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Description of document: Documents related to "the Fabrazyme matter" including periodic regular updates to the National Institutes of Health (NIH) required from the Mount Sinai School of Medicine and Correspondence, 2011

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Update posted: 30-January-2012

Date/date range of document: 03-January-2011 – 01-December-2011

Source of document: FOIA Request  
Freedom of Information Office, NIH  
Building 31, Room 5B35  
9000 Rockville Pike  
Bethesda, MD 20892  
Fax: (301) 402-4541  
Email: [nihfoia@mail.nih.gov](mailto:.nihfoia@mail.nih.gov)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
National Institutes of Health

Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard  
Rockville, MD 20852

August 31, 2011

Re: FOIA Case No. 39172

This is our final response to your August 14, 2011 Freedom of Information Act (FOIA) request addressed to NIH. You requested "a copy of the periodic regular updates to NIH required from the Mount Sinai School of Medicine regarding the Fabrazyme matter."

Please note that we asked the Mount Sinai School of Medicine to advise this office if release of the material you requested will adversely affect any confidential commercial or financial information. Following receipt of this advice, we reviewed the materials and removed information under the foregoing DHHS policy. If you feel that materials have been omitted that should have been made available to you, please write to me and I will consult with the NIH Freedom of Information Officer.

Provisions of the FOIA and DHHS FOIA Regulations allow us to recover part of the cost of responding to your request. Because the cost is below the \$25 minimum, there is no charge for the enclosed materials.

Sincerely,

A handwritten signature in cursive script that reads "Bonny Harbinger".

Bonny Harbinger  
Freedom of Information Coordinator  
NIH's Office of Technology Transfer

Enclosures: 70 pages



January 18, 2012

Re: FOIA Case No. 39568

This is our final response to your January 7, 2012 Freedom of Information Act (FOIA) request addressed to NIH. You requested "a copy of the periodic regular updates to NIH required from the Mount Sinai School of Medicine regarding the Fabrazyme matter."

Please note that we asked the Mount Sinai School of Medicine to advise this office if release of the material you requested will adversely affect any confidential commercial or financial information. Following receipt of this advice, we reviewed the materials and removed information under the foregoing D1IHS policy. If you feel that materials have been omitted that should have been made available to you, please write to me and I will consult with the NIH Freedom of Information Officer.

Provisions of the FOIA and DHHS FOIA Regulations allow us to recover part of the cost of responding to your request. Because the cost is below the \$25 minimum, there is no charge for the enclosed materials.

Sincerely,

A handwritten signature in cursive script, appearing to read "Bonny Harbinger".

Bonny Harbinger  
Freedom of Information Coordinator  
NIH's Office of Technology Transfer

Enclosures: 5 pages

**From:** [Strauss, Sally](#)  
**To:** [Hammersla, Ann \(NIH/OD\) \[E\]](#)  
**Subject:** Mount Sinai's January submission  
**Date:** Monday, January 03, 2011 11:27:12 AM  
**Attachments:** [nihmonthlyupdate jan.docx](#)

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Ann,

Attached is our submission to the NIH as requested in Mark Rohrbaugh's December 3<sup>rd</sup> letter to Dean Charney.

Please let me know if you need anything further . I hope you had a relaxing holiday.

Regards,

Sally



The Mount Sinai Medical Center

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Office of the  
General Counsel

*Sally Strauss*  
Sr. Associate General Counsel  
Tel (212) 659-8105

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January 3, 2011

Ms. Ann Hammersla  
Director, Division of Policy  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard  
Rockville, MD 20852

Dear Ms. Hammersla:

This letter shall serve as Mount Sinai School of Medicine's first monthly submission to the NIH pursuant to its request and Determination not to exercise its March-in-Authority. Since much of the requested information relates to Genzyme and the status of its distribution and production of Fabrazyme, Genzyme has submitted an update directly to you. MSSM has no additional information on the issues of distribution and production at this time.

With respect to the request for a license to the 804 patent and related patents owned by Mount Sinai, we note that Shire has advised us that it may file a motion with a German court seeking a compulsory license for the territory of Germany. Shire has stated that it also intends to seek a preliminary decision on such compulsory license in the event that a finding of infringement is made in the pending infringement proceedings allowing Mount Sinai to impose an injunction against Repligal. We have confirmed to Shire and to the German court overseeing the infringement action that we will not enforce an injunction during any period of drug shortage. Therefore, it would not be necessary for a court to intervene and grant a compulsory license in Germany. However, if Shire chooses to proceed with its Motion despite this confirmation, we will immediately inform the NIH and keep you informed of the status of the proceeding.

Please advise me if you need additional information or would prefer our monthly submissions in a different format.

Regards,

Sally Strauss

Cc: Dennis Charney, Dean Mount Sinai School of Medicine

**From:** [Strauss, Sally](#)  
**To:** [Hammersla, Ann \(NIH/OD\) \[E\]](#)  
**Cc:** [Charney, Dennis \(MSSM\)](#)  
**Subject:** Mount Sinai's February Submission to the NIH  
**Date:** Tuesday, February 01, 2011 10:32:02 AM  
**Attachments:** [nihmonthlyupdate feb.docx](#)

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Ann, please see the attached. Hope all is otherwise well.

Sally



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February 1, 2011

Ms. Ann Hammersla  
Director, Division of Policy  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard  
Rockville, MD 20852

Dear Ms. Hammersla:

This letter shall serve as Mount Sinai School of Medicine's second monthly submission to the NIH pursuant to its request and Determination not to exercise its March-in-Authority. As we set forth last month, since much of the requested information relates to Genzyme and the status of its distribution and production of Fabrazyme, Genzyme has submitted an update directly to you. MSSM has no additional information on the issues of distribution and production at this time.

With respect to the request for a license to the 804 patent and related patents owned by Mount Sinai, we have not received any such requests since our last communication. In addition, in our January submission we advised you of the possibility that Shire would serve us with a motion for a compulsory license for the territory of Germany. To date, we still have not been served with this threatened motion.

