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 NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/374,528	03/04/2009	Heiner Will	23782	9344

23389 7590 12/21/2011

SCULLY SCOTT MURPHY & PRESSER, PC
400 GARDEN CITY PLAZA
SUITE 300
GARDEN CITY, NY 11530

EXAMINER	
BLAKELY III, NELSON CLARENCE	
ART UNIT	**PAPER NUMBER**
1629	

MAIL DATE	DELIVERY MODE
12/21/2011	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)	
	12/374,528	WILL, HEINER	
	Examiner	Art Unit	
	NELSON BLAKELY III	1629	

-- 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 *02 December 2011*.

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

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ 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

5)☒ Claim(s) *1-32* is/are pending in the application.

5a) Of the above claim(s) *12 and 18-32* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-11 and 13-17* is/are rejected.

8)☒ Claim(s) *5-11 and 13-17* is/are objected to.

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

Application Papers

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

11)☐ 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).

12)☐ 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

13)☒ 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 *03/13/2009 and 05/31/2011*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other:

DETAILED ACTION

Application Status

Claims 1-32 of the instant application are pending. Claims 12 and 18-32 are withdrawn pursuant to Applicant's response, filed 12/02/2011. Accordingly, instant claims 1-11 and 13-17 are presented for examination on their merits.

Election/Restrictions

Applicant's election ***with*** ***traverse*** of Group II, drawn to instant claims 1-17, in the reply filed on 12/02/2011, is acknowledged. The traversal is on the grounds that Hoekstra *et al*. do not provide any teaching at all with regard to the concentration of the administered solutions. Further, Applicant traverses that the aforementioned reference only teaches a higher absolute dose of methotrexate, in particular, doses between 25 and 40 mg methotrexate per week.

This is not found persuasive because, as recited in the previous Office action, Hoekstra *et al*. disclose a study to determine the bioavailability of higher doses of methotrexate (MTX) in adult patients with rheumatoid arthritis (RA) through oral and subcutaneous administration, wherein the latter enhances bioavailability. Further, Hoekstra *et al*. disclose, in the first paragraph, left column, page 645, wherein the efficacy of high intravenous doses of MTX (40-500 mg/m^2), in patients with refractory RA, was described in several studies. Additionally, in the *Materials and Methods*, page 646, Hoekstra *et al*. disclose wherein patients with RA, who were treated with MTX in a stable (≥ 3 months) dose of ≥ 25 mg weekly, orally or parenterally, were studied.

Accordingly, one of ordinary skill in the art, at the time of the invention, would have envisaged an embodiment wherein the high dose MTX comprised 25+ mg in 1 mL of solution.

Therefore, the requirement is still deemed proper and is therefore made **FINAL**.

It is noted wherein Applicant elected rheumatoid arthritis as the inflammatory autoimmune disease, and wherein no preservatives are required.

Claims 12 and 18-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected subject matter, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/02/2011.

Priority

Receipt is acknowledged of the certified copy of DE10 2006 033 837.5, filed 07/21/2006, submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. It is noted wherein the aforementioned document is not in English.

Information Disclosure Statement

The Information Disclosure Statements, filed 03/13/2009 and 05/31/2011, are acknowledged and considered. With regard to the Jansen *et al.* NPL reference (IDS on 03/13/2009) and Rote Liste Service and the European Search Report NPL references (IDS on 05/31/2011), the aforementioned references were considered pursuant to their relevance, as set forth, and not their content. Said references are not in English.

Claim Objections

Claims 5-11 and 13-17 are objected to for the following informalities:

Claims 5-11 and 13-17 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

With regard to instant claim 17, the aforementioned claim is dependent upon itself. For the purposes of examination, the Examiner has interpreted instant claim 17 to depend from instant claim 16.

Appropriate correction is required.

Claim Rejections - 35 USC § 101/§ 112, 1st Paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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.

Claims 1-11 and 13-17 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.