

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 06-019306-A-00007-0000

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Eve. 378 FASENACIONALI

Act. 329 CTOINFORMACION

Folios: 19

Señor

SUPERINTENDENTE DE INDUSTRIA Y COMERCIO

E. _____ S. _____ D. _____

Re: PI.-**ABBOTT LABORATORIES.**-Solicitud de Patente de
Invención en Fase Nacional PCT para "**FORMA DE DOSIS**
FARMACÉUTICA SÓLIDA QUE COMPRENDE RITONAVIR
FORMULADO EN DISPERSIÓN SÓLIDA".-Clase **A61K**
31/00.-Expediente número **06-019.306A.**-

1. Me refiero al recurso de reposición presentado el 12 de Abril de 2012.
2. Dando alcance al escrito arriba mencionado, me permito presentar a ese Despacho copia del documento correspondiente a la Declaración rendida por el Dr. Jörg Rosenberg, junto con su traducción oficial al español, el cual reposa en el Expediente No. 06-019.306.
3. Ruego a Usted tomar atenta nota y proceder de conformidad.

Del Señor Superintendente,

ALICIA LLOREDA RICAURTE

T.P. 53.215

EN LA OFICINA DE PATENTES COLOMBIANA
(SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO)

Solicitante: Abbott Laboratories

Fecha de presentación: Febrero 27, 2006

Prioridad: US 10/650,178 de Agosto 28, 2003

Para: FORMA DE DOSIS FARMACÉUTICA
SÓLIDA

Número de las solicitudes colombianas:

06-019.306

06-019.306 A(Solicitud divisional presentada
en Septiembre, 2010)

DECLARACIÓN DE JÖRG ROSENBERG, PH.D.

1. Soy Jörg Rosenberg, residente de Alemania. Estoy empleado por Abbott GmbH & Co. KG, una sucursal de Laboratorios Abbott. Soy director en la organización de desarrollo de medicamentos farmacéuticos de Abbott GmbH & Co. KG, y estuve liderando el grupo de desarrollo farmacéutico dentro de la unidad de negocios de distribución de fármacos SOLIQS de Abbott GmbH & Co. KG desde el 2005 hasta el 2010. Recibí mi título de Ph.D. en química orgánica y bioorgánica de la Universidad Libre de Berlín, Berlín, Alemania. Tengo más de 20 años de experiencia en el campo de las formulaciones farmacéuticas, y he desarrollado y creado un conjunto de plataformas de formulación para mejorar la biodisponibilidad de principios activos farmacéuticos muy poco solubles en agua. Una copia de mi currículum se anexa a la presente.
2. Soy co-inventor de la solicitud de patente identificada previamente (de aquí en adelante solicitud '306), y estoy familiarizado con la invención descrita en

la misma. Un aspecto de la solicitud '306 describe una forma de dosis sólida que comprende ritonavir, lopinavir, un polímero soluble en agua farmacéuticamente aceptable que tiene una Tg de al menos 50 °C, y un tensoactivo farmacéuticamente aceptable que tiene un valor de HLB desde 4 hasta 10. Ejemplos no limitantes de esta forma de dosis sólida se proveen en los Ejemplos 2, 3, 4 y 5 de la solicitud '306.