Finally, we note that on January 13, 2011 the petitioners in the March-in petition filed a citizen's petition with the FDA. They appear to be asking the FDA to direct Genzyme to allocate a larger percentage of Fabrazyme to the United States market. Since this request is directed at the FDA's existing regulatory oversight of Genzyme, we do not anticipate submitting any materials to the FDA.

Please contact me if you have further questions.

Regards,

Sally Strauss

Cc: Dennis Charney, Dean Mount Sinai School of Medicine



**From:** [Strauss, Sally](#)  
**To:** [Hammersla, Ann \(NIH/OD\) \[E\]](#)  
**Cc:** [Charney, Dennis \(MSSM\)](#)  
**Subject:** mount sinai march update  
**Date:** Tuesday, March 01, 2011 9:09:34 AM  
**Attachments:** [nihmonthlyupdate\\_march.docx](#)

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Please see our attached monthly update . Thanks and hope all is well.

Sally Strauss



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March 1, 2011

Ms. Ann Hammersla  
Director, Division of Policy  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard  
Rockville, MD 20852

Dear Ms. Hammersla:

This letter shall serve as Mount Sinai School of Medicine's third monthly submission to the NIH pursuant to its request and Determination not to exercise its March-in-Authority. As we set forth previously, since much of the requested information relates to Genzyme and the status of its distribution and production of Fabrazyme, Genzyme has submitted an update directly to you. MSSM has no additional information on the issues of distribution and production at this time.

With respect to the request for a license to the 804 patent and related patents owned by Mount Sinai, we have now been served with Shire's motion for a compulsory license for the territory of Germany. This motion was served on us several weeks after the German Court ruled that Replagal infringed our German patent. Shire's motion is predicated on the possibility that Mount Sinai would enforce an injunction against the sale of Replagal in Germany. Mount Sinai, however, has repeatedly confirmed that it will not pursue such an injunction during any periods of existing or future shortages of Fabrazyme. We, therefore, do not believe that a compulsory license is warranted or that the proceedings have any merit. We trust that this will be appropriately dealt with and adequately decided by the German court. Mount Sinai's response to Shire's motion is due on March 15, 2011. We will keep you apprised of the developments in the German proceeding.

Please contact me if you have further questions.

Regards,

Sally Strauss

Cc: Dennis Charney, Dean Mount Sinai School of Medicine

**From:** [Strauss, Sally](#)  
**To:** [Hammersla, Ann \(NIH/OD\) \[E\]](#)  
**Cc:** [Charney, Dennis \(MSSM\)](#)  
**Subject:** Mount Sinai April submission  
**Date:** Tuesday, March 29, 2011 5:15:27 PM  
**Attachments:** [nihmonthlyupdate april.docx](#)

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Ann, since I am heading down your way for the next two days (to go to the Medicare/Medicaid AHLA/CMS conference in Baltimore) I wanted to send you Mount Sinai's April letter a few days early. I understand from Tracy Quarles that Genzyme will be sending you its submission tomorrow.

If you happen to be in Baltimore at this conference let me know, I would love to meet you in person.

Thanks Sally



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April 1, 2011

Ms. Ann Hammersla  
Director, Division of Policy  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard  
Rockville, MD 20852

Dear Ms. Hammersla:

This letter shall serve as Mount Sinai School of Medicine's fourth monthly submission to the NIH pursuant to its request and Determination not to exercise its March-in-Authority. As we set forth previously, since much of the requested information relates to Genzyme and the status of its distribution and production of Fabrazyme, Genzyme has submitted an update directly to you. MSSM has no additional information on the issues of distribution and production at this time.

With respect to the request for a license to the 804 patent and related patents owned by MSSM, we advised you in our March letter that Shire had filed and served a motion for a compulsory license for the territory of Germany. We filed preliminary papers with the Court outlining our opposition to the motion and our full brief is due on June 15<sup>th</sup>. At this time the Court has not set a hearing date for Shire's motion. Of course, we will keep you apprised of the developments in the German proceeding. We have not received any other requests for a license to the 804 patent.

Please contact me if you have further questions.

Regards,

Sally Strauss

Cc: Dennis Charney, Dean Mount Sinai School of Medicine

**From:** [Strauss, Sally](#)  
**To:** [Hammersla, Ann \(NIH/OD\) \[E\]](#)  
**Cc:** [Charney, Dennis \(MSSM\)](#)  
**Subject:** Mount Sinai's May submission to the NIH  
**Date:** Monday, May 02, 2011 10:40:04 AM  
**Attachments:** [nihmonthlyupdate may.docx](#)

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Ann,

Attached please find our May submission.

Please call me if you have any questions.

Sally



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May 2, 2011

Ms. Ann Hammersla  
Director, Division of Policy  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard  
Rockville, MD 20852

Dear Ms. Hammersla:

This letter shall serve as Mount Sinai School of Medicine's fifth monthly submission to the NIH pursuant to its request and Determination not to exercise its March-in-Authority. As we set forth previously, since much of the requested information relates to Genzyme and the status of its distribution and production of Fabrazyme, Genzyme has submitted an update directly to you.

Although MSSM has no additional information on the issues of distribution and production, we note that Genzyme in its April 20<sup>th</sup> interim submission confirmed that it remained on track to support full dose for current patients in the second half of 2011 and was actively enrolling new patients for treatment. Thus, it appears that the recent acquisition of Genzyme by Sanofi has not impacted the company's commitments to resolve the Fabrazyme shortage by the end of this year. In this regard, we continue to reach out to the company's leadership to stress the critical importance of restoring the Fabrazyme supply to U.S. patients.

With respect to the request for a license to the 804 patent and related patents owned by MSSM, there has been no significant developments since our April 13<sup>th</sup> submission where we provided you with the details on the status of the German compulsory license proceeding. Aside from that proceeding, we have not received any requests for a license to the 804 patent.

