4-triazole with heterocyclic carboxylic acids" <i>Aust. J. Chem.</i> , 1998, pp. 403-408, Vol. 51.	
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	R218	MASTROPAOLO, D. <i>et al.</i> "Hydrogen bonding interaction of diphenylhydantoin and 9-ethyladenine" <i>Molecular Pharmacology</i> , 1983, pp. 273-277, Vol. 23.	
	R219	MARYANOFF, B. "Stereochemistry in a medium-sized ring. Highly diastereoselective N-oxidation of a substituted 3-benzazonine. X-ray crystal structure of an unusual complex between an amine N-oxide and saccharin" <i>J. Org. Chem.</i> , 1990, pp. 760-764, Vol. 55.	
	R220	MARTIN, R. <i>et al.</i> "The caffeine-potassium chlorogenate molecular complex" <i>Phytochemistry</i> , 1987, pp. 273-279, Vol. 26, No. 1.	
	R221	ANDERSON, J. "Constitution of aurous compounds: Gold mirrors" <i>Nature</i> , October 2, 1937, pp. 583-584, Letters to the Editor.	
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		Group Art Unit	1617
		Examiner Name	Leonard Williams
		Attorney Docket Number	TPI-350C1

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	R222	ROBBINS, A. H. <i>et al.</i> "The crystal structure of the 1:2 adduct of potassium triiodide and 5,5-diethylbarbituric acid (barbital)" <i>American Crystallographic Association- Series 2, Papers and Abstracts</i> , 1973, p. 87.	
	R223	BEERGES, P. <i>et al.</i> "Phenothiazine tetracyanoethylene" <i>Private Communication</i> , 1994.	
	R224	MADARASZ, J. <i>et al.</i> "Thermal, ftr and xrd study on some 1:1 molecular compounds of theophylline" <i>Journal of Thermal Analysis and Calorimetry</i> , 2002, pp. 281-290, Vol. 69.	
	R225	CARONNA, T. <i>et al.</i> "Halogen bonding and $\pi\cdots\pi$ stacking control reactivity in the solid state" <i>J. Am. Chem. Soc.</i> , 2004, pp. 4500-4501, Vol. 126.	
	R226	ZERKOWSKI, J. <i>et al.</i> "Steric control of secondary, solid-state architecture in 1:1 complexes of melamines and barbiturates that crystallize as crinkled tapes" <i>J. Am. Chem. Soc.</i> , 1994, pp. 4298-4304, Vol. 116.	
	R227	ZAITU, S. <i>et al.</i> "1:1 Molecular complex of theophylline and <i>p</i> -nitroaniline" <i>Acta Cryst.</i> , 1995, pp. 2390-2392, Vol. C51.	
	R228	KOFLER, L. <i>et al.</i> , <i>Thermal micromethods for the study of organic compounds and their mixtures</i> , pp. 1-145, 148-351, 354-386, Innsbruck, Austria, 1980.	
	R229	QUEHENBERGER, H. "Concerning organic molecular compounds and their polymorphism" <i>Monatshefte für Chemie</i> , 1949, pp. 595-606, Vol. 80, No. 5.	X
	R230	WIEDENFELD, H. <i>et al.</i> "The crystal structure of the theophylline-urea complex" <i>Arch. Pharm.</i> , 1986, pp. 654-659, Vol. 319.	X
	R231	BUNICK, G. <i>et al.</i> "The crystal and molecular structure of the complex 2,6-diamino-9-ethylpurine 5,5-diethylbarbituric acid" <i>American Crystallographic Association, Abstract Papers</i> Winter 1976, p. 30.	
	R232	BUCZAK, G. <i>et al.</i> "Crystal structure and vibrational spectra of the 1:1 and 1:2 complexes of pyridine betaine with pentachlorophenol" <i>Journal of Molecular Structure</i> , 1997, pp. 143-151, Vol. 436-437.	
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	R233	TOMURA, M. <i>et al.</i> "One-dimensional zigzag chain structures with intermolecular C-H... π and C-H...O interactions consisted of phthalic acid and pyridine derivatives" <i>Chemistry Letters</i> , 2001, pp. 532-533.	
	R234	ZERKOWSKI, J. <i>et al.</i> "Design of organic structures in the solid state: molecular tapes based on the network of hydrogen bonds present in the cyanuric acid-melamine complex" <i>J. Am. Chem. Soc.</i> , 1994, pp. 2382-2391, Vol. 116.	
	R235	HARKEMA, S. <i>et al.</i> "The crystal structure of urea oxalic acid (2:1)" <i>Acta Cryst.</i> , 1972, pp. 1646-1648, Vol. B28.	
	R236	KRANTZ, J. <i>et al.</i> "Sodium theophylline glycinate" <i>Journal of the American Pharmaceutical Association</i> , 1946, pp. 248-250.	
	R237	DATTA, S. <i>et al.</i> "Crystal structures of drugs: advances in determination, prediction and engineering" <i>Nature</i> , January 2004, pp. 42-57, Vol. 3.	
	R238	AAKERÖY, C. <i>et al.</i> "Charge-assisted hydrogen bonds and halogen-halogen interactions in organic salts: benzylammonium benzoates and pentafluorobenzoates" <i>Structural Chemistry</i> , 1999, pp. 229-242, Vol. 10, No. 3.	
	R239	CHILDS, S. <i>et al.</i> "Crystal engineering approach to forming cocrystals of amine hydrochlorides with organic acids. Molecular complexes of fluoxetine hydrochloride with benzoic, succinic, and fumaric acids" <i>J. Am. Chem. Soc.</i> , 2004, pp. 13335-13342, Vol. 126.	
	R240	AAKERÖY, C. <i>et al.</i> "Modular supramolecular synthesis based on a dominance hierarchy of intermolecular interactions (Abstract)" 223 rd ACS National Meeting in Orlando, FL., April 7-11, 2002, published by the American Chemical Society, Washington, D.C.	
	R241	HELFRICH, B. <i>et al.</i> "Polymorphism as an indication of structural versatility (Abstract)" 223 rd ACS National Meeting in Orlando, FL., April 7-11, 2002, published by the American Chemical Society, Washington, D.C.	
	R242	WEBER, E. <i>et al.</i> "Synthesis of new Schiff bases: reaction of monofluorobenzaldehydes with 3-aminosulfolane hydrochloride (Abstract)" 216 th ACS National Meeting in Boston, MA., August 23-27, 1998, published by the American Chemical Society, Washington, D.C.	

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	R243	SCARBROUGH, F. <i>et al.</i> "Crystal structure of a complex between lumiflavin and 2,6-diamino-9-ethylpurine: a flavin adenine dinucleotide model exhibiting charge-transfer interactions" <i>Proc. Natl. Acad. Sci. USA</i> , November 1976, pp. 3807-3811, Vol. 73, No. 11.	
	R244	MUNN, R. <i>et al.</i> "A Model for resonance-assisted hydrogen bonding in crystals and its graph set analysis" <i>J. Phys. Chem. A</i> , 2001, pp. 6938-6942, Vol. 105.	
	R245	LYNCH, D. <i>et al.</i> "1:1 Molecular complexes of 4-amino-N-(4,6-dimethylpyrimidin-2-yl) benzene-sulfonamide (sulfamethazine) with indole-2-carboxylic acid and 2,4-dinitrobenzoic acid" <i>Aust. J. Chem.</i> , 2000, pp. 383-387, Vol. 53.	
	R246	AAKERÖY, C. <i>et al.</i> "Solid state, crystal engineering and hydrogen bonds" <i>Comprehensive Coordination Chemistry II</i> (ed. by McCleverty, J. <i>et al.</i>), pp. 679-688, Elsevier Ltd., Oxford, UK.	
	R247	LEVIN, B. <i>et al.</i> "The not-so-trivial synthesis and characterization of heterocyclic boronic acids (Abstract)" 38 th Midwest Regional Meeting of the American Chemical Society in Columbia, MO., November 5-7, 2003, published by the American Chemical Society, Washington, D.C.	
	R248	SMITH, G. <i>et al.</i> "Interactions of aromatic carboxylic acids with quinolin-8-ol (oxine): Synthesis and the crystal structures of the proton-transfer compounds with the nitro-substituted benzoic acids" <i>Aust. J. Chem.</i> , 2001, pp. 171-175, Vol. 54.	
	R249	STALKER, R. <i>et al.</i> "Asymmetric synthesis of two new conformationally constrained lysine derivatives" <i>Tetrahedron</i> , 2002, pp. 4837-4849, Vol. 58.	
	R250	VOET, D. <i>et al.</i> "Barbiturates and adenine derivatives. Molecular structure of a hydrogen-bonded complex" <i>Journal of the American Chemical Society</i> , August 9, 1972, pp. 5888-5891, Vol. 94, No. 16.	
	R251	VISHWESHWAR, P. <i>et al.</i> "Molecular complexes of homologous alkanedicarboxylic acids with isonicotinamide: X-ray crystal structures, hydrogen bond synthons, and melting point alternation" <i>Crystal Growth & Design</i> , 2003, pp. 783-790, Vol. 3, No. 5.	
	R252	LE JEUNNE, C. <i>et al.</i> "Comparative efficacy and safety of calcium carbasalate plus metoclopramide versus ergotamine tartrate plus caffeine in the treatment of acute migraine attacks" <i>Eur. Neurol.</i> , 1999, pp. 37-43, Vol. 41.	
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NOVARTIS EXHIBIT 1023

Novartis v. Regents, IPR2023-01346

Page 604 of 1101

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	10/660,202		
		Filing Date	September 11, 2003		
		First Named Inventor	Örn Almarsson		
		Group Art Unit	1617		
		Examiner Name	Leonard Williams		
Sheet	32	of	36	Attorney Docket Number	TPI-350C1

NON PATENT LITERATURE DOCUMENTS			
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	R254	HU, Z. <i>et al.</i> "Separation of 4-aminobenzoic acid by cocrystallization: Crystal structure of the complex of 4-aminobenzoic acid with (2R,3R)-tartaric acid" <i>Journal of Chemical Crystallography</i> , December 2002, pp. 525-529, Vol. 32, No. 12.	
	R255	GUARRERA, D. <i>et al.</i> "Molecular self-assembly in the solid state. The combined use of solid state NMR and differential scanning calorimetry for the determination of phase constitution" <i>Chem. Mater.</i> , 1994, pp. 1293-1296, Vol. 6.	
	R256	DOI, M. <i>et al.</i> "Conformational study of a potent human renin inhibitor: x-ray crystal structure of isopropyl (2R, 3S) -4-cyclohexyl-2-hydroxy-3-{N-[(2R)-2-morpholinocarbonylmethyl-3-(1-naphthyl) propionyl] -L-histidylamino}butyrate (KRI-1314), a pentapeptide analogue with amino acid sequence corresponding to the cleavage site of angiotensinogen" <i>J. Chem. Soc. Perkin Trans. 1</i> , 1991, pp. 1153-1158.	
	R257	CRIFIELD, A. <i>et al.</i> "Crystal engineering through halogen bonding. 2. Complexes of diacetylene-linked heterocycles with organic iodides" <i>Crystal Growth & Design</i> , 2003, pp. 313-320, Vol. 3, No. 3.	
	R258	AAKERÖY, C. <i>et al.</i> "A versatile route to porous solids: organic-inorganic hybrid materials assembled through hydrogen bonds" <i>Angew. Chem. Int. Ed.</i> , 1999, pp. 1815-1819, Vol. 38, No. 12.	
	R259	SHEFTER, E. <i>et al.</i> , ACS, Abstr. Papers (Summer), 1970, 35, compound name: sulfathiazole-theophylline complex.	
	R260	SHEFTER, E. <i>et al.</i> , ACS, Abstr. Papers (Summer), 1970, 35, compound name: sulfathiazole-sulfanilamide complex.	
	R261	WIEDENFELD, H. <i>et al.</i> "Solubilization of aminophenazone" <i>Arch. Pharm.</i> , 1982, pp. 633-641, Vol. 315.	x
	R262	CACCIAPUOTI, A. <i>et al.</i> "In vitro and in vivo activities of SCH 56592 (Posaconazole), a new triazole antifungal agent, against <i>Aspergillus</i> and <i>Candida</i> " <i>Antimicrobial Agents and Chemotherapy</i> , August 2000, pp. 2017-2022, Vol. 44, No. 8.	
	R263	CALLAHAN, J.C. <i>et al.</i> "Equilibrium moisture content of pharmaceutical excipients" <i>Drug Development and Industrial Pharmacy</i> , 1982, pp. 355-369, Vol. 8, No. 3.	
	R264	DANNAOUI, E. <i>et al.</i> "Acquired itraconazole resistance in <i>Aspergillus fumigatus</i> " <i>Journal of Antimicrobial Chemotherapy</i> , 2001, pp. 333-340, Vol. 47.	

Examiner Signature	Date Considered
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NOVARTIS EXHIBIT 1023

Novartis v. Regents, IPR2023-01346

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		Filing Date	September 11, 2003
		First Named Inventor	Örn Almarsson
		Group Art Unit	1617
		Examiner Name	Leonard Williams
		Attorney Docket Number	TPI-350C1
Sheet	33	of	36

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	R265	DENNING, D. W. <i>et al.</i> "In vitro activity of Saperconazole (R66 905) compared with Amphotericin B and Itraconazole against <i>Aspergillus</i> species" <i>Eur. J. Clin. Microbial. Infect. Dis.</i> , 1990, pp. 693-697, Vol. 9.	
	R267	DRESSMAN, J. B. <i>et al.</i> "Dissolution testing as a prognostic tool for oral drug absorption: immediate release dosage forms" <i>Pharmaceutical Research</i> , 1998, pp. 11-22, Vol. 15, No. 1.	
	R268	EBERT, W. R. "Soft elastic gelatin capsules: a unique dosage form" <i>Pharmaceutical Technology</i> , October 1977, pp. 44-50, Vol. 1, No. 5.	
	R269	GASCON, M. -P. <i>et al.</i> "In vitro forecasting of drugs which may interfere with the biotransformation of midazolam" <i>Eur. J. Clin. Pharmacol.</i> , 1991, pp. 573-578, Vol. 41.	
	R270	HEERES, J. <i>et al.</i> "Antimycotic azoles. 7. Synthesis and antifungal properties of a series of novel triazol-3-ones" <i>J. Med. Chem.</i> , 1984, pp. 894-900, Vol. 27.	
	R271	HONIG, P. K. <i>et al.</i> "Itraconazole affects single-dose Terfenadine pharmacokinetics and cardiac repolarization pharmacodynamics" <i>J. Clin. Pharmacol.</i> , 1993, pp. 1201-1206, Vol. 33.	
	R272	IMAI, T. <i>et al.</i> "Successful treatment of cerebral Aspergillosis with a high oral dose of Itraconazole after excisional surgery" <i>Internal Medicine</i> , October 1999, pp. 829-832, Vol. 38, No. 10.	
	R273	KOVACS, J. <i>et al.</i> "New type of bridged monoamino-β-cyclodextrins" <i>Journal of Inclusion Phenomena and Molecular Recognition in Chemistry</i> , 1996, pp. 53-56, Vol. 25.	
	R274	LAVRIJSEN, A. P. M. <i>et al.</i> "Hepatic injury associated with itraconazole" <i>The Lancet</i> , July 25, 1992, pp. 251-252, Vol. 340.	
	R275	NEUVONEN, P. J. <i>et al.</i> "Itraconazole drastically increases plasma concentrations of lovastatin and lovastatin acid" <i>Clinical Pharmacology & Therapeutics</i> , 1996, pp. 54-61, Vol. 60, No. 1.	
	R276	NOMEIR, A. A. <i>et al.</i> "Pharmacokinetics of SCH 56592, a new azole broad-spectrum antifungal agent, in mice, rats, rabbits, dogs, and cynomolgus monkeys" <i>Antimicrobial Agents and Chemotherapy</i> , March 2000, pp. 727-731, Vol. 44, No. 3.	

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		First Named Inventor	Örn Almarsson		
		Group Art Unit	1617		
		Examiner Name	Leonard Williams		
Sheet	34	of	36	Attorney Docket Number	TPI-350C1

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	R277	ODDS, F. C. "Antifungal activity of saperconazole (R 66 905) <i>in vitro</i> " <i>Journal of Antimicrobial Chemotherapy</i> , 1989, pp. 533-537, Vol. 24.	
	R278	REMENAR, J. F. <i>et al.</i> "Crystal engineering of novel cocrystals of a triazole drug with 1,4-dicarboxylic acids" <i>J. Am. Chem. Soc.</i> , 2003, pp. 8456-8457, Vol. 125.	
	R279	SAKSENA, A. K. <i>et al.</i> "Advances in the chemistry of novel broad-spectrum orally active azole antifungals: recent studies leading to the discovery of SCH 56592" in <i>Advances in the Chemistry of Novel Broad-Spectrum Orally Active Azole Antifungals</i> (Royal Soc. Chem., Cambridge), 1997, pp. 180-199.	
	R280	SAKSENA, A. K. <i>et al.</i> "Concise asymmetric routes to 2,2,4-trisubstituted tetrahydrofurans via chiral titanium imide enolates: key intermediates towards synthesis of highly active azole antifungals SCH 51048 and SCH 56592" <i>Tetrahedron Letters</i> , 1996, pp. 5657-5660, Vol. 37, No. 32.	
	R281	HEPPERLE, M. <i>et al.</i> "Mono <i>N</i> -arylation of piperazine(III): metal-catalyzed <i>N</i> -arylation and its application to the novel preparations of the antifungal posaconazole and its advanced intermediate" <i>Tetrahedron Letters</i> , 2002, pp. 3359-3363, Vol. 43.	
	R282	CUTSEM, J. V. <i>et al.</i> "Oral and parenteral therapy with saperconazole (R 66905) of invasive aspergillosis in normal and immunocompromised animals" <i>Antimicrobial Agents and Chemotherapy</i> , December 1989, pp. 2063-2068, Vol. 33, No. 12.	
	R283	VILLA, L. A. <i>et al.</i> "Central nervous system paracoccidioidomycosis. Report of a case successfully treated with itraconazole" <i>Rev. Inst. Med. Trop. S. Paulo</i> , July-August, 2000, pp. 231-234, Vol. 42, No. 4.	
	R284	WEST, A. R., "Solid Solutions" In: <i>Solid State Chemistry and its Applications</i> , 1988, p. 358, p. 365, Wiley, NY.	
	R285	ARONHIME, J. <i>et al.</i> "Crystalline forms of pharmaceuticals and characterization thereof", Oral Presentation, March 8, 2005, USPTO, Alexandria, VA.	
	R286	DESIRAJU, G. R. "Chemistry beyond the molecule" <i>Nature</i> , July 26, 2001, pp. 397-400, Vol. 412.	
	R287	GAVEZZOTTI, A. "Are crystal structures predictable?" <i>Acc. Chem. Res.</i> , 1994, pp. 309-314, Vol. 27.	

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	R288	Physician's Desk Reference, 56 th Ed., pp. 1800-1804, 2002.	
	R289	KIM, H. <i>et al.</i> "High-performance liquid chromatographic analysis of the anti-fungal agent SCH 56592 in dog serum" <i>Journal of Chromatography B</i> , 2000, pp. 93-98, Vol. 738.	
	R290	VIPPAGUNTA, S. R. <i>et al.</i> "Crystalline solids" <i>Advanced Drug Delivery Reviews</i> , 2001, pp. 3-26, Vol. 48.	
	R291	MCCRONE, W. C. "Polymorphism", In: <i>The Physics and Chemistry of the Organic Solid State</i> , Vol. II, FOX, D. <i>et al.</i> (eds.), 1965, pp. 725-767, Interscience, New York.	
	R292	LEGER, J.M. <i>et al.</i> "Crystal Structure of the 1:1 Sulfacetamide-Caffeine Complex" <i>Acta Cryst.</i> , 1977, pp. 1455-1459, Vol. B33.	X
	R293	SIMONOV, Y. <i>et al.</i> "Structure of the caffeine-copper(II) acetate additional compound", <i>Izvestiya Akademii Nauk Moldavskoi SSR, Seriya Fiziko-Tekhnicheskikh i Matematicheskikh Nauk</i> , 1972, Vol. 3, pp. 83-84, abstract only.	
	R294	WEISSBUCH, I. <i>et al.</i> "Understanding and control of nucleation, growth, habit, dissolution and structure of two- and three-dimensional crystals using 'tailor-made' auxiliaries" <i>Acta Cryst.</i> , 1995, B51:115-148.	
	R295	FAUGHT, E. <i>et al.</i> "Topiramate Dose-Ranging Trial in Refractory Partial Epilepsy", <i>Amer. Epilepsy Soc. Proc.</i> , (1995), pg. 33, Vol. 36, Supp. 4.	
	R296	PRIVITERA, M. <i>et al.</i> "Dose-Ranging Trial with Higher Doses of Topiramate in Patients with Resistant Partial Seizures", <i>Amer. Epilepsy Soc. Proc.</i> , 1995, pg. 33, Vol. 36, Supp. 4.	
	R297	SACHDEO, S. K. <i>et al.</i> "Topiramate: Double-Blind Trial as Monotherapy", <i>Amer. Epilepsy Soc. Proc.</i> , 1995, pg. 33, Vol. 36, Supp. 4.	
	R298	Press Release. "Clinical Development of Topiramate for Obesity Extended to Simplify Dosing, Improve Tolerability". http://www.orthomcneil.com/news/article020402.html (February 4, 2002), N.J.	X

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	R299	ROSENFELD, W. E. "Topiramate: A Review of Preclinical, Pharmacokinetic, and Clinical Data", <i>Clinical Therapeutics</i> , 1997, pp. 1294-1308, Vol. 19, No. 6.	
	R300	Physician's Desk Reference, 56 th Edition, 2002, pp. 2590-2595.	
	R301	DATABASE WPI, Section Ch, Week 197936, Derwent Publishing Ltd., London, Great Britain, Class B02, AN 1979-65538B, XP002282989 and JP 54 095589A (Sumitomo) 1979 Abstract.	
	R302	FUNG <i>et al.</i> , "Solvent Effects on Comparative Dissolution of Pharmaceutical Solvates," <i>Chem. Farm. Bull.</i> , 22(2), pgs. 454-458 (1974).	
	R303	RUBINO <i>et al.</i> , "Influence of Solvent Composition on the Solubilities and Solid-State Properties of the Sodium Salts of Some Drugs", <i>Int. J. of Pharma</i> , 65, pgs. 141-145 (1990).	
	R304	FITZGERALD, G. A. "The Coxibs, Selective Inhibitors of Cyclooxygenase-2", <i>New England Journal of Medicine</i> , Vol. 345, No. 6, August 9, 2001.	
	R305		
	R306		
	R307		
	R308		
	R309		

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COMPANY:	U.S. Patent Office	DATE:	September 21, 2006
FAX NO.:	(571)273-8300	NO. OF PAGES (INCLUDING COVER SHEET):	4

SUBJECT/MESSAGE:

Re: U.S. Patent Application Docket No. TPI-350C1
PHARMACEUTICAL CO-CRYSTAL COMPOSITIONS
(Almarsson *et al.*)
Serial No. 10/660,202; filed September 11, 2003

Attachment: Information Disclosure Statement and Form PTO/SB/08 (3 pages)

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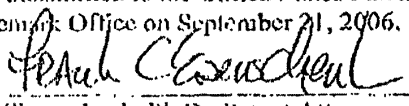
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**SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT**

Examining Group 1653
Patent Application
Docket No. TPI-350C1
Serial No. 10/606,202

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Leonard M. Williams
Art Unit : 1653
Applicants : Örn Almarsson, Magali Bourghol Hickey, Matthew L. Peterson, Michael J.
Zaworotko, Brian Moulton, Nair Rodriguez-Hernando
Serial No. : 10/606,202
Filed : September 11, 2003
Conf. No. : 6536
For : Pharmaceutical Co-Crystal Compositions

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.97 AND 1.98

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. However, Applicants have not submitted copies of the U.S. patents cited on attached Form PTO/SB/08 pursuant to 37 C.F.R. 1.98(a)(2)(ii).

It is respectfully requested that the references cited on the attached form PTO/SB/08 be considered in the examination of the subject application and that their consideration be made of record.

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PAGE 2/4 * RCVD AT 9/21/2006 12:32:48 PM [Eastern Daylight Time] * SVR:USPTO-EFAXF-3/22 * DNIS:2738300 * CSID:3523725800 * DURATION (mm:ss):01:34

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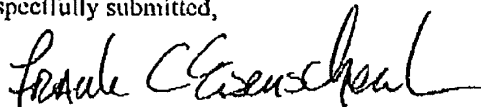
NOVARTIS EXHIBIT 1023
Novartis v. Regents, IPR2023-01346
Page 611 of 1101

2

Docket No. TPI-350C1
Serial No. 10/606,202

Applicants respectfully assert that the substantive provisions of 37 C.F.R. §§ 1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,



Frank C. Eissenschek, Ph.D.
Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: P.O. Box 142950
Gainesville, FL 32614-2950

FCE/gyl

Attachment: Form PTO/SB/08

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PTO/S&C/A (08-03)

Approved for use through 07/31/2008 OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO		Complete if Known			
		Application Number	10/606,202		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Filing Date	September 11, 2003		
		First Named Inventor	Orn Almarsson		
		Art Unit	1653		
		Examiner Name			
Sheet	1	of	1	Attorney Docket Number	TPI-350C1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Class No.	Document Number Number - Kind Code* (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U1	US-3,028,420	04-03-1962	Petrow et al.	All
	U2	US-5,521,207	05-28-1996	Graneto	All
	U3	US-			
	U4	US-			
	U5	US-			
	U6	US-			
	U7	US-			
	U8	US-			
	U9	US-			

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Class No.	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	F1				
	F2				
	F3				
	F4				
	F5				
	F6				
	F7				

Examiner Signature	Date Considered
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*EXAMINER: Initial if references considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard T3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 10 if possible. ⁶ Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,202	09/11/2003	Orn Almarsson	TPI-350C1	6536

23557 7590 12/06/2006

SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO BOX 142950
GAINESVILLE, FL 32614-2950

EXAMINER

COTTON, ABIGAIL MANDA

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 12/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/660,202		ALMARSSON ET AL.	
	Examiner		Art Unit	
	Abigail M. Cotton		1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 11 September 2003.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-37 is/are pending in the application.

 4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892) 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ 5) ☐ Notice of Informal Patent Application 6) ☐ Other: _____
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Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, 9-11 and 37, drawn to a pharmaceutical co-crystal composition comprising an API (active pharmaceutical ingredient) and a co-crystal former, wherein the API and co-crystal former are hydrogen-bonded to each other, classified in class 424, subclass 489, for example.
- II. Claims 3-4, drawn to a pharmaceutical co-crystal composition comprising an API, co-crystal former and a third molecule, wherein the API and co-crystal former are both hydrogen bonded to the third molecule, classified in class 424, subclass 489, for example.
- III. Claims 5-6, drawn to a pharmaceutical co-crystal composition comprising first and second APIs wherein the APIs are hydrogen bonded to a molecule, classified in class 424, subclass 489, for example.
- IV. Claims 7-8, drawn to a pharmaceutical co-crystal composition comprising first and second co-crystal formers, wherein the co-crystal former are both hydrogen bonded to a molecule, classified in class 424, subclass 489, for example.
- V. Claims 12-13 and 20-36, drawn to a process for preparing a pharmaceutical co-crystal composition comprising an API and a co-crystal former, as well as processes for modulating the solubility, dose response, dissolution, bioavailability, increasing the stability and decreasing the hygroscopicity of the API for use in a pharmaceutical composition, or

incorporating a difficult to salt API, among other methods, comprising providing the API and co-crystal former, providing crystallization conditions such that the API and co-crystal former are hydrogen bonded to one another and isolating the crystals formed thereby, classified in class 424, subclass 489, for example.

- VI. Claims 14-15, drawn to a process for preparing a pharmaceutical co-crystal composition comprising an API, a co-crystal former and a third molecule, by providing the API and co-crystal former, providing crystallization conditions such that the API and co-crystal former are hydrogen bonded to the third molecule, and isolating the crystals formed thereby, classified in class 424, subclass 489, for example.
- VII. Claims 16-17, drawn to a process for preparing a pharmaceutical co-crystal composition comprising first and second APIs, by providing the first and second APIs, providing crystallization conditions such that the APIs are hydrogen bonded to a molecule, and isolating the crystals formed thereby, classified in class 424, subclass 489, for example.
- VIII. Claims 18-19, drawn to a process for preparing a pharmaceutical co-crystal composition comprising first and second co-crystal formers, by providing the first and second co-crystal formers, providing crystallization conditions such that the co-crystal formers are bonded to a molecule, and isolating the crystals formed thereby, classified in class 424, subclass 489, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are related to inventions V-VIII as product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the products as claimed can be made by other materially different process, such as for example by introducing different heating and/or dissolution steps and/or by providing different crystallization solvents.

Because these inventions are distinct for the reasons given above and the search required for Groups I-IV is not required for Groups V-VIII, restriction for examination purposes as indicated is proper. It is noted that while the searches of Groups I-IV and V-VIII may be overlapping, there is no reason to believe that the searches would be co-extensive. In searching Groups V-VIII, the Examiner will be focusing on the patentability of the processes themselves, and not the compositions of Groups I-IV. Conversely, in searching Groups I-IV, the Examiner will be focusing on the patentability of the compositions and not the processes themselves. Accordingly, a search for all groups would pose an undue burden on the Office.

Inventions I-IV are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design and mode of operation, because each invention recites a different combination of components (APIs, co-crystal formers, third molecules, etc) that are uniquely hydrogen bonded to each other. For example, the composition of Group I requires an API and a co-crystal former that are hydrogen-bonded to one another, whereas the composition of Group II requires an API, co-crystal former and third molecule where the API and co-crystal former are hydrogen bonded to the third molecule. Thus, the inventions have different designs with regards to the compositional makeup and hydrogen bonding structure, and thus also have a different mode of operation. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper. In particular, it is noted that while the searches may overlap, the searches would not necessarily be co-extensive.