3. Fue totalmente inesperado que los tensoactivos con un valor de HLB desde 4 hasta 10 podían mejorar de forma significativa la biodisponibilidad de ritonavir y lopinavir en formas de dosis sólidas.
4. Span 20 es un tensoactivo que tiene un valor de HLB de 8.6 ± 1 , mientras que Cremophor RH40 es otro tensoactivo que tiene un valor de HLB entre 14 y 16.
5. Como se demuestra con el Ejemplo 2 de la solicitud '306, el uso de Span 20 mejoró drásticamente la biodisponibilidad de ritonavir y lopinavir en comparación con el uso de Cremophor RH40 (Ejemplo 1 de la solicitud '306) o sin el uso de ningún tensoactivo (Ejemplo Comparativo de la solicitud '306).
6. El Lauroglicol FCC es un tensoactivo que tiene un valor de HLB de 4.
7. El Lauroglicol FCC (Gattefosse) se utilizó para preparar una composición que contenía 6% p/p de ritonavir, 24% p/p de lopinavir, 61% p/p de copovidona, 8% de lauroglicol FCC y 1% de Aerosil 200. La biodisponibilidad de ritonavir y lopinavir en esta composición fue comparable a una tableta de referencia similar a aquella del Ejemplo 2 de la solicitud '306. Específicamente, cuando la composición se administró a perros, las AUCs de lopinavir y ritonavir tenían estimados puntuales de 0.80 y 0.82, respectivamente, relativos a aquellos de la tableta de referencia.
8. La vitamina E-TGPS (Eastman) es un tensoactivo que tiene un valor de HLB de 13.
9. La vitamina E-TGPS se utilizó para preparar una composición que contiene 6% p/p de ritonavir, 24% p/p de lopinavir, 61% p/p de copovidona, 8% de vitamina E_TGPS y 1% de Aerosil 200. Cuando la composición se

administró a perros, las concentraciones de ritonavir y lopinavir en plasma estaban apenas sobre los límites de cuantificación en todos los perros en los que se probó. La AUC de Lopinavir fue 0.32 µg/ml, y las concentraciones de ritonavir en plasma tenían valores de $C_{\text{máx}}$ de menos de 15 ng/ml para 10 de 11 perros.

10. Todas las afirmaciones hechas aquí de mi propio conocimiento son verdaderas y todas las afirmaciones hechas sobre información y creencia se creen ciertas.

11 ABR 2012

Fecha

Signature Illegible

Jörg Rosenberg

Jörg Rosenberg, Ph.D.

EXPERIENCIA

ABBOTT GMBH & CO KG

Director

Dirigiendo el grupo de desarrollo farmacéutico dentro de Abbott & Co KG desde 01/2011

ABBOTT GMBH & CO KG

Director SOLIQS

Dirigiendo grupo de Desarrollo Farmacéutico en SOLIQS desde 12/2006

ABBOTT GMBH & CO KG

Director Asociado SOLIQS

Dirigiendo grupo de Desarrollo Farmacéutico en SOLIQS desde 09/2005

ABBOTT GMBH & CO KG (desde 2001)

Investigador Adjunto Asociado SOLIQS desde 1997

- Formulador principal dentro de diferentes proyectos de distribución de fármacos incluyendo fabricación de muestras para ensayos clínicos.
- Descubrió y desarrolló formulaciones y procesos para mejorar la tasa de disolución y biodisponibilidad de farmacéuticos muy poco solubles en agua.
- Responsable como “Jefe de Producción” desde 02/2006 de fabricación de medicación para uso en humanos en estudios clínicos.

KNOLL AG/ BASF PHARMA 1992-1997

Investigador Adjunto Asociado en I+D empresarial

KNOLL AG/ BASF PHARMA 1986-1991

Científico Investigador/ Científico Investigador Senior en I+D empresarial

EDUCACIÓN

UNIVERSIDAD LIBRE DE BERLÍN, Berlín, Alemania 1977- 1986

PhD. summa cum laude en Química Orgánica y Bioorgánica 1986

Sintetizó lípidos diastereoméricos y enantioméricos y estudió su auto-organización en agua utilizando diferentes métodos analíticos.