We are continuing our efforts to negotiate a commercially reasonable settlement with Shire and will apprise you of any significant developments.

Please contact me if you have further questions.

Regards,

Sally Strauss

Cc: Dennis Charney, Dean Mount Sinai School of Medicine

**From:** [Hammersla, Ann \(NIH/OD\) \[E\]](#)  
**To:** [Hammersla, Ann \(NIH/OD\) \[E\]](#)  
**Subject:** FW: Mount Sinai's June submission to the NIH  
**Date:** Wednesday, August 17, 2011 9:51:52 AM  
**Attachments:** [nihmonthlyupdate ine.docx](#)

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**From:** Strauss, Sally [[Sally.Strauss@mountsinai.org](mailto:Sally.Strauss@mountsinai.org)]  
**Sent:** Wednesday, June 01, 2011 9:19 AM  
**To:** Hammersla, Ann (NIH/OD) [E]  
**Cc:** Charney, Dennis (MSSM)  
**Subject:** Mount Sinai's June submission to the NIH

Ann,

Attached is Mount Sinai's June submission to the NIH regarding Fabrazyme.

Please call me if you have any questions.

Regards, Sally



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June 1, 2011

Ms. Ann Hammersla  
Director, Division of Policy  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard  
Rockville, MD 20852

Dear Ms. Hammersla:

This letter shall serve as Mount Sinai School of Medicine's sixth monthly submission to the NIH pursuant to its request and Determination not to exercise its March-in-Authority. As we have specified previously, since much of the requested information relates to Genzyme and the status of its distribution and production of Fabrazyme, Genzyme is submitting an update directly to you.

Although MSSM has no additional information on the issues of distribution and production, we understand that Genzyme remains on track to restore supply of Fabrazyme by year-end. Moreover, in the interim, Genzyme has been able to add new patients in the U.S. onto Fabrazyme. Thus, although Genzyme has not yet been able to restore its patients to full dosage, it is making steady progress towards achieving this goal by fourth quarter of 2011 and no other company has stepped forward and indicated that it is willing to or capable of resolving the shortage within this time frame.

With respect to the European patent infringement litigation with Shire, our motion opposing the compulsory license in Germany is due on June 15<sup>th</sup> and we shall provide you with a translated copy of our motion upon filing. Meanwhile, the various other lawsuits in the United Kingdom and Sweden and the appeal of the infringement decision in Germany continue; in the UK, the discovery cut-off is in July; in Sweden, we are submitting an opposition to Shire's validity motions on June 30<sup>th</sup>; and, our opposition to Shire's appeal of the infringement decision in Germany is due on June 22. As we pursue our rights against Shire in these various jurisdictions, we are also continuing to seek a commercially reasonable resolution of our dispute with Shire. Although Shire has currently chosen to postpone any further negotiations, it has affirmed its interest in resolving this dispute; and, we are



hopeful that they will agree to resume discussions in the next few months. Finally, and most importantly, Mount Sinai wants to underscore to the NIH that our first priority remains the patients, and we remain committed to ensuring that we will take no action in the various litigations that could jeopardize the welfare of patients.

Please contact me if you would like any additional information.

Regards,

Sally Strauss

Cc: Dennis Charney, Dean Mount Sinai School of Medicine

**From:** [Strauss, Sally](#)  
**To:** [Hammersla, Ann \(NIH/OD\) \[E\]](#)  
**Cc:** [Charney, Dennis \(MSSM\)](#)  
**Subject:** Mount Sinai's July submission  
**Date:** Tuesday, July 05, 2011 4:14:52 PM  
**Attachments:** [nihmonthlyupdate\\_july.docx](#)

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Ann, here is our July submission. Thank for your flexibility in sending this today. hope all is otherwise well.

Sally



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July 1, 2011

Ms. Ann Hammersla  
Director, Division of Policy  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard  
Rockville, MD 20852

Dear Ms. Hammersla:

This letter shall serve as Mount Sinai School of Medicine's seventh monthly submission to the NIH pursuant to its request and Determination not to exercise its March-in-Authority. As we have specified previously, since much of the requested information relates to Genzyme and the status of its distribution and production of Fabrazyme, Genzyme is submitting an update directly to you.

With respect to the request for a license to the 804 patent and related patents owned by MSSM, there has been no significant developments since our June submission where we provided you with the details on the status of the various proceedings with Shire. Aside from these proceedings, and Shire's motion in Germany for a compulsory license, we have not received any other requests for a license to the 804 patent. On a related note, Mount Sinai continues to stand by its commitment not to enforce the Mannheim Court's judgment regarding the imposition of an injunction of the sale of Repligal in Germany. We had previously advised Shire that we would commit to not pursuing an injunction through September 30, 2011. We have recently advised Shire that we would extend this categorical commitment at least through December 31, 2011.

Please contact me if you would like any additional information.

Regards,

Sally Strauss

Cc: Dennis Charney, Dean, Mount Sinai School of Medicine

**From:** [Strauss, Sally](#)  
**To:** [Hammersla, Ann \(NIH/OD\) \[E\]](#)  
**Cc:** [Charney, Dennis \(MSSM\)](#); [Willev, Teri](#)  
**Subject:** August update from Mount Sinai  
**Date:** Monday, August 01, 2011 5:26:23 PM  
**Attachments:** [nihmonthlyupdate.august.docx](#)

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Ann,

Please find our August update attached to this email.

Thank you as always for your patience and consideration.

Sally Strauss



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August 1, 2011

Ms. Ann Hammersla  
Director, Division of Policy  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard  
Rockville, MD 20852

Dear Ms. Hammersla:

This letter shall serve as Mount Sinai School of Medicine's eighth monthly submission to the NIH pursuant to its request and Determination not to exercise its March-in-Authority. As we have specified previously, since virtually all of the requested information relates to Genzyme and the progress it is making towards resolving the shortage of Fabrazyme, Genzyme is submitting an update directly to you.