For example, in searching the subject matter of Group I, the Examiner will be focusing on the patentability of co-crystals having an API and a co-crystal former that are hydrogen bonded to one another, and not co-crystals having an API and co-crystal former that are hydrogen-bonded to a third molecule, as in Group II. Conversely, in searching Group II, the Examiner will be focusing on the patentability of co-crystals having an API and co-crystal former that are hydrogen bonded to a third molecule, and not on co-crystals having the API and co-crystal former hydrogen bonded to one another, as in Group I. Accordingly, a search for all groups would pose an undue burden on the Office.

Inventions V-VIII are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design and mode of operation, because each invention recites a different combination of components (APIs, co-crystal formers, third molecules, etc) that are uniquely hydrogen bonded to each other. For example, the process of Group V requires an API and a co-crystal former that are hydrogen-bonded to one another, whereas the process of Group VIII requires an API, co-crystal former and third molecule where the API and co-crystal former are hydrogen bonded to the third molecule. Thus, the inventions have different designs with regards

to the compositional makeup and hydrogen bonding structure, and thus also have a different mode of operation. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper. In particular, it is noted that while the searches may overlap, the searches would not necessarily be co-extensive. For example, in searching the subject matter of Group V, the Examiner will be focusing on the patentability of methods of forming co-crystals having an API and a co-crystal former that are hydrogen bonded to one another, and not co-crystals having an API and co-crystal former that are hydrogen-bonded to a third molecule, as in Group VI. Conversely, in searching Group VI, the Examiner will be focusing on the patentability of methods of forming co-crystals having an API and co-crystal former that are hydrogen bonded to a third molecule, and not on co-crystals having the API and co-crystal former hydrogen bonded to one another, as in Group V. Accordingly, a search for all groups would pose an undue burden on the Office.

Inventions I and VI-VIII, Inventions II, V and VII-VIII, Inventions II, V-VI and VIII and Inventions III and V-VII are directed to an unrelated product and process. Product

and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case the products as recited in each of Groups I-IV requires a specific compositional makeup and hydrogen bonding structure such that the products cannot be made by processes that involve components and/or hydrogen bonding configurations other than those specified. For example, the product of Group I requires an API and a co-crystal former that are hydrogen-bonded to one another, and as such cannot be made by the method of Group VI that involves forming a co-crystal of an API, co-crystal former and third molecule where the API and co-crystal former are hydrogen bonded to the third molecule.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper. In particular, it is noted that while the searches may overlap, the searches would not necessarily be co-extensive. For example, in searching the subject matter of Group I, the Examiner will be focusing on the patentability of co-crystals having an API and a co-crystal former that are hydrogen bonded to one another, and not methods of forming co-crystals having an API and co-crystal former that are hydrogen-bonded to a third molecule, as in Group VI. Conversely, in searching Group VI, the Examiner will be focusing on the patentability of methods of forming co-crystals having an API and co-crystal former that are hydrogen bonded to a third molecule, and not on co-crystals having the API and co-crystal former

hydrogen bonded to one another, as in Group I. Accordingly, a search for all groups would pose an undue burden on the Office.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Due to the complicated nature of the restriction, the restriction requirement is being made via written correspondence in lieu of a telephone interview.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

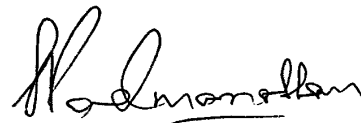
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

Index of Claims 	Application/Control No.		Applicant(s)/Patent under Reexamination	
	10/660,202		ALMARSSON ET AL.	
	Examiner		Art Unit	
	Abigail M. Cotton		1617	

✓	Rejected
=	Allowed

—	(Through numeral) Cancelled
+	Restricted

N	Non-Elected
I	Interference

A	Appeal
O	Objected

Claim		Date											
Final	Original	11/27/06											
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FACSIMILE COVER SHEET

SALIWANCHIK, LLOYD & SALIWANCHIK

A Professional Association

P.O. Box 142950

Gainesville, FL 32614-2950

Telephone (352) 375-8100

Facsimile (352) 372-5800

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JAN 08 2007

TO: Examiner Abigail Manda Cotton FROM: Frank C. Eisenschenk
Examining Group 1617 Patent Attorney
Registration No. 45,332

COMPANY: United States Patent and DATE: January 8, 2007
Trademark Office

FAX NO.: 571-273-8300 NO. OF PAGES
(INCLUDING COVER SHEET): 2

SUBJECT/MESSAGE:

Re: U.S. Patent Application Docket No. TPI-350C1
PHARMACEUTICAL CO-CRYSTAL COMPOSITIONS
Serial No.: 10/660,202; Date filed: September 11, 2003
Applicant: Orn Almarsson

Submission to PTO:

1. Election under 35 U.S.C. §121

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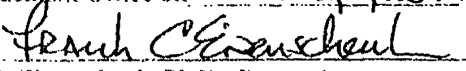
JAN-08-07 MON 05:55 PM SALIWANCHIK LLOYD

FAX NO. 3523725800 RECEIVED P. 02

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JAN 08 2007

I hereby certify that this correspondence is being
facsimile transmitted to the United States Patent
and Trademark Office on JANUARY 8, 2007.


Frank C. Eisenschenk, Ph.D., Patent Attorney

ELECTION UNDER 35 U.S.C. §121
Examining Group 1617
Patent Application
Docket No. TPI-350C1
Serial No. 10/660,202

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Abigail Manda Cotton
Art Unit : 1617
Applicants : Örn Almarsson, Magali Bourghol Hickey, Matthew L. Peterson,
Michael J. Zaworotko, Brian Moulton, Nair Rodriguez-Hernando
Serial No. : 10/660,202
Filed : September 11, 2003
For : Pharmaceutical Co-Crystal Compositions

MS AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

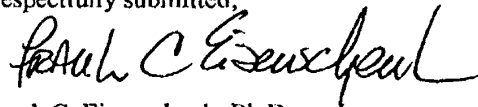
ELECTION UNDER 35 U.S.C. §121

Sir:

In response to the written restriction requirement dated December 6, 2006, the applicants hereby elect with traverse to prosecute the Group I claims, e.g., claims 1-2, 9-11, and 37, drawn to a pharmaceutical co-crystal composition comprising an API and a co-crystal former, wherein the API and co-crystal former are hydrogen-bonded to each other.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.
Patent Attorney
Registration No. 45,332
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

FCE/mv

J:\PI\350C1\Amend-Resp\Election.doc\DNM/mv



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APPLICATION NUMBER	FILING OR 371(c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
10/660,202	09/11/2003	Orn Almarsson	TPI-350C1

CONFIRMATION NO. 6536

23557
SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO BOX 142950
GAINESVILLE, FL32614-2950

Title: Pharmaceutical co-crystal compositions

Publication No. US-2007-0026078-A1

Publication Date: 02/01/2007

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publicly available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <http://pair.uspto.gov/>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 703-305-3028.

Pre-Grant Publication Division, 703-605-4283

EAST Search History

AMC

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	146	(co adj crystal\$ or co\$1crystal\$).ab.	US-PGPUB; USPAT; USOCR	OR	ON	2007/03/20 15:23
L3	98	l2 and @ad<="20030215"	US-PGPUB; USPAT; USOCR	OR	ON	2007/03/20 15:20
L4	98	l2 and @ad<"20030215"	US-PGPUB; USPAT; USOCR	OR	ON	2007/03/20 15:23
L5	572	(co adj crystal\$ or co\$1crystal\$).ab.	FPRS; EPO; JPO; DERWENT	OR	ON	2007/03/20 15:23
L6	333	l5 and @ad<"20030215"	FPRS; EPO; JPO; DERWENT	OR	ON	2007/03/20 15:32

=> d his

AMC

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L2 1 S L1 EXA SAM

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L3 STR 298-46-4
L4 75 S L3 FAM FUL

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L7 22 S L6 AND AD<20020215 AND PATENT/DT
L8 109 S L6 AND PY<2002 AND NONPATENT/DT
L9 131 S L7 OR L8
L10 105 S L9 AND (CRYSTAL? OR POLYMORPH?)/AB
L11 3 S L10 AND (SACCARIN? OR NICOTINAMIDE OR TRIMES? OR PHTHALALDEHY
L12 85 S L10 AND (CARBAMAZEPINE)/AB
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L14 3492 S (CO-CRYSTAL? OR CO(A)CRYSTAL?)
L15 0 S L9 AND L14

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FILE 'CAPLUS' ENTERED AT 13:47:44 ON 20 MAR 2007

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L17 1 S L16 EXA SAM

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L18 STR 84625-61-6
L19 83 S L18 FAM FUL

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L28 4375 S L26 OR L27
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L30 0 S L4 AND L28

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L32 1 S L31 EXA SAM

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L33 STR 68693-11-8
L34 63 S L33 FAM FUL

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 L55 1 S 500225-89-8

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 L56 1 S 595564-74-2/RN

FILE 'CAPLUS' ENTERED AT 14:18:10 ON 20 MAR 2007
 L57 4 S L56

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 L58 1 S 595564-73-1/RN

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 L59 4 S L58

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 L61 2 S L60

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 L62 1 S 572916-60-0/RN

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 L64 1 S 572916-56-4/RN

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 L69 FILE 'CAPLUS' ENTERED AT 14:18:17 ON 20 MAR 2007
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 L76 FILE 'REGISTRY' ENTERED AT 14:20:59 ON 20 MAR 2007
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 SET NOTICE LOGIN DISPLAY
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 L99 FILE 'REGISTRY' ENTERED AT 14:27:22 ON 20 MAR 2007
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 L100 FILE 'CAPLUS' ENTERED AT 14:27:23 ON 20 MAR 2007
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 1 S 756835-66-2/RN
 L102 FILE 'CAPLUS' ENTERED AT 14:27:24 ON 20 MAR 2007
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 L115 0 S L113 AND PY<2002 AND NONPATENT/DT
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 L119 FILE 'CAPLUS' ENTERED AT 14:29:41 ON 20 MAR 2007
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 1 S 922167-06-4/RN
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 1 S 922167-05-3/RN
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 1 S 922167-03-1/RN
 L127 FILE 'CAPLUS' ENTERED AT 14:29:45 ON 20 MAR 2007
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 1 S 922167-00-8/RN

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L133      1 S L132

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L134      1 S 756853-47-1/RN

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L135      2 S L134

FILE 'REGISTRY' ENTERED AT 14:29:50 ON 20 MAR 2007
L136      1 S 756836-16-5/RN

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L137      2 S L136
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L140      0 S L138 AND PY<2002 AND NONPATENT/DT

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L142      592 S L141 AND (CRYSTAL? OR COCRYSTAL?)
L143      79 S L142 AND (CO-CRYSTAL? OR COCRYSTAL? OR CO(A)CRYSTAL?)
L144      61 DUP REM L143 (18 DUPLICATES REMOVED)
L145      45 S L144 AND NONPATENT/DT

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L147      167 S L146 AND PY<2002
L148      23 S L147 AND (DRUG OR PHARMACEUTICAL? OR MEDICINE OR MEDICAMENT O
L149      94 S L147 AND (CRYSTALL?)

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FILE 'CAPLUS' ENTERED AT 15:06:25 ON 20 MAR 2007
L150      70 S L149 AND (CRYSTAL? OR COCRYSTAL? OR CO-CRYSTAL?)/AB

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Amc

(FILE 'HOME' ENTERED AT 13:22:11 ON 20 MAR 2007)

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L2 1 S L1 EXA SAM

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L3 STR 84625-61-6
L4 83 S L3 FAM FUL

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L8 0 S L6 AND PY<2002 AND NONPATENT/DT
L9 66 S L5 AND CRYSTAL?
L10 16 S L9 AND AD<20020215 AND PATENT/DT
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L12 26 S L10 OR L11
L13 53 S L5 AND POLYMORPH?
L14 5 S L13 AND AD<20020215 AND PATENT/DT
L15 10 S L12 AND PY<2002 AND NONPATENT/DT
L16 15 S L14 OR L15

L74 ANSWER 1 OF 1 CAPLUS COPYRIGHT 2007 ACS on STN

ACCESSION NUMBER: 1990:542666 CAPLUS

DOCUMENT NUMBER: 113:142666

TITLE: Crystal and molecular structure of a complex of
18-crown-6 with 6-chloro-7-sulfamido-3,4-dihydro-1,2,4-
benzothiadiazine-1,1-dioxide (hypothiazide) of 1:1
composition

AUTHOR(S): Dvorkin, A. A.; Simonov, Yu. A.; Lipkowski, Janusz;
Fonar, M. S.; Malinovskii, T. I.; Ganin, E. V.;
Kotlyar, S. A.

CORPORATE SOURCE: Inst. Prikl. Fiz., Kishinev, USSR

SOURCE: Kristallografiya (1990), 35(3), 682-6

CODEN: KRISAJ; ISSN: 0023-4761

DOCUMENT TYPE: **Journal**

LANGUAGE: Russian

AB The title compound is monoclinic, space group P21/a, with a 11.533(11), b
10.172(6), c 15.023(7) Å, and γ 60.79(3)°; $d_c = 1.422(8)$
for Z = 4. The atomic coordinates are given. The structure was solved by
direct methods and refined by least-squares to R = 0.053. The bond
lengths and angles are given. The H-bonding is described.

SO Kristallografiya (1990), 35(3), 682-6

CODEN: KRISAJ; ISSN: 0023-4761

DT **Journal**

IT 129530-31-0

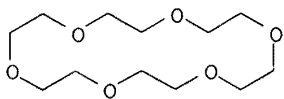
RL: PRP (Properties)

(crystal structure of)

L75 ANSWER 1 OF 1 REGISTRY COPYRIGHT 2007 ACS on STN
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 1,1-dioxide, compd. with 1,4,7,10,13,16-hexaoxacyclooctadecane (1:1) (9CI)
 (CA INDEX NAME)
 OTHER CA INDEX NAMES:
 CN 1,4,7,10,13,16-Hexaoxacyclooctadecane, compd. with 6-chloro-3,4-dihydro-2H-
 1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide (1:1) (9CI)
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 SR CA
 LC STN Files: CA, CAPLUS, USPATFULL

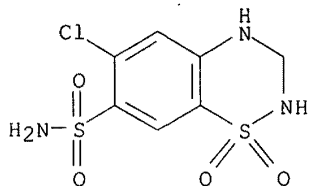
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CM 2

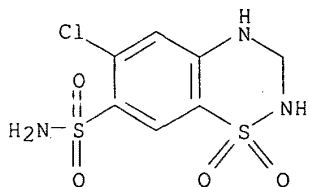
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2 REFERENCES IN FILE CA (1907 TO DATE)
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L77 ANSWER 1 OF 1 REGISTRY COPYRIGHT 2007 ACS on STN
 RN 58-93-5 REGISTRY
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 CN 6-Chloro-3,4-dihydro-2H-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide
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 CN 6-Chloro-7-sulfamoyl-3,4-dihydrobenzo-1,2,4-thiadiazine-1,1-dioxide
 CN Acuretic
 CN Apo-Hydro
 CN Apresazide
 CN Aquarius
 CN Aquazide H
 CN Caplaril
 CN Carozide
 CN Chlorosulthiadil
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 CN Clothia
 CN Dichlothiazide
 CN Dichlotiazid
 CN Dichlotride
 CN Dichlozid
 CN Diclotride
 CN Didralin
 CN Dihydrochlorothiazide
 CN Dihydrochlorothiazidum
 CN Dihydrochlorurit
 CN Dihydrochlorurite
 CN Disalunil
 CN Disothiazide
 CN Diuret-P
 CN Diurex
 CN Diurizid
 CN Drenol
 CN Esidrex
 CN Esidrix
 CN HCT
 CN HCTZ
 CN HCZ
 CN HH 25/25
 CN HH 50/50
 CN Hidrenox
 CN Hidril
 CN Hydrochlortiazid
 CN Hidrosaluretil
 CN Hidrotiazida
 CN Hydrex
 CN Hydrex-semi
 CN Hydril
 CN Hydro Par
 CN Hydro-Aquil
 CN Hydro-Diuril
 CN Hydro-T
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 CI COM
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 BIOTECHNO, CA, CABA, CAOLD, CAPLUS, CASREACT, CBNB, CHEMCATS, CHEMLIST,

CIN, CSCHEM, CSNB, DDFU, DRUGU, EMBASE, HSDB*, IFICDB, IFIPAT, IFIUDB,
IMSCOSEARCH, IMSDRUGNEWS, IMSPATENTS, IMSRESEARCH, IPA, MEDLINE, MRCK*,
MSDS-OHS, PATDPASPC, PHAR, PROMT, PS, RTECS*, SCISEARCH, SPECINFO,
TOXCENTER, TULSA, USAN, USPAT2, USPATFULL, VETU
(*File contains numerically searchable property data)
Other Sources: DSL**, EINECS**, TSCA**, WHO
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PROPERTY DATA AVAILABLE IN THE 'PROP' FORMAT

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3786 REFERENCES IN FILE CAPLUS (1907 TO DATE)
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,202	09/11/2003	Om Almarsson	TPI-350C1	6536
23557 7590 03/30/2007 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			EXAMINER COTTON, ABIGAIL MANDA	
			ART UNIT	PAPER NUMBER
			1617	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/30/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/660,202	ALMARSSON ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 08 January 2007.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) 3-8 and 12-36 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1, 2 and 9-11 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date See Continuation Sheet.

4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/10/03,4/5/04,6/21/04,9/2/04,8/31/06 and 9/21/06.

DETAILED ACTION

Claims 1-37 are pending in the application, with claims 3-8 and 12-36 having been withdrawn as drawn to a non-elected invention. Accordingly, claims 1-2, 9-11 and 37 are being examined on the merits herein.

Election/Restrictions

Applicant's election of the claims of Group I, namely claims 1-2, 9-11 and 37 in the reply filed on January 8, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, claims 3-8 and 12-36 are being withdrawn from examination as being drawn to non-elected inventions

Priority

Applicants' claim of priority as a CIP of PCT/US03/27772 filed September 4, 2003, which is a CIP of 10/378,956, filed March 3, 2003, and claim of priority as a CIP of application serial nos. 10/367,829, 10/449,307 and 10/601,092, as well as the priority claims to the provisional and non-provisional applications to which these application claim priority, is acknowledged.

However, Applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 or 119(e) as follows:

The later-filed application must be an application for a patent for an invention that is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, including application nos. 10/378,956, 10/367,829, 10/449,307 and 10/601,092, as well as the provisional and non-provisional applications to which they claim priority, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. In particular, these prior applications do not provide adequate support for all pharmaceutical co-crystal compositions in general having an API that is a liquid or a solid at room temperature, and a co-crystal former that is solid at room temperature, where the API and co-crystal former are hydrogen bonded to each other, as recited in claim 1. The prior applications also do not teach all of the specific co-crystal formers as recited in claim 2, all of the specific co-crystal API and co-crystal former combinations as in claim 11, and also do not teach all of the exceptions as listed

in claim 37. Instead, U.S. Patent Application Serial No. 10/378,956, for example, discloses that co-crystals can comprise specific co-crystal combinations such as carbamazepine and nicotinamide, but does not disclose the general co-crystal formulations as recited in claims 1-2, 9-10, and 37, and also does not disclose certain specific co-crystal combinations as recited in claim 11, such as modafinil and mandelic acid. Accordingly, the instant claims do not receive benefit of the filing dates of these prior applications or the provisional and non-provisional application to which they claim priority.

The claims are fully supported under 35 U.S.C. 112, first paragraph, by the PCT application No. PCT/US03/27772, filed September 4, 2003, and thus receive benefit of the filing date of the PCT application. Accordingly, the instant claims are granted the effective filing date of September 4, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description Rejection

Claims 1-2, 9-10 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In particular, Applicants have only shown the formation of the particular co-crystals recited in claim 11, such as for example crystals of cabamazepine and saccharin, but do not exemplify or otherwise show the formation of all co-crystals containing any solid API and any co-crystal former that is liquid or solid, and where the components are hydrogen bonded to one another, or co-crystals with any of the numerous and divers different co-crystal formers in claim 2 or APIs as in claim 9. Applicants have not described or shown how the numerous and diverse different co-crystals as claimed could be obtained.

The specification only describes the preparation of the particular co-crystals recited in claim 11 (see pages 7-10, in particular.) Accordingly, the specification does not describe the claimed subject matter in a manner sufficient to convey to one of ordinary skill in art that the inventors were in possession of the entire invention, including the formation of co-crystals containing any API and any co-crystal former that are hydrogen bonded and are solid or liquid, as recited in the claims.

Enablement Rejection

Claims 1-2, 9-10 and 37 are rejected under 35 U.S.C. 112, first paragraph, for lacking enablement for the full scope of the claims. The specification is enabling for the preparation and use of the particular pharmaceutical co-crystals as recited in claim 11, such as co-crystals of carbamazepine and saccharin, or celecoxib and nicotinamide. However, the specification is not enabling for the preparation of all co-crystals having any API that is solid, and any co-crystal former that solid and liquid, where the components are hydrogen bonded to one another, as recited in claim 1, or all co-crystals having the numerous and diverse APIs and co-crystal formers as in claims 2, 9-10 and 37.

The instant specification fails to provide information that would allow the skilled artisan to fully make and use the instant invention without **undue experimentation**. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the

court set fourth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

1. The nature of the invention: The instant invention pertains a co-crystal composition containing a solid API and a solid or liquid co-crystal former, where the API and co-crystal former are hydrogen bonded to one another.

2. The state of the prior art: The skilled artisan would view the formation of different crystalline forms as being unpredictable due to the numerous different crystallization factors needing to be controlled to provide different crystal states, as well as the unpredictability in predicting the different types of crystals that may exist. For example, as disclosed by Angelo Gavezzotti ("Are Crystal Structures Predictable?" by Gavezzotti, Acc. Chem. Res, 1994, Vol. 27, pages 309-314), the formation and structure of crystals is unpredictable at best (see first full paragraph, in particular.) Gavezzotti teaches that it can be unpredictable whether compounds will crystallize at all, crystal growth from solution is known to be problematic, and in general "a crystal is

more readily destroyed than built" (see first full paragraph of right hand column on page 309.) Thus, Gavezzotti teaches that the production of crystals is unpredictable at best, with the particular process parameters suitable for crystallizing a compound typically not being known in advance, and thus desired crystals can generally only be arrived at via experimentation and dealing with "tough problems in the control of solidification, crystal growth, and crystal morphology, mainly due to perverse kinetic control of nucleation (see first full paragraph of right hand column on page 309.)

3. The relative skill of those in the art: the relative skill of those in the art is typically very high, i.e. experienced scientists having advanced degrees in the chemical and biochemical fields.

4. The predictability of the art: As discussed above, the production of crystal forms is highly unpredictable, with crystal growth from solution being problematic. (see see page 309 of Gavezzotti, in particular.)

5. The breadth of the claims: the unpredictable nature of the invention is exacerbated by the breadth of the claims. The claims require co-crystal composition that has any API that is solid, in general, with any crystal co-former that is solid or liquid, in general, where the components are hydrogen bonded, as in claim 1. Thus, the claims as instantly presented encompass all co-crystals having any solid API and any

solid or liquid co-crystal former, where the component are hydrogen bonded to one another.

6. The amount of direction or guidance presented: the specification does not provide any direction or guidance as to how to go about manufacturing and/or finding all of the different crystal forms that contain an API and a co-crystal former and that are hydrogen bonded to one another, and that thus fall within the scope of the claim. The specification generally teaches that hydrogen bonding is a dominant interaction in the formation of a co-crystal (see page 10 of specification, in particular), but does not teach how one of ordinary skill in the art would go about finding the proper crystallization process parameters, such as the proper crystallization solvent, temperature, etc, to allow for the formation of all of the co-crystals encompassed by the claims, without requiring undue experimentation.

7. The presence or absence of working examples: The specification does not provide working examples that are sufficient to show one of ordinary skill in the art how to arrive at all of the co-crystal forms. Instead, the specification merely provides examples showing the fabrication of the particular co-crystals recited in claim 11, including carbamazepine and saccharin, and topiramate and 18-crown-6 co-crystals (see Examples 1-37, in particular.) Thus, while the specification provides guidance for forming the particular co-crystals specifically disclosed in the specification and recited in claim 11, the specification does not provide adequate guidance as to how one of

ordinary skill in the art could prepare all other crystals containing any API and co-crystal former.

8. The quantity of experimentation necessary: As the specification does not provide adequate guidance to allow one of ordinary skill in the art to readily determine the manufacturing conditions required to achieve crystallization of all of API/co-crystal formers, nor to determine which combinations of API and co-crystal former would even be capable of being recovered in crystal form, it is considered that one of ordinary skill in the art would have to engage in **undue experimentation** in order to be able to fully make and use the invention to the full extent of the claims.

In particular, as the parameters crucial to forming all of the API/co-crystal former crystals are not known, one of ordinary skill in the art would have to perform an exhaustive search to find all of those APIs and co-crystal formers, as well as all crystallization parameters, that are necessary to provide the crystal forms. To make all of the possible crystals, one of ordinary skill in the art would have to first have to select a particular API and co-crystal former combination, and then discover the means of achieving the crystalline form of the combination by performing numerous and exhaustive crystal manufacturing processes and making incremental changes in each manufacturing parameter, such as solvent and temperature parameters, to try and obtain the compounds in co-crystal form. If the components failed to crystallize, the crystal manufacturing process would have to be repeated, again with incremental

changes in parameters, to attempt to achieve a new crystal form. If a crystal were achieved, the crystal would have to be analyzed by X-ray diffraction or other method to determine whether hydrogen bonding existed in the crystal. The above procedure would have to be repeated numerous different times with a variety of different process parameters, as well as with different APIs and co-crystal formers, in order for one of ordinary skill in the art to discover all those co-crystal forms that fall within the scope of the claim, and thus to be able to fully make and use the invention commensurate with the full scope of the claim. Therefore, the skilled artisan would have to exercise **undue experimentation** to practice the instant invention.

Thus, the specification fails to provide sufficient support for the broad recitation of a co-crystal composition containing any solid API, in general, with any solid or liquid co-crystal-former, in general, in which the components are hydrogen bonded to each other. As a result, one of ordinary skill in the art would be required to perform an exhaustive search for the embodiments of the co-crystal compositions that are suitable for the practice of the invention.

Genentech, 108 F.3d at 1366, states that “a patent is not a hunting license. It is not a reward for a search, but compensation for its successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.”

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in undue experimentation to make and use all of the co-crystal compositions encompassed by the instant claims, with no assurance of success.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 9-11 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by the article entitled “The Formation of Paracetamol (acetaminophen) Adducts with Hydrogen-Bond Acceptors” by Oswald et al, 2002, Acta Crystallographica Section B, Vol. B58, pages 1057-1066.

Oswald et al. teaches preparing crystal forms of paracetamol (i.e. acetaminophen), including adducts with 4,4'-bipyridine (see abstract, in particular.) Oswald et al. teaches that the compounds in the adduct are hydrogen bonded (see Section 3.3, in particular.) Accordingly, Oswald et al. teaches one of the specific co-

crystals as recited in claim 11, and which also meet the co-crystal and API/co-crystal former combination limitations as recited in claims 1-2, 9 and 37.

Regarding claim 10, Oswald et al. teaches that the compounds can be used for the formation of tablets (see first full paragraph of Introduction on page 1057, in particular), and thus anticipates providing the compounds with a pharmaceutically acceptable carrier, excipient or diluent, as recited in the claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-2, 9-10, 11 and 37 are rejected under 35 U.S.C. 102(a) as being anticipated by the article entitled "Crystal Engineering of Novel Co-Crystals of a Triazole Drug with 1,4-Dicarboxylic Acids" by Remenar et al, JACS, Vol. 125, pages 8456-8457, published on the web on June 21, 2003.

Remenar et al. teaches non co-crystals of itraconazole with 1,4-dicarboxylic acids including fumaric acid, succinic acid, and malic acid (see Table 1, in particular), and teaches that the co-crystals are hydrogen bonded (see paragraph bridging right and left hand columns on page 8456, in particular.) Accordingly, Remenar et al. teaches the

specific co-crystals as recited in claim 11, and which also meet the co-crystal and API/co-crystal former combination limitations as recited in claims 1-2, 9 and 37.

Regarding claim 10, Remenar et al. teaches that the compounds are pharmaceutical solids for pharmaceutical uses (see first full paragraph of page 8456, in particular), and thus anticipates providing the compounds with a pharmaceutically acceptable carrier, excipient or diluent, as recited in the claim.

Claims 1-2, 9-10, 11 and 37 are rejected under 35 U.S.C. 102(a) as being anticipated by the article entitled "Crystal Engineering of the Composition of Pharmaceutical Phases: Multiple-Component Crystalline Solids Involving Carbamazepine" by Fleischman et al, Crystal Growth and Design, Vol. 3, No. 6, pages 909-919, published on the web on June 17, 2003.

Fleischman et al. teaches forming co-crystals of carbamazepine (CBZ) with benzoquinone, saccharin, nicotinamide, trimesic acid, 5-nitroisophthalic acid and adamantane-1,3,4,5-tetracarboxylic acid (see abstract, in particular.) Fleischmann et al. teaches that the resulting crystals contain hydrogen bonds (see Table 2, in particular.) Accordingly, Fleischman et al. teaches the specific co-crystals as recited in claim 11, and which also meet the co-crystal and API/co-crystal former combination limitations as recited in claims 1-2, 9 and 37.

Regarding claim 10, Fleischman et al. teaches that the compounds contain CBZ as an active pharmaceutical ingredient (API), which has analgesic and anticonvulsant properties (see abstract and Introduction, in particular), and thus anticipates providing the compounds with a pharmaceutically acceptable carrier, excipient or diluent, as recited in the claim.

Claims 1-2, 9, 11 and 37 are rejected under 35 U.S.C. 102(a) as being anticipated by the article entitled "Crystal and Molecular Structure of a Complex of 18-Crown-6 with 6-chloro 7-sulfamido-3,4-dihydro-1,2,4-benzothiadiazine" by Dvorkin et al, Kristallografiya, 1990, Vol. 35, No. 3, pages 682-686 (English abstract.)