UNIVERSIDAD LIBRE DE BERLÍN, Berlín, Alemania

Título Oficial ("Diplom") en Química Orgánica

1983

PUBLICACIONES Y CONFERENCIAS

- J.H. Fuhrhop, P. Schnieder, J. Rosenberg, E. Boekema
"The chiral bilayer effect stabilizes micellar fibres", J. Am. Chem. Soc. 109, (1987), 3387-3390

- J. Breitenbach, G. Berndl, J. Neumann, J. Rosenberg, D. Simon, J. Zeidler
"Solid Dispersions By An Integrated Melt Extrusion System", Proceed 25th International Symposion Controlled Release Bioact. Mater.(1998), 804-805

- J. Breitenbach, S. Grabowski, J. Rosenberg
"Extrusion von Polymer-Wirkstoff-Gemischen zur Herstellung von Arzneiformen", Spektrum der Wissenschaft 11, (1995), 18-19

- V. Christmann, J. Rosenberg, J. Seega, C.M. Lehr
"Simultaneous In Vivo Visualization and Localization of Solid Oral Dosage Forms in the Rat Gastrointestinal Tract by Magnetic Resonance Imaging (MRI)"
 Pharm. Res. 14, (1997), 1066-1072

- V. Christmann, B. Elger, J. Rosenberg, J. Seega, C.M. Lehr
"Magnetic Resonance Imaging of solid oral dosage forms in the rat intestinal tract in vivo"
 APV 42nd Annual meeting 1996

- V. Christmann, B. Elger, J. Rosenberg, J. Seega, C.M. Lehr
"Magnetic Resonance Imaging of a tablet formulation in vivo in the gastrointestinal tract of the rat"
 Proceed. Intern. Symp. Control. Rel. Bioact. Mater. 22, (1995), 304-305

- V. Christmann, B. Elger, J. Rosenberg, J. Seega, C.M. Lehr

“Double contrast MRI technique for the visualization of tablets in vivo in the gastrointestinal tract in vivo”

Conferencia International sobre MRI de Abdomen y Pelvis – Nuevas técnicas y medios de contraste

Munich, 1995 (Poster)

- V. Christmann, B. Elger, J. Rosenberg, J. Seega, C.M. Lehr

“Visualization of solid oral dosage forms in the GI tract by combined ¹H- and ¹⁹F MRI”

23rd International Symposium on Controlled Release of Bioactive Materials

Kyoto, Japón 1996 (Poster)

- J. Rosenberg, M. Degenhardt, M. Mägerlein, K. Fastnacht, G. Berndl, J. Breitenbach

“Melt extrusion: Assessing the potential of poorly soluble drugs to form glass solutions”

226th ACS National Meeting, Septiembre 7-11, 2003, Ciudad de New York (presentación oral)

Abstract of papers American Chemical Society, Vol 226, no. 1-2, 2003, página PMSE 128, XP009054930 (ISSN: 0065-7727)

- J. Rosenberg

“Pellets durch Schmelzextrusion”

APV seminar Junio 24, 2003 Bielefeld, Alemania (presentación oral)

- J. Rosenberg, B. Liepold, U. Reinhold, G. Berndl, J. Breitenbach, T. Hantke

“Formulation of insoluble drug compounds by Meltrex®-technology”

Proc. 4th World Meeting ADRITELF / APV / APGI, Florencia, 8/11 Abril 2002

- J. Breitenbach, B. Liepold, J. Neumann, M. Mägerlein, U. Reinhold, J. Rosenberg, Ch. Vollgraf, J. Zeidler

“Modified Release Metoprolol tablets by melt extrusion and on-line calendering”

Proceedings 26th Int. Symp. Controlled Release Bioact. Mater. (1999), 941-942

- J. Rosenberg, G. Berndl, J. Breitenbach, B. Liepold, M. Maegerlein, U. Reinhold

“Meltrex®-formulations containing solid solutions of nearly insoluble drugs: Formation of nanoparticles on dissolution in water”

Proceedings 28th Int. Symp. Controlled Release Bioact. Mater. (2001), 738-739

- M. Mägerlein, D. Gessner, J. Rosenberg, J. Breitenbach, H. Seidel

“Miscibility of Span 40 and Kollidon VA-64: Characterization of mixtures and impact on pharmaceutical parameters”

International Symposium on Controlled Release of Bioactive Materials

Glasgow, Gran Bretaña 2003 (Poster)