With respect to the Compulsory License Proceeding in Germany, the German Federal Patent Court recently issued a notice setting a hearing date for February 14, 2012 at 9:30 am. Shire's reply to our opposition is due on August 18, 2011. We will provide you with a copy of the reply brief in our next submission. Aside from these proceedings, we have not received any requests for a license to the 804 patent.

We also understand that the FDA has recently extended the time for its review of the citizen's petition in which the same individuals who submitted the March-In Petition, submitted a citizen's petition asking the FDA to, among other things, require Genzyme to allocate full doses of Fabrazyme to U.S. citizens.

Please contact me if you would like any additional information.

Regards,

Sally Strauss

Cc: Dennis Charney, M.D., Dean, Mount Sinai School of Medicine  
Teri Willey, Vice President, Office of Technology and Business Development



**From:** [Strauss, Sally](#)  
**To:** [Hammersla, Ann \(NIH/OD\) \[E\]](#)  
**Cc:** [Charney, Dennis \(MSSM\)](#)  
**Subject:** FW:  
**Date:** Thursday, April 14, 2011 10:45:32 AM  
**Attachments:** [20110413173241909.pdf](#)

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Ann,

Attached is Mount Sinai's supplemental letter to its April submission with referenced attachments. Please note that the letter contains confidential, non-public information relating to the negotiations between Shire and Mount Sinai so we would ask that you keep this version confidential. I am also sending a redacted version of the letter and corresponding attachments for the public record.

Thanks and please do not hesitate to call me if you have any questions.

Sally



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April 13, 2011

*(Contains Confidential and Proprietary Information)*

Ms. Ann Hammersla  
Director, Division of Policy  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard  
Rockville, MD 20852

Dear Ms. Hammersla:

Thank you for the opportunity to provide supplemental materials to our April NIH submission. This letter provides further details on: (1) our ongoing commitment to the NIH, the Fabry patient/physician community, and Shire that Mount Sinai will not seek to enforce an injunction against Replagal during any period of an existing or future shortage of Fabrazyme; (2) the status of the compulsory license proceeding in Germany; and, (3) Genzyme's confirmation that it has not changed its allocation of Fabrazyme to the United States market.

As we underscored in our prior communications, Mount Sinai is first and foremost a health care provider and research institution dedicated to developing more effective medical treatments and providing the highest quality care for its patients. Many of our geneticists have devoted virtually their entire careers to treating Fabry patients and developing treatments for Fabry and other lysosomal storage disorders. Mount Sinai and its scientists are committed to these dual missions of research and patient care and would not take any steps that would jeopardize the health of the Fabry patient community.

In this regard, Mount Sinai has repeatedly issued written commitments to the NIH and to Shire that it will not seek to enforce an injunction against Shire's product Replagal during any period where there is a current or future shortage of Fabrazyme.<sup>1</sup> For example, after Mount Sinai

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<sup>1</sup> It is important to note, that only the German Court has ruled on the patent infringement issue. Accordingly, at this time an injunction could only be enforced in Germany. The court's opinion where it concluded that Replagal infringed Mount Sinai's patent is attached at Tab A.



received the German Court's infringement decision authorizing an injunction, it reached out to Shire in a letter dated January 19, 2011 to reiterate that it would not seek to enforce an injunction against the marketing and sale of Replagal during any period of an existing or future shortage of Fabrazyme. Further, Mount Sinai explicitly committed not to pursue the enforcement of an injunction in Germany before September 30, 2011 and to provide Shire with specific notice on July 1, 2011 as to whether it will extend this categorical commitment. (We have attached this letter and an English translation at Tab B). Consistent with this commitment, Mount Sinai submitted a reduced bond with the Mannheim Court only related to that portion of the Court's judgment requiring Shire to provide financial information and an accounting. If Mount Sinai had sought to enforce an injunction it would have had to place a much higher bond with the Court. (We have attached the bond submission and a corresponding translation at Tab C<sup>2</sup>). Mount Sinai confirmed this commitment to Shire yet again in connection with the lawsuit in the United Kingdom where Shire sued Mount Sinai attacking the validity of our patent, and Mount Sinai counterclaimed with an infringement action. In two sequential letters to Shire (attached hereto in Tab D) Mount Sinai reiterated that it will not seek to enforce an injunction during any period of shortage. Finally, Mount Sinai voiced this commitment most recently to the German Court overseeing Shire's motion for a compulsory license (Tab E).<sup>3</sup>

Shire filed the compulsory license action with the German Federal Patent Court shortly before the German Regional Court in Mannheim issued its ruling that Shire infringes Mount Sinai's patent. As a jurisdictional matter, the Federal Patent Court retains exclusive jurisdiction over such compulsory licensing proceedings in Germany. These actions are relatively rare and the statutory standard set forth in Section 24 of the German Patent Act warranting the issuance of a license is high. According to our German counsel, since 1945 the Court has received approximately 40 applications for a compulsory license but granted none.

To prevail in a compulsory license proceeding, the plaintiff must show that it has: (1) sought a license from the patentee for a reasonable duration of time; (2) offered reasonable terms; and (3) either a) that the public interest warrants the issuance of compulsory license or (b) that plaintiff's newer patent presents an important technological advancement of significant economic relevance over the patentee's existing patent but can't be used without infringing the earlier patent. We have provided you with a translation of our preliminary objection to the motion, which explains that Shire has failed to satisfy any of these criteria. In this regard, we underscored that we do not believe a compulsory license is necessary or appropriate given Mount Sinai's commitment not to seek an injunction as outlined above. Given this commitment, there is no public interest basis warranting the court to intercede in these ongoing commercial negotiations.