Dvorkin et al. teaches the preparation of a co-crystal of 18-crown-6 with 6-chloro 7-sulfamido-3,4-dihydro-1,2,4-benzothiadiazine (hydrochlorothiazide), and teaches that the hydrogen bonding of the crystal is described (see abstract, in particular.) Accordingly, Dvorkin et al. teaches the specific co-crystals as recited in claim 11, and which also meet the co-crystal and API/co-crystal former combination limitations as recited in claims 1-2, 9 and 37.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 9-10 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,559,293 to Almarsson et al, issued May 6, 2003.

Almarsson et al. teaches novel salts of topiramate and co-crystals thereof (abstract, in particular.) Almarsson et al. teaches that the co-crystals can be hydrogen bonded, and provides the specific co-crystal example of topiramate and caffeine (see paragraph bridging columns 14-15, in particular.) Thus, Almarsson et al. teaches a co-crystal composition comprising a solid API (topiramate) and a solid co-crystal former (caffeine), which are hydrogen bonded to one another, as in claim 1, and that has the functional groups as recited in claim 2.

Regarding claims 9 and 37, Almarsson et al. teaches the topiramate and caffeine co-crystal, and thus teaches the composition wherein the API is topiramate, as in claim 9, and teaches a crystal that is not one of those excluded by claim 37.

Regarding claim 10, Almarsson et al. teaches that the compounds are intended as pharmaceutically acceptable materials for the treatment of conditions such as tremors and seizures (see abstract, in particular), and thus anticipates providing the

compounds with a pharmaceutically acceptable carrier, excipient or diluent, as recited in the claim.

Claims 1-2, 9-10, 11 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 03/074474 to Zaworotko et al, published September 12, 2003.

Zaworotko et al. teaches forming co-crystals of various pharmaceutical compounds, including acetaminophen/4,4'-bipyridine, phenytoin/pyridine, aspirin/4,4'-bipyridine, ibuprofen/4,4'-bipyridine, flurbiprofen/4,4'-bipyridine, among many others (see abstract and pages 7-9, in particular.) Zaworotko et al. teaches that the crystals contain hydrogen bonds (see pages 7-9, in particular.) Accordingly, Zaworotko et al. teaches the specific co-crystals as recited in claim 11, and which also meet the co-crystal and API/co-crystal former combination limitations as recited in claims 1-2, 9 and 37.

Regarding claim 10, Zaworotko et al. teaches that the compounds are for pharmaceutical entities and contain at least one active pharmaceutical ingredient (see abstract and Introduction, in particular), and thus anticipates providing the compounds with a pharmaceutically acceptable carrier, excipient or diluent, as recited in the claim.

Claims 1-2 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. 2004/0176335 to Scott L. Childs, published September 9, 2004.

Childs teaches novel cocrystals and methods of cocrystallization using the salt of an active agent (see abstract, in particular.) Childs teaches that the cocrystals are formed by providing strong hydrogen bond donor molecules to the crystal system (see paragraph 0006, in particular), and thus teaches forming a cocrystal of an API with a co-crystal former that is hydrogen bonded, as recited in claim 1. Childs provides the specific example of a co-crystal comprising fluoxetine HCl and succinic acid (see Examples 2 and 5, in particular), and thus teaches a crystal having a solid API and a solid or liquid co-crystal former (note that instant claim 11 recites succinic acid as a suitable co-crystal former for itraconazole), and thus meets the limitations of claim 1 and the co-crystal former functional group limitation of claim 2.

Regarding claim 10, Childs teaches that the composition is intended to include and active pharmaceutical ingredient (see abstract, in particular), and thus anticipates providing the compounds with a pharmaceutically acceptable carrier, excipient or diluent, as recited in the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 9-11 and 37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No.7,078,526 to Remenar et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are to co-crystals of APIs and co-crystal formers, including the specific crystals listed in claim 11, such as itraconazole and tartaric acid, whereas the patented claims are to only the specific co-crystal that contains itraconazole and tartaric acid. Accordingly, the instant claims are obvious over the specific patented co-crystal, and thus are not patentably distinct over the 7,078,526 patent.

Claims 1-2 and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 86-93 of copending Application No. 10/546,963, as published in U.S. Patent Application Publication No. 2007/0059356 to Almarsson et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are to co-crystals having any API and any co-crystal former that are hydrogen bonded, whereas the published claims are to co-crystal compositions having APIs and co-crystal formers with functional groups that allow for hydrogen bonding. Accordingly, the broader class of co-crystals as claimed is obvious over the co-crystals having the specific functional groups as in the published application, and the instant claims are not patentably distinct from those in the 2007/0059356 publication.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-2, 9-11 and 37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-49 and 72-87 of copending Application No. 10/570,405, as published in U.S. Patent Application Publication No. 2007/0021510 to Hickey et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are to co-crystals having any API and any co-crystal former that are hydrogen bonded, including modafinil and malonic acid, whereas the published claims are to co-crystal

compositions having modafinil as the APIs and co-crystal formers that hydrogen bond to one another, such as malonic acid. Accordingly, the broader class of co-crystals as claimed is obvious over the specific modafinil co-crystals as in the published application, and the instant claims are not patentably distinct from those in the 2007/0021510 publication.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-2, 9-11 and 37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 66-72 of copending Application No. 10/551,014, as published in U.S. Patent Application Publication No. 2006/0223794 to Bourghol Hickey et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are to co-crystals having any API and any co-crystal former that are hydrogen bonded, including olanzapine and nicotinamide, whereas the published claims are to the specific co-crystal compositions having olanzapine and nicotinamide as the co-crystal components. Accordingly, the broader class of co-crystals as claimed is obvious over the specific olanzapine co-crystals as in the published application, and the instant claims are not patentably distinct from those in the 2006/00223794 publication.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-2, 9-11 and 37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-7, 16 and 18 of copending Application No. 10/926,842, as published in U.S. Patent Application Publication No. 2005/0070551 to Remenar et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are to co-crystals having any API and any co-crystal former that are hydrogen bonded, including itraconazole and various acids such as succinic acid, fumaric acid and tartaric acid, whereas the published claims are to the specific co-crystal compositions having itraconazole and acids such as malonic acid, fumaric acid, tartaric acid, etc, as well as other co-crystal forms. Accordingly, the scope of the instant claims overlaps with that of the published application, and accordingly, the instant claims are not patentably distinct from those in the 2005/0070551 publication.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

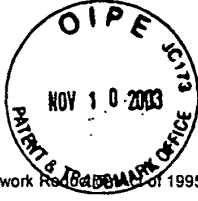
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER



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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	10/978,956 P1660, 702		
		Filing Date	September 11, 2003		
		First Named Inventor	Örn Almarsson		
		Art Unit			
		Examiner Name			
Sheet	1	of	2	Attorney Docket Number	TPI-350C1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U1	US-			
	U2	US-			
	U3	US-			
	U4	US-			
	U5	US-			
	U6	US-			
	U7	US-			
	U8	US-			
	U9	US-			

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁴
		Country Code ³	- Number ⁴ - Kind Code ⁵ (if known)				
1AC1	F1		GB 1 297 261 A	11-22-1972 (22 Nov 1972)	E.R. Squibb & Sons, Inc.	whole document	
	F2						
	F3						
	F4						
	F5						
	F6						
	F7						

Examiner Signature	/Abigail Cotton/ (03/20/2007)	Date Considered	03/20/2007
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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known	
		Application Number	10/378,956-1/160,202
		Filing Date	September 11, 2003
		First Named Inventor	Örn Almarsson
		Group Art Unit	
		Examiner Name	
Sheet	2	of	2
		Attorney Docket Number	TPI-350C1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/AC/	R1	BRADER, M.L. et al. <i>Nature Biotechnol.</i> , 2002, 20 : 800-804.	
/AC/	R2	EL-NAHHAS, S.A. <i>Pharmazie</i> , 1996, 51(12):960-963.	
/AC/	R3	FLEISCHMAN, S.G. et al. <i>Crystal Growth & Design</i> , 2003, 3(6): 909-919.	
/AC/	R4	OSWALD, I.D.H. et al. <i>Acta Cryst.</i> , 2002, B58:1057-1066.	
/AC/	R5	REYNOLDS, J.E.F. (ed). Martindale, The Extra Pharmacopoeia, 1993, The Pharmaceutical Press, London, England, 13 th Edition, pp. 1431 (e.g., Acetaminophen, Aspirin, and Caffeine Tablets), 1465 (e.g., Aspirin plus C), 1521 (Codafen Continus), 1610 (Gaboril Complex).	
/AC/	R6	WALSH, R.D. Bailey et al. <i>Chem. Commun.</i> , 2003, 2003:186-187.	
	R7		
	R8		
	R9		
	R10		
	R11		
	R12		
	R13		

Examiner Signature	/Abigail Cotton/ (03/20/2007)	Date Considered	03/20/2007
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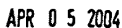
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NOVARTIS EXHIBIT 1023

Novartis v. Regents, IPR2023-01346

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Sheet	1
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of 2

Complete if Known

Application Number	10/660.202
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Filing Date	September 11, 2003
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First Named Inventor	Orn Almarsson
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Art Unit

Examiner Name

Attorney Docket Number	TPI-350C1
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U. S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear
		Country Code ² Number ³ Kind Code ⁴ (if known)			
IAC/ IAC/	1	WO 03/074474 A2	09-12-2003	Zaworotko et al	Pls review all
IAC/ IAC/	2	WO 03/033462 A2	04-24-2003	Matzger et al.	Pls review all
IAC/ IAC/	3	WO 01/51919 A2	07-19-2001	Levinson et al.	Pls review all
	4	WO 01/42222 A1	06-14-2001	Ferro et al.	Pls review all

Examiner

/Abigail Cotton/ (03/20/2007)

Date _____

	Not Considered	Considered
1. The number of people who are affected by the problem.		
2. The severity of the problem.		
3. The likelihood of the problem occurring.		
4. The cost of the problem.		
5. The time it takes to solve the problem.		
6. The complexity of the problem.		
7. The availability of resources to solve the problem.		
8. The impact of the problem on the organization's reputation.		
9. The potential for legal action against the organization.		
10. The overall risk to the organization.		

03/20/2007

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				Application Number	10/660,202
				Filing Date	September 11, 2003
				First Named Inventor	Orn Almarsson
				Art Unit	
				Examiner Name	
Sheet	2	of	2	Attorney Docket Number	TPI-350C1

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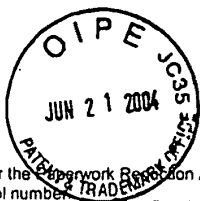
Examiner Signature	/Abigail Cotton/ (03/20/2007)	Date Considered	03/20/2007
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* Applicant's unique creation designation number (optional): * Applicant is to place a check mark here if English language translation is attached.
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		Application Number	10/660,202
		Filing Date	September 11, 2003
		First Named Inventor	Örn Almarsson
		Art Unit	
Examiner Name		Attorney Docket Number	TPI-350C1
Sheet	1	of	1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. 1	Document Number Number - Kind Code* (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	U1	US-			
	U2	US-			
	U3	US-			
	U4	US-			
	U5	US-			
	U6	US-			
	U7	US-			
	U8	US-			
	U9	US-			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. 1	Foreign Patent Document Country Code 3 - Number 4 - Kind Code* (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T*
/ACI/	F1	WO 02/056878 A2	07-25-2002	Pharmacia Corp.	All	---
/ACI/	F2	WO 01/41536 A2	06-14-2001	Pharmacia Corp.	All	---
/ACI/	F3	EP 1167355 A1	01-02-2002	Fako Iladani A.S.	All	---
	F4					
	F5					
	F6					
	F7					

Examiner Signature	/Abigail Cotton/ (03/20/2007)	Date Considered	03/20/2007
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Substitute for form 1449A/PTO		Complete if Known			
		Application Number	10/606,202		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Filing Date	September 11, 2003		
		First Named Inventor	Orn Almarsson		
		Art Unit	1653		
		Examiner Name			
Sheet	1	of	1	Attorney Docket Number	TPI-350C1

U.S. PATENT DOCUMENTS					
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		Country Code ³	Number ⁴ - Kind Code ⁵ (if known)			
IAC/	F1	WO	01/42221 A1	06-14-2001	Pharmacia Corp.	All
	F2					
	F3					
	F4					
	F5					
	F6					
	F7					

Examiner Signature	/Abigail Cotton/ (03/20/2007)	Date Considered	03/20/2007
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				Application Number	10/660,202
				Filing Date	September 11, 2003
				First Named Inventor	Örn Almarsson
				Art Unit	1617
				Examiner Name	Leonard Williams
Sheet	1	of	36	Attorney Docket Number	TPI-350C1

U.S. PATENT DOCUMENTS					
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/AC/	U1	US-2,711,411	06-21-1955	Holbert, <i>et al.</i>	All
	U2	US-4,198,507	04-15-1980	Barry, <i>et al.</i>	All
	U3	US-4,368,197	01-11-1983	Shefter, <i>et al.</i>	All
	U4	US-4,994,604	02-19-1991	Tung, <i>et al.</i>	All
	U5	US-5,177,262	01-15-1993	Taylor, <i>et al.</i>	All
	U6	US-5,332,834	07-26-1994	Bhattacharya, <i>et al.</i>	All
	U7	US-5,338,644	08-16-1994	Taylor, <i>et al.</i>	All
	U8	US-5,380,867	01-10-1995	Bhattacharya, <i>et al.</i>	All
	U9	US-5,412,094	05-02-1995	Amos, <i>et al.</i>	All
	U10	US-5,523,090	06-04-1996	Znaiden, <i>et al.</i>	All
	U11	US-5,614,342	03-25-1997	Molaire, <i>et al.</i>	All
	U12	US-5,998,413	12-07-1999	Heeres, <i>et al.</i>	All
	U13	US-6,001,996	12-14-1999	Amos, <i>et al.</i>	All
	U14	US-6,268,385	07-31-2001	Whittle, <i>et al.</i>	All
	U15	US-6,570,036	05-27-2003	Reuter	All
	U16	US-2003/0162226	08-28-2003	Cima, <i>et al.</i>	All
	U17	US-2003/0166581	09-04-2003	Almarsson, <i>et al.</i>	All
	U18	US-2003/0224006	12-04-2003	Zaworotko, <i>et al.</i>	All
✓	U19	US-2004/0019211	01-29-2004	Remenar, <i>et al.</i>	All
	U20	US-2004/0106052	06-03-2004	Molaire	All

Examiner Signature	/Abigail Cotton/ (03/20/2007)	Date Considered	03/20/2007
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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	10/660,202
				Filing Date	September 11, 2003
				First Named Inventor	Örn Almarsson
				Art Unit	1617
				Examiner Name	Leonard Williams
Sheet	2	of	36	Attorney Docket Number	TPI-350C1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/AC/	U21	US-2004/0106053	06-03-2004	Molaire, <i>et al.</i>	All
	U22	US-2004/0106055	06-03-2004	Molaire, <i>et al.</i>	All
	U23	US-2004/0171062	09-02-2004	Hirth, <i>et al.</i>	All
	U24	US-2004/0176335	09-09-2004	Childs	All
	U25	US-2005/0070551	03-31-1995	Remenar, <i>et al.</i>	All
	U26	US-2005/0181041	08-18-2005	Goldman	All
	U27	US-2005/0169982	08-04-2005	Almarsson, <i>et al.</i>	All
	U28	US-2005/0252649	11-17-2005	Chiu, <i>et al.</i>	All
	U29	US-2005/0256127	11-17-2005	Ku, <i>et al.</i>	All
	U30	US-6,559,293	05-06-2003	Almarsson, <i>et al.</i>	All
	U31	US-6,699,840	03-02-2004	Almarsson, <i>et al.</i>	All
	U32	US-2004-0053853	03-18-2004	Almarsson, <i>et al.</i>	All
	U33	US-2005/0070551 A1	03-31-2005	Remenar, <i>et al.</i>	All
	U34	US-2003/00224006	12-04-2003	Zaworotko <i>et al.</i>	All
	U35	US-3,536,809	04-09-1991	Schaller <i>et al.</i>	All
	U36	US-3,598,123	08-10-1971	Zaffaroni	All
	U37	US-3,845,770	11-05-1974	Theeuwes <i>et al.</i>	All
	U38	US-3,916,899	11-04-1975	Theeuwes <i>et al.</i>	All
	U39	US-4,008,719	02-22-1977	Theeuwes <i>et al.</i>	All
✓	U40	US-4,267,179	05-12-1981	Heeres <i>et al.</i>	All
	U41	US-4,764,604	08-16-1988	Muller	All

Examiner Signature	/Abigail Cotton/ (03/20/2007)	Date Considered	03/20/2007
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Substitute for form 1449A/PTO		Complete if Known			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/660,202		
		Filing Date	September 11, 2003		
		First Named Inventor	Örn Almarsson		
		Art Unit	1617		
		Examiner Name	Leonard Williams		
Sheet	3	of	36	Attorney Docket Number	TPI-350C1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/ACI	U42	US-4,916,134	04-10-1990	Heeres <i>et al.</i>	All
	U43	US-5,006,513	04-09-1991	Hector <i>et al.</i>	All
	U44	US-5,059,595	10-22-1991	Le Grazie	All
	U45	US-5,073,543	12-17-1991	Marshall <i>et al.</i>	All
	U46	US-5,120,548	06-09-1992	McClelland <i>et al.</i>	All
	U47	US-5,354,556	10-11-1994	Sparks <i>et al.</i>	All
	U48	US-5,414,997	05-16-1995	Tailer	All
	U49	US-5,474,997	12-12-1995	Gray <i>et al.</i>	All
	U50	US-5,591,767	01-07-1997	Mohr <i>et al.</i>	All
	U51	US-5,633,015	05-27-1997	Gillis <i>et al.</i>	All
	U52	US-5,639,476	06-17-1997	Oshlack <i>et al.</i>	All
	U53	US-5,661,151	08-26-1997	Saksena <i>et al.</i>	All
	U54	US-5,674,533	10-07-1997	Santus <i>et al.</i>	All
	U55	US-5,707,975	01-13-1998	Francois <i>et al.</i>	All
	U56	US-5,733,566	03-31-1998	Lewis	All
	U57	US-2003/0096014	05-22-2003	Sherman	All
	U58	US-4,513,006	04-23-1995	Maryanoff <i>et al.</i>	All
	U59	US-6,191,117	02-20-2001	Kozachuk	All
✓	U60	US-6,201,010	03-13-2001	Cottrell	All
	U61	US-5,753,693	05-19-1998	Shank	All

Examiner Signature	/Abigail Cotton/ (03/20/2007)	Date Considered	03/20/2007
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/660,202
		Filing Date	September 11, 2003
		First Named Inventor	Örn Almarsson
		Art Unit	1617
		Examiner Name	Leonard Williams
Sheet	4	of	36
		Attorney Docket Number	TPI-350C1

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/AC/	U62	US-5,998,380	12-07-1999	Ehrenberg <i>et al.</i>	All
	U63	US-6,319,903	11-20-2001	Carrazana <i>et al.</i>	All
	U64	US-5,935,933	08-10-1999	Shank <i>et al.</i>	All
	U65	US-5,760,007	06-02-1999	Shank <i>et al.</i>	All
	U66	US-5,952,187	09-14-1999	Stenglein <i>et al.</i>	All
	U67	US-5,242,942	09-07-1993	Costanzo <i>et al.</i>	All
	U68	US-5,384,327	01-24-1995	Costanzo <i>et al.</i>	All
	U69	US-6,071,537	06-06-2000	Shank	All
	U70	US-6,503,884	01-07-2003	Ehrenberg <i>et al.</i>	All
	U71	US-2003/0069190	04-10-2003	Abdel-Magid <i>et al.</i>	All
	U72	US-2002/0042446	04-11-2002	Dewey <i>et al.</i>	All
	U73	US-2002/0037925	03-28-2002	Dewey <i>et al.</i>	All
	U74	US-2003/0072802	04-17-2003	Cutler	All
	U75	US-6,488,962	12-03-2002	Berner <i>et al.</i>	All
	U76	US- 7,078,526	07-18-2006	Remenar <i>et al.</i>	All
	U77	US-6,294,192	9-25-2001	Patel <i>et al.</i>	All
	U78	US-5,466,823	11-14-1995	Talley <i>et al.</i>	All
	U79	US-4,008,321	02-15-1977	Kamishita <i>et al.</i>	All
✓	U80	US-4,853,379	08-01-1989	Shroot <i>et al.</i>	All
	U81	US-5,641,512	06-24-1997	Cimiluca	All

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			Art Unit	1617	
			Examiner Name	Leonard Williams	
Sheet	5	of	36	Attorney Docket Number	TPI-350C1

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IACI	U82	US-6,420,394 B1	07-16-2002	Supersaxo	All
IACI	U83	US-2003/0224006 A1	12-04-2003	Zaworotko <i>et al.</i>	All
	U84	US-			
	U85	US-			
	U86	US-			
	U87	US-			
	U88	US-			
	U89	US-			
	U90	US-			
	U91	US-			
	U92	US-			
	U93	US-			
	U94	US-			
	U95	US-			
	U96	US-			
	U97	US-			
	U98	US-			
	U99	US-			
	U100	US-			
	U101	US-			

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		Filing Date	September 11, 2003
		First Named Inventor	Örn Almarsson
		Art Unit	1617
		Examiner Name	Leonard Williams
Sheet	6	of	36
		Attorney Docket Number	TPI-350C1

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		Country Code ²	Number ⁴ - Kind Code ⁵ (if known)			
IAC	F1	EP	413528 B1	11-15-1995	Yu, R. et al.	All
	F2	EP	1364649 A1	11-26-2003	Cilag AG	All
	F3	WO	94/16733 A1	08-04-1994	Chiesi Farmaceutici S.P.A.	All
	F4	WO	96/07331 A1	03-14-1996	Xyrofin Oy	All
	F5	WO	98/57967 A1	12-23-1998	Dong-A Pharmaceutical Co., Ltd.	All
	F6	WO	2000/53283 A1	09-14-2000	Reuter Chemische Apparatebau KG	All
	F7	WO	2001/13904 A2	03-01-2001	Ortho-McNeil Pharmaceutical, Inc.	All
	F8	JP	54-16494	02-07-1979	Yamanouchi Pharmaceutical Co., Ltd.	All
	F9	WO	00/50020 A2	08-31-2000	University of Cincinnati	All
	F10	FR	769,586	06-11-1934	Chemische Fabrik von Heyden	All
	F11	IT	01303251	11-06-2000	Industriale Chimica, S.R.L.	All
	F12	WO	2001/97853 A1	12-27-2001	Biochemie Gesellschaft MBH	All
	F13	EP	0310122 B1	04-05-1989	Kaken Pharma	All
	F14	WO	2002/062318 A2	08-15-2002	DSM N.V.	All
	F15	EP	0283992 B1	09-16-1992	Janssen Pharma	All
	F16	WO	2003/101392 A2	12-11-2003	Transform Pharmaceuticals, Inc.	All
	F17	WO	2004/054571 A1	07-01-2004	Cilag AG	All
↓	F18	WO	2004/078161 A1 (CD-ROM)	09-16-2004	Transform Pharmaceuticals, Inc.	All
	F19	WO	2004/078163 A2 (CD-ROM)	09-16-2004	Transform Pharmaceuticals, Inc.	All

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				Application Number	10/660,202
				Filing Date	September 11, 2003
				First Named Inventor	Örn Almarsson
				Group Art Unit	1617
				Examiner Name	Leonard Williams
				Attorney Docket Number	TPI-350C1
Sheet	7	of	36		

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		Country Code ³	- Number ⁴ - Kind Code ⁵ (if known)			
/AC/	F20		WO 2004/089313 A2	10-21-2004	Transform Pharmaceuticals, Inc.	All
	F21		WO 2005/023198 A2 (CD-ROM)	03-17-2005	Transform Pharmaceuticals, Inc.	All
	F22		WO 2005/037424 A1	04-28-2005	Salvias AG	All
	F23		WO 2005/055983 A2	06-23-2005	Medcrystalforms, LCC	All
	F24		WO 2005/060968 A1 (CD-ROM)	07-07-2005	Sepracor, Inc.	All
	F25		WO 2005/089375 A2 (CD-ROM)	09-29-2005	S.S.C.I., Inc.	All
	F26		WO 2005/094804 A1	10-13-2005	The Regents of the University of Michigan	All
	F27		WO 2006/024930 A1	03-09-2006	Pharmacia and Upjohn Co., LCC	All
	F28		WO 03/070738 A2	08-28-2003	Transform Pharmaceuticals, Inc.	All
	F29		WO 03/074474 A2	09-12-2003	Univ. South Fl	All
	F30		WO 95/17407 A1	06-29-1995	Schering Corp	All
	F31		WO 00/07583 A2	02-17-2000	Brookhaven Science Associates	All
	F32		WO 00/72841 A1	12-07-2000	Berlant, Jeffrey	All
	F33		WO 03 033462 A2	04-23-2003	Regents of Univ. Mich.	All
	F34		WO 01 51919 A2	07-19-2001	Transform Pharm. Inc.	All
	F35		WO 01 42222 A1	06-14-2001	Pharmacia Corp.	All
	F36		WO 95/23596 A1	09-08-1995	The Boots Co.	All
	F37		WO 00/32189 A1	06-08-2000	G. D. Searle & Co.	All
	F38		WO 01/41760 A3	06-14-2001	Pharmacia Corporation	All
	F39		WO 01/78724 A1	10/25/2001	Pharmacia Corporation	All
V	F40		WO 01/91750 A1	12/06/2001	Pharmacia Corporation	All
	F41		WO 02/00627 A1	01/03/2002	Fako Ilacari A.S.	All
	F42		IN 182620	12-24-1994	Bajaj et al.	All

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		Filing Date	September 11, 2003
		First Named Inventor	Örn Almarsson
		Group Art Unit	1617
		Examiner Name	Leonard Williams
		Attorney Docket Number	TPI-350C1
Sheet	8	of	36

NON PATENT LITERATURE DOCUMENTS			
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IAC/ ↓	R1	AAKERÖY, C. <i>et al.</i> "Crystal engineering of hydrogen-bonded assemblies- a progress report" <i>Aust. J. Chem.</i> , 2001, pp. 409-421, Vol. 54.	
	R2	BINGHAM, A. <i>et al.</i> "Over one hundred solvates of sulfathiazole" <i>Chem. Commun.</i> , 2001, pp. 603-604.	
	R3	BYRIEL, K., <i>et al.</i> "Molecular cocrystals of carboxylic acids. IX Carboxylic acid interactions with organic heterocyclic bases. The crystal structures of the adducts of (2,4-dichlorophenoxy) acetic acid with 3-hydroxypyridine, 2,4,6-trinitrobenzoic acid with 2-aminopyrimidine, and 4-nitrobenzoic acid with 3-amino-1,2,4-triazole" <i>Aust. J. Chem.</i> , 1992, pp. 969-981, Vol. 45, No. 6.	
	R4	SALMON, J. <i>et al.</i> "Supramolecular chemistry of boronic acids (Abstract)" 38 th Midwest Regional Meeting of the American Chemical Society in Columbia, MO., November 5-7, 2003, published by the American Chemical Society, Washington, D.C.	
	R5	URBINA, J. <i>et al.</i> "Supramolecular design of inorganic/organic networks using flexible ligands with self-complementary hydrogen bonds (Abstract)" 38 th Midwest Regional Meeting of the American Chemical Society in Columbia, MO., November 5-7, 2003, published by the American Chemical Society, Washington, D.C.	

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IAC/	R6	SMITH, D. <i>et al.</i> "Structure confirmation by single crystal X-ray diffraction of a series of new schiff bases and theoretical computations on 3-(N-2- α , α -trifluorotoluyldiene amino) tetrahydrothiophene-1, 1-dioxide (Abstract)" 216 th ACS National Meeting in Boston, MA., August 23-27, 1998, published by the American Chemical Society, Washington, D.C.	
	R7	DESIRAJU, G. "Supramolecular synthons in crystal engineering- A new organic synthesis" <i>Angew. Chem. Int. Ed. Engl.</i> , 1995, pp. 2311-2327, Vol. 34.	
	R8	FRITCHIE, C. <i>et al.</i> "The configuration of phenothiazine in various molecular complexes" <i>Chem. Commun.</i> , 1968, pp. 833-834.	
	R9	HUANG, C.-M. <i>et al.</i> "Molecular packing modes. Part XI. Crystal structures of the 2:1 complexes of benzamide with succinic acid and furamide with oxalic acid" <i>J. Chem. Soc. Perkins Trans. 2: Physical Organic Chemistry</i> , 1973, pp. 503-508, Vol. 5.	
	R10	JACKISCH, M. <i>et al.</i> "Structures of three related biphenyl compounds: 4,4'-biphenyldiol, 3, 3', 5, 5'-tetra- <i>tert</i> -butyl-4,4'-biphenyldiol, and 3,3', 5, 5'- tetra- <i>tert</i> -butyl-1,1'-bicyclohexa-2,5-dienyldiene-4,4'-dione" <i>Acta Cryst.</i> , 1990, pp. 919-922, Vol. C46.	
	R11	KIM, S. <i>et al.</i> "The structure of a crystalline complex containing one phenobarbital molecule and two adenine derivatives" <i>Proc. Natl. Acad. Sci. USA</i> , 1968, pp. 402-408, Vol. 60.	
	R12	KOBAYASHI, H. <i>et al.</i> "Sinusoidal structure of the 1:1 complex of phenothiazine and 7,7,8,8-tetracyanoquinodimethane, PTZ-TCNQ" <i>Acta Cryst.</i> , 1974, pp. 1010-1017, Vol. B30.	
	R13	ERMER, O. <i>et al.</i> "Molecular recognition among alcohols and amines: super-tetrahedral crystal architectures of linear diphenol-diamine complexes and aminophenols" <i>J. Chem. Soc. Perkins Trans. 2</i> , 1994, pp. 925-944.	
	R14	MARTIN, R. <i>et al.</i> "Polyphenal-caffeine complexation" <i>J. Chem. Soc., Chem. Commun.</i> , 1986, pp. 105-106.	
✓	R15	LEHN, J.-M. <i>et al.</i> "Molecular recognition directed self-assembly of ordered supramolecular strands by cocrystallization of complementary molecular components" <i>Chem. Soc., Chem. Commun.</i> , 1990, pp. 479-481.	