- J. Rosenberg, M. Degenhardt, J. Breitenbach, M. Mägerlein, G. Berndt, T. Hantke

“Amorphous embedding of a lipophilic drug substance by Meltrex® - technology”

Proc. 7th European Symposium on Controlled Drug Delivery

Noordwijk aan Zee (Netherlands), April 3-5, 2002 (Poster)

- J. Breitenbach, B. Liepold, K. Fastnacht, T. Hantke, J. Neumann, M. Mägerlein, B. Rehbock, U. Reinhold, J. Rosenberg, W. Schrof, C. Vollgraf, J. Zeidler

Screening tool for solid dispersions, mapping of drugs and dissolution behaviour: Confocal Raman spectroscopy”

Millennial World Congress of Pharmaceutical Sciences

San Francisco, April 16 – 20, 2000 (Poster)

- J. Rosenberg

“Bioavailability Enhancement by Melt Extrusion”

AAPS Conference “Pharmaceutics and Drug Delivery”

Filadelfia, PA, Junio 7-9, 2004 (presentación oral)

- J. Rosenberg

“A new approach to a classic challenge: What are the significant trends in the development of poorly water-soluble drugs?”

4th Annual European Drug Delivery Partnerships Conference

París, Francia, April 28, 2005 (presentación oral)

- J. Rosenberg

"Schmelzextrusion von Wirkstoffen mit PVP-Polymeren: MELTRETREX – Potential zur Freisetzungssteuerung und Erhöhung der Bioverfügbarkeit"

APV seminar "Extrusion in development and production" 02 Junio 2005, Bielefeld, Germany (presentación oral)

- J. Rosenberg, M. Degenhardt, C. Pujara, H. van Lishaut, K. Marsh:

"NanoMorph® – SOLIQS's nanoparticle platform enhancing bioavailability and source for early tox formulations"

Presentación interna de poster (Volwiler Scientific Meeting Septiembre 2005)

- M. Degenhardt, B. Liepold, M. Mägerlein, J. Rosenberg, V. Vucenovic:

"SoliSolv™ – SOLIQS's new solvent for screening systems and liquid formulation concepts"

Presentación interna de poster (Volwiler Scientific Meeting Septiembre 2005)

- M. Mägerlein, J. Rosenberg, B. Liepold, J. Zeidler, J. Breitenbach:

"An on-line melt-shaping technology mimicking a multiparticulate system like Metoprolol Beloc-ZOK™"

Presentación interna de poster (Volwiler Scientific Meeting Septiembre 2005)

- J. Rosenberg, B. Liepold, J. Morris, E. Schmitt:

"The next generation: Meltrex® paving the way for Kaletra's enhanced bioavailability"

Presentación interna de poster (Volwiler Scientific Meeting Septiembre 2005)

- J. Rosenberg, M. Knobloch, K. Marsh, J. Breitenbach:

"Overcoming biological barriers for insoluble drug actives: Meltrex technology for enhancement of bioavailability of ABT-869"

Presentación interna de poster (Volwiler Scientific Meeting Septiembre 2005)

- J. Rosenberg

"Oral dosage forms: Novel technologies and considerations"

SMi Drug Delivery Global Summit, 20 Sep 2006, Londres (presentación oral)

- J. Rosenberg:

"Manufacturing of Pharmaceutical Dosage Forms using Melt-extrusion Technology",

en: U. Bröckel, W. Meier, G. Wagner (Ed.): Product Design and Engineering", Wiley-VCH

Verlag, Weinheim (2007), Volumen 1, página 247-257

- Neeraj Gupta, Boon-Cher Goh, Ross Soo, Chiung Ing Wong, Jun Zhang, Bernd Liepold, Jörg Rosenberg, Martin Knobloch, Joyce Steinberg, Rod Humerickhouse:

"Relative bioavailability study of multiple receptor tyrosine kinase inhibitor ABT- 869 for comparison of oral solution and tablet formulation"