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<sup>2</sup> In its order, the German Court established different security amounts to correspond to the provisional enforcement of the different types of relief granted in its decision. Thus it required a bond in the amount of 100,000 Euros to compel Shire to satisfy the disclosure directives, but increased this amount to 2,000,000 Euros if Mount Sinai chose to enforce the injunction. Mount Sinai posted a bond in the amount of 100,000 Euros. (See tab A at page 4)

<sup>3</sup> Since this document includes proprietary and confidential information pertaining to settlement negotiations between Shire and Mount Sinai that are subject to a non-disclosure agreement, we are submitting this version of the letter and its corresponding attachments as confidential and submitting a redacted version for the public record.

Pursuant to the Court's scheduling order, Mount Sinai intends to submit its opposition papers to Shire's motion on June 15. The Court has not yet set a hearing date for the motion, but we will keep you apprised of the course of this litigation.

Simultaneous with the pursuit and defense of the various European actions, Mount Sinai has continued its efforts to try and reach a reasonable and appropriate settlement with Shire. We have devoted substantial resources towards this end. We have hired separate counsel dedicated to the settlement effort and over the past several months engaged in two relatively lengthy negotiating sessions and had multiple discussions with senior members of the Shire team. We are continuing our dialogue with Shire and have recently sent them a letter underscoring our goal "to settle this case and move on." We will keep you apprised of our progress as we push ahead with our settlement discussions.

Finally, we understand that Genzyme is providing you with further detail on the status of the distribution of Fabrazyme to the patients in the United States and the potential impact, if any, of the small lot of Fabrazyme that was rejected by the inspectors. We have also reached out to Genzyme, in light of the concern raised by its March 25<sup>th</sup> letter to confirm its commitment to the U.S. patient community.<sup>4</sup> Although Mount Sinai does not have any contractual authority pursuant to the licensing agreement over Genzyme's distribution decisions, it has continued to forcefully advocate with the senior physician leaders at Genzyme the critical importance of focusing on the United States patient community since Fabrazyme remains the only approved drug for this condition in this country. In our most recent discussions with the Genzyme leadership team, Genzyme confirmed that its allocation to U.S. patients has not changed as a result of the rejected lot. Furthermore, Genzyme assured Mount Sinai that it is continuing to treat all existing patients in the United States and has opened enrollment and treatment to new patients in the U.S. It also has confirmed that the approval process for the new plant is on schedule for the second half of 2011.

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<sup>4</sup> Mount Sinai notes that the earlier group of Petitioners recently filed papers with the NIH asking for a rehearing of the NIH's December 1, 2010 decision. (The Petitioners also propose a number of new regulations relating to Bayh-Dole which we do not intend to address in this forum). We believe that the motion for a rehearing is predicated on a number of misunderstandings and mischaracterizations of Genzyme's allocation decisions and manufacturing progress that will be addressed by Genzyme in its submission. In short, however, as explained herein, there are no new facts that would warrant a march-in petition at this time. Shire is not precluded from seeking FDA approval for its drug in the U.S. by the Mount Sinai patent and Genzyme is on track to secure approval of its new manufacturing plant and resolve the shortage within this year.

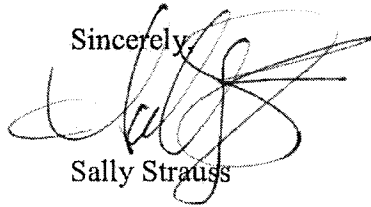
Ms. Ann Hammersla

April 13, 2011

Page 4

Mount Sinai believes that based on the above information, there are no new facts that would warrant the NIH to reverse its earlier decision and issue a march-in petition at this time. If you would like any additional information on the issues discussed above do not hesitate to call me. Otherwise, we will provide you with an update on the status of the various litigations in Europe and our negotiations with Shire in our next monthly submission due in May.

Sincerely,

A handwritten signature in black ink, appearing to read 'Sally Strauss', written over the word 'Sincerely,'.

Sally Strauss

Cc: Dennis S. Charney, M.D.  
Dean, Mount Sinai School of Medicine

Tab A

Reference No.:  
2 O 75/10

- Copy -

Announced on  
18 January 2011

[Crest]

Freisinger, JOSin  
Records clerk of the Court  
Registry

**Regional Court Mannheim**  
2nd Civil Chamber

Re:

**Mount Sinai School of Medicine of New York University**  
represented by Dean Dennis Charney

One Gustave Levy Place, New York, New York 10029-6574

- Plaintiff -

Legal representatives:

Attorneys-at-law Jones Day, Prinzregentenstr. 11, 80538 München (702827-600005)

**Judgment**  
**in the Name of the People** [Stamp]

**versus**

1. **Shire Deutschland GmbH**  
represented by its Managing Director, Leonhard Terp, Friedrichstr. 149, 10117 Berlin
2. **Leonhard Terp**  
c/o Shire Deutschland GmbH  
Friedrichstr. 149, 10117 Berlin
3. **Werner Föllner**  
c/o Shire Deutschland GmbH  
Friedrichstr. 149, 10117 Berlin
4. **James Nicholas Bowling**  
c/o Shire Deutschland GmbH  
Friedrichstr. 149, 10117 Berlin
5. **Gian Piero Reverberi**  
c/o Shire Deutschland GmbH  
Friedrichstr. 149, 10117 Berlin
6. **Mark Andrew Rothera**  
c/o Shire Deutschland GmbH  
Friedrichstr. 149, 10117 Berlin

- Defendants -

Legal representatives for 1 to 6:

Attorneys-at-law Hogan Lovells, Kennedydamm 24, 40476 Düsseldorf  
(AVF/MK 355120.1)

**In the complaint for patent infringement following the hearing of 9  
November 2010 and assisted by**

Presiding Regional Court Judge Dr. Kircher

Regional Court Judge Gauch

Judge Lehmeier

the 2nd Civil Chamber of the Regional Court in Mannheim has **found:**

I. 1. The defendants are ordered

in order to avoid a fine to be determined by the court of up to EUR 250,000 for each violation (alternatively custody) or custody for up to six months; in the case of repeated violation up to a total of two years, whereby custody of the defendants under 1. shall be enforced for the respective managing directors, to refrain in the Federal Republic of Germany from

offering and/or placing onto the market and/or importing or possessing for the designated purposes

secreted human  $\alpha$ -2,6 sialylated  $\alpha$ -galactosidase A ( $\alpha$ -Gal A) containing mannose-6-phosphate.