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IAC/	R16	LYNCH, D. <i>et al.</i> "Molecular cocrystals of carboxylic acids. XV. Preparation and characterization of heterocyclic base adducts with a series of carboxylic acids, and the crystal structures of the adducts of 2-aminopyrimidine with 2,6-dihydroxybenzoic acid, 4-aminobenzoic acid, phenoxycetic acid, (2,4-dichlorophenoxy) acetic acid, (3,4-dichlorophenoxy)-acetic acid and salicylic acid, and 2-aminopyridine with 2,6-dihydroxybenzoic acid" <i>Aust. J. Chem.</i> , 1994, pp. 1097-1115, Vol. 47.	
	R17	MCINTOSH, J. <i>et al.</i> "Chemotherapeutic drugs in anaerobic infections of wounds" <i>The Lancet</i> , June 26, 1943, pp. 793-795.	
	R18	MCINTOSH, J. <i>et al.</i> "Zinc peroxide, proflavine and penicillin in experimental <i>cl. welchii</i> infections" <i>The Lancet</i> , December 26, 1942, pp. 750-752.	
	R19	SMITH, G. <i>et al.</i> "Molecular cocrystals of carboxylic acids. XXI. The role of secondary group interactions in adduct formation between 2-aminopyrimidine and substituted benzoic acids: the crystal structures of the adducts with <i>o</i> -phthalic acid, <i>o</i> -nitrobenzoic acid, <i>o</i> -aminobenzoic acid and <i>m</i> -aminobenzoic acid" <i>Aust. J. Chem.</i> , 1995, pp. 1151-1166, Vol. 48.	
	R20	WEISSBUCH, I. <i>et al.</i> "Crystal morphology control with tailor-made additives; a stereochemical approach" <i>Advances in Crystal Growth Research</i> , 2001, pp. 381-400.	
	R21	MCMAHON, J. <i>et al.</i> "Crystal engineering of the composition of pharmaceutical phases. 3'. Primary amide supramolecular heterosynthons and their role in the design of pharmaceutical co-crystals" <i>Z. Kristallogr.</i> , 2005, pp. 340-350, Vol. 220.	
	R22	MEEJOO, S. <i>et al.</i> "The interplay of aryl-perfluoroaryl stacking interactions and interstack hydrogen bonding in controlling the structure of a molecular cocrystal" <i>Chemphyschem</i> , 2003, pp. 766-769, Vol. 4.	
	R23	MIRMEHRABI, M. <i>et al.</i> "Improving the filterability and solid density of ranitidine hydrochloride form 1" <i>Journal of Pharmaceutical Sciences</i> , July 2004, pp. 1692-1700, Vol. 93, No. 7.	
	R24	MORRIS, K. <i>et al.</i> "Theoretical approaches to physical transformations of active pharmaceutical ingredients during manufacturing processes" <i>Advanced Drug Delivery Reviews</i> , 2001, pp. 91-114, Vol. 48.	

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		Group Art Unit	1617
		Examiner Name	Leonard Williams
		Attorney Docket Number	TPI-350C1
Sheet	11	of	36

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IACI	R25	NAKANISHI, I. <i>et al.</i> "X-ray structural studies on two forms of β -cyclodextrin barbitol complexes" <i>Journal of Inclusion Phenomena</i> , 1984, pp. 689-699, Vol. 2.	
	R26	NAKAO, S. <i>et al.</i> "The crystal and molecular structure of the 2:1 molecular complex of theophylline with phenobarbital" <i>Acta Cryst.</i> , 1977, pp. 1373-1378, Vol. B33.	
	R27	NATARAJAN, S. <i>et al.</i> "Reinvestigation of the crystal structure of diglycine hydrochloride" <i>Zeitschrift für Kristallographie</i> , 1992, pp. 265-270, Vol. 198.	
	R28	OLENIK, B. <i>et al.</i> "Cooperative and anticooperative effects in the cocrystals of mono- and diazanaphthalenes with meso-1, 2-diphenyl-1,2-ethanediol" <i>Crystal Growth & Design</i> , 2003, pp. 175-181, Vol. 3, No. 2.	
	R29	OLENIK, B. <i>et al.</i> "Supramolecular synthesis by cocrystallization of oxalic and fumaric acid with diazanaphthalenes" <i>Crystal Growth & Design</i> , 2003, pp. 183-188, Vol. 3, No. 2.	
	R30	GROTH, P. "d-Glucose-sodium chloride-monohydrate (glucose-sodium chloride) = $2C_6H_{12}O_6 \cdot NaCl \cdot H_2O$ " <i>Chemische Kristallographie</i> , 1910, pp. 438-439.	X
	R31	OSWALD, I. <i>et al.</i> "Rationalisation of co-crystal formation through knowledge-mining" <i>Crystallography Reviews</i> , 2004, pp. 57-66, Vol. 10, No. 1.	
	R32	OUYANG, X. <i>et al.</i> "Single-crystal-to-single-crystal topochemical polymerizations of a terminal diacetylene: two remarkable transformations give the same conjugated polymer" <i>J. Am. Chem. Soc.</i> , 2003, pp. 12400-12401, Vol. 125.	
	R33	PATEL, U. <i>et al.</i> "Structure of the 1:1 complex between 4-amino-N-(4,6-dimethyl-2-pyrimidinyl)- benzenesulfonamide (sulfadimidine) and 2-hydroxybenzoic acid (salicylic acid)" <i>Acta Cryst.</i> , 1988, pp. 1264-1267, Vol. C44.	
	R34	REDDY, L. <i>et al.</i> "Phenyl-perfluorophenyl synthon mediated cocrystallization of carboxylic acids and amides" <i>Crystal Growth & Design</i> , 2004, pp. 89-94, Vol. 4, No. 1.	
	R35	REMENAR, J. <i>et al.</i> "Crystal engineering of novel cocrystals of a triazole drug with 1,4-dicarboxylic acids" <i>J. Am. Chem. Soc.</i> , 2003, pp. 8456-8457, Vol. 125.	

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/AC/	R36	SCHMIDT, G. "Photodimerization in the solid state" <i>Pure Appl. Chem.</i> , 1971, pp. 647-678, Vol. 27.	
	R37	SHAN, N. <i>et al.</i> "Co-crystal of 4,7-phenanthroline and carboxylic acids: synthon competition and prediction" <i>Tetrahedron Letters</i> , 2002, pp. 8721-8725, Vol. 43.	
	R38	SHAN, N. <i>et al.</i> "Crystal engineering using 4,4'-bipyridyl with di- and tricarboxylic acids" <i>Crystal Engineering</i> , 2002, pp. 9-24, Vol. 5.	
	R39	SHAN, N. <i>et al.</i> "Supramolecular synthons in the co-crystal structures of 2-aminopyrimidine with diols and carboxylic acids" <i>Tetrahedron Letters</i> , 2002, pp. 3101-3104, Vol. 43.	
	R40	MCINTOSH, J. <i>et al.</i> "Further observations on the chemotherapy of experimental gas gangrene: flavazole, marfanil, V187 and V335" <i>British Journal of Experimental Pathology</i> , 1946, pp. 46-54, Vol. 27.	
	R41	SHAVIV, R. <i>et al.</i> "Magnetochemistry of the tetrahaloferrate (III) ions 6. Crystal structure and magnetic ordering in [(pyH) ₃ Cl] [FeCl ₄] ₂ " <i>Inorganica Chimica Acta</i> , 1992, pp. 613-621, Vol. 198-200.	
	R42	SHEFTER, E. "Structural studies on complexes IV: Crystal structure of a 1:1 5-chlorosalicylic acid and theophylline complex" <i>Journal of Pharmaceutical Sciences</i> , 1969, pp. 710-714, Vol. 58.	
	R43	SHIMIZU, N. <i>et al.</i> "Structure of 2,4-diamino-5-(3,4,5-trimethoxybenzyl) pyrimidine-5,5-diethylbarbituric acid (1:1)" <i>Acta Cryst.</i> , 1982, pp. 2309- 2311, Vol. B38.	
	R44	SINGH, N. B. <i>et al.</i> "Solid state reaction between 8-hydroxyquinoline and <i>p</i> -nitrobenzoic acid" <i>Indian Journal of Chemistry</i> , May 1988, pp. 429-432, Vol. 37B.	
	R45	SMITH, G. <i>et al.</i> "The 1:1 adduct of 4-aminobenzoic acid with 4-aminobenzonitrile" <i>Acta Cryst.</i> , 2000, pp. 1155-1156, Vol. C56.	

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IACI	R46	STEINER, T. "Donor and acceptor strengths in C-H...O hydrogen bonds quantified from crystallographic data of small solvent molecules" <i>New. J. Chem.</i> , 1998, pp. 1099-1103.	
	R47	STOREY, R. et al. "Automation of solid form screening procedures in the pharmaceutical industry- how to avoid the bottlenecks" <i>Crystallography Reviews</i> , 2004, pp. 45-56, Vol. 10, No. 1.	
	R48	SZAFRAN, M. et al. "Molecular structures and hydrogen bonding in the 1:1 and 1:2 complexes of pyridine betaine with 2,6-dichloro-4-nitrophenol; an example of strongly coupled hydrogen bonds, O-H...O=C-O-H...O-" <i>Journal of Molecular Structure</i> , 1997, pp. 145-160, Vol. 416.	
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		Application Number	10/660,202
		Filing Date	September 11, 2003
		First Named Inventor	Örn Almarsson
		Group Art Unit	1617
		Examiner Name	Leonard Williams
		Attorney Docket Number	TPI-350C1

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/ACI/	R56	TRASK, A. <i>et al.</i> "Crystal engineering of organic cocrystals by the solid-state grinding approach" <i>Top Curr. Chem.</i> , 2005, pp. 41-70, Vol. 254.	
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	R58	TRASK, A. <i>et al.</i> "Solvent-drop grinding: green polymorph control of cocrystallisation" <i>Chem. Commun.</i> , 2004, pp. 890-891 in addition to supplemental materials.	
	R59	TROWBRIDGE, L. <i>et al.</i> "Composites for nonlinear optics: Crystal growth and polymorphism" <i>University of Sussex, Falmer Brighton UK, School of Chemistry and Molecular Sciences</i> , pp. 272.	
	R60	UNO, T. <i>et al.</i> "Structure of 5,5-diphenylhydantoin-1- (4-bromophenyl)-4-dimethylamino-2,3-dimethyl-3-pyrazolin-5-one (1:1)" <i>Acta Cryst.</i> , 1980, pp. 2794-2796, Vol. B36.	
	R61	VAN ROEY, P. <i>et al.</i> "Structure-activity studies of non-steroidal aromatase inhibitors: the crystal and molecular structures of CGS 16949A and CGS 18320B" <i>J. Enzyme Inhibition</i> , 1991, pp. 119-132, Vol. 5.	
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/AQ/	R67	VOET, D. <i>et al.</i> "The crystal and molecular structure of the intermolecular complex 9-ethyladenine-5, 5-diethylbarbituric acid" <i>Journal of the American Chemical Society</i> , November 15, 1972, pp. 8213-8222, Vol. 94, No. 23.	
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IAC	R78	ZERKOWSKI, J. <i>et al.</i> "Investigations into the robustness of secondary and tertiary architecture of hydrogen-bonded crystalline tapes" <i>Chem. Mater.</i> , 1994, pp. 1250-1257, Vol. 6.	
	R79	ZERKOWSKI, J. <i>et al.</i> "New varieties of crystalline architecture produced by small changes in molecular structure in tape complexes of melamines and barbiturates" <i>J. Am. Chem. Soc.</i> , 1994, pp. 4305-4315, Vol. 116.	
	R80	ZERKOWSKI, J. <i>et al.</i> "Polymorphic packing arrangements in a class of engineered organic crystals" <i>Chem. Mater.</i> , 1997, pp. 1933-1941, Vol. 9.	
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✓	R88	AAKERÖY, C. <i>et al.</i> "Crystal engineering of ionic solids" <i>Modular Chemistry</i> (ed. by Michl, J.), 1997, pp. 153-162, Kluwer Academic Publishers, The Netherlands.	✓

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/ACI	R89	AAKERÖY, C. <i>et al.</i> "Crystal engineering: strategies and architectures" <i>Acta Cryst.</i> , 1997, pp. 569-586, Vol. B53.	
	R90	AAKERÖY, C. <i>et al.</i> "Crystal engineering using intermolecular hydrogen-bonded connectors and classic coordination chemistry" <i>Transactions ACA</i> , 1998, pp. 97-103, Vol. 33.	
	R91	AAKERÖY, C. <i>et al.</i> "The crystal structure of the molecular cocrystal L-malic acid L-tartaric acid (1/1)" <i>Supramolecular Chemistry</i> , 1996, pp. 153-156, Vol. 7.	
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✓	R99	AAKERÖY, C. <i>et al.</i> "Hydrogen-bonding in solids" <i>Crystal Engineering</i> (ed. by Seddon, K. R. <i>et al.</i>), 1999, pp. 303-324, Kluwer Academic Publishers, The Netherlands.	✓
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/AC/	R100	AAKERÖY, C. <i>et al.</i> "Low-dimensional architectures of silver coordination compounds assembled via amide-amide hydrogen bonds" <i>Crystal Engineering</i> , 1998, pp. 39-49, Vol. 1, No. 1.	
	R101	AAKERÖY, C. <i>et al.</i> "Molecular mechanics and crystal engineering" <i>Crystal Engineering</i> (ed. by Seddon, K. R. <i>et al.</i>), 1999, pp. 69-82, Kluwer Academic Publishers, The Netherlands.	
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	R107	AAKERÖY, C. <i>et al.</i> "Supramolecular assembly of low-dimensional silver (I) architectures via amide-amide hydrogen bonds" <i>Chem. Commun.</i> , 1998, pp. 1067-1068.	
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✓	R109	AAKERÖY, C. <i>et al.</i> "Two-fold interpenetration of 3-D nets assembled via three-co-ordinate silver(I) ions and amide-amide hydrogen bonds" <i>J. Chem. Soc., Dalton Trans.</i> , 1998, pp. 1943-1945.	
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		Group Art Unit	1617
		Examiner Name	Leonard Williams
		Attorney Docket Number	TPI-350C1
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IACI	R111	AKAZOME, M. <i>et al.</i> "Enantioselective inclusion of methyl phenyl sulfoxides and benzyl methyl sulfoxides by (R)-phenylglycyl-(R)-phenylglycine and the crystal structures of the inclusion cavities" <i>J. Org. Chem.</i> , 2000, pp. 68-76, Vol. 65.	
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	R113	ALLEN, F. <i>et al.</i> "Systematic analysis of structural data as a research technique in organic chemistry" <i>Acc. Chem. Res.</i> , 1983, pp. 146-153, Vol. 16.	
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	R121	BERKOVITCH-YELLIN, Z. <i>et al.</i> "The role played by C-H...O and C-H...N interactions in determining molecular packing and conformation" <i>Acta Cryst.</i> , 1984, pp. 159-165, Vol. B40.	
✓	R122	BERL, V. <i>et al.</i> "Induced fit selection of a barbiturate receptor from a dynamic structural and conformational/configurational library" <i>Eur. J. Org. Chem.</i> , 1999, pp. 3089-3094.	✓
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/AC/	R123	BERTOLASI, V. <i>et al.</i> "Competition between hydrogen bonding and donor-acceptor interactions in co-crystals of 1,3-dimethylbarbituric acid with aromatic amines" <i>New J. Chem.</i> , 2001, pp. 408-415, Vol. 25.	
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	R125	BETTINETTI, G. <i>et al.</i> "Structure and solid-state chemistry of anhydrous and hydrated crystal forms of the trimethoprim-sulfamethoxypyridazine 1:1 molecular complex" <i>Journal of Pharmaceutical Sciences</i> , April 2000, pp. 478-489, Vol. 89, No. 4.	
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	R127	BETTIS, J. <i>et al.</i> "Biopharmaceutics and dosage form design" <i>Amer. J. Hosp. Pharm.</i> , March 1973, pp. 240-243, Vol. 30.	
	R128	BOLTON, S. <i>et al.</i> "Complexes formed in solution by homologs of caffeine" <i>Journal of the American Pharmaceutical Association</i> , January 1957, pp. 38-41, Vol. XLVI, No. 1.	
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	R133	BRAGA, D. <i>et al.</i> "Hydrogen bonding interactions between ions: a powerful tool in molecular crystal engineering" <i>Structure and Bonding</i> , 2004, pp. 1-32, Vol. 111.	
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/AC/	R135	BURGI, H. <i>et al.</i> "Crystallisation of supramolecular materials" <i>Current Opinion in Solid State & Materials Science</i> , 1998, pp. 425-430, Vol. 3.	
	R136	BYRN, S. R. <i>et al.</i> "Solid-state pharmaceutical chemistry" <i>Chem. Mater.</i> , 1994, pp. 1148-1158, Vol. 6.	
	R137	CAIRA, M. "Molecular complexes of sulfonamides. Part 1. 1:1 complexes between sulfadimidine [4-amino-N-(4,6-dimethyl-2-pyrimidinyl) benzenesulfonamide] and 2- and 4-aminobenzoic acids" <i>Journal of Crystallographic and Spectroscopic Research</i> , 1991, pp. 641-648, Vol. 21, No. 5.	
	R138	CAIRA, M. "Molecular complexes of sulfonamides. Part 2. 1:1 complexes between drug molecules: sulfadimidine-acetylsalicylic acid and sulfadimidine-4-aminosalicylic acid" <i>Journal of Crystallographic and Spectroscopic Research</i> , 1992, pp. 193-200, Vol. 22, No. 2.	
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	R141	CAIRA, M. <i>et al.</i> "Selective formation of hydrogen bonded cocrystals between a sulfonamide and aromatic carboxylic acids in the solid state" <i>J. Chem. Soc. Perkin Trans. 2</i> , 1995, pp. 2213-2216.	
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/AC/	R146	CHINNAKALI, K. <i>et al.</i> "2-aminopyrimidine and <i>p</i> -phenylene-diacetic acid (1:1) co-crystal" <i>Acta Cryst.</i> , 1999, pp. 399-401, Vol. C55.	
	R147	CHOI, C. <i>et al.</i> "Cocrystallization of melaminium levulinate monohydrate" <i>Acta Cryst.</i> , 2004, pp. o295-o296, Vol. C60.	
	R148	CHOW, Y. P. <i>et al.</i> "Complexation of acetaminophen with methyl xanthenes" <i>Journal of Pharmaceutical Sciences</i> , 1972, pp. 1454-1458, Vol. 61.	
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	R153	CRAVEN, M. <i>et al.</i> "The 2:1 crystal complex of 5, 5-diethylbarbituric acid (barbital) and caffeine" <i>Acta Cryst.</i> , 1974, pp. 1191-1195, Vol. B30.	
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✓	R155	CUDNEY, B. <i>et al.</i> "Screening and optimization strategies for macromolecular crystal growth" <i>Acta Cryst.</i> , 1994, pp. 414-423, Vol. D50.	✓
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/ACI	R156	DATTA, S. <i>et al.</i> "Molecular complex formation between riboflavin and salicylate in an aqueous medium" <i>Bull. Chem. Soc. Jpn.</i> , 2003, pp. 1729-1734, Vol. 76.	
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		Application Number	10/660,202
		Filing Date	September 11, 2003
		First Named Inventor	Örn Almarsson
		Group Art Unit	1617
		Examiner Name	Leonard Williams
		Attorney Docket Number	TPI-350C1

NON PATENT LITERATURE DOCUMENTS			
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/AC/	R167	ETTER, M. "Encoding and decoding hydrogen-bond patterns of organic compounds" <i>Acc. Chem. Res.</i> , 1990, pp. 120-126, Vol. 23.	
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NOVARTIS EXHIBIT 1023

Novartis v. Regents, IPR2023-01346

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		Group Art Unit	1617
		Examiner Name	Leonard Williams
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		Attorney Docket Number	TPI-350C1

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IAC/	R179	GAO, X. <i>et al.</i> "Supramolecular construction of molecular ladders in the solid state" <i>Angew. Chem. Int. Ed.</i> , 2004, pp. 232-236, Vol. 43.	
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NOVARTIS EXHIBIT 1023

Novartis v. Regents, IPR2023-01346

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		Group Art Unit	1617
		Examiner Name	Leonard Williams
		Attorney Docket Number	TPI-350C1

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/AC/	R189	HENCK, J. <i>et al.</i> "Disappearing and reappearing polymorphs. The benzocaine:picric acid system" <i>J. Am. Chem. Soc.</i> , 2001, pp. 1834-1841, Vol. 123.	
	R190	HIGUCHI, T. <i>et al.</i> "Complexation of organic substances in aqueous solution by hydroxyaromatic acids and their salts" <i>J. Pharm. Sci.</i> , 1961, pp. 905-909, Vol. 50.	
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/AC/	R200	ISHIDA, T. <i>et al.</i> "Structural study of histamine H ₂ -receptor antagonists. Five 3-[2-(diamino-methyleneamino)-4-thiazolymethylthio] propionamidine and -amide derivatives" <i>Acta Cryst.</i> , 1989, pp. 505-512, Vol. B45.			
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	R206	KIRYU, S. <i>et al.</i> "Crystal structure of a 1:1 aminopyrine-barbital complex" <i>Journal of Pharmaceutical Sciences</i> , May 1971, pp. 699-703, Vol. 60, No. 5.			
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✓	R210	KOSHIMA, H. <i>et al.</i> "Polymorphs of a cocrystal with achiral and chiral structures prepared by pseudoseeding: tryptamine/hydrocinnamic acid" <i>Crystal Growth & Design</i> , 2001, pp. 355-357, Vol. 1, No. 5.		✓	
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IACI	R211	KRISHNAMOHAN SHARMA, C. V. <i>et al.</i> "X-ray crystal structure of C ₆ H ₃ (CO ₂ H) ₃ -1,3,5-1.5(4,4'-bipy): a 'super trimesic acid' chicken-wire grid" <i>Chem. Commun.</i> , 1996, pp. 2655-2656.	
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↓	R221	ANDERSON, J. "Constitution of aurous compounds: Gold mirrors" <i>Nature</i> , October 2, 1937, pp. 583-584, Letters to the Editor.	↓
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		Application Number	10/660,202
		Filing Date	September 11, 2003
		First Named Inventor	Örn Almarsson
		Group Art Unit	1617
		Examiner Name	Leonard Williams
		Attorney Docket Number	TPI-350C1

NON PATENT LITERATURE DOCUMENTS			
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IAC	R222	ROBBINS, A. H. <i>et al.</i> "The crystal structure of the 1:2 adduct of potassium triiodide and 5,5-diethylbarbituric acid (barbital)" <i>American Crystallographic Association- Series 2, Papers and Abstracts</i> , 1973, p. 87.	
	R223	BEERGES, P. <i>et al.</i> "Phenothiazine tetracyanoethylene" <i>Private Communication</i> , 1994.	
	R224	MADARASZ, J. <i>et al.</i> "Thermal, fir and xrd study on some 1:1 molecular compounds of theophylline" <i>Journal of Thermal Analysis and Calorimetry</i> , 2002, pp. 281-290, Vol. 69.	
	R225	CARONNA, T. <i>et al.</i> "Halogen bonding and $\pi\cdots\pi$ stacking control reactivity in the solid state" <i>J. Am. Chem. Soc.</i> , 2004, pp. 4500-4501, Vol. 126.	
	R226	ZERKOWSKI, J. <i>et al.</i> "Steric control of secondary, solid-state architecture in 1:1 complexes of melamines and barbiturates that crystallize as crinkled tapes" <i>J. Am. Chem. Soc.</i> , 1994, pp. 4298-4304, Vol. 116.	
	R227	ZAITU, S. <i>et al.</i> "1:1 Molecular complex of theophylline and <i>p</i> -nitroaniline" <i>Acta Cryst.</i> , 1995, pp. 2390-2392, Vol. C51.	
	R228	KOFLER, L. <i>et al.</i> , <i>Thermal micromethods for the study of organic compounds and their mixtures</i> , pp. 1-145, 148-351, 354-386, Innsbruck, Austria, 1980.	
	R229	QUEHENBERGER, H. "Concerning organic molecular compounds and their polymorphism" <i>Monatshefte für Chemie</i> , 1949, pp. 595-606, Vol. 80, No. 5.	K
	R230	WIEDENFELD, H. <i>et al.</i> "The crystal structure of the theophylline-urea complex" <i>Arch. Pharm.</i> , 1986, pp. 654-659, Vol. 319.	K
	R231	BUNICK, G. <i>et al.</i> "The crystal and molecular structure of the complex 2,6-diamino-9-ethylpurine 5,5-diethylbarbituric acid" <i>American Crystallographic Association, Abstract Papers</i> Winter 1976, p. 30.	
↓	R232	BUCZAK, G. <i>et al.</i> "Crystal structure and vibrational spectra of the 1:1 and 1:2 complexes of pyridine betaine with pentachlorophenol" <i>Journal of Molecular Structure</i> , 1997, pp. 143-151, Vol. 436-437.	✓

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		First Named Inventor	Örn Almarsson
		Group Art Unit	1617
		Examiner Name	Leonard Williams
Sheet	23	of	36
		Attorney Docket Number	TPI-350C1

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IAC/	R233	TOMURA, M. <i>et al.</i> "One-dimensional zigzag chain structures with intermolecular C-H... π and C-H...O interactions consisted of phthalic acid and pyridine derivatives" <i>Chemistry Letters</i> , 2001, pp. 532-533.	
	R234	ZERKOWSKI, J. <i>et al.</i> "Design of organic structures in the solid state: molecular tapes based on the network of hydrogen bonds present in the cyanuric acid-melamine complex" <i>J. Am. Chem. Soc.</i> , 1994, pp. 2382-2391, Vol. 116.	
	R235	HARKEMA, S. <i>et al.</i> "The crystal structure of urea oxalic acid (2:1)" <i>Acta Cryst.</i> , 1972, pp. 1646-1648, Vol. B28.	
	R236	KRANTZ, J. <i>et al.</i> "Sodium theophylline glycinate" <i>Journal of the American Pharmaceutical Association</i> , 1946, pp. 248-250.	
	R237	DATTA, S. <i>et al.</i> "Crystal structures of drugs: advances in determination, prediction and engineering" <i>Nature</i> , January 2004, pp. 42-57, Vol. 3.	
	R238	AAKERÖY, C. <i>et al.</i> "Charge-assisted hydrogen bonds and halogen-halogen interactions in organic salts: benzylammonium benzoates and pentafluorobenzoates" <i>Structural Chemistry</i> , 1999, pp. 229-242, Vol. 10, No. 3.	
	R239	CHILDS, S. <i>et al.</i> "Crystal engineering approach to forming cocrystals of amine hydrochlorides with organic acids. Molecular complexes of fluoxetine hydrochloride with benzoic, succinic, and fumaric acids" <i>J. Am. Chem. Soc.</i> , 2004, pp. 13335-13342, Vol. 126.	
	R240	AAKERÖY, C. <i>et al.</i> "Modular supramolecular synthesis based on a dominance hierarchy of intermolecular interactions (Abstract)" 223 rd ACS National Meeting in Orlando, FL., April 7-11, 2002, published by the American Chemical Society, Washington, D.C.	
	R241	HELFRICH, B. <i>et al.</i> "Polymorphism as an indication of structural versatility (Abstract)" 223 rd ACS National Meeting in Orlando, FL., April 7-11, 2002, published by the American Chemical Society, Washington, D.C.	
✓	R242	WEBER, E. <i>et al.</i> "Synthesis of new Schiff bases: reaction of monofluorobenzaldehydes with 3-aminosulfolane hydrochloride (Abstract)" 216 th ACS National Meeting in Boston, MA., August 23-27, 1998, published by the American Chemical Society, Washington, D.C.	✓

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		Filing Date	September 11, 2003
		First Named Inventor	Örn Almarsson
		Group Art Unit	1617
		Examiner Name	Leonard Williams
		Attorney Docket Number	TPI-350C1