American Association of Cancer Research (AACR-NCI-EORTC International Conference; Presentación en Poster)

- J. Kanzer, S. Hupfeld, I. Tho, J. Rosenberg, M. Mägerlein, G. Fricker, M. Brandl:

"Melt Extrudates do form Nanosuspensions upon Dispersion in aqueous medium"

Poster AAPS 2008

MEMBRESÍAS

Gesellschaft Deutscher Chemiker (Sociedad Química Alemana), desde 1979

7/11/06/

IN THE COLOMBIAN PATENT OFFICE
(SUPERINTENDENCY OF INDUSTRY AND TRADE)

Applicant: Abbott Laboratories

Filed: February 27, 2006

Priority application: US 10/650,178 of August
28, 2003

For: SOLID PHARMACEUTICAL DOSAGE
FORM

Colombian Applications numbers:

06-019.306

06-019.306 A(Divisional filed on September,
2010)

DECLARATION OF JÖRG ROSENBERG, PH.D.

1. I am Jörg Rosenberg, a resident of Germany. I am employed by Abbott GmbH & Co. KG, a subsidiary of Abbott Laboratories. I am a Director in the pharmaceutical drug development organization of Abbott GmbH & Co. KG, and have been heading the Pharmaceutical Development group within the SOLIQS drug delivery business unit of Abbott GmbH & Co KG from 2005 to 2010. I received my Ph.D. in organic and bioorganic chemistry from Free University Berlin, Berlin, Germany. I have more than 20 years experience in the field of pharmaceutical formulations, and have developed and

created a number of formulation platforms to improve the bioavailability of poorly water soluble pharmaceutical actives. A copy of my curriculum vitae is attached herewith.

2. I am a co-inventor of the above-identified patent application (hereinafter the '442 application), and I am familiar with the invention described therein. One aspect of the '442 application describes a solid dosage form comprising ritonavir, lopinavir, a pharmaceutical acceptable water-soluble polymer having a Tg of at least 50 °C, and a pharmaceutically acceptable surfactant having an HLB value of from 4 to 10. Non-limiting examples of this solid dosage form are provided in Examples 2, 3, 4 and 5 of the '442 application.
3. It was totally unexpected that surfactants having an HLB value of from 4 to 10 can significantly improve the bioavailability of ritonavir and lopinavir in solid dosage forms.
4. Span 20 is a surfactant having a HLB value of 8.6 ± 1 , while Cremophor RH40 is another surfactant having a HLB value of between 14 and 16.
5. As demonstrated by Example 2 of the '442 application, the use of Span 20 drastically improved the bioavailability of ritonavir and lopinavir as compared to the use of Cremophor RH40 (Example 1 of the '442 application) or without the use of any surfactant (Comparative Example of the '442 application).
6. Lauroglycol FCC is a surfactant having an HLB value of 4.
7. Lauroglycol FCC (Gattefosse) was used to prepare a composition containing 6% w/w ritonavir, 24% w/w lopinavir, 61% w/w copovidone, 8% lauroglycol FCC and 1% Aerosil 200. The bioavailability of ritonavir and lopinavir in this composition was comparable to a reference tablet similar to that of Example 2 of the '442 application. Specifically, when the composition was administered to dogs, lopinavir and ritonavir

AUCs had point estimates of 0.80 and 0.82, respectively, relative to those of the reference tablet.

8. Vitamin E-TPGS (Eastman) is a surfactant having an HLB value of 13.
9. Vitamin E-TPGS was used to prepare a composition containing 6% w/w ritonavir, 24% w/w lopinavir, 61% w/w copovidone, 8% Vitamin E-TPGS and 1% Aerosil 200. When the composition was administered to dogs, the ritonavir and lopinavir plasma concentrations were barely above the limits of quantitation in all dogs tested. Lopinavir AUC was 0.32 µg/ml, and ritonavir plasma concentrations had C_{max} values of less than 15 ng/ml for 10 of 11 dogs.
10. All statements made herein of my own knowledge are true and all statements made upon information and belief are believed to be true.