2. The defendants are ordered to provide the plaintiff with

a) information regarding origin and channels of distribution of the products identified under I. 1. including written data regarding

aa. names and addresses of any manufacturers, suppliers or anyone in previous possession (in particular shipping and storage companies) as well as the quantities of these either produced and/or delivered products, with the corresponding prices paid,

bb. names and addresses of any commercial customers and ordering entities as well as the quantities of the respective products delivered to these customers and/or ordered by them, accompanied by information on the point of sale for which they were ordered, and the respective prices paid,

and such data shall be accompanied by copies of the relevant evidence (order vouchers, order confirmations, invoices, delivery slips and customs documents);

- b) a uniform, organized list accompanied by copies of the relevant evidence (order vouchers, order confirmations, invoices, delivery slips and customs documents) to comprehensively account for the scope of actions taken by them as identified under I. 1., including information regarding
- aa. the sales achieved with products identified under I.1., broken down by individual deliveries and description of type, each with data regarding time of delivery, the name and address of the customer, the quantity delivered and the price per item,
  - bb. the production and marketing costs broken down by individual cost factors with factual information that will allow the determination of whether the individual cost factor arose exclusively through production and/or through marketing of the products identified under I. 1.,
  - cc. the profit achieved with the products identified under I. 1.,
  - dd. the advertising efforts, broken down by advertising medium, production and distribution circulation, advertising period and region and, with respect to internet, information regarding the domains, periods advertised and page view numbers,

whereby

- the information regarding I. 2. a) shall only be provided for the period since 14 April 2010 and the information regarding I. 2. b) only for the period since 14 May 2010,
- the evidence shall be provided with the stipulation that data not related to the requested information and accounting and which is subject to justified interest in confidentiality of the defendants, may be covered or blacked out,
- the defendants reserve the right to provide the names and addresses of their non-commercial customers and addressees of their offers to a certified auditor resident in Germany, to be designated by the plaintiff, instead of providing such to the plaintiff, and such auditor shall be bound to confidentiality vis-à-vis the plaintiff, as long as the defendants agree to bear the costs of such an arrangement, and authorize and request the auditor to provide the plaintiff upon request information regarding whether a certain delivery, customer, offer, and/or recipient of an offer is including in the invoices provided.

3. The defendant under 1. is ordered

to destroy, or at the discretion of the defendants under 1. to surrender to a bailiff to be designated by the plaintiff for the purpose of destruction, at the expense of the defendants, any products identified under I.1 located in the Federal Republic of Germany in its direct or indirect possession, including possession acquired by means according to I.4.

4. The defendant under 1. is ordered to

- a) recall from the distribution channels in writing and accompanied by a binding offer to reimburse any necessary expenses and outlays resulting from the recall and to refund the purchase price,

and

- b) to completely remove from distribution channels

the products identified above under I. 1 in the possession of third parties and produced since 14 May 2010 for third parties and/or offered to third parties and/or placed onto the market to third parties and/or utilized and/or possessed for these purposes.

II. It is determined that the defendants are obligated as joint and several debtors to compensate the plaintiff for all damages already and yet to be incurred by it through actions identified in I. 1. and carried out since 14 May 2010.

III. The remainder of the complaint is dismissed.

IV. The defendants shall bear the cost of the legal dispute.

V. The judgment is provisionally enforceable upon payment of security in the amount of

- EUR 2,000,000 with respect to I.1 (injunction),
- EUR 100,000 with respect to I.2 (disclosure),
- EUR 50,000 with respect to I.3 (destruction),
- EUR 50,000 with respect to I.4 (recall and removal)
- 120% of the respective expense amount to be executed pursuant to IV.

## Facts

The plaintiff asserts claims against the defendants regarding alleged patent infringement for injunction, disclosure, destruction and recall and removal from distribution channels, and requests the court to determine liability of the defendants for compensation of damages.

The plaintiff is the holder of the European Patent EP 1 942 189 (hereinafter: patent in suit) regarding a procedure for the manufacture of secreted proteins as well as such proteins. The patent is in force in Germany. The filing date of the patent in suit is 30 November 1993, whereby the patent in suit claims the priority of U.S. Patent Application 983451 of 30 November 1992. The application was published on 9 July 2008, and notice of the grant of the patent in suit was published on 14 April 2010.

Claim 3 of the patent in suit is as follows:

*secreted human  $\alpha$ -2,6-sialylated  $\alpha$ -galactosidase A containing mannose-6-Phosphate.*

Regarding the remaining content of the patent specification, reference is made to the European patent specification (Exhibit K1) in English, and the German translation provided by the plaintiff (Exhibit K2).

A notice of opposition was filed at the European Patent Office against the patent in suit by a company of the Shire Group, of which the defendant under 1. is a member. The opposition brief has been submitted, also in German translation, as Exhibits 9, 9a and 10 of the exhibits submitted to the European Patent Office. Another brief of the opponents directed to the EPO was submitted as Exhibit HL 15, and in translation, as Exhibit HL 15a. The plaintiff's reply has not yet been submitted in the opposition proceedings.

With the license agreement of 3 February 1995, the plaintiff granted Genzyme Corporation an exclusive license to the patent in suit (submitted in excerpts under Exhibit K12). On this basis, Genzyme Corporation markets under the name



"Fabrazyme" a medicament that contains a form of the enzyme  $\alpha$ -Galactosidase A [hereinafter  $\alpha$ -Gal A].