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IACI	R243	SCARBROUGH, F. <i>et al.</i> "Crystal structure of a complex between lumiflavin and 2,6-diamino-9-ethylpurine: a flavin adenine dinucleotide model exhibiting charge-transfer interactions" <i>Proc. Natl. Acad. Sci. USA</i> , November 1976, pp. 3807-3811, Vol. 73, No. 11.	
	R244	MUNN, R. <i>et al.</i> "A Model for resonance-assisted hydrogen bonding in crystals and its graph set analysis" <i>J. Phys. Chem. A</i> , 2001, pp. 6938-6942, Vol. 105.	
	R245	LYNCH, D. <i>et al.</i> "1:1 Molecular complexes of 4-amino-N-(4,6-dimethylpyrimidin-2-yl) benzene-sulfonamide (sulfamethazine) with indole-2-carboxylic acid and 2,4-dinitrobenzoic acid" <i>Aust. J. Chem.</i> , 2000, pp. 383-387, Vol. 53.	
	R246	AAKERÖY, C. <i>et al.</i> "Solid state, crystal engineering and hydrogen bonds" <i>Comprehensive Coordination Chemistry II</i> (ed. by McCleverty, J. <i>et al.</i>), pp. 679-688, Elsevier Ltd., Oxford, UK.	
	R247	LEVIN, B. <i>et al.</i> "The not-so-trivial synthesis and characterization of heterocyclic boronic acids (Abstract)" 38 th Midwest Regional Meeting of the American Chemical Society in Columbia, MO., November 5-7, 2003, published by the American Chemical Society, Washington, D.C.	
	R248	SMITH, G. <i>et al.</i> "Interactions of aromatic carboxylic acids with quinolin-8-ol (oxine): Synthesis and the crystal structures of the proton-transfer compounds with the nitro-substituted benzoic acids" <i>Aust. J. Chem.</i> , 2001, pp. 171-175, Vol. 54.	
	R249	STALKER, R. <i>et al.</i> "Asymmetric synthesis of two new conformationally constrained lysine derivatives" <i>Tetrahedron</i> , 2002, pp. 4837-4849, Vol. 58.	
	R250	VOET, D. <i>et al.</i> "Barbiturates and adenine derivatives. Molecular structure of a hydrogen-bonded complex" <i>Journal of the American Chemical Society</i> , August 9, 1972, pp. 5888-5891, Vol. 94, No. 16.	
	R251	VISHWESHWAR, P. <i>et al.</i> "Molecular complexes of homologous alkanedicarboxylic acids with isonicotinamide: X-ray crystal structures, hydrogen bond synthons, and melting point alternation" <i>Crystal Growth & Design</i> , 2003, pp. 783-790, Vol. 3, No. 5.	
	R252	LE JEUNNE, C. <i>et al.</i> "Comparative efficacy and safety of calcium carbasalate plus metoclopramide versus ergotamine tartrate plus caffeine in the treatment of acute migraine attacks" <i>Eur. Neurol.</i> , 1999, pp. 37-43, Vol. 41.	
↓	R253	AAKERÖY, C. <i>et al.</i> "Hydrogen-bonded layers of hydrogentartrate anions: two-dimensional building blocks for crystal engineering" <i>J. Mater. Chem.</i> , 1993, 1129-1135, Vol. 3, No. 11.	↓

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		Group Art Unit	1617
		Examiner Name	Leonard Williams
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		Attorney Docket Number	TPI-350C1

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IAC		HU, Z. <i>et al.</i> "Separation of 4-aminobenzoic acid by cocrystallization: Crystal structure of the complex of 4-aminobenzoic acid with (2R,3R)-tartaric acid" <i>Journal of Chemical Crystallography</i> , December 2002, pp. 525-529, Vol. 32, No. 12.	
	R254		
		GUARRERA, D. <i>et al.</i> "Molecular self-assembly in the solid state. The combined use of solid state NMR and differential scanning calorimetry for the determination of phase constitution" <i>Chem. Mater.</i> , 1994, pp. 1293-1296, Vol. 6.	
	R255		
		DOI, M. <i>et al.</i> "Conformational study of a potent human renin inhibitor: x-ray crystal structure of isopropyl (2R, 3S) -4-cyclohexyl-2-hydroxy-3-{N-[(2R)-2-morpholinocarbonylmethyl-3-(1-naphthyl) propionyl] -L-histidylamino}butyrate (KRI-1314), a pentapeptide analogue with amino acid sequence corresponding to the cleavage site of angiotensinogen" <i>J. Chem. Soc. Perkin Trans. 1</i> , 1991, pp. 1153-1158.	
	R256		
		CRIFIELD, A. <i>et al.</i> "Crystal engineering through halogen bonding. 2. Complexes of diacetylene-linked heterocycles with organic iodides" <i>Crystal Growth & Design</i> , 2003, pp. 313-320, Vol. 3, No. 3.	
	R257		
		AAKERÖY, C. <i>et al.</i> "A versatile route to porous solids: organic-inorganic hybrid materials assembled through hydrogen bonds" <i>Angew. Chem. Int. Ed.</i> , 1999, pp. 1815-1819, Vol. 38, No. 12.	
	R258		
		SHEFTER, E. <i>et al.</i> , ACS, Abstr. Papers (Summer), 1970, 35, compound name: sulfathiazole-theophylline complex.	
	R259		
		SHEFTER, E. <i>et al.</i> , ACS, Abstr. Papers (Summer), 1970, 35, compound name: sulfathiazole-sulfanilamide complex.	
	R260		
		WIEDENFELD, H. <i>et al.</i> "Solubilization of aminophenazone" <i>Arch. Pharm.</i> , 1982, pp. 633-641, Vol. 315.	
	R261		
		CACCIAPUOTI, A. <i>et al.</i> "In vitro and in vivo activities of SCH 56592 (Posaconazole), a new triazole antifungal agent, against <i>Aspergillus</i> and <i>Candida</i> " <i>Antimicrobial Agents and Chemotherapy</i> , August 2000, pp. 2017-2022, Vol. 44, No. 8.	
	R262		
		CALLAHAN, J.C. <i>et al.</i> "Equilibrium moisture content of pharmaceutical excipients" <i>Drug Development and Industrial Pharmacy</i> , 1982, pp. 355-369, Vol. 8, No. 3.	
	R263		
↓		DANNAOUI, E. <i>et al.</i> "Acquired itraconazole resistance in <i>Aspergillus fumigatus</i> " <i>Journal of Antimicrobial Chemotherapy</i> , 2001, pp. 333-340, Vol. 47.	↓
	R264		

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/ACI/	R265	DENNING, D. W. <i>et al.</i> "In vitro activity of Saperconazole (R66 905) compared with Amphotericin B and Itraconazole against <i>Aspergillus</i> species" <i>Eur. J. Clin. Microbial. Infect. Dis.</i> , 1990, pp. 693-697, Vol. 9.	
	R267	DRESSMAN, J. B. <i>et al.</i> "Dissolution testing as a prognostic tool for oral drug absorption: immediate release dosage forms" <i>Pharmaceutical Research</i> , 1998, pp. 11-22, Vol. 15, No. 1.	
	R268	EBERT, W. R. "Soft elastic gelatin capsules: a unique dosage form" <i>Pharmaceutical Technology</i> , October 1977, pp. 44-50, Vol. 1, No. 5.	
	R269	GASCON, M. -P. <i>et al.</i> "In vitro forecasting of drugs which may interfere with the biotransformation of midazolam" <i>Eur. J. Clin. Pharmacol.</i> , 1991, pp. 573-578, Vol. 41.	
	R270	HEERES, J. <i>et al.</i> "Antimycotic azoles. 7. Synthesis and antifungal properties of a series of novel triazol-3-ones" <i>J. Med. Chem.</i> , 1984, pp. 894-900, Vol. 27.	
	R271	HONIG, P. K. <i>et al.</i> "Itraconazole affects single-dose Terfenadine pharmacokinetics and cardiac repolarization pharmacodynamics" <i>J. Clin. Pharmacol.</i> , 1993, pp. 1201-1206, Vol. 33.	
	R272	IMAI, T. <i>et al.</i> "Successful treatment of cerebral Aspergillosis with a high oral dose of Itraconazole after excisional surgery" <i>Internal Medicine</i> , October 1999, pp. 829-832, Vol. 38, No. 10.	
	R273	KOVACS, J. <i>et al.</i> "New type of bridged monoamino- β -cyclodextrins" <i>Journal of Inclusion Phenomena and Molecular Recognition in Chemistry</i> , 1996, pp. 53-56, Vol. 25.	
	R274	LAVRIJSEN, A. P. M. <i>et al.</i> "Hepatic injury associated with itraconazole" <i>The Lancet</i> , July 25, 1992, pp. 251-252, Vol. 340.	
	R275	NEUVONEN, P. J. <i>et al.</i> "Itraconazole drastically increases plasma concentrations of lovastatin and lovastatin acid" <i>Clinical Pharmacology & Therapeutics</i> , 1996, pp. 54-61, Vol. 60, No. 1.	
✓	R276	NOMEIR, A. A. <i>et al.</i> "Pharmacokinetics of SCH 56592, a new azole broad-spectrum antifungal agent, in mice, rats, rabbits, dogs, and cynomolgus monkeys" <i>Antimicrobial Agents and Chemotherapy</i> , March 2000, pp. 727-731, Vol. 44, No. 3.	✓

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known	
		Application Number	10/660,202
		Filing Date	September 11, 2003
		First Named Inventor	Örn Almarsson
		Group Art Unit	1617
		Examiner Name	Leonard Williams
		Attorney Docket Number	TPI-350C1

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
IACI	R277	ODDS, F. C. "Antifungal activity of saperconazole (R 66 905) <i>in vitro</i> " <i>Journal of Antimicrobial Chemotherapy</i> , 1989, pp. 533-537, Vol. 24.	
	R278	REMENAR, J. F. <i>et al.</i> "Crystal engineering of novel cocrystals of a triazole drug with 1,4-dicarboxylic acids" <i>J. Am. Chem. Soc.</i> , 2003, pp. 8456-8457, Vol. 125.	
	R279	SAKSENA, A. K. <i>et al.</i> "Advances in the chemistry of novel broad-spectrum orally active azole antifungals: recent studies leading to the discovery of SCH 56592" in <i>Advances in the Chemistry of Novel Broad-Spectrum Orally Active Azole Antifungals</i> (Royal Soc. Chem., Cambridge), 1997, pp. 180-199.	
	R280	SAKSENA, A. K. <i>et al.</i> "Concise asymmetric routes to 2,2,4-trisubstituted tetrahydrofurans via chiral titanium imide enolates: key intermediates towards synthesis of highly active azole antifungals SCH 51048 and SCH 56592" <i>Tetrahedron Letters</i> , 1996, pp. 5657-5660, Vol. 37, No. 32.	
	R281	HEPPERLE, M. <i>et al.</i> "Mono <i>N</i> -arylation of piperazine(III): metal-catalyzed <i>N</i> -arylation and its application to the novel preparations of the antifungal posaconazole and its advanced intermediate" <i>Tetrahedron Letters</i> , 2002, pp. 3359-3363, Vol. 43.	
	R282	CUTSEM, J. V. <i>et al.</i> "Oral and parenteral therapy with saperconazole (R 66905) of invasive aspergillosis in normal and immunocompromised animals" <i>Antimicrobial Agents and Chemotherapy</i> , December 1989, pp. 2063-2068, Vol. 33, No. 12.	
	R283	VILLA, L. A. <i>et al.</i> "Central nervous system paracoccidioidomycosis. Report of a case successfully treated with itraconazole" <i>Rev. Inst. Med. Trop. S. Paulo</i> , July-August, 2000, pp. 231-234, Vol. 42, No. 4.	
	R284	WEST, A. R., "Solid Solutions" In: <i>Solid State Chemistry and its Applications</i> , 1988, p. 358, p. 365, Wiley, NY.	
	R285	ARONHIME, J. <i>et al.</i> "Crystalline forms of pharmaceuticals and characterization thereof", Oral Presentation, March 8, 2005, USPTO, Alexandria, VA.	
	R286	DESIRAJU, G. R. "Chemistry beyond the molecule" <i>Nature</i> , July 26, 2001, pp. 397-400, Vol. 412.	
	R287	GAVEZZOTTI, A. "Are crystal structures predictable?" <i>Acc. Chem. Res.</i> , 1994, pp. 309-314, Vol. 27.	

Examiner Signature	/Abigail Cotton/ (03/20/2007)	Date Considered	03/20/2007
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known	
		Application Number	10/660,202
		Filing Date	September 11, 2003
		First Named Inventor	Örn Almarsson
		Group Art Unit	1617
		Examiner Name	Leonard Williams
		Attorney Docket Number	TPI-350C1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/AC/	R288	Physician's Desk Reference, 56 th Ed., pp. 1800-1804, 2002.	
	R289	KIM, H. <i>et al.</i> "High-performance liquid chromatographic analysis of the anti-fungal agent SCH 56592 in dog serum" <i>Journal of Chromatography B</i> , 2000, pp. 93-98, Vol. 738.	
	R290	VIPPAGUNTA, S. R. <i>et al.</i> "Crystalline solids" <i>Advanced Drug Delivery Reviews</i> , 2001, pp. 3-26, Vol. 48.	
	R291	MCCRONE, W. C. "Polymorphism", In: <i>The Physics and Chemistry of the Organic Solid State</i> , Vol. II, FOX, D. <i>et al.</i> (eds.), 1965, pp. 725-767, Interscience, New York.	
	R292	LEGER, J.M. <i>et al.</i> "Crystal Structure of the 1:1 Sulfacetamide-Caffeine Complex" <i>Acta Cryst.</i> , 1977, pp. 1455-1459, Vol. B33.	x
	R293	SIMONOV, Y. <i>et al.</i> "Structure of the caffeine-copper(II) acetate additional compound", <i>Izvestiya Akademii Nauk Moldavskoi SSR, Seriya Fiziko-Tekhnicheskikh i Matematicheskikh Nauk</i> , 1972, Vol. 3, pp. 83-84, abstract only.	
	R294	WEISSBUCH, I. <i>et al.</i> "Understanding and control of nucleation, growth, habit, dissolution and structure of two- and three-dimensional crystals using 'tailor-made' auxiliaries" <i>Acta Cryst.</i> , 1995, B51:115-148.	
	R295	FAUGHT, E. <i>et al.</i> "Topiramate Dose-Ranging Trial in Refractory Partial Epilepsy", <i>Amer. Epilepsy Soc. Proc.</i> , (1995), pg. 33, Vol. 36, Supp. 4.	
	R296	PRIVITERA, M. <i>et al.</i> "Dose-Ranging Trial with Higher Doses of Topiramate in Patients with Resistant Partial Seizures", <i>Amer. Epilepsy Soc. Proc.</i> , 1995, pg. 33, Vol. 36, Supp. 4.	
	R297	SACHDEO, S. K. <i>et al.</i> "Topiramate: Double-Blind Trial as Monotherapy", <i>Amer. Epilepsy Soc. Proc.</i> , 1995, pg. 33, Vol. 36, Supp. 4.	
↓	R298	Press Release. "Clinical Development of Topiramate for Obesity Extended to Simplify Dosing, Improve Tolerability". http://www.orthomcneil.com/news/article020402.html (February 4, 2002), N.J.	x

Examiner Signature	/Abigail Cotton/ (03/20/2007)	Date Considered	03/20/2007
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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known	
		Application Number	10/660,202
		Filing Date	September 11, 2003
		First Named Inventor	Örn Almarsson
		Group Art Unit	1617
		Examiner Name	Leonard Williams
		Attorney Docket Number	TPI-350C1
Sheet	36	of	36

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/AC/	R299	ROSENFELD, W. E. "Topiramate: A Review of Preclinical, Pharmacokinetic, and Clinical Data", <i>Clinical Therapeutics</i> , 1997, pp. 1294-1308, Vol. 19, No. 6.	
	R300	Physician's Desk Reference, 56 th Edition, 2002, pp. 2590-2595.	
	R301	DATABASE WPI, Section Ch, Week 197936, Derwent Publishing Ltd., London, Great Britain, Class B02, AN 1979-65538B, XP002282989 and JP 54 095589A (Sumitomo) 1979 Abstract.	
	R302	FUNG <i>et al.</i> , "Solvent Effects on Comparative Dissolution of Pharmaceutical Solvates," <i>Chem. Farm. Bull.</i> , 22(2), pgs. 454-458 (1974).	
	R303	RUBINO <i>et al.</i> , "Influence of Solvent Composition on the Solubilities and Solid-State Properties of the Sodium Salts of Some Drugs", <i>Int. J. of Pharma</i> , 65, pgs. 141-145 (1990).	
	R304	FITZGERALD, G. A. "The Coxibs, Selective Inhibitors of Cyclooxygenase-2", <i>New England Journal of Medicine</i> , Vol. 345, No. 6, August 9, 2001.	
	R305		
	R306		
	R307		
	R308		
	R309		

Examiner Signature	/Abigail Cotton/ (03/20/2007)	Date Considered	03/20/2007
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Substitute for form 1443A/PTO

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

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of

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Complete if Known

Application Number	10/606,202
Filing Date	September 11, 2003
First Named Inventor	Orn Almarsson
Art Unit	1653
Examiner Name	
Attorney Docket Number	TPI-350C1

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number - Kind Code* (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/ACI	U1	US-3,028,420	04-03-1962	Petrov et al.	All
/ACI	U2	US-5,521,207	05-28-1998	Granelo	All
	U3	US-			
	U4	US-			
	U5	US-			
	U6	US-			
	U7	US-			
	U8	US-			
	U9	US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
	F1					
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Notice of References Cited	Application/Control No. 10/660,202	Applicant(s)/Patent Under Reexamination ALMARSSON ET AL.	
	Examiner Abigail M. Cotton	Art Unit 1617	Page 1 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
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	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Angelo Gavezzotti, Are Crystal Structures Predictable?, 1994, Acc. Chem. Res., Vol. 27, pages 309-314.
	V	Oswald et al, The Formation of Paracetamol (Acetaminophen) Adducts with Hydrogen-Bond Acceptors, 2002, Acta Crystallographica, Vol. B58, pages 1057-1066. /
	W	Remenar et al, Crystal Engineering of Novel Cocrystals of a Triazole Drug with 1,4-Dicarboxylic Acids, 2003, JACS, Vol. 125, pages 8456-8457. /
	X	Fleischman et al, Crystal Engineering of the Composition of Pharmaceutical Phases: Multiple-Component Crystalline Solids Involving Carbamazepine, 2003, Crystal Growth and Design, Vol. 3, No. 6, pages 909-919. /

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Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited	Application/Control No. 10/660,202	Applicant(s)/Patent Under Reexamination ALMARSSON ET AL.	
	Examiner Abigail M. Cotton	Art Unit 1617	Page 2 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,559,293	05-2003	Almarsson et al.	536/18.7
*	B	US-2004/0176335	09-2004	Childs, Scott L.	514/165
*	C	US-7,078,526	07-2006	Remenar et al.	544/336
*	D	US-2007/0021510	01-2007	Hickey et al.	514/618
*	E	US-2007/0059356	03-2007	Almarsson et al.	424/464
*	F	US-2006/0223794	10-2006	Bourghol Hickey et al.	514/220
*	G	US-2005/0070551	03-2005	Remenar et al.	514/254.07
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N	WO 2003074474 A2 /	09-2003	World Intellect	ZAWOROTKO et al.	
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Dvorkin et al, Crystal and Molecular Structure of a Complex of 18-crown-6 with 6-chloror-7-sulfamido-3,4-dihydro-1,2,4-benzothiadiazine-1,1-dioxide (hypothiazide) of 1:1 Composition, 1990, Kristallografiya, Vol. 35, No. 3, pages 682-686 (with English abstract.)
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CONFIRMATION NO. 6536

SERIAL NUMBER 10/660,202	FILING OR 371(c) DATE 09/11/2003 RULE	CLASS 424	GROUP ART UNIT 1617	ATTORNEY DOCKET NO. TPI-350C1
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APPLICANTS

Orn Almarsson, Shrewsbury, MA;
 Magali Bourghol Hickey, Medford, MA;
 Matthew L. Peterson, Framingham, MA;
 Michael J. Zaworotko, Tampa, FL;
 Brian Moulton, Providence, RI;
 Nair Rodriguez-Hornedo, Ann Arbor, MI;

Amc 3/27/2007

**** CONTINUING DATA *******

This application is a CIP of PCT/US03/27772 09/04/2003 which is a CIP of 10/378,956 03/03/2003 which claims benefit of 60/360,768 03/01/2002 and said PCT/US03/27772 09/04/2003 claims benefit of 60/451,213 02/28/2003 and claims benefit of 60/463,962 04/18/2003 and claims benefit of 60/487,064 07/11/2003
 This application 10/660,202 is a CIP of 10/637,829 08/08/2003 ABN which is a DIV of 10/295,995 11/18/2002 PAT 6,699,840 which is a CON of 10/232,589 09/03/2002 PAT 6,559,293 which claims benefit of 60/406,974 08/30/2002 and claims benefit of 60/380,288 05/15/2002 and claims benefit of 60/356,764 02/15/2002
 This application 10/660,202 is a CIP of 10/449,307 05/30/2003 PAT 7,078,526 which claims benefit of 60/463,962 04/18/2003 and claims benefit of 60/444,315 01/31/2003 and claims benefit of 60/439,282 01/10/2003 and claims benefit of 60/384,152 05/31/2002
 This application 10/660,202 is a CIP of 10/601,092 06/20/2003 ABN and claims benefit of 60/451,213 02/28/2003 and claims benefit of 60/463,962 04/18/2003 and claims benefit of 60/487,064 07/11/2003

Amc 3/27/2007

**** FOREIGN APPLICATIONS *******

IF REQUIRED, FOREIGN FILING LICENSE GRANTED SMALL ENTITY ****
**** 07/20/2004**

Foreign Priority claimed ☐ yes ☒ no	35 USC 119 (a-d) conditions met ☐ yes ☒ no ☐ Met after Allowance	STATE OR COUNTRY MA	SHEETS DRAWING 66	TOTAL CLAIMS 37	INDEPENDENT CLAIMS 20
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Verified and Acknowledged *Almarsson* Examiner's Signature *Amc* Initials

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NOVARTIS EXHIBIT 1023

Novartis v. Regents, IPR2023-01346

Page 713 of 1101

23557		
TITLE		
Pharmaceutical co-crystal compositions		
FILING FEE RECEIVED 1307	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:	☐ All Fees
		☐ 1.16 Fees (Filing)
		☐ 1.17 Fees (Processing Ext. of time)
		☐ 1.18 Fees (Issue)
		☐ Other _____
		☐ Credit

Index of Claims 	Application/Control No.		Applicant(s)/Patent under Reexamination	
	10/660,202		ALMARSSON ET AL.	
	Examiner		Art Unit	
	Abigail M. Cotton		1617	

√	Rejected
=	Allowed

-	(Through numeral) Cancelled
+	Restricted

N	Non-Elected
I	Interference

A	Appeal
O	Objected

Claim		Date					
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Search Notes 		Application/Control No. 10/660,202		Applicant(s)/Patent under Reexamination ALMARSSON ET AL.	
		Examiner Abigail M. Cotton		Art Unit 1617	

SEARCHED			
Class	Subclass	Date	Examiner

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
Inventor Search on Palm	3/27/2007	AMC
EAST (USPAT, UOCR, USPG-PUB, EPO, JPO, DERWENT, FPRS) - See Search History Results	3/20/2007	AMC
STN (CAplus, Medline, Embase) - See Search History Results	3/20/2007	AMC
English Abstracts only available for Drorin et al. article. Full English translation will be submitted to Applicants upon receipt.		

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Glenn P. Ladwig, Patent Attorney

AMENDMENT UNDER 37 C.F.R. § 1.111
Patent Application
Docket No. TPI-350C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Abigail Manda Cotton
Art Unit : 1617
Applicants : Örn Almarsson, Magali Bourghol Hickey, Matthew L. Peterson, Michael J. Zaworotko, Brian Moulton, Nair Rodriguez-Hornedo
Serial No. : 10/660,202
Filed : September 11, 2003
Conf. No. : 6536
For : Pharmaceutical Co-Crystal Compositions

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

AMENDMENT UNDER 37 C.F.R. § 1.111

Sir:

Applicants request that the period for response be extended three months through and including October 1, 2007, the fees for which have been paid at the time this Amendment was filed.

In response to the Office Action dated March 30, 2007, please amend the above-identified patent application as follows:

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In the Claims

1 (currently amended). A pharmaceutical co-crystal composition, comprising: an API and a co-crystal former, wherein:

a) the API is a liquid or a solid at room temperature and the co-crystal former is a solid at room temperature; ~~and wherein~~

b) the API and co-crystal former are hydrogen bonded to each other; and

c) specifically excluding a co-crystal selected from the group consisting of: nabumetone:2,3-naphthalenediol, fluoxetine HCl:benzoic acid, fluoxetine HCl:succinic acid, acetaminophen:piperazine, acetaminophen:theophylline, theophylline:salicylic acid, theophylline:p-hydroxybenzoic acid, theophylline:sorbic acid, theophylline:1-hydroxy-2-naphthoic acid, theophylline:glycolic acid, theophylline:2,5-dihydroxybenzoic acid, theophylline:chloroacetic acid, bis(diphenylhydantoin):9-ethyladenine acetylacetone solvate, bis(diphenylhydantoin):9-ethyladenine 2,4-pentanedione solvate, 5,5-diphenylbarbituric acid:9-ethyladenine, bis(diphenylhydantoin):9-ethyladenine, 4-aminobenzoic acid:4-aminobenzonitrile, sulfadimidine:salicylic acid, 8-hydroxyquinolinium 4-nitrobenzoate:4-nitrobenzoic acid, sulfaproxyline:caffeine, retro-inverso-isopropyl (2R,3S)-4-cyclohexyl-2-hydroxy-3-(N-((2R)-2-morpholinocarbonylmethyl-3-(1-naphthyl)propionyl)-L-histidylamino)butyrate:cinnamic acid monohydrate, benzoic acid:isonicotinamide, 3-(2-N',N'-(dimethylhydrazino)-4-thiazolylmethylthio)-N''-sulfamoylpropionamidine:maleic acid, diglycine hydrochloride (C₂H₅NO₂:C₂H₆NO₂⁺Cl⁻), octadecanoic acid:3-pyridinecarboxamide, cis-N-(3-methyl-1-(2-(1,2,3,4-tetrahydro)naphthyl)-piperidin-4-yl)-N-phenylpropanamide hydrochloride:oxalic acid, trans-N-(3-methyl-1-(2-(1,2,3,4-tetrahydro)naphthyl)-piperidin-4-yl)-N-phenylpropanamide oxalate:oxalic acid dihydrate, bis(1-(3-((4-(2-isopropoxyphenyl)-1-piperazinyl)methyl)benzoyl)piperidine) succinate:succinic acid, bis(p-cyanophenyl)imidazolylmethane:succinic acid, cis-1-((4-(1-imidazolylmethyl)cyclohexyl)methyl)imidazole:succinic acid, (+)-2-(5,6-dimethoxy-1,2,3,4-tetrahydro-1-naphthyl)imidazoline:(+)-dibenzoyl-D-tartaric acid, raclopride:tartaric acid, 2,6-diamino-9-ethylpurine:5,5-diethylbarbituric acid, 5,5-diethylbarbituric acid:bis(2-aminopyridine),

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5,5-diethylbarbituric acid:acetamide, 5,5-diethylbarbituric acid:KI₃, 5,5-diethylbarbituric acid:urea,
bis(barbital):hexamethylphosphoramide, 5,5-diethylbarbituric acid:imidazole, barbital:1-
methylimidazole, 5,5-diethylbarbituric acid:N-methyl-2-pyridone, 2,4-diamino-5-(3,4,5-
trimethoxybenzyl)-pyrimidine:5,5-diethylbarbituric acid, bis(barbital):caffeine, bis(barbital):1-
methylimidazole, bis(beta-cyclodextrin):bis(barbital) hydrate, tetrakis(beta-
cyclodextrin):tetrakis(barbital), 9-ethyladenine:5,5-diethylbarbituric acid, barbital:N'-(p-
cyanophenyl)-N-(p-iodophenyl)melamine, barbital:2-amino-4-(m-bromophenylamino)-6-chloro-
1,3,5-triazine, 5,5-diethylbarbituric acid:N,N'-diphenylmelamine, 5,5-diethylbarbituric acid:N,N'-
bis(p-chlorophenyl)melamine, N,N'-bis(p-bromophenyl)melamine:5,5-diethylbarbituric acid, 5,5-
diethylbarbituric acid:N,N'-bis(p-iodophenyl)melamine, 5,5-diethylbarbituric acid:N,N'-bis(p-
tolyl)melamine, 5,5-diethylbarbituric acid:N,N'-bis(m-tolyl)melamine, 5,5-diethylbarbituric
acid:N,N'-bis(m-chlorophenyl)melamine, N,N'-Bis(m-methylphenyl)melamine:barbital, N,N'-
bis(m-chlorophenyl)melamine:barbital tetrahydrofuran solvate, 5,5-diethylbarbituric acid:N,N'-bis(t-
butyl)melamine, 5,5-diethylbarbituric acid:N,N'-di(t-butyl)melamine, 6,6'-diquinolyl ether:5,5-
diethylbarbituric acid, 5-t-butyl-2,4,6-triaminopyrimidine:diethylbarbituric acid, N,N'-bis(4-
carboxymethylphenyl)melamine:barbital ethanol solvate, N,N'-bis(4-t-
butylphenyl)melamine:barbital, tris(5,17-N,N'-bis(4-amino-6-(butylamino)-1,3,5-triazin-2-
yl)diamino-11,23-dinitro-25,26,27,28-tetrapropoxycalix(4)arene):hexakis(diethylbarbituric acid)
toluene solvate, N,N'-bis(m-fluorophenyl)melamine:barbital, N,N'-bis(m-
bromophenyl)melamine:barbital acetone solvate, N,N'-bis(m-iodophenyl)melamine:barbital
acetonitrile solvate, N,N'-bis(m-trifluoromethylphenyl)melamine:barbital acetonitrile solvate,
aminopyrine:barbital, N,N'-bis(4-fluorophenyl)melamine:barbital, N,N'-bis(4-
trifluoromethylphenyl)melamine:barbital, 2,4-diamino-5-(3,4,5-
trimethoxybenzyl)pyrimidine:barbital, hydroxybutyrate:hydroxyvalerate, 2-
aminopyrimidine:succinic acid, 1,3-bis(((6-methylpyrid-2-yl)amino)carbonyl)benzene:glutaric acid,
5-t-butyl-2,4,6-triaminopyrimidine:diethylbarbituric acid, bis(dithiobiuret-S,S')nickel(II):diuracil,
platinum 3,3'-dihydroxymethyl-2,2'-bipyridine dichloride:AgF₃CSO₃, 4,4'-bipyridyl:isophthalic
acid, 4,4'-bipyridyl:1,4-naphthalenedicarboxylic acid, 4,4'-bipyridyl:1,3,5-cyclohexane-tricarboxylic
acid, 4,4'-bipyridyl:tricarballylic acid, urotropin:azelaic acid, insulin:C8-HI (octanoyl-N^c-LysB29-