18 APR 2012

Date

Jörg Rosenberg
Jörg Rosenberg

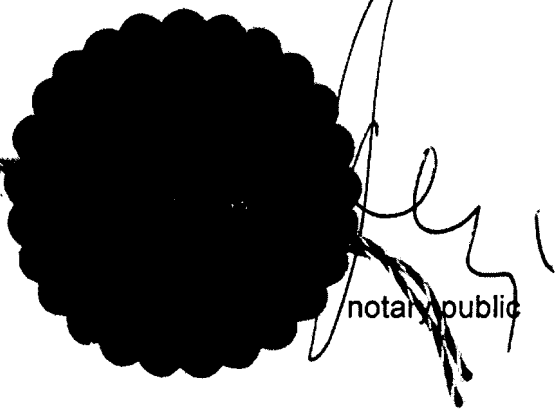
Urk.R.Nr. 899/2012

I, Dr. Matthias Meyer, notary public at Ludwigshafen/Rhine, Federal Republic of Germany, hereby testify and confirm that the foregoing signature of

Dr. Jörg Rosenberg, born on August 9, 1956, business address at Abbott GmbH & Co. KG, 67061 Ludwigshafen/Rhine, Knollstraße, Federal Republic of Germany, identified by identity card,

is true and valid.

Ludwigshafen/Rhine, this 18th day of April, 2012

A circular notary seal is partially obscured by a handwritten signature. The signature is written in black ink and appears to be 'J. Meyer'. Below the signature, the words 'notary public' are printed in a small, sans-serif font.

notary public

Wert: 10.000,-- Euro

Apostille

(Convention de La Haye du 5 octobre 1961)

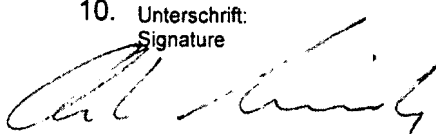
1. Land: Bundesrepublik Deutschland
Country:

Diese öffentliche Urkunde
This public document

2. ist unterschrieben von Notar Dr. Meyer
has been signed by
3. in seiner Eigenschaft als öffentlicher Notar
acting in the capacity of
4. sie ist versehen mit dem Siegel / Stempel des Notars Dr. Matthias Meyer in Ludwigshafen
bears the seal/stamp of am Rhein

Bestätigt certified

5. in Frankenthal (Pfalz) 6. am 19. April 2012
at the
7. durch die Präsidentin des Landgerichts
by
8. unter Nr.: 91 Eb – 512/2012
N°
9. Siegel/Stempel
Seal/Stamp
10. Unterschrift:
Signature



(Christian Köneke)
(Richter am Landgericht)

EXPERIENCE

ABBOTT GMBH & CO KG

Director

Heading a pharmaceutical development group within Abbott GmbH & Co KG since 01/2011

ABBOTT GMBH & CO KG

Director SOLIQS

heading Pharmaceutical Development group within SOLIQS since 12/2006

ABBOTT GMBH & CO KG

Associate Director SOLIQS

heading Pharmaceutical Development group within SOLIQS since 09/2005

ABBOTT GMBH & CO KG (since 2001)

Associate Research Fellow SOLIQS

since 1997

- Principal formulator within different drug delivery projects including manufacturing of clinical trial samples.
- Discovered and developed formulations and processes to improve the dissolution rate and bioavailability of poorly water soluble pharmaceuticals
- Responsible as "Head of production" according to German law from 02/2006 to 01/2011 for manufacturing of medication for use in humans within clinical studies.

KNOLL AG / BASF PHARMA

1992 – 1997

Associate Research Fellow in Corporate R&D

KNOLL AG / BASF PHARMA

1986 – 1991

Research Investigator Scientist/Senior Research Scientist in Corporate R&D

EDUCATION

FREE UNIVERSITY BERLIN, Berlin, Germany

1977 - 1986

Ph.D. summa cum laude in Organic and Bioorganic Chemistry

1986

Synthesized diastereomeric and enantiomeric lipids and studied their self-organization in water using different analytical methods.