The defendants under 1., whose managing directors are the defendants under 2. to 6., market the medicament "Replagal" in Germany, which is available for purchase in all pharmacies in Germany and is produced by the affiliate Shire Human Genetic Therapies AB in Sweden. The information for the user (package insert) provided by the defendants as well as the product design and advertisement is shown in Exhibits K 5-10. The defendants under 1. had still not responded to the plaintiff's suggestion to initiate a discussion on granting a license to the patent in suit by the conclusion of the hearing.

Fabrazyme and Replagal are both approved in Germany as medications for the treatment of the metabolic disease Fabry Disease and are used for this purpose. The parties do not dispute that there are no other medications besides Fabrazyme and Replagal approved in Germany for the treatment of Fabry Disease.

For the medicament Fabrazyme, supply shortages occurred for at least the period between June 2009 and November 2010, due to technical problems at the plaintiff's licensee that caused a partial production stop for Fabrazyme.

The plaintiff is of the opinion that the defendants realized Claim 3 of the patent in suit by marketing the medicinal product Replagal. Here it suffices that this product contains an enzyme that literally realizes all the features of Claim 3 of the patent in suit. In particular, it is immaterial when assessing the question of infringement whether this enzyme is present in the pure form or is sold as an enzyme mixture in Replagal, in which the patented form of the enzyme is present among other forms.

The plaintiff states that it reserved its right to grant further licenses in its license agreement with Genzyme Corporation. For this reason, it was therefore in the position to also grant a license to the patent in suit to the defendant under 1. This leads to its right to sue. Furthermore, the plaintiff is entitled to claims for damages, because it receives a portion of the sales of its licensees and, additionally, the payments owed

under the license agreement should be reduced if third parties market an according to the patent product.

The plaintiff **petitions the court,**

I. 1., 2., 4. and II.: as ordered by the court.

I. 3. The defendant under 1. shall be ordered

to destroy, or at the discretion of the plaintiff, to surrender to a bailiff to be designated by the plaintiff for the purpose of destruction, at the expense of the defendants, any products identified under I.1. in its direct or indirect possession ownership located in the Federal Republic of Germany, also insofar as possession is obtained by means pursuant to I.4.

The defendants **petition the court,**

I. to dismiss the action,

alternatively: to suspend the dispute until a decision has been issued by in the opposition proceedings pending against the patent in suit;

II. alternatively: to allow the defendants to avoid enforcement by posting security (a guarantee issued by a bank or a savings and loan) or deposit of security regardless of whether the plaintiff posts security.

The defendants object to the plaintiff's right to sue.

The defendants are furthermore of the opinion that there is no evident use of the patent in suit. The medicament Replagal is not an  $\alpha$ -Gal A, which is solely  $\alpha$ 2,6-sialylated; to the contrary, Replagal is a natural mixture containing differently sialylated enzymes. Claim 3 of the patent in suit, however, teaches the skilled person a pure form of  $\alpha$ -Gal A, with the specified features.

Alternatively, the defendants claim that use of the teachings of the patent in suit was not unlawful. Supply of the patented medicament (assuming the plaintiff's interpretation) to patients requiring it could no longer be ensured by the plaintiff's licensee, as is evidenced by the declarations and notices of the European Medicines Agency (EMA) and Genzyme Corporation in Exhibits HL 2, 3, 4 5, 11, 12, 13, 17 and 18. It was

expected that Genzyme Corporation would have supply shortages in any case until the end of 2011. As a result of supply shortages of their product Fabrazyme, a substantial number of patients had experienced deterioration of their health. An alternative treatment of patients using the product Replagal of the defendant under 1. had been recommended by the EMA, the defendants claim. Therefore, marketing of Replagal by the defendant under 1. was justified on the grounds of the immediate danger to the lives of the patients pursuant to Sec. 904 of the German Civil Code.

The defendants are of the opinion that the revocation of the patent in suit could be expected in the opposition proceedings. The patent in suit should be revoked due to inadmissible amendment, because absolute product protection, as is the subject of Claim 3, had not originally been disclosed. Furthermore, due to the previously published state of the art, the invention lacks novelty, or at least an inventive step. In addition, no sufficient disclosure of the invention is present.

With regard to further details of the allegations of the parties reference is made to the briefs and accompanying exhibits exchanged by the parties.

In the defendants' brief of 10 December 2010, submitted after conclusion of the hearing, they stated their intent to initiate a complaint for compulsory license before the Federal Patent Court and correspondingly to request the stay of the proceedings.

## Grounds

The complaint is to the greatest possible extent admissible and justified.

The complaint was to be dismissed only to a minor extent in petition 1.3 (destruction). In particular, the petition lacks legitimate interest in protection of property and thereby admissibility, as far as the selection of the method for destruction should be left up the discretion of the plaintiff. Insofar as the plaintiff makes use of the right to select a method, there is no need to wait for the execution of such right until after the time of instigation of an action to destroy, and to maintain uncertainty for the defendant under 1. regarding the method ultimately requested by the plaintiff even after the judgment has become enforceable. As an admissible minus, however, as demonstrated by the legal policy behind Sec. 264 (2) of the German Civil Code, the petition comprises the legal consequences ordered in 1.3., namely fulfilment of the claim for destruction pursuant to the various methods specified in the petition, however, at the discretion of the defendants under 1.

As for the rest, the complaint is successful in its entirety.

### A.

The plaintiff is entitled to the award claims on the grounds of illegal utilization of the patent in suit by the defendants.

### I.

The patent in suit involves a particular form of the human enzyme  $\alpha$ -Gal A.  $\alpha$ -Gal A is a lysosomal enzyme, that is, an enzyme that fulfils its function in human cells in the lysosome. There it carries out an important function in the glycolipid metabolism.

In case of a lack of activity of this enzyme (due to a genetic defect), an intermediary product of lipid degradation accumulates in the cell. This pathological glycolipid storage

leads to kidney damage in the patient and damage to the blood vessels of many organs. This metabolic disorder is called Fabry Disease and, if left untreated, results in a shortened life expectancy.