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human insulin), isonicotinamide:cinnamic acid, isonicotinamide:3-hydroxybenzoic acid, isonicotinamide:3-N,N-dimethylaminobenzoic acid, isonicotinamide:3,5-bis(trifluoromethyl)-benzoic acid, isonicotinamide:d,l-mandelic acid, isonicotinamide:chloroacetic acid, isonicotinamide:fumaric acid monoethyl ester, isonicotinamide:12-bromododecanoic acid, isonicotinamide:fumaric acid, isonicotinamide:succinic acid, isonicotinamide:4-ketopimelic acid, isonicotinamide:thiodiglycolic acid, 1,3,5-cyclohexane-tricarboxylic acid:hexamethyltetramine, 1,3,5-cyclohexane-tricarboxylic acid:4,7-phenanthroline, 4,7-phenanthroline:oxalic acid, 4,7-phenanthroline:terephthalic acid, 4,7-phenanthroline: 1,3,5-cyclohexane-tricarboxylic acid, 4,7-phenanthroline:1,4-naphthalenedicarboxylic acid, pyrazine:methanoic acid, pyrazine:ethanoic acid, pyrazine:propanoic acid, pyrazine:butanoic acid, pyrazine:pentanoic acid, pyrazine:hexanoic acid, pyrazine:heptanoic acid, pyrazine:octanoic acid, pyrazine:nonanoic acid, pyrazine:decanoic acid, diammine-(deoxy-quanyl-quanyl-N⁷,N⁷)-platinum:tris(glycine) hydrate, 2-aminopyrimidine:p-phenylenediacetic acid, bis(2-aminopyrimidin-1-ium)fumarate:fumaric acid, 2-aminopyrimidine:indole-3-acetic acid, 2-aminopyrimidine:N-methylpyrrole-2-carboxylic acid, 2-aminopyrimidine:thiophen-2-carboxylic acid, 2-aminopyrimidine:(+)-camphoric acid, 2,4,6-Trinitrobenzoic acid: 2-aminopyrimidine, 2-aminopyrimidine:4-aminobenzoic acid, 2-aminopyrimidine:bis(phenoxyacetic acid), 2-aminopyrimidine:(2,4-dichlorophenoxy)acetic acid, 2-aminopyrimidine:(3,4-dichlorophenoxy)acetic acid, 2-aminopyrimidine:indole-2-carboxylic acid, 2-aminopyrimidine:terephthalic acid, 2-aminopyrimidine:bis(2-nitrobenzoic acid), 2-aminopyrimidine:bis(2-aminobenzoic acid), 2-aminopyrimidine:3-aminobenzoic acid, 2-hexeneoic acid:isonicotinamide, 4-nitrobenzoic acid:isonicotinamide, 3,5-dinitrobenzoic acid:isonicotinamide:4-methylbenzoic acid, 2-amino-5-nitropyrimidine:2-amino-3-nitropyridine, 3,5-dinitrobenzoic acid:4-chlorobenzamide, 3-dimethylaminobenzoic acid:4-chlorobenzamide, fumaric acid:4-chlorobenzamide, oxine:4-nitrobenzoic acid, oxine:3,5-dinitrobenzoic acid, oxine:3,5-dinitrosalicylic acid, 3-[2-(N',N'-dimethylhydrazino)-4-thiazolylmethylthio]-N²-sulfamoylpropionamide:maleic acid, 5-fluorouracil:9-ethylhypoxanthine, 5-fluorouracil:cytosine dihydrate, 5-fluorouracil:theophylline monohydrate, stearic acid:nicotinamide, cis-1-{[4-(1-imidazolylmethyl)cyclohexyl]methyl}imidazole:succinic acid, CGS18320B:succinic acid, sulfaproxyline:caffeine, 4-aminobenzoic acid:4-aminobenzonitrile, 3,5-dinitrobenzoic

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acid:isonicotinamide:3-methylbenzoic acid, 3,5-dinitrobenzoic acid:isonicotinamide:4-(dimethylamino)benzoic acid, 3,5-dinitrobenzoic acid:isonicotinamide:4-hydroxy-3-methoxycinnamic acid, isonicotinamide:oxalic acid, isonicotinamide:malonic acid, isonicotinamide:succinic acid, isonicotinamide:glutaric acid, isonicotinamide:adipic acid, benzoic acid:isonicotinamide, mazapertine:succinate, betaine:dichloronitrophenol, betainepyridine:dichloronitrophenol, betainepyridine:pentachlorophenol, 4-{2-[1-(2-hydroxyethyl)-4-pyridylidene]-ethylidene}-cyclo-hexa-2,5-dien-1-one:methyl 2,4-dihydroxybenzoate, 4-{2-[1-(2-hydroxyethyl)-4-pyridylidene]-ethylidene}-cyclo-hexa-2,5-dien-1-one:2,4-dihydroxypropiophenone, 4-{2-[1-(2-hydroxyethyl)-4-pyridylidene]-ethylidene}-cyclo-hexa-2,5-dien-1-one:2,4-dihydroxyacetophenone, squaric acid:4,4'-dipyridylacetylene, squaric acid:1,2-bis(4-pyridyl)ethylene, chloranilic acid:1,4-bis[(4-pyridyl)ethynyl]benzene, 4,4'-bipyridine:phthalic acid, 4,4'-dipyridylacetylene:phthalic acid, bis(pentamethylcyclopentadienyl)iron:bromanilic acid, bis(pentamethylcyclopentadienyl)iron:chloranilic acid, bis(pentamethylcyclopentadienyl)iron:cyananilic acid, pyrazinotetrathiafulvalene:chloranilic acid, phenol:pentafluorophenol, co-crystals of itraconazole, and co-crystals of topiramate or hydrochlorothiazide.

2 (original). The pharmaceutical co-crystal composition according to claim 1, wherein:

- (a) the co-crystal former is selected from a co-crystal former of Table I or Table II;
- (b) the API is selected from an API of Table IV;
- (c) the API is selected from an API of Table IV and the co-crystal former is selected from a co-crystal former of Table I or Table II;
- (d) the API is a liquid at room temperature;
- (e) the API is a solid at room temperature;
- (f) the API has at least one functional group selected from the group consisting of ether, thioether, alcohol, thiol, aldehyde, ketone, thioketone, nitrate ester, phosphate ester, thiophosphate ester, ester, thioester, sulfate ester, carboxylic acid, phosphonic acid, phosphinic acid, sulfonic acid, amide, primary amine, secondary amine, ammonia, tertiary amine, sp² amine, thiocyanate, cyanamide, oxime,

nitrile, diazo, organohalide, nitro, s-heterocyclic ring, thiophene, n-heterocyclic ring, pyrrole, o-heterocyclic ring, furan, epoxide, peroxide, hydroxamic acid, imidazole, and pyridine;

- (g) the co-crystal former has at least one functional group selected from the group consisting of ether, thioether, alcohol, thiol, aldehyde, ketone, thioketone, nitrate ester, phosphate ester, thiophosphate ester, ester, thioester, sulfate ester, carboxylic acid, phosphonic acid, phosphinic acid, sulfonic acid, amide, primary amine, secondary amine, ammonia, tertiary amine, sp² amine, thiocyanate, cyanamide, oxime, nitrile diazo, organohalide, nitro, s-heterocyclic ring, thiophene, n-heterocyclic ring, pyrrole, o-heterocyclic ring, furan, epoxide, peroxide, hydroxamic acid, imidazole, and pyridine;
- (h) the difference in pK_a between the API and the co-crystal former does not exceed 2;
- (i) the solubility of the co-crystal is increased as compared to the API;
- (j) the dose response of the co-crystal is increased as compared to the API;
- (k) the dissolution of the co-crystal is increased as compared to the API;
- (l) the bioavailability of the co-crystal is increased as compared to the API;
- (m) the stability of the co-crystal is increased as compared to the API;
- (n) a difficult to salt or unsaltable API is incorporated into the co-crystal;
- (o) the hygroscopicity of the co-crystal is decreased as compared to the API;
- (p) an amorphous API is crystallized as a component of the co-crystal;
- (q) the form diversity of the co-crystal is decreased as compared to the API; or
- (r) the morphology of the co-crystal is modulated as compared to the API.

3-8 (canceled).

9 (currently amended). The pharmaceutical co-crystal composition according to claim 1, wherein the API is selected from celecoxib, carbamazepine, ~~itraconazole~~, olanzapine, ~~topiramate~~,

modafinil, 5-fluorouracil, hydrochlorothiazide, acetaminophen, aspirin, flurbiprofen, phenytoin, or ibuprofen.

10 (original). The pharmaceutical co-crystal composition according to claim 1, further comprising a pharmaceutically acceptable diluent, excipient, or carrier.

11 (currently amended). A co-crystal comprising an API and a co-crystal former selected from:

- (a) carbamazepine and saccharin;
- (b) carbamazepine and nicotinamide;
- (c) carbamazepine and trimesic acid;
- (d) celecoxib and nicotinamide;
- (e) olanzapine and nicotinamide;
- (f) celecoxib and 18-crown-6;
- ~~(g)~~ itraconazole and succinic acid;
- ~~(h)~~ itraconazole and fumaric acid;
- ~~(i)~~ itraconazole and tartaric acid;
- ~~(j)~~ itraconazole and malic acid;
- ~~(k)~~ ~~(g)~~ itraconazole HCl and tartaric acid;
- ~~(l)~~ ~~(h)~~ modafinil and malonic acid;
- ~~(m)~~ ~~(i)~~ modafinil and benzamide;
- ~~(n)~~ ~~(j)~~ modafinil and mandelic acid;
- ~~(o)~~ ~~(k)~~ modafinil and glycolic acid;
- ~~(p)~~ ~~(l)~~ modafinil and fumaric acid;
- ~~(q)~~ ~~(m)~~ modafinil and maleic acid;
- ~~(r)~~ topiramate and 18-crown-6;
- ~~(s)~~ ~~(n)~~ 5-fluorouracil and urea;
- ~~(t)~~ hydrochlorothiazide and nicotinic acid;
- ~~(u)~~ hydrochlorothiazide and 18-crown-6;

~~(v)~~hydrochlorothiazide and piperazine;
~~(w)~~(o) _____ acetaminophen and 4,4'-bipyridine;
~~(x)~~(p) _____ phenytoin and pyridone;
~~(y)~~(q) _____ aspirin and 4,4'-bipyridine;
~~(z)~~(r) _____ ibuprofen and 4,4'-bipyridine;
~~(aa)~~(s) _____ flurbiprofen and 4,4'-bipyridine;
~~(bb)~~(t) _____ flurbiprofen and trans-1,2-bis(4-pyridyl) ethylene;
~~(cc)~~(u) _____ carbamazepine and p-phthalaldehyde;
~~(dd)~~(v) _____ carbamazepine and 2,6-pyridinecarboxylic acid;
~~(ee)~~(w) _____ carbamazepine and 5-nitroisophthalic acid;
~~(ff)~~(x) _____ carbamazepine and 1,3,5,7-adamantane tetracarboxylic acid; or
~~(gg)~~(y) _____ carbamazepine and benzoquinone.

12-37 (canceled).

38 (new). The pharmaceutical co-crystal composition according to claim 1, wherein:

(a) the API comprises an amide, an amine or a carboxylic acid group as hydrogen bonded moiety and the co-crystal former comprises aldehyde, amide, carboxylic acid, ketone or pyridine group as hydrogen bonded moiety, or

(b) the API comprises an aldehyde, aromatic nitrogen, ether or sulfonyl group as hydrogen bonded moiety and the co-crystal former comprises amide, carboxylic acid or pyridine as hydrogen bonded moiety, or

(c) the API comprises an alcohol, organochloride group as hydrogen bonded moiety and the co-crystal former comprises amide, carboxylic acid or pyridine as hydrogen bonded moiety, or

(d) one of said API and said co-crystal former comprises an alcohol, aldehyde, amide, secondary amine, carboxylic acid, ether, ester, ketone, nitrile, organochloride pyridine, sulfonyl or sulfonamide group as hydrogen bonded moiety and the other of said API and co-crystal former comprises aldehyde, amide, carboxylic acid, ketone or pyridine as hydrogen-bonded moiety.

39 (new). The pharmaceutical co-crystal composition according to claim 38, wherein the API comprises an amide, an amine or a carboxylic acid group as hydrogen bonded moiety and the co-crystal former comprises aldehyde, amide, carboxylic acid, ketone or pyridine group as hydrogen bonded moiety.

40 (new). The pharmaceutical co-crystal composition according to claim 38, wherein the API comprises an aldehyde, aromatic nitrogen, ether or sulfonyl group as hydrogen bonded moiety and the co-crystal former comprises amide, carboxylic acid or pyridine as hydrogen bonded moiety.

41 (new). The pharmaceutical co-crystal composition according to claim 38, wherein the API comprises an alcohol, organochloride group as hydrogen bonded moiety and the co-crystal former comprises amide, carboxylic acid or pyridine as hydrogen bonded moiety.

42 (new). The pharmaceutical co-crystal composition according to claim 38, wherein one of said API and said co-crystal former comprises an alcohol, aldehyde, amide, secondary amine, carboxylic acid, ether, ester, ketone, nitrile, organochloride pyridine, sulfonyl or sulfonamide group as hydrogen bonded moiety and the other of said API and co-crystal former comprises aldehyde, amide, carboxylic acid, ketone or pyridine as hydrogen-bonded moiety.

Remarks

Claims 1-37 are pending in the subject application. By this Amendment, Applicants have canceled claims 3-8 and 12-37, amended claims 1, 9, and 11, and added new claims 38-42. Support for the amendments and new claims can be found throughout the subject specification and in the claims as originally filed (see, for example, previously pending claim 37, page 12, line 24 through page 13, line 9 and page 28, lines 24-25). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1, 2, 9-11 and 38-42 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Claims 1, 2, 9, 10 and 37 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action argues that Applicants have shown the formation of particular co-crystals, such as those recited within claim 11, but do not exemplify the formation of all co-crystals containing any solid API and any-co-crystal former that is liquid or solid and where the components are hydrogen bonded to one another or co-crystals with any of the numerous and diverse different co-crystal formers recited in claim 2 or the APIs recited within claim 6. The Office Action also indicates that the specification describes only the preparation of the particular co-crystals recited within claim 11 and does not describe the claimed invention in a manner sufficient to convey that the inventors were in possession of the entire claimed invention, including the formation of co-crystals containing any API and any co-crystal former that are hydrogen bonded. Applicants traverse.

It is incumbent upon the Patent Office to clearly establish that the as-filed specification fails to provide an adequate written description for the claimed invention. As set forth at § 2163(III):

A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Wertheim*, 541 F.2d at 263, 191 U.S.P.Q. at 97. In rejecting a claim, the examiner must set forth express findings of fact regarding the above analysis which support the lack of written description conclusion. These findings should:

- (A) Identify the claim limitation at issue; and
- (B) Establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed. A general allegation of “unpredictability in the art” is not a sufficient reason to support a rejection for lack of adequate written description.

In the case of the instant application, Applicants respectfully submit that a *prima facie* case providing reasons why one skilled in the art would not have recognized that the inventor was in possession of the claimed invention has not been established. Rather, the Office Action makes a general allegation that the as-filed specification fails to provide adequate written description of the claimed invention because the examples do not exemplify or otherwise show the formation of all co-crystals.

Applicants also respectfully submit that compliance with the written description requirement does not turn on the number of examples provided in the as-filed specification. Specifically, the Federal Circuit held that “and in accordance with our prior case law, that (1) examples are not necessary to support the adequacy of a written description (2) the written description standard may be met (as it is here) even where actual reduction to practice of an invention is absent; and (3) there is no *per se* rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure” (see *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366, 79 U.S.P.Q.2d 1001 (Fed. Cir. 2006)). Accordingly, Applicants respectfully request that the rejection be withdrawn as it fails to establish a *prima facie* case that the written description provided by the as-filed specification is insufficient.

Claims 1, 2, 9, 10 and 37 are rejected under 35 U.S.C. §112, first paragraph, as nonenabled by the subject specification. The Office Action argues that the undue experimentation would be required to practice the claimed invention because the formation of different crystalline forms of APIs is unpredictable due to the numerous factors that must be controlled in order to provide different crystal states as well as the unpredictability in predicting the different types of crystals that may exist. The Office Action also argues that the specification fails to teach adequate process parameters for making the claimed co-crystals and that the as-filed specification fails to provide adequate guidance in this regard as well. Finally, the Office Action argues that undue

experimentation would be required in order for one skilled in the art to fully make and use the claimed invention. Applicants traverse.

Applicants respectfully submit that the as-filed specification clearly enables the claimed invention. For example, the as-filed specification sets forth those substances that are co-crystal formers as well as APIs (see Tables I-IV). These tables also set forth various functional groups found on the disclosed APIs and co-crystal formers as well as those moieties that interact with the disclosed functional groups (see also page 12, line 24 through page 32, line 20. Thus, the as-filed specification clearly provides teachings to those skilled in the art as to the starting materials suitable for use in the claimed invention.

The as-filed specification also sets forth at least one high throughput method for the preparation of co-crystals (see pages 43-44, referring to the CRYSTALMAX platform). The use of the CRYSTALMAX platform is described in U.S. Patent Application Publication 2002/0177167 A1 and 2002/0048610 A1. Additional high throughput methods for the formation of crystalline structures were also known around the time of the filing date of the instant invention (see, for example, WO 2002/52919 which discloses another high throughput method for the identification of crystalline forms of APIs).

Turning to the allegation that undue experimentation would be required to practice the claimed invention, Applicants respectfully submit that this is not the case. As noted above, the as-filed specification clearly sets forth APIs and co-crystal formers that can be used in the practice of the claimed invention. Additionally, the as-filed specification discloses at least one high throughput method for the identification of crystalline structures recited within the claims and additional high throughput methodologies for identifying new crystalline forms of APIs were known in the art at, or around the time the instant application was filed. As the Patent Office is aware, “The test [for enablement] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed”. *Ex parte Jackson*, 217 U.S.P.Q. 804, 807 (1982); *see also Ex parte Erlich* 3 U.S.P.Q.2d 1011 (B.P.A.I. 1982) (observing that although a method might be “tedious and laborious,” such experimentation is

nevertheless “routine” defining “routine” experiments as those which use known methods in combination with the variables taught in the patent to achieve the expected, specific, patented result). As is clear from the foregoing discussion, the known methods exist for high throughput development of novel crystalline forms of known APIs. These methods allow one to vary a number of parameters simultaneously in order to identify new crystalline forms of known compounds. Thus, while some experimentation might be required to identify new API/co-crystal compounds and this experimentation may be “tedious and laborious”, it would not be undue in view of the state of the art, the knowledge in the art and the teachings of the as-filed specification. Accordingly reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1, 2, 9-11 and 37 are rejected under 35 U.S.C. § 102(b) as anticipated by Oswald *et al.* The Office Action argues that the Oswald *et al.* publication anticipates the claimed invention as the reference teaches co-crystal forms of acetaminophen that include adducts with 4,4'-bipyridine. Applicants respectfully submit that the cited publication is not prior art to the claimed invention. The claimed acetaminophen co-crystals were disclosed in Provisional Patent Application No. 60/360,786, filed March 1, 2002 (see Example 1) and to which priority is claimed by this application. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1, 2, 9-11 and 37 are rejected under 35 U.S.C. § 102(a) as anticipated by Remenar *et al.* The Office Action argues that the Remenar *et al.* publication anticipates the claimed invention as the reference teaches co-crystal forms of itraconazole with 1,4-dicarboxylic acids (such as fumaric acid, succinic acid, and malic acid). Applicants respectfully submit that the cited publication is not prior art to the claimed invention. The claimed itraconazole co-crystals were disclosed in U.S. Patent Application 10/449,307, filed May 30, 2003 (see paragraphs 81 and 471) and to which priority is claimed by this application. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1, 2, 9-11 and 37 are rejected under 35 U.S.C. § 102(a) as anticipated by Fleischman *et al.* The Office Action argues that the Fleischman *et al.* publication anticipates the claimed invention as the reference teaches co-crystal forms of carbamazepine with benzoquinone, saccharin, nicotinamide, trimesic acid, 5-nitroisophthalic acid and adamantane-1,3,4,5-tetracarboxylic acid. Applicants respectfully submit that the cited publication is not prior art to the claimed invention.

The claimed carbamazepine co-crystals were disclosed in U.S. Patent Application 10/378,956, filed March 3, 2003 (see paragraph 39) and to which priority is claimed by this application. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1, 2, 9-11 and 37 are rejected under 35 U.S.C. § 102(a) as anticipated by Dvorkin *et al.* Claims 1-2, 9-10, and 37 are rejected under 35 U.S.C. § 102(e) as anticipated by Almarsson *et al.* (U.S. Patent No. 6,559,293). Claims 1, 2, and 10 are rejected under 35 U.S.C. § 102(e) as anticipated by Childs (U.S. Patent Application Publication No. 2004/0176335, published September 9, 2004). The Office Action argues that the Dvorkin *et al.* reference anticipates the claimed invention as it teaches co-crystals of hydrochlorothiazide and that the Almarsson *et al.* patent anticipates the claimed invention on the basis it teaches co-crystals of topiramate and caffeine. The Office Action argues that the Childs publication anticipates the claimed invention on the basis that it teaches co-crystals of fluoxetine HCl and succinic acid. Applicants respectfully submit that these rejections are moot in view of the amendments made to the claims cancelling the recited topiramate, hydrochlorothiazide, and fluoxetine co-crystals. Support for the exclusionary language presented in claim 1 can be found in previously pending claim 34 (now incorporated into independent claim 1) and the as-filed specification (at page 28, lines 24-25) where it is indicated that that any API listed in Table IV can be excluded from the invention (*e.g.*, hydrochlorothiazide). Accordingly, reconsideration and withdrawal of each rejection is respectfully requested.

Claims 1, 2, 9-11 and 37 are rejected under 35 U.S.C. § 102(e) as anticipated by Zaworotko *et al.* (WO 03/074474). The Office Action argues that the Zaworotko *et al.* publication anticipates the claimed invention as the reference teaches various co-crystals encompassed by the rejected claims. Applicants respectfully submit that the cited publication is not prior art to the claimed invention. The claimed co-crystals were disclosed in Provisional Patent Application No. 60/360,786, filed March 1, 2002 (see, for example, pages 5-6 and Examples 1-5 at pages 11-15) and to which the benefit of priority is claimed by this application. The earliest claimed filing date of the cited reference is also March 1, 2002 via the same priority document. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §102(e) is respectfully requested.

Claims 1, 2, 9-11, and 37 are rejected for “obviousness type” double patenting over claims 1-10 of U.S. Patent No. 7,078,526 (Remenar *et al.*). Claims 1, 2, and 10 are provisionally rejected on

the ground of nonstatutory “obviousness-type” double patenting over claims 86-93 of copending Application No. 10/546,963. Claims 1, 2, 9-11, and 37 are provisionally rejected on the ground of nonstatutory “obviousness-type” double patenting over claims 1-49 and 72-87 of copending Application No. 10/570,405 (U.S. Patent Application Publication No. 2007/0021510 to Hickey *et al.*), over claims 66-72 of copending Application No. 10/551,014 (U.S. Patent Application Publication No. 2006/0223794 to Bourghol Hickey *et al.*), and over claims 2-7, 16, and 18 of copending Application No. 10/926,842 (U.S. Patent Application Publication No. 2005/0070551 to Remenar *et al.*). Applicants respectfully request that these rejections be held in abeyance until such time that allowable subject matter is indicated.

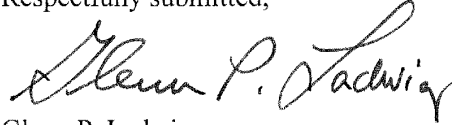
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants’ agreement with or acquiescence in the Examiner’s position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Glenn P. Ladwig
Patent Attorney
Registration No. 46,853
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

GPL/sl

Electronic Patent Application Fee Transmittal				
Application Number:		10660202		
Filing Date:		11-Sep-2003		
Title of Invention:		Pharmaceutical co-crystal compositions		
First Named Inventor/Applicant Name:		Orn Almarsson		
Filer:		Glenn Ladwig/Michelle Vandernoot		
Attorney Docket Number:		TPI-350C1		
Filed as Small Entity				
Utility Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 3 months with \$0 paid	2253	1	510	510

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				510

Electronic Acknowledgement Receipt	
EFS ID:	2265708
Application Number:	10660202
International Application Number:	
Confirmation Number:	6536
Title of Invention:	Pharmaceutical co-crystal compositions
First Named Inventor/Applicant Name:	Orn Almarsson
Customer Number:	23557
Filer:	Glenn Ladwig/Michelle Vandernoot
Filer Authorized By:	Glenn Ladwig
Attorney Docket Number:	TPI-350C1
Receipt Date:	01-OCT-2007
Filing Date:	11-SEP-2003
Time Stamp:	18:10:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment was successfully received in RAM	\$ 510
RAM confirmation Number	2916
Deposit Account	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
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1		Amd-rev.pdf	1548564 0fc4e55cd5af54cd25e447d3b1f37c168f d4bcf5	yes	16
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment - After Non-Final Rejection		1	1	
	Claims		2	9	
	Applicant Arguments/Remarks Made in an Amendment		10	16	
Warnings:					
Information:					
2	Fee Worksheet (PTO-06)	fee-info.pdf	8137 67e7bb2a50f7c445f391a13fca8502798 744734a	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			1556701		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

PATENT APPLICATION FEE DETERMINATION RECORD
Effective January 1, 2003

Application or Docket Number

10-660,202

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	37	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	37 minus 20 =	* 17
INDEPENDENT CLAIMS	20 minus 3 =	* 17
MULTIPLE DEPENDENT CLAIM PRESENT ☐		

* If the difference in column 1 is less than zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

10-1-07

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	* 10	Minus ** (37)	=
Independent	* 2	Minus *** 20	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus **	=
Independent	*	Minus ***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT C	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus **	=
Independent	*	Minus ***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
 ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
 *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
 The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

SMALL ENTITY TYPE ☐

OR OTHER THAN SMALL ENTITY

RATE	FEE
BASIC FEE	375.00
X\$ 9=	
X42=	
+140=	
TOTAL	

RATE	FEE
BASIC FEE	750.00
X\$18=	153.00
X84=	1680.00
+280=	
TOTAL	2208.00

SMALL ENTITY

OR OTHER THAN SMALL ENTITY

RATE	ADDITIONAL FEE
X\$ 9=	
X42=	
+140=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$18=	
X84=	
+280=	
TOTAL ADDIT. FEE	2

RATE	ADDITIONAL FEE
X\$ 9=	
X42=	
+140=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$18=	
X84=	
+280=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$ 9=	
X42=	
+140=	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$18=	
X84=	
+280=	
TOTAL ADDIT. FEE	

EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	4424	carbamazepine	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 14:31
S2	29841	saccharin	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 14:31
S3	510	S1 and S2	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 14:31
S4	7	S1 near S2	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:01
S5	14547	nicotinamide	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:01
S6	7	S1 near S5	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:02
S7	4788	trimesic adj acid	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:02
S8	5	S1 near S7	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:03
S9	4881	celecoxib	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:03
S10	7	S5 near S9	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:14
S11	2183	olanzapine	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:14

EAST Search History

S12	6	S5 near S11	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:15
S13	5613	18-crown-6	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:15
S14	5	S9 near S13	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:15
S15	611	modafinil	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:15
S16	35957	malonic adj acid	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:15
S17	5	S15 near S16	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:16
S18	21665	benzamide	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:16
S19	2	S15 near S18	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:18
S20	13295	mandelic adj acid	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:18
S21	2	S15 near S20	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:18
S22	37991	glycolic adj acid	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:18
S23	5	S15 near S22	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:18

EAST Search History

S24	78352	fumaric adj acid	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:18
S25	4	S15 near S24	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:21
S26	124581	maleic adj acid	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:21
S27	5	S15 near S26	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:21
S28	20463	5-fluorouracil	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:21
S29	238179	urea	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:21
S30	7	S28 near S29	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:22
S31	10642	acetaminophen	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:22
S32	432	4,4'-bipyridine	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:22
S33	4	S31 near S32	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:22
S34	4902	phenytoin	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:22
S35	9754	pyridone	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:22

EAST Search History

S36	6	S34 near S35	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:23
S37	26817	aspirin	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:23
S38	6	S32 near S37	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:25
S39	19289	ibuprofen	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:25
S40	6	S39 near S32	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:26
S41	6827	flurbiprofen	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:26
S42	6	S32 and S41	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2007/12/06 15:26



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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,202	09/11/2003	Om Almarsson	TPI-350C1	6536
23557 7590 12/10/2007 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			EXAMINER CLAYTOR, DEIRDRE RENEE	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 12/10/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/660,202		ALMARSSON ET AL.	
	Examiner		Art Unit	
	Renee Claytor		1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 01 October 2007.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1,2,9-11 and 38-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1,2,9-11 and 38-42 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892) 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ 5) ☐ Notice of Informal Patent Application 6) ☐ Other: _____
--	--

DETAILED ACTION

Applicant's response filed on 10/1/2007 is hereby acknowledged. Currently, claims 1-2, 9-11 and 38-42 are pending, with claims 3-8 and 12-37 being cancelled.

Response to Arguments

Applicants argue over the 35 USC 112, first paragraph rejection (Written Description) that a *prima facie* case providing reasons why one skilled in the art would not have recognized that the inventor was in possession of the claimed invention has not been established and that the rejection fails to establish a *prima facie* case that the written description provided is insufficient.

In response to the above arguments, it is noted that claim 1 broadly reads on any solid API and any co-crystal former that is liquid or solid, and where the components are hydrogen bonded to one another, or the co-crystals with any of the numerous diverse and different co-crystal formers in claim 2 or APIs as in claim 9. There is no description to convey to one of skill in the art that the inventors were in possession of the numerous and diverse co-crystals as claimed, including any API and any co-crystal former that are hydrogen bonded and are solid or liquid. Therefore, the rejection is maintained.

Applicants argue over the 35 USC 112, first paragraph rejection (Enablement) that the specification sets forth substances that are co-crystal formers as well as APIs and clearly provides teaching of the starting materials suitable for use in the claimed invention. Applicants further argue that the specification sets forth at least one high throughput method for the preparation of co-crystals. Applicants conclude by stating

that there are known methods for high throughput development of novel crystalline forms of known APIs.