FREE UNIVERSITY BERLIN, Berlin, Germany

1983

Diploma ("Diplom") in Organic Chemistry

PUBLICATIONS AND CONFERENCES

- J.H. Fuhrhop, P. Schnieder, J. Rosenberg, E. Boekema
"The chiral bilayer effect stabilizes micellar fibres", J. Am. Chem. Soc. 109, (1987), 3387-3390
- J. Breitenbach, G. Berndt, J. Neumann, J. Rosenberg, D. Simon, J. Zeidler
"Solid Dispersions By An Integrated Melt Extrusion System",
Proceed 25th International Symposium Controlled Release Bioact. Mater. (1998), 804-805
- J. Breitenbach, S. Grabowski, J. Rosenberg
"Extrusion von Polymer-Wirkstoff-Gemischen zur Herstellung von Arzneiformen",
Spektrum der Wissenschaft 11, (1995), 18-19
- V. Christmann, J. Rosenberg, J. Seega, C.M. Lehr
"Simultaneous In Vivo Visualization and Localization of Solid Oral Dosage Forms
in the Rat Gastrointestinal Tract by Magnetic Resonance Imaging (MRI)
Pharm. Res. 14, (1997), 1066-1072
- V. Christmann, B. Elger, J. Rosenberg, J. Seega, C.M. Lehr
"Magnetic Resonance Imaging of solid oral dosage forms in the rat intestinal tract
in vivo"
APV 42nd Annual meeting 1996
- V. Christmann, B. Elger, J. Rosenberg, J. Seega, C.M. Lehr
"Magnetic Resonance Imaging of a tablet formulation in vivo in the gastrointestinal
tract of the rat"
Proceed. Intern. Symp. Control. Rel. Bioact. Mater. 22, (1995), 304-305
- V. Christmann, B. Elger, J. Rosenberg, J. Seega, C.M. Lehr
"Double contrast MRI technique for the visualization of tablets in vivo in the
gastrointestinal tract in vivo"
International Conference on MRI of the Abdomen and Pelvis – New techniques and
contrast media
Munich, 1995 (Poster)
- V. Christmann, B. Elger, J. Rosenberg, J. Seega, C.M. Lehr
"Visualization of solid oral dosage forms in the GI tract by combined 1H- and 19F-
MRI"

23rd International Symposium on Controlled Release of Bioactive Materials
Kyoto, Japan 1996 (Poster)