In response to the above arguments, it is noted that the specification is enabled for the preparation and use of the particular pharmaceutical co-crystals as recited in claim 11; however, the specification is not enabled for the preparation of all co-crystals having any API that is solid, as broadly recited in claim 1. As discussed in the rejection, the state of the art regarding the formation of different crystalline forms is unpredictable due to the numerous different crystallization factors needed to be controlled to provide different crystal states. Further, the formation of crystals is usually arrived at via experimentation. The scope of claim 1 is very broad and reads on any API that is solid with any crystal co-former that is solid or liquid and where the components are hydrogen bonded. As explained previously, the specification does not provide any direction or guidance as to how to go about manufacturing all of the different crystal forms that contain an API and a co-crystal former that are hydrogen bonded to one another. Accordingly, the rejection is being maintained.

Applicant's amendments and arguments have necessitated the withdrawal of the 35 USC 102 rejections over Oswald et al., Remenar et al., Fleishman et al., Zaworotko et al., Dvorkin et al., Almarsson et al., and Childs et al. In particular, Applicants point out the priority documents that were filed before the publication dates of Oswald et al., Remenar et al., Fleishman et al. and Zaworotko et al. and Applicants have deleted subject matter that was contained in Dvorkin et al., Almarsson et al. and Childs et al.

Regarding the Double Patenting rejections, it is noted that Applicants amendments have necessitated the removal of the obviousness-type double patenting rejection over Remenar et al. (US Patent 7,078,526); however, the obviousness-type double patenting rejections over Applications 10/546,963, 10/570,405, 10/551,014, and 10/926,842 remain obvious over the pending claims and are given below.

Due to Applicants amendments to the claims, the following modified rejections are given below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description Rejection

Claims 1-2, 9-10 and 38-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In particular, Applicants have only shown the formation of the particular co-crystals recited in claim 11, such as for example crystals of carbamazepine and saccharin, but do not exemplify or otherwise show the formation of all co-crystals containing any solid API and any co-crystal former that is liquid or solid, and where the components are hydrogen bonded to one another, or co-crystals with any of the numerous and diverse different co-crystal formers in claim 2 or APIs as in claim 9. Applicants have not described or shown how the numerous and diverse different co-crystals as claimed could be obtained.

The specification only describes the preparation of the particular co-crystals recited in claim 11 (see pages 7-10, in particular.) Accordingly, the specification does not describe the claimed subject matter in a manner sufficient to convey to one of ordinary skill in art that the inventors were in possession of the entire invention, including the formation of co-crystals containing any API and any co-crystal former that are hydrogen bonded and are solid or liquid, as recited in the claims.

Enablement Rejection

Claims 1-2, 9-10 and 38-42 are rejected under 35 U.S.C. 112, first paragraph, for lacking enablement for the full scope of the claims. The specification is enabling for the preparation and use of the particular pharmaceutical co-crystals as recited in claim 11, such as co-crystals of carbamazepine and saccharin, or celecoxib and nicotinamide.

However, the specification is not enabling for the preparation of all co-crystals having any API that is solid, and any co-crystal former that solid and liquid, where the components are hydrogen bonded to one another, as recited in claim 1, or all co-crystals having the numerous and diverse APIs and co-crystal formers as in claims 2, 9-10 and 38-42.

The instant specification fails to provide information that would allow the skilled artisan to fully make and use the instant invention without **undue experimentation**. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

1. The nature of the invention: The instant invention pertains a co-crystal composition containing a solid API and a solid or liquid co-crystal former, where the API and co-crystal former are hydrogen bonded to one another.

2. The state of the prior art: The skilled artisan would view the formation of different crystalline forms as being unpredictable due to the numerous different crystallization factors needing to be controlled to provide different crystal states, as well as the unpredictability in predicting the different types of crystals that may exist. For example, as disclosed by Angelo Gavezzotti ("Are Crystal Structures Predictable?" by Gavezzotti, Acc. Chem. Res, 1994, Vol. 27, pages 309-314), the formation and structure of crystals are unpredictable at best (see first full paragraph, in particular.) Gavezzotti teaches that it can be unpredictable whether compounds will crystallize at all, crystal growth from solution is known to be problematic, and in general "a crystal is more readily destroyed than built" (see first full paragraph of right hand column on page 309.) Thus, Gavezzotti teaches that the production of crystals is unpredictable at best, with the particular process parameters suitable for crystallizing a compound typically not being known in advance, and thus desired crystals can generally only be arrived at via experimentation and dealing with "tough problems in the control of solidification, crystal growth, and crystal morphology, mainly due to perverse kinetic control of nucleation (see first full paragraph of right hand column on page 309.)

3. The relative skill of those in the art: the relative skill of those in the art is typically very high, i.e. experienced scientists having advanced degrees in the chemical and biochemical fields.

4. The predictability of the art: As discussed above, the production of crystal forms is highly unpredictable, with crystal growth from solution being problematic. (see page 309 of Gavezzotti, in particular.)

5. The breadth of the claims: the unpredictable nature of the invention is exacerbated by the breadth of the claims. The claims require co-crystal composition that has any API that is solid, in general, with any crystal co-former that is solid or liquid, in general, where the components are hydrogen bonded, as in claim 1. Thus, the claims as instantly presented encompass all co-crystals having any solid API and any solid or liquid co-crystal former, where the components are hydrogen bonded to one another.

6. The amount of direction or guidance presented: the specification does not provide any direction or guidance as to how to go about manufacturing and/or finding all of the different crystal forms that contain an API and a co-crystal former and that are hydrogen bonded to one another, and that thus fall within the scope of the claim. The specification generally teaches that hydrogen bonding is a dominant interaction in the formation of a co-crystal (see page 10 of specification, in particular), but does not teach how one of ordinary skill in the art would go about finding the proper crystallization process parameters, such as the proper crystallization solvent, temperature, etc, to

allow for the formation of all of the co-crystals encompassed by the claims, without requiring undue experimentation.

7. The presence or absence of working examples: The specification does not provide working examples that are sufficient to show one of ordinary skill in the art how to arrive at all of the co-crystal forms. Instead, the specification merely provides examples showing the fabrication of the particular co-crystals recited in claim 11, including carbamazepine and saccharin, and topiramate and 18-crown-6 co-crystals (see Examples 1-37, in particular.) Thus, while the specification provides guidance for forming the particular co-crystals specifically disclosed in the specification and recited in claim 11, the specification does not provide adequate guidance as to how one of ordinary skill in the art could prepare all other crystals containing any API and co-crystal former.

8. The quantity of experimentation necessary: As the specification does not provide adequate guidance to allow one of ordinary skill in the art to readily determine the manufacturing conditions required to achieve crystallization of all of API/co-crystal formers, nor to determine which combinations of API and co-crystal former would even be capable of being recovered in crystal form, it is considered that one of ordinary skill in the art would have to engage in **undue experimentation** in order to be able to fully make and use the invention to the full extent of the claims.

In particular, as the parameters crucial to forming all of the API/co-crystal former crystals are not known, one of ordinary skill in the art would have to perform an exhaustive search to find all of those APIs and co-crystal formers, as well as all crystallization parameters, that are necessary to provide the crystal forms. To make all of the possible crystals, one of ordinary skill in the art would have to first have to select a particular API and co-crystal former combination, and then discover the means of achieving the crystalline form of the combination by performing numerous and exhaustive crystal manufacturing processes and making incremental changes in each manufacturing parameter, such as solvent and temperature parameters, to try and obtain the compounds in co-crystal form. If the components failed to crystallize, the crystal manufacturing process would have to be repeated, again with incremental changes in parameters, to attempt to achieve a new crystal form. If a crystal were achieved, the crystal would have to be analyzed by X-ray diffraction or other method to determine whether hydrogen bonding existed in the crystal. The above procedure would have to be repeated numerous different times with a variety of different process parameters, as well as with different APIs and co-crystal formers, in order for one of ordinary skill in the art to discover all those co-crystal forms that fall within the scope of the claim, and thus to be able to fully make and use the invention commensurate with the full scope of the claim. Therefore, the skilled artisan would have to exercise **undue experimentation** to practice the instant invention.

Thus, the specification fails to provide sufficient support for the broad recitation of a co-crystal composition containing any solid API, in general, with any solid or liquid co-crystal-former, in general, in which the components are hydrogen bonded to each other. As a result, one of ordinary skill in the art would be required to perform an exhaustive search for the embodiments of the co-crystal compositions that are suitable for the practice of the invention.

Genentech, 108 F.3d at 1366, states that “a patent is not a hunting license. It is not a reward for a search, but compensation for its successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.”

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in undue experimentation to make and use all of the co-crystal compositions encompassed by the instant claims, with no assurance of success.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 9-11 and 38-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7,078,526 to Remenar et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are to co-crystals of APIs and co-crystal formers, including the specific crystals listed in claim 11, such as itraconazole and tartaric acid, whereas the patented claims are to only the specific co-crystal that contains itraconazole and tartaric acid. Accordingly, the instant claims are obvious over the specific patented co-crystal, and thus are not patentably distinct over the 7,078,526 patent.

Claims 1-2 and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 86-93 of copending Application No. 10/546,963, as published in U.S. Patent Application

Publication No. 2007/0059356 to Almarsson et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are to co-crystals having any API and any co-crystal former that are hydrogen bonded, whereas the published claims are to co-crystal compositions having APIs and co-crystal formers with functional groups that allow for hydrogen bonding. Accordingly, the broader class of co-crystals as claimed is obvious over the co-crystals having the specific functional groups as in the published application, and the instant claims are not patentably distinct from those in the 2007/0059356 publication.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-2, 9-11 and 38-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-49 and 72-87 of copending Application No. 10/570,405, as published in U.S. Patent Application Publication No. 2007/0021510 to Hickey et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are to co-crystals having any API and any co-crystal former that are hydrogen bonded, including modafinil and malonic acid, whereas the published claims are to co-crystal compositions having modafinil as the APIs and co-crystal formers that hydrogen bond to one another, such as malonic acid. Accordingly, the broader class of co-crystals as claimed is obvious over the specific modafinil co-crystals as in the

published application, and the instant claims are not patentably distinct from those in the 2007/0021510 publication.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-2, 9-11 and 38-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 66-72 of copending Application No. 10/551,014, as published in U.S. Patent Application Publication No. 2006/0223794 to Bourghol Hickey et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are to co-crystals having any API and any co-crystal former that are hydrogen bonded, including olanzapine and nicotinamide, whereas the published claims are to the specific co-crystal compositions having olanzapine and nicotinamide as the co-crystal components. Accordingly, the broader class of co-crystals as claimed is obvious over the specific olanzapine co-crystals as in the published application, and the instant claims are not patentably distinct from those in the 2006/00223794 publication.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-2, 9-11 and 38-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-7, 16 and 18 of copending Application No. 10/926,842, as published in U.S. Patent Application Publication No. 2005/0070551 to Remenar et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are to co-crystals having any API and any co-crystal former that are hydrogen bonded, including itraconazole and various acids such as succinic acid, fumaric acid and tartaric acid, whereas the published claims are to the specific co-crystal compositions having itraconazole and acids such as malonic acid, fumaric acid, tartaric acid, etc, as well as other co-crystal forms. Accordingly, the scope of the instant claims overlaps with that of the published application, and accordingly, the instant claims are not patentably distinct from those in the 2005/0070551 publication.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 1-2, 9-11 and 38-42 are free of the art. The Examiner suggests to the Applicant to consider:

1. deleting part c) from claim 1, adding the limitation to claim 9 into part c),
2. delete claim 2,

3. keep claims 10-11 and 38-42.

The Examiner feels that the above changes will put the application in better condition for allowance.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

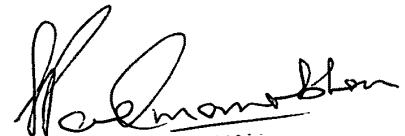
Application/Control Number:
10/660,202
Art Unit: 1617

Page 17

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

A handwritten signature in black ink, appearing to read 'S. Padmanabhan', with a horizontal line underneath.

Index of Claims 	Application/Control No. 10660202	Applicant(s)/Patent Under Reexamination ALMARSSON ET AL.
	Examiner Claytor, Renee	Art Unit 1617

✓	Rejected
=	Allowed

-	Cancelled
÷	Restricted

N	Non-Elected
I	Interference

A	Appeal
O	Objected

☐ Claims renumbered in the same order as presented by applicant			☐ CPA			☐ T.D.			☐ R.1.47		
CLAIM		DATE									
Final	Original	12/07/2007									
	1	✓									
	2	✓									
	3	-									
	4	-									
	5	-									
	6	-									
	7	-									
	8	-									
	9	✓									
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<i>Index of Claims</i> 	Application/Control No. 10660202	Applicant(s)/Patent Under Reexamination ALMARSSON ET AL.
	Examiner Claytor, Renee	Art Unit 1617

✓	Rejected
=	Allowed

-	Cancelled
÷	Restricted

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I	Interference

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☐ Claims renumbered in the same order as presented by applicant			☐ CPA			☐ T.D.			☐ R.1.47		
CLAIM			DATE								
Final	Original	12/07/2007									
	37	-									
	38	✓									
	39	✓									
	40	✓									
	41	✓									
	42	✓									

Search Notes 	Application/Control No. 10660202	Applicant(s)/Patent Under Reexamination ALMARSSON ET AL.
	Examiner Claytor, Renee	Art Unit 1617

SEARCHED			
Class	Subclass	Date	Examiner
424	400	12/7/2007	RC

SEARCH NOTES		
Search Notes	Date	Examiner
PALM Inventor Search	12/7/2007	RC
EAST	12/7/2007	RC

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

SALIWANCHIK, LLOYD

Fax: 352-3725800

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SALIWANCHIK, LLOYD & SALIWANCHIK

A Professional Association
P.O. Box 142950
Gainesville, FL 32614-2950

Telephone (352) 375-8100
Facsimile (352) 372-5800

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OFFICE OF PETITIONS

TO:	Examiner Leonard Williams	FROM:	Frank C. Eisenschenk, Ph.D.
COMPANY:	U.S. Patent Office	DATE:	December 19, 2007
FAX NO.:	(571)273-8300	NO. OF PAGES	
		(INCLUDING COVER SHEET):	3

SUBJECT/MESSAGE:

Re: U.S. Patent Application Docket No. TPI-350C1
PHARMACEUTICAL CO-CRYSTAL COMPOSITIONS
(Almarsson *et al.*)
Serial No. 10/660,202; filed September 11, 2003

Attachment: Transmittal Letter authorizing additional extension of time fee (2 pages)

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PAGE 1/3 * RCVD AT 12/19/2007 2:38:29 PM [Eastern Standard Time] * SVR:USPTO-EFXXRF-6/19 * DNIS:2738300 * CSID:352 3725800 * DURATION (mm:ss):01:16

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NOVARTIS EXHIBIT 1023

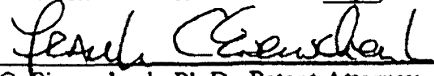
Novartis v. Regents, IPR2023-01346

Page 763 of 1101

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facsimile transmitted to the United States Patent
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Frank C. Eisenschenk, Ph.D., Patent Attorney

TRANSMITTAL LETTER

Examining Group 1617

Patent Application

Pocket No. TPI-350C1

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OFFICE OF PETITIONS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Abigail Manda Cotton
Art Unit : 1617
Applicants : Örn Almarsson, Magali Bourghol Hickey, Matthew L. Peterson, Michael J.
Zaworotko, Brian Moulton, Nair Rodriguez-Hornedo
Serial No. : 10/660,202
Filed : September 11, 2003
Conf. No. : 6536
For : Pharmaceutical Co-Crystal Compositions

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

12/27/2007 DALLEN 00000016 190065 10660202

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TRANSMITTAL LETTER

Sir:

Applicants, by the undersigned, herein requests that the fees for the above-identified application be charged based on its status as a large entity. Applicants filed an Amendment Under 37 C.F.R. § 1.111 and authorized the payment of a three-month Extension of Time in the subject application. The fee for a three-month extension of time was inadvertently authorized based on small entity status rather than large entity status. Accordingly, Applicants respectfully submit that the extension fee charge as a small entity fee of \$510 was in error; thus, the three month extension fee for a large entity should have been charged.

The additional fee of \$540 (based on the fees in effect as of September 30, 2007), which is the fee covering the difference in the amount authorized for payment as a small entity upon filing of the Amendment Under 37 C.F.R. § 1.111 and the amount due as a large entity, was paid at the time this Transmittal Letter was filed.

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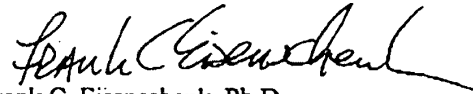
Docket No. TPI-350C1
Patent No. 10/660,202

The Commissioner is hereby authorized to charge any additional fees under 37 CFR §§1.16
or 1.17 which may be required to Deposit Account 19-0065.

Respectfully submitted,

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DEC 19 2007



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: P.O. Box 142950
Gainesville, FL 32614-2950

FCE/sl

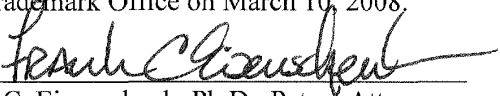
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PAGE 3/3 * RCVD AT 12/19/2007 2:38:29 PM [Eastern Standard Time] * SVR:USPTO-EF XRF-6/19 * DNIS:2738300 * CSID:352 3725800 * DURATION (mm:ss):01:16

NPC-UNIV-000005691

NOVARTIS EXHIBIT 1023
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Page 765 of 1101

I hereby certify that this correspondence is being electronically filed in the United States Patent and Trademark Office on March 10, 2008.


Frank C. Eisenschenk, Ph.D., Patent Attorney

RESPONSE UNDER 37 C.F.R. § 1.116
Patent Application
Docket No. TPI-350C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Abigail Manda Cotton
Art Unit : 1617
Applicants : Örn Almarsson, Magali Bourghol Hickey, Matthew L. Peterson, Michael J. Zaworotko, Brian Moulton, Nair Rodriguez-Hornedo
Serial No. : 10/660,202
Filed : September 11, 2003
Conf. No. : 6536
For : Pharmaceutical Co-Crystal Compositions

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

RESPONSE UNDER 37 C.F.R. § 1.116

Sir:

The remarks that follow are submitted for the Examiner's consideration in the above-referenced patent application in response to the Office Action dated December 10, 2007.

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Remarks

Claims 1, 2, 9-11 and 38-42 are pending in the subject application and currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, Applicants gratefully acknowledge the Examiner's withdrawal of the previous rejection under 35 U.S.C. § 102 and the obviousness-type double patenting rejection over Remenar *et al.* Although the obviousness-type double patenting rejection over Remenar *et al.* (U.S. Patent No. 7,078,526) is withdrawn on page 4 of the Office Action, the rejection remains on page 12. The Examiner indicated during a telephonic interview on December 27, 2007 that the rejection was an error and that no response was required. Applicants also acknowledge the Examiner's indication that claims 1, 2, 9-11, and 38-42 are free of the prior art.

Claims 1, 2, 9, 10 and 38-42 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action argues that Applicants have shown the formation of particular co-crystals, such as those recited within claim 11, but do not exemplify the formation of all co-crystals containing any solid API and any co-crystal former that is liquid or solid and where the components are hydrogen bonded to one another or co-crystals with any of the numerous and diverse different co-crystal formers recited in claim 2 or the APIs recited within claim 6. The Office Action also indicates that the specification describes only the preparation of the particular co-crystals recited within claim 11 and does not describe the claimed invention in a manner sufficient to convey that the inventors were in possession of the entire claimed invention, including the formation of co-crystals containing any API and any co-crystal former that are hydrogen bonded. Applicants traverse.

It is incumbent upon the Patent Office to clearly establish that the as-filed specification fails to provide an adequate written description for the claimed invention; the written description of the as-filed specification is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, *e.g.*, *In re Marzocchi*, 439 F.2d 220, 224, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971). In the case of the instant application, Applicants respectfully submit that a *prima facie* case providing reasons why one skilled in the art would not have recognized that the inventors were in possession of the claimed invention has not been established. Rather, the Office Action makes a general allegation that the as-filed specification

fails to provide adequate written description of the claimed invention because the examples do not exemplify or otherwise show the formation of all co-crystals. Applicants also respectfully submit that compliance with the written description requirement does not turn on the number of examples provided in the as-filed specification. Specifically, the Federal Circuit held that examples are not necessary to support the adequacy of a written description and that the written description standard may be met even where actual reduction to practice of an invention is absent. See *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366, 79 U.S.P.Q.2d 1001 (Fed. Cir. 2006). Accordingly, Applicants respectfully request that the rejection be withdrawn as the grounds articulated for maintaining the rejection are inconsistent with governing law and because the Office Action fails to establish a *prima facie* case that the written description provided by the as-filed specification is insufficient.

Claims 1, 2, 9, 10 and 38-42 are rejected under 35 U.S.C. §112, first paragraph, as nonenabled by the subject specification. The Office Action acknowledges that the specification is enabled for the preparation and use of the particular pharmaceutical co-crystals, but it is not enabled for the preparation of all co-crystals having any API that is solid, and any co-crystal former that solid and liquid, where components are hydrogen bonded to one another, or all co-crystals having the numerous and diverse APIs and co-crystal formers. Thus, the specification fails to provide sufficient support for the broad recitation of a co-crystal composition containing any solid API, in general, with any solid or liquid co-crystal-former, in general, in which the components are hydrogen bonded to each other.

The Office Action states that the application is enabling for the preparation and use of the particular pharmaceutical co-crystals as recited in claim 11, but is not enabling of all co-crystals having any API that is solid, and any co-crystal former that is solid or liquid, where the components are hydrogen bonded to one another, or all co-crystals having the numerous and diverse APIs and co-crystal formers. The Office Action states that the instant specification fails to provide information that would allow the skilled artisan to fully make and use the instant invention without undue experimentation and cites the eight factors identified in *Ex parte Forman*, 230 U.S.P.Q. 546 (Bd. Pat. App. Int. 1986) at 547.

Of the eight factors, the Office Action identifies that the nature of the invention pertains to a

co-crystal composition containing a solid API and a solid or liquid co-crystal former, where the API and co-crystal former are hydrogen bonded to one another. The Office Action identifies that the relative skill of those in the art to be very high, typically having advanced degrees. The Office Action also states the breadth of the claims to be so broad so as to exacerbate the lack of predictability (relating to the use of any API and any solid or liquid co-crystal former) and that the specification does not provide any direction or guidance that is sufficient for one of ordinary skill in the art. Although the Office Action states that the specification provides working examples showing the fabrication of the 32 particular co-crystals recited in original claim 11, it concludes that such examples are not adequate guidance as to how one of ordinary skill in the art could prepare all other crystals containing any API and co-crystal former. Ultimately, the Office Action states that the quantity of experimentation required is considered undue and that one of ordinary skill could not determine the manufacturing conditions required to achieve crystallization or what combinations of APIs and co-crystal formers would even be capable of being recovered in crystal form. In support of its position regarding the unpredictability, the Office Action characterizes the state of the art as being unpredictable due to numerous different crystallization factors needed to be controlled and the unpredictability to predicting the different types of crystals that may exist. Support for this position, it is argued, is supplied by Gavezzotti "Are Crystal Structures Predictable?" (Acc. Chem. Res. 1994, vol. 27, pages 309-14). The Office Action alleges that Gavezzotti indicates that the formation and structure of crystals are unpredictable at best. Applicants respectfully traverse the rejection.

Gavezzotti is a reference published about eight (8) years prior to the priority date for the instant application and has little relevance to the claimed invention. Applicants note that this reference is directed to mono-crystals of compounds rather than co-crystals of the compounds. Additionally, it is respectfully submitted that the cited reference does not accurately reflect the state of the art at the time of the invention was made (e.g., compositions comprising co-crystals of APIs co-crystal formers). Further, the cited reference does not address the considerations and teachings provided in the specification for identifying appropriate APIs and co-crystal formers to be used in making the claimed compositions. In this regard, Applicants note that crystal engineering is an art recognized field related to the rational design of pharmaceutical co-crystals. For example, Almarsson *et al.* (Ref. R114 in the Information Disclosure Statement filed September 21, 2006)

indicates that “... it has become clear that a wide array of multiple component pharmaceutical phases, so called pharmaceutical co-crystals, can be rationally designed using crystal engineering ...” (see page 1889, column 1, paragraph 1). Thus, it is respectfully submitted that Gavezzotti fails to support the position that making pharmaceutical co-crystals is an unpredictable area.

As the Patent Office is aware, enablement is a legal determination of whether a patent enables one skilled in the art to make and use the claimed invention (*Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983)) and is not precluded even if some experimentation is necessary. *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 U.S.P.Q. 409, 413 (Fed. Cir. 1984); *W.L. Gore and Associates v. Garlock, Inc.*, 721 F.2d 1540, 1556, 220 U.S.P.Q. 303, 315 (Fed. Cir. 1983). Additionally, the Patent and Trademark Office Board of Patent Appeals and Interferences has stated: “The test [for enablement] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed”. *Ex parte Jackson*, 217 U.S.P.Q. 804, 807 (1982); *see also Ex parte Erlich* 3 U.S.P.Q.2d 1011 (B.P.A.I. 1982) (observing that although a method might be “tedious and laborious,” such experimentation is nevertheless “routine” defining “routine” experiments as those which use known methods in combination with the variables taught in the patent to achieve the expected, specific, patented result).

In this case and as noted in the Office Action, the claimed co-crystal compositions are made up of solid APIs and solid or liquid co-crystal formers that are hydrogen bonded. Non-limiting examples of APIs are provided in the as-filed specification in Table 4 and non-limiting examples of co-crystal formers and their functionalities are disclosed in Tables 1 and 2. The as-filed specification also teaches how one skilled in the art is to form the claimed co-crystal compositions (*e.g.*, melt recrystallization, grinding, milling, standing, solution evaporation, thermally driven crystallization from solution, vapor diffusion, anti-solvents, high throughput crystallization protocols, *etc.*, see, for example, page 14, lines 8-19 and page 43 of the as-filed specification). Thus, Applicants respectfully submit that the as-filed specification provides adequate teaching to one skilled in the art as to how to make the claimed compositions. Furthermore, while it is possible that a considerable amount of

experimentation may be required, Applicants respectfully submit that this experimentation is permissible as it is merely routine and the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed and enables those skilled in the art to practice the invention as claimed. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1, 2, and 10 are provisionally rejected on the ground of nonstatutory “obviousness-type” double patenting over claims 86-93 of copending Application No. 10/546,963. Claims 1, 2, 9-11, and 38-42 are provisionally rejected on the ground of nonstatutory “obviousness-type” double patenting over claims 1-49 and 72-87 of copending Application No. 10/570,405, over claims 66-72 of copending Application No. 10/551,014, and over claims 2-7, 16, and 18 of copending Application No. 10/926,842. Applicants respectfully request that these rejections be held in abeyance until such time that allowable subject matter is indicated.

Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: P.O. Box 142950
Gainesville, FL 32614-2950

FCE/sl

Electronic Acknowledgement Receipt	
EFS ID:	2974225
Application Number:	10660202
International Application Number:	
Confirmation Number:	6536
Title of Invention:	Pharmaceutical co-crystal compositions
First Named Inventor/Applicant Name:	Orn Almarsson
Customer Number:	23557
Filer:	Frank Christopher Eisenschenk/Sherry Loke
Filer Authorized By:	Frank Christopher Eisenschenk
Attorney Docket Number:	TPI-350C1
Receipt Date:	10-MAR-2008
Filing Date:	11-SEP-2003
Time Stamp:	16:38:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		Amd-final.pdf	581619	yes	7
			d430daa5579789da0359ce93810eb11 baa177738		

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Amendment After Final	1	1
	Applicant Arguments/Remarks Made in an Amendment	2	7
Warnings:			
Information:			
Total Files Size (in bytes):		581619	
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.			
<u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.			
<u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.			
<u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.			



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,202	09/11/2003	Orn Almarsson	TPI-350C1	6536
23557 7590 03/25/2008 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			EXAMINER CLAYTOR, DEIRDRE RENEE	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 03/25/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/660,202	Applicant(s) ALMARSSON ET AL.	
	Examiner Renee Claytor	Art Unit 1617	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 March 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ They raise the issue of new matter (see NOTE below);

(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see Continuation sheet.

12. ☐ Note the attached Information *Disclosure Statement(s)*. (PTO/SB/08) Paper No(s). _____

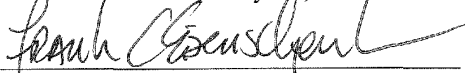
13. ☐ Other: _____.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617

Applicants arguments have been fully considered. In particular, Applicants argue that compliance with the written description requirement does not turn on the number of examples provided in the as-filed specification. It is noted that claim 1 broadly reads on any solid API and any co-crystal former that is liquid or solid and where the components are hydrogen bonded to one another or the co-crystals with any of the numerous diverse and different co-crystal formers in claim 2 or APIs as in claim 9. There is no description to convey to one of skill in the art that the inventors were in possession of the numerous and diverse co-crystals as claimed, including any API and any co-crystal former that are hydrogen bonded and are solid or liquid. Therefore, the rejection is maintained.

Applicants arguments over the enablement rejection have been fully considered and are not found persuasive. In particular, Applicants argue that the specification provides adequate teaching to one skilled in the art as to how to make the claimed compositions. Applicants argue that a considerable amount of experimentation may be required, but submit that this experimentation is permissible as it is routine and the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed and enables those skilled in the art to practice the invention as claimed. In particular, Applicants argue that the Gavezzotti reference was published 8 years prior to the priority date for the present application and has little relevance. In response to the above arguments, it is noted that the specification is enabled for the preparation and use of the particular pharmaceutical co-crystals as recited in claim 11; however, the specification is not enabled for the preparation of all co-crystals having any API that is solid, as broadly recited in claim 1. As discussed in the rejection, the state of the art regarding the formation of different crystalline forms is unpredictable due to the numerous different crystallization factors needed to be controlled to provide different crystal states. Regarding the Gavezzotti reference, it is noted that without proof that the article has no relevance, the content of the article is considered to be substantial to make the argument that the formation and structure of crystals is unpredictable.

I hereby certify that this correspondence is being electronically filed in the United States Patent and Trademark Office on May 29, 2008.



Frank C. Eisenschenk, Ph.D., Patent Attorney

SUPPLEMENTAL AMENDMENT
UNDER 37 C.F.R. § 1.116
Patent Application
Docket No. TPI-350C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Deirdre Renee Claytor
Art Unit : 1617
Applicants : Örn Almarsson, Magali Bourghol Hickey, Matthew L. Peterson, Michael J. Zaworotko, Brian Moulton, Nair Rodriguez-Hornedo
Serial No. : 10/660,202
Filed : September 11, 2003
Conf. No. : 6536
For : Pharmaceutical Co-Crystal Compositions

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

SUPPLEMENTAL AMENDMENT UNDER 37 C.F.R. § 1.116

Sir:

Applicants request that the period for response be extended three months through and including June 10, 2008, the fees for which have been paid at the time this Supplemental Amendment was filed.

In response to the Advisory Action dated March 25, 2008, please amend the above-identified patent application as follows:

J:\TPI\350C1\Amend-Resp\Amd-final-supp.doc\DNB/sl

In the Claims

1 (currently amended). A pharmaceutical co-crystal composition, comprising: an API and a co-crystal former, wherein:

- a) the API is selected from celecoxib, carbamazepine, 5-fluorouracil, acetaminophen, aspirin, flurbiprofen, phenytoin or ibuprofen ~~liquid or a solid at room temperature and the co-crystal former is a solid at room temperature;~~
- b) the API and co-crystal former are hydrogen bonded to each other; and
- c) specifically excluding a co-crystal selected from the group consisting of: 5-fluorouracil:9-ethylhypoxanthine, 5-fluorouracil:cytosine dihydrate, 5-fluorouracil:theophylline monohydrate, acetaminophen:piperazine and acetaminophen:theophylline ~~nabumetone:2,3-naphthalenediol, fluoxetine HCl:benzoic acid, fluoxetine HCl:succinic acid, acetaminophen:piperazine, acetaminophen:theophylline, theophylline:salicylic acid, theophylline:p-hydroxybenzoic acid, theophylline:sorbic acid, theophylline:1-hydroxy-2-naphthoic acid, theophylline:glycolic acid, theophylline:2,5-dihydroxybenzoic acid, theophylline:chloroacetic acid, bis(diphenylhydantoin):9-ethyladenine acetylacetone solvate, bis(diphenylhydantoin):9-ethyladenine 2,4-pentanedione solvate, 5,5-diphenylbarbituric acid:9-ethyladenine, bis(diphenylhydantoin):9-ethyladenine, 4-aminobenzoic acid:4-aminobenzonitrile, sulfadimidine:salicylic acid, 8-hydroxyquinolinium 4-nitrobenzoate:4-nitrobenzoic acid, sulfaproxyline:caffeine, retro-inverso-isopropyl (2R,3S) 4-cyclohexyl 2-hydroxy-3-(N-((2R)-2-morpholinocarbonylmethyl-3-(1-naphthyl)propionyl)-L-histidylamino)butyrate:cinnamic acid monohydrate, benzoic acid:isonicotinamide, 3-(2-N',N'-(dimethylhydrazino)-4-thiazolylmethylthio)-N''-sulfamoylpropionamide:maleic acid, diglycine hydrochloride (C₂H₅NO₂:C₂H₆NO₂⁺Cl⁻), octadecanoic acid:3-pyridinecarboxamide, cis-N-(3-methyl-1-(2-(1,2,3,4-tetrahydro)naphthyl)-piperidin-4-yl)-N-phenylpropanamide hydrochloride:oxalic acid, trans-N-(3-methyl-1-(2-(1,2,3,4-tetrahydro)naphthyl)-piperidin-4-yl)-N-phenylpropanamide oxalate:oxalic acid dihydrate, bis(1-(3-((4-(2-isopropoxyphenyl)-1-piperazinyl)methyl)benzoyl)piperidine)succinate:succinic acid, bis(p-eyanophenyl)imidazolylmethane:succinic acid, cis-1-((4-(1-imidazolylmethyl)cyclohexyl)methyl)imidazole:succinic acid, (+)-2-(5,6-dimethoxy-1,2,3,4-~~

tetrahydro-1-naphthyl)imidazoline:(+)-dibenzoyl-D-tartaric acid, raclopride:tartaric acid, 2,6-diamino-9-ethylpurine:5,5-diethylbarbituric acid, 5,5-diethylbarbituric acid:bis(2-aminopyridine), 5,5-diethylbarbituric acid:acetamide, 5,5-diethylbarbituric acid:KI₃, 5,5-diethylbarbituric acid:urea, bis(barbital):hexamethylphosphoramide, 5,5-diethylbarbituric acid:imidazole, barbital:1-methylimidazole, 5,5-diethylbarbituric acid:N-methyl-2-pyridone, 2,4-diamino-5-(3,4,5-trimethoxybenzyl)pyrimidine:5,5-diethylbarbituric acid, bis(barbital):caffeine, bis(barbital):1-methylimidazole, bis(beta-cyclodextrin):bis(barbital) hydrate, tetrakis(beta-cyclodextrin):tetrakis(barbital), 9-ethyladenine:5,5-diethylbarbituric acid, barbital:N¹-(p-cyanophenyl)-N-(p-iodophenyl)melamine, barbital:2-amino-4-(m-bromophenylamino)-6-chloro-1,3,5-triazine, 5,5-diethylbarbituric acid:N,N'-diphenylmelamine, 5,5-diethylbarbituric acid:N,N'-bis(p-chlorophenyl)melamine, N,N'-bis(p-bromophenyl)melamine:5,5-diethylbarbituric acid, 5,5-diethylbarbituric acid:N,N'-bis(p-iodophenyl)melamine, 5,5-diethylbarbituric acid:N,N'-bis(p-tolyl)melamine, 5,5-diethylbarbituric acid:N,N'-bis(m-tolyl)melamine, 5,5-diethylbarbituric acid:N,N'-bis(m-chlorophenyl)melamine, N,N'-Bis(m-methylphenyl)melamine:barbital, N,N'-bis(m-chlorophenyl)melamine:barbital tetrahydrofuran solvate, 5,5-diethylbarbituric acid:N,N'-bis(t-butyl)melamine, 5,5-diethylbarbituric acid:N,N'-di(t-butyl)melamine, 6,6'-diquinolyl ether:5,5-diethylbarbituric acid, 5-t-butyl-2,4,6-triaminopyrimidine:diethylbarbituric acid, N,N'-bis(4-carboxymethylphenyl)melamine:barbital ethanol solvate, N,N'-bis(4-t-butylphenyl)melamine:barbital, tris(5,17-N,N'-bis(4-amino-6-(butylamino)-1,3,5-triazin-2-yl)diamino-11,23-dinitro-25,26,27,28-tetrapropoxycalix(4)arene):hexakis(diethylbarbituric acid) toluene solvate, N,N'-bis(m-fluorophenyl)melamine:barbital, N,N'-bis(m-bromophenyl)melamine:barbital acetone solvate, N,N'-bis(m-iodophenyl)melamine:barbital acetonitrile solvate, N,N'-bis(m-trifluoromethylphenyl)melamine:barbital acetonitrile solvate, aminopyrine:barbital, N,N'-bis(4-fluorophenyl)melamine:barbital, N,N'-bis(4-trifluoromethylphenyl)melamine:barbital, 2,4-diamino-5-(3,4,5-trimethoxybenzyl)pyrimidine:barbital, hydroxybutyrate:hydroxyvalerate, 2-aminopyrimidine:succinic acid, 1,3-bis(((6-methylpyrid-2-yl)amino)carbonyl)benzene:glutaric acid, 5-t-butyl-2,4,6-triaminopyrimidine:diethylbarbituric acid, bis(dithiobiuret-S,S')nickel(II):diuracil, platinum-3,3'-dihydroxymethyl-2,2'-bipyridine dichloride:AgF₃CSO₃, 4,4'-bipyridyl:isophthalic

acid, 4,4'-bipyridyl:1,4-naphthalenedicarboxylic acid, 4,4'-bipyridyl:1,3,5-cyclohexane-tricarboxylic acid, 4,4'-bipyridyl:tricarballic acid, urotropin:azelaic acid, insulin:C8-HI (octanoyl-N⁶-LysB29-human-insulin), isonicotinamide:cinnamic acid, isonicotinamide:3-hydroxybenzoic acid, isonicotinamide:3-N,N-dimethylaminobenzoic acid, isonicotinamide:3,5-bis(trifluoromethyl)-benzoic acid, isonicotinamide:d,l-mandelic acid, isonicotinamide:chloroacetic acid, isonicotinamide:fumaric acid monoethyl ester, isonicotinamide:12-bromododecanoic acid, isonicotinamide:fumaric acid, isonicotinamide:succinic acid, isonicotinamide:4-ketopimelic acid, isonicotinamide:thiodiglycolic acid, 1,3,5-cyclohexane-tricarboxylic acid:hexamethyltetramine, 1,3,5-cyclohexane-tricarboxylic acid:4,7-phenanthroline, 4,7-phenanthroline:oxalic acid, 4,7-phenanthroline:terephthalic acid, 4,7-phenanthroline:1,3,5-cyclohexane-tricarboxylic acid, 4,7-phenanthroline:1,4-naphthalenedicarboxylic acid, pyrazine:methanoic acid, pyrazine:ethanoic acid, pyrazine:propanoic acid, pyrazine:butanoic acid, pyrazine:pentanoic acid, pyrazine:hexanoic acid, pyrazine:heptanoic acid, pyrazine:octanoic acid, pyrazine:nonanoic acid, pyrazine:decanoic acid, diammine (deoxy-quanyl-quanyl-N⁷,N⁷)-platinum:tris(glycine)-hydrate, 2-aminopyrimidine:p-phenylenediacetic acid, bis(2-aminopyrimidin-1-ium)fumarate:fumaric acid, 2-aminopyrimidine:indole-3-acetic acid, 2-aminopyrimidine:N-methylpyrrole-2-carboxylic acid, 2-aminopyrimidine:thiophen-2-carboxylic acid, 2-aminopyrimidine:(+)-camphoric acid, 2,4,6-Trinitrobenzoic acid:2-aminopyrimidine, 2-aminopyrimidine:4-aminobenzoic acid, 2-aminopyrimidine:bis(phenoxyacetic acid), 2-aminopyrimidine:(2,4-dichlorophenoxy)acetic acid, 2-aminopyrimidine:(3,4-dichlorophenoxy)acetic acid, 2-aminopyrimidine:indole-2-carboxylic acid, 2-aminopyrimidine:terephthalic acid, 2-aminopyrimidine:bis(2-nitrobenzoic acid), 2-aminopyrimidine:bis(2-aminobenzoic acid), 2-aminopyrimidine:3-aminobenzoic acid, 2-hexeneoic acid:isonicotinamide, 4-nitrobenzoic acid:isonicotinamide, 3,5-dinitrobenzoic acid:isonicotinamide:4-methylbenzoic acid, 2-amino-5-nitropyrimidine:2-amino-3-nitropyridine, 3,5-dinitrobenzoic acid:4-chlorobenzamide, 3-dimethylaminobenzoic acid:4-chlorobenzamide, fumaric acid:4-chlorobenzamide, oxine:4-nitrobenzoic acid, oxine:3,5-dinitrobenzoic acid, oxine:3,5-dinitrosalicylic acid, 3-[2-(N²,N²-dimethylhydrazino)-4-thiazolylmethylthio]-N²-sulfamoylpropionamide:maleic acid, 5-fluorouracil:9-ethylhypoxanthine, 5-fluorouracil:cytosine dihydrate, 5-fluorouracil:theophylline monohydrate, stearic acid:nicotinamide, cis-1-[[4-(1-

~~imidazolylmethyl)cyclohexyl)methyl}imidazole:succinic acid, CGS18320B:succinic acid, sulfaproxyline:caffeine, 4-aminobenzoic acid:4-aminobenzonitrile, 3,5-dinitrobenzoic acid:isonicotinamide:3-methylbenzoic acid, 3,5-dinitrobenzoic acid:isonicotinamide:4-(dimethylamino)benzoic acid, 3,5-dinitrobenzoic acid:isonicotinamide:4-hydroxy-3-methoxycinnamic acid, isonicotinamide:oxalic acid, isonicotinamide:malonic acid, isonicotinamide:succinic acid, isonicotinamide:glutaric acid, isonicotinamide:adipic acid, benzoic acid:isonicotinamide, mazapertine:succinate, betaine:dichloronitrophenol, betainepyridine:dichloronitrophenol, betainepyridine:pentachlorophenol, 4-{2-[1-(2-hydroxyethyl)-4-pyridylidene]-ethylidene}-cyclo-hexa-2,5-dien-1-one:methyl-2,4-dihydroxybenzoate, 4-{2-[1-(2-hydroxyethyl)-4-pyridylidene]-ethylidene}-cyclo-hexa-2,5-dien-1-one:2,4-dihydroxypropiophenone, 4-{2-[1-(2-hydroxyethyl)-4-pyridylidene]-ethylidene}-cyclo-hexa-2,5-dien-1-one:2,4-dihydroxyacetophenone, squaric acid:4,4'-dipyridylacetylene, squaric acid:1,2-bis(4-pyridyl)ethylene, chloranilic acid:1,4-bis[(4-pyridyl)ethynyl]benzene, 4,4'-bipyridine:phthalic acid, 4,4'-dipyridylacetylene:phthalic acid, bis(pentamethylelopentadienyl)iron:bromanilic acid, bis(pentamethylelopentadienyl)iron:chloranilic acid, bis(pentamethylelopentadienyl)iron:cyananilic acid, pyrazinotetrathiafulvalene:chloranilic acid, phenol:pentafluorophenol, co-crystals of itraconazole, and co-crystals of topiramate or hydrochlorothiazide.~~

2-9 (canceled).

10 (original). The pharmaceutical co-crystal composition according to claim 1, further comprising a pharmaceutically acceptable diluent, excipient, or carrier.

11 (currently amended). A co-crystal comprising an API and a co-crystal former selected from:

- (a) carbamazepine and saccharin;
- (b) carbamazepine and nicotinamide;
- (c) carbamazepine and trimesic acid;

- (d) celecoxib and nicotinamide;
- ~~(e)~~olanzapine and nicotinamide;
- ~~(f)~~(e) celecoxib and 18-crown-6;
- ~~(g)~~
- ~~(f)~~modafinil and malonic acid;
- ~~(g)~~modafinil and benzamide;
- ~~(h)~~modafinil and mandelic acid;
- ~~(i)~~modafinil and glycolic acid;
- ~~(j)~~modafinil and fumaric acid;
- ~~(k)~~modafinil and maleic acid;
- ~~(n)~~(f) 5-fluorouracil and urea;
- ~~(o)~~(g) acetaminophen and 4,4'-bipyridine;
- ~~(p)~~(h) phenytoin and pyridone;
- ~~(q)~~(i) aspirin and 4,4'-bipyridine;
- ~~(r)~~(j) ibuprofen and 4,4'-bipyridine;
- ~~(s)~~(k) flurbiprofen and 4,4'-bipyridine;
- ~~(t)~~(l) flurbiprofen and trans-1,2-bis(4-pyridyl) ethylene;
- ~~(u)~~(m) carbamazepine and p-phthalaldehyde;
- ~~(v)~~(n) carbamazepine and 2,6-pyridinecarboxylic acid;
- ~~(w)~~(o) carbamazepine and 5-nitroisophthalic acid;
- ~~(x)~~(p) carbamazepine and 1,3,5,7-adamantane tetracarboxylic acid; or
- ~~(y)~~(q) carbamazepine and benzoquinone.

12-42 (canceled).

Remarks

Claims 1, 2, 9-11 and 38-42 are pending in the subject application and currently before the Examiner. By way of this amendment, claims 9 and 38-42 have been canceled and claims 1 and 11 have been amended in accordance with the Examiner's suggestion in the final office action. Claim 1 has also been amended to align subsection (c) with the APIs listed in subsection (a) of the claim. Favorable consideration of the pending claims (claims 1, 10 and 11) is respectfully requested.

Applicants, again, gratefully acknowledge the Examiner's withdrawal of the previous rejection under 35 U.S.C. § 102 and the obviousness-type double patenting rejection over Remenar *et al.* Although the obviousness-type double patenting rejection over Remenar *et al.* (U.S. Patent No. 7,078,526) is withdrawn on page 4 of the Office Action, the rejection remains on page 12. The Examiner indicated during a telephonic interview on December 27, 2007 that the rejection was an error and that no response was required. Applicants also acknowledge the Examiner's indication that claims 1, 2, 9-11, and 38-42 are free of the prior art.

Claims 1, 2, 9, 10 and 38-42 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action argues that Applicants have shown the formation of particular co-crystals, such as those recited within claim 11, but do not exemplify the formation of all co-crystals containing any solid API and any-co-crystal former that is liquid or solid and where the components are hydrogen bonded to one another or co-crystals with any of the numerous and diverse different co-crystal formers recited in claim 2 or the APIs recited within claim 6. The Office Action also indicates that the specification describes only the preparation of the particular co-crystals recited within claim 11 and does not describe the claimed invention in a manner sufficient to convey that the inventors were in possession of the entire claimed invention, including the formation of co-crystals containing any API and any co-crystal former that are hydrogen bonded.

Claims 1, 2, 9, 10 and 38-42 are also rejected under 35 U.S.C. §112, first paragraph, as nonenabled by the subject specification. The Office Action acknowledges that the specification is enabled for the preparation and use of the particular pharmaceutical co-crystals, but it is not enabled for the preparation of all co-crystals having any API that is solid, and any co-crystal former that solid and liquid, where components are hydrogen bonded to one another, or all co-crystals having the

numerous and diverse APIs and co-crystal formers. Thus, the specification fails to provide sufficient support for the broad recitation of a co-crystal composition containing any solid API, in general, with any solid or liquid co-crystal-former, in general, in which the components are hydrogen bonded to each other.

Applicants respectfully maintain that the claimed invention complies with both the written description and enablement requirements of section 112; however, in order to advance prosecution in this matter the rejected portions of the claims have been canceled thereby rendering these issues moot. Accordingly, reconsideration and withdrawal of the rejections is respectfully requested.

Claims 1, 2, and 10 are provisionally rejected on the ground of nonstatutory “obviousness-type” double patenting over claims 86-93 of copending Application No. 10/546,963. Applicants respectfully submit that a nonstatutory “obviousness-type” double patenting rejection for the instantly claimed invention should be withdrawn since it would not appear that the co-crystals recited in the currently pending claims would be obvious in view of the broader class of co-crystals claimed by specific functional groups in the ‘963 application; however, in the interest of expediting prosecution in this matter, a terminal disclaimer is being filed along with this response. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Claims 1, 2, 9-11, and 38-42 are provisionally rejected on the ground of nonstatutory “obviousness-type” double patenting over claims 1-49 and 72-87 of copending Application No. 10/570,405. With respect to this rejection, Applicants respectfully submit that this nonstatutory “obviousness-type” double patenting rejection should be withdrawn as the scope of the currently pending claims does not include modafinil co-crystals. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Claims 1, 2, 9-11, and 38-42 are provisionally rejected on the ground of nonstatutory “obviousness-type” double patenting over claims 66-72 of copending Application No. 10/551,014 and over claims 2-7, 16, and 18 of copending Application No. 10/926,842. Applicants respectfully submit that each of these rejections is inapplicable to the presently claimed invention as the scope of the claims no longer includes co-crystals of olanzapine or itraconazole. Accordingly, reconsideration and withdrawal of these rejections is respectfully requested.

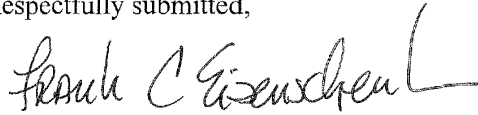
Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.

Patent Attorney

Registration No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: P.O. Box 142950
Gainesville, FL 32614-2950

FCE/sl

Attachment: Terminal Disclaimer

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Deirdre Renee Claytor
Art Unit : 1617
Applicants : Örn Almarsson, Magali Bourghol Hickey, Matthew L. Peterson, Michael J. Zaworotko, Brian Moulton, Nair Rodriguez-Hornedo
Serial No. : 10/660,202
Filed : September 11, 2003
Conf. No. : 6536
For : Pharmaceutical Co-Crystal Compositions

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

TERMINAL DISCLAIMER

Sir:

The owners, University of South Florida, Transform Pharmaceuticals, Inc. and The Regents of the University of Michigan, of equal interest in the above-identified patent application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173, as shortened by any terminal disclaimer, of co-pending application Serial No. 10/546,963. The owners hereby agree that any patent so granted on the instant application shall be enforceable only for and during such period that it and the co-pending application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owners do not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of the co-pending patent application,

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as shortened by any terminal disclaimer, in the event that it later expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer.

I am the attorney of record.

The fee of \$130.00 under 37 CFR 1.20(d) was paid at the time this Terminal Disclaimer was filed. The Commissioner is hereby authorized to charge any other fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Date

May 29, 2008

Frank C. Eisenschenk, Ph.D.

Patent Attorney

Reg. No. 45,332

Phone No.: 352-375-8100

Fax No.: 352-372-5800

Address: P.O. Box 142950
Gainesville, FL 32614-2950

FCE/sl

Electronic Patent Application Fee Transmittal				
Application Number:		10660202		
Filing Date:		11-Sep-2003		
Title of Invention:		Pharmaceutical co-crystal compositions		
First Named Inventor/Applicant Name:		Orn Almarsson		
Filer:		Frank Christopher Eisenschenk/Jenny Bedner		
Attorney Docket Number:		TPI-350C1		
Filed as Large Entity				
Utility Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Statutory disclaimer	1814	1	130	130
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension - 3 months with \$0 paid	1253	1	1050	1050
Miscellaneous:				
Total in USD (\$)				1180

Electronic Acknowledgement Receipt	
EFS ID:	3375499
Application Number:	10660202
International Application Number:	
Confirmation Number:	6536
Title of Invention:	Pharmaceutical co-crystal compositions
First Named Inventor/Applicant Name:	Orn Almarsson
Customer Number:	23557
Filer:	Frank Christopher Eisenschenk/Jenny Bedner
Filer Authorized By:	Frank Christopher Eisenschenk
Attorney Docket Number:	TPI-350C1
Receipt Date:	29-MAY-2008
Filing Date:	11-SEP-2003
Time Stamp:	16:18:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$ 1180
RAM confirmation Number	1447
Deposit Account	190065
Authorized User	EISENSCHENK,FRANK C.
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)					
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Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)					
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		Amd-final-supp.pdf	1056703 12320b5c270c3634bdf13d90ea466df7d073f850	yes	11
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment After Final		1	1	
	Claims		2	6	
	Applicant Arguments/Remarks Made in an Amendment		7	9	
	Terminal Disclaimer Filed		10	11	
Warnings:					
Information:					
2	Fee Worksheet (PTO-06)	fee-info.pdf	8303 a5ea97d9980a4e158b8cb78806e9244a3525bde8	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			1065006		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

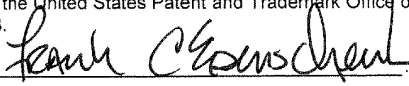
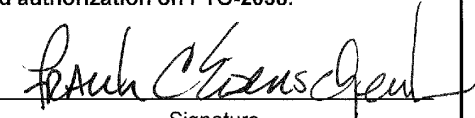
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 10/660,202		Filing Date 09/11/2003		☐ To be Mailed			
APPLICATION AS FILED – PART I												
(Column 1)			(Column 2)		SMALL ENTITY ☒ OR			OTHER THAN SMALL ENTITY				
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)					
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A						
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A						
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A						
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$	=		X \$	=					
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$	=		X \$	=					
☐ APPLICATION SIZE FEE (37 CFR 1.16(s)) If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).												
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))												
* If the difference in column 1 is less than zero, enter "0" in column 2.												
APPLICATION AS AMENDED – PART II												
(Column 1)			(Column 2)		(Column 3)			SMALL ENTITY OR			OTHER THAN SMALL ENTITY	
AMENDMENT	05/29/2008	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)		RATE (\$)	ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	* 3	Minus	** 37	= 0	X \$25 =	0	OR	X \$ =			
	Independent (37 CFR 1.16(h))	* 2	Minus	***20	= 0	X \$105 =	0	OR	X \$ =			
	☐ Application Size Fee (37 CFR 1.16(s))											
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))											
						TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE			
(Column 1)			(Column 2)		(Column 3)							
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)		RATE (\$)	ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =		OR	X \$ =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =		OR	X \$ =			
	☐ Application Size Fee (37 CFR 1.16(s))											
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))											
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.												

 Legal Instrument Examiner:
 /WILLIAM N. PHILLIPS/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

NOTICE OF APPEAL FROM THE EXAMINER TO THE BOARD OF PATENT APPEALS AND INTERFERENCES		Docket Number (Optional) TPI-350C1
I hereby certify that this correspondence is being electronically transmitted to the United States Patent and Trademark Office on June 10, 2008.		In re Application of Örn Almarsson, Magali Bourghol Hickey, Matthew L. Peterson, Michael J. Zaworotko, Brian Moulton, Nair Rodriguez-Hornedo
Signature <u></u>	Application Number 10/660,202 Filed September 11, 2003	
Typed or printed name <u>Frank C. Eisenschenk, Ph.D.</u>	For Pharmaceutical Co-Crystal Compositions	
Art Unit 1641		Examiner James L. Grun, Ph.D.
Applicants hereby appeal to the Board of Patent Appeals and Interferences from the last decision of the examiner.		
The fee for this Notice of Appeal is (37 CFR 41.20(b)(1))		\$ <u>510.00</u>
☐ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by half, and the resulting fee is: \$ _____		
☐ A check in the amount of the fee is enclosed.		
☒ Payment by credit card. Form PTO-2038 is attached.		
☐ The Director has already been authorized to charge fees in this application to a Deposit Account. I have enclosed a duplicate copy of this sheet.		
☐ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. _____. I have enclosed a duplicate copy of this sheet.		
☐ A petition for an extension of time under 37 CFR 1.136(a) (PTO/SB/22) is enclosed.		
WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.		
I am the		
☐ applicant/inventor.		
☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)		
☒ attorney or agent of record. Registration number <u>45,332</u>		
☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____		
<u></u> Signature		<u>Frank C. Eisenschenk, Ph.D.</u> Typed or printed name
_____ Telephone Number		<u>(352) 375-8100</u> Telephone Number
_____ Date		<u>June 10, 2008</u> Date
NOTE: Signatures of all the inventors or assignees of record of the entire interest of their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.		
☐ *Total of _____ forms are submitted.		

This collection of information is required by 37 CFR 1.191. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

J:\TPI\350C1\PTO\NoticeofAppeal.doc\DNB/sl

Electronic Patent Application Fee Transmittal				
Application Number:		10660202		
Filing Date:		11-Sep-2003		
Title of Invention:		Pharmaceutical co-crystal compositions		
First Named Inventor/Applicant Name:		Orn Almarsson		
Filer:		Frank Christopher Eisenschenk/Sherry Loke		
Attorney Docket Number:		TPI-350C1		
Filed as Large Entity				
Utility Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Notice of appeal	1401	1	510	510
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				510

Electronic Acknowledgement Receipt	
EFS ID:	3430584
Application Number:	10660202
International Application Number:	
Confirmation Number:	6536
Title of Invention:	Pharmaceutical co-crystal compositions
First Named Inventor/Applicant Name:	Orn Almarsson
Customer Number:	23557
Filer:	Frank Christopher Eisenschenk/Sherry Loke
Filer Authorized By:	Frank Christopher Eisenschenk
Attorney Docket Number:	TPI-350C1
Receipt Date:	10-JUN-2008
Filing Date:	11-SEP-2003
Time Stamp:	13:52:35
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$510
RAM confirmation Number	7883
Deposit Account	190065
Authorized User	EISENSCHENK,FRANK C.
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)					
Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)					
Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)					
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Notice of Appeal Filed	NoticeofAppeal.pdf	121094	no	1
			99e361e8db5e43c10d331506542e6f0cd297cd19		
Warnings:					
Information:					
2	Fee Worksheet (PTO-06)	fee-info.pdf	8137	no	2
			67a2aa5c26665854be3b4688b6785116847329e		
Warnings:					
Information:					
Total Files Size (in bytes):			129231		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

Application Number 	Application/Control No. 10/660,202	Applicant(s)/Patent under Reexamination ALMARSSON ET AL.
Document Code - DISQ		Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed : 05/29/08	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:
Felicia D. Roberts 10/546,963 (2007/0059356)

U.S. Patent and Trademark Office



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United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,202	09/11/2003	Orn Almarsson	TPI-350C1	6536
23557 7590 07/17/2008 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			EXAMINER CLAYTOR, DEIRDRE RENEE	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 07/17/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/660,202	Applicant(s) ALMARSSON ET AL.	
	Examiner Renee Claytor	Art Unit 1617	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 May 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because

(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ They raise the issue of new matter (see NOTE below);

(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): Double Patenting.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617

Applicant's have amended the claims in an effort to overcome the 35 USC 112 rejections. However, it is noted that the rejection over Written Description is still maintained because Applicants have only shown the formation of the particular co-crystals listed in claim 11 but do not exemplify the formation of all co-crystals with the API's listed in amended claim 1. It is not described or shown how the numerous and diverse different co-crystals could be obtained. Regarding the Enablement rejection, the specification is enabled for the preparation and use of the particular co-crystals recited in claim 11 but is not enabled for the preparation of all co-crystals with the particular API's listed and any co-crystal former. Applicants filing of a Terminal Disclaimer over Application 10/546,963 is sufficient to overcome the rejection. Further Applicants amendments are sufficient to overcome the Double Patenting rejections over Applications 10/570,405, 10/551,014 and 10/926,842.