- J. Rosenberg, M. Degenhardt, M. Mägerlein, K. Fastnacht, G. Berndt, J. Breitenbach
"Melt extrusion: Assessing the potential of poorly soluble drugs to form glass solutions"
226th ACS National Meeting, September 7-11, 2003, New York City (oral presentation)
Abstract of papers American Chemical Society, Vol 226, no. 1-2, 2003, page PMSE 128, XP009054930 (ISSN: 0065-7727)
- J. Rosenberg
"Pellets durch Schmelzextrusion"
APV seminar June 24th, 2003 Bielefeld, Germany (oral presentation)
- J. Rosenberg, B. Liepold, U. Reinhold, G. Berndt, J. Breitenbach, T. Hantke
"Formulation of insoluble drug compounds by Meltrex®-technology"
Proc. 4th World Meeting ADRITELF / APV / APGI, Florence, 8/11 April 2002
- J. Breitenbach, B. Liepold, J. Neumann, M. Mägerlein, U. Reinhold, J. Rosenberg, Ch. Vollgraf, J. Zeidler
"Modified Release Metoprolol tablets by melt extrusion and on-line calendaring"
Proceedings 26th Int. Symp. Controlled Release Bioact. Mater. (1999), 941-942
- J. Rosenberg, G. Berndt, J. Breitenbach, B. Liepold, M. Mägerlein, U. Reinhold
"Meltrex®-formulations containing solid solutions of nearly insoluble drugs: Formation of nanoparticles on dissolution in water"
Proceedings 28th Int. Symp. Controlled Release Bioact. Mater. (2001), 738-739
- M. Mägerlein, D. Gessner, J. Rosenberg, J. Breitenbach, H. Seidel
"Miscibility of Span 40 and Kollidon VA-64: Characterization of mixtures and impact on pharmaceutical parameters"
International Symposium on Controlled Release of Bioactive Materials
Glasgow, Great Britain 2003 (Poster)
- J. Rosenberg, M. Degenhardt, J. Breitenbach, M. Mägerlein, G. Berndt, T. Hantke
"Amorphous embedding of a lipophilic drug substance by Meltrex® - technology"
Proc. 7th European Symposium on Controlled Drug Delivery
Noordwijk aan Zee (Netherlands), April 3-5, 2002 (Poster)
- J. Breitenbach, B. Liepold, K. Fastnacht, T. Hantke, J. Neumann, M. Mägerlein, B. Rehbock, U. Reinhold, J. Rosenberg, W. Schrof, C. Vollgraf, J. Zeidler
"Screening tool for solid dispersions, mapping of drugs and dissolution behaviour: Confocal Raman spectroscopy"
Millennial World Congress of Pharmaceutical Sciences
San Francisco, April 16 – 20, 2000 (Poster)
- J. Rosenberg
"Bioavailability Enhancement by Melt Extrusion"
AAPS Conference "Pharmaceutics and Drug Delivery"
Philadelphia, PA, June 7-9, 2004 (oral presentation)
- J. Rosenberg
"A new approach to a classic challenge: What are the significant trends in the development of poorly water-soluble drugs?"
4th Annual European Drug Delivery Partnerships Conference
Paris, France, April 28th, 2005 (oral presentation)
- J. Rosenberg
"Schmelzextrusion von Wirkstoffen mit PVP-Polymeren: MELTREX – Potential zur Freisetzungsteuerung und Erhöhung der Bioverfügbarkeit"

APV seminar „Extrusion in development and production“ 02 June 2005, Bielefeld, Germany (oral presentation)

- J. Rosenberg, M. Degenhardt, C. Pujara, H. van Lishaut, K. Marsh:
“NanoMorph® – SOLIQS’s nanoparticle platform enhancing bioavailability and source for early tox formulations”
 Internal poster presentation (Volwiler Scientific Meeting September 2005)
- M. Degenhardt, B. Liepold, M. Mägerlein, J. Rosenberg, V. Vucenovic:
“SoliSolv™ – SOLIQS’s new solvent for screening systems and liquid formulation concepts”
 Internal poster presentation (Volwiler Scientific Meeting September 2005)
- M. Mägerlein, J. Rosenberg, B. Liepold, J. Zeidler, J. Breitenbach:
“An on-line melt-shaping technology mimicking a multiparticulate system like Metoprolol Beloc-ZOK™”
 Internal poster presentation (Volwiler Scientific Meeting September 2005)
- J. Rosenberg, B. Liepold, J. Morris, E. Schmitt:
“The next generation: Meltrex® paving the way for Kaletra’s enhanced bioavailability”
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- J. Rosenberg, M. Knobloch, K. Marsh, J. Breitenbach:
“Overcoming biological barriers for insoluble drug actives: Meltrex technology for enhancement of bioavailability of ABT-869”
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- J. Rosenberg
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“Manufacturing of Pharmaceutical Dosage Forms using Melt-extrusion Technology”,
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“Relative bioavailability study of multiple receptor tyrosine kinase inhibitor ABT-869 for comparison of oral solution and tablet formulation”
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- J. Kanzer, S. Hupfeld, I. Tho, J. Rosenberg, M. Mägerlein, G. Fricker, M. Brandl:
“Melt Extrudates do form Nanosuspensions upon Dispersion in aqueous medium”
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