Even before the priority date of the patent in suit, there were signs that an enzyme replacement therapy involving the administration of the  $\alpha$ -Gal A enzyme could be useful. However, the effectiveness of such a therapy, according to the description in the patent in suit, could not be demonstrated at that point in time due to the lack of sufficient supply of the human enzyme. In order to produce larger amounts of  $\alpha$ -Gal A, it was attempted to use genetically manipulated bacteria cells for the production of this enzyme. However, this method in the state of the art only yielded the enzyme at low concentrations; additionally, it could not be purified from the bacteria. It was demonstrated that the enzyme produced using this method was instable, in particular, due to the lack of normal glycosylation.

Furthermore, at the priority date, it was known in the state of the art that cells of patients could take up the mannose-6-phosphate-bearing form of the enzyme by means of mannose-6-phosphate receptors. Inside the cell, the mannose-6-phosphate residue on the enzyme fundamentally causes the enzyme to be directed to the lysosome (so-called "targeting"), where it can perform its metabolic function.

The problem underlying the invention is to provide a form of  $\alpha$ -Gal A that is equipped with mannose-6-phosphate residues, which allows the cells to take up the enzyme easily, and which at the same time is only slowly broken down by the human body. In order to achieve the latter goal, the invention takes advantage of the fact that during the natural production of enzymes in the human cell, the enzyme, during correct processing, passes through certain cotranslational and posttranslational processing steps, for example glycosylation, phosphorylation and, in particular, the addition of sialic acid residues (sialylation) (see Exhibit K2, p. 6). Such correct processing is present in enzymes that are secreted by human cells, that is, following the (natural) production cycle inside the human cell, are secreted by the cell. The fact that the invention attempts to exploit these circumstances for a, with respect to the state of the art, advantageous manufacturing process and the provision of an enzyme that can be advantageously utilized, respectively, results from the realization that (in particular

$\alpha$ 2,6-)sialylated  $\alpha$ -Gal A enzyme demonstrates a markedly longer half-life in the bloodstream than non-( $\alpha$ 2,6-)sialylated  $\alpha$ -Gal A enzyme (see Exhibit K2, p. 62) and that the  $\alpha$ 2,6-sialylated glycoform of the enzyme can be readily purified (see Exhibit K2, p. 13).

As a solution to the problem the patent in suit proposes an  $\alpha$ -Gal A pursuant to Claim 3, which can be outlined as follows:

1.  $\alpha$ -Gal A,
  - 1.1 human,
  - 1.2 secreted,
2.  $\alpha$ 2,6-sialylated,
3. contains mannose-6-phosphate.

According to the specification at page 6 of the patent in suit in the German translation (Exhibit K2), the invention provides for the first time secreted human  $\alpha$ 2,6-sialylated  $\alpha$ -Gal A containing mannose-6-phosphate.

## II.

The infringing product makes literal use of the teaching of Claim 3 of the patent in suit.

The realization of the features 1, 1.1 and 1.2 is undisputed by the parties, for reasons of appropriate considerations. The defendant's product Replagal contains human  $\alpha$ -Gal A obtained by being secreted from human cells, i.e., released from the human cells in a medium, whereby it has already passed through natural processing in the cells prior to its secretion or release. In particular, no further explanation is necessary at this point regarding which properties are defined by the feature "secreted", which describes the patented product as corresponding to the resulting product of a certain production process. Since the enzyme contained in Replagal is undisputedly produced by human cells and secreted by the same, it possesses in any case the properties taught in Feature 1.2.

In marketing the infringing product the defendants also realize Features 2 and 3, contrary to their own point of view. It is hereby sufficient that the medicinal product in dispute, Replagal, contains  $\alpha$ -Gal A, that is present as  $\alpha$ -2,6-sialylated form, and contains mannose-6-phosphate.

1. Feature 2 (" $\alpha$ 2,6-sialylated ") is fulfilled.

Human  $\alpha$ -Gal A contains one or more asparagin-bound glucose chains (see Exhibit K16). The term "sialylation" describes in greater detail the glucose chains, because it is understood as an addition of a particular type of carbohydrate chains, that is, sialic acid residues. These particular carbohydrate chains are bound to various positions on the enzyme, by being attached to the  $\alpha$ -Gal A in the Golgi apparatus (see Exhibits K17 and K23). The specific form of sialylation can be described in greater detail by specifying which carbohydrate molecules are linked together. In an  $\alpha$ -2,6-sialylated combination, according to the teaching in Claim 3, the carbon molecule number 2 of this residue is linked to the carbon molecule number 6 of the other sugar residue via an oxygen molecule.

It cannot be deduced from the wording of Claim 3 of the patent that within a particular  $\alpha$ -Gal A molecule only an  $\alpha$ -2,6 sialylation should be present. According to the Chamber's interpretation of the patent in suit, those enzymes that comprise several sialylation forms next to each other on the same enzyme, also fall within the scope of protection.

The scope of protection of a claimed object is determined by the content of the respective claims (Art. 69 (1) sentence 1 EPC), for the interpretation of which the description and drawings of the patent specification may be supplementary employed (Art. 69 (1) p. 2 EPC). In order to determine whether a patent has been infringed, it is first necessary to examine the technical teaching, which, from the view point of the skilled person dealing with the patent in suit, results from each individual feature of the patent claims and all the features taken together in their entirety (BGHZ 171, 120, Tz. 18 - *Kettenradanordnung*). The interpretation of the patent claims should be guided especially by the purpose of each individual feature and all the features taken together in their entirety as expressed in the patent specification, (GRUR 1999, 909, 911 - *Spannschraube*, BGH GRUR 2001, 232, 233

- *Brieflocher*, GRUR 2005, 41, 42 - *Staubsaugersaugrohr*). The importance of the  $\alpha$ -2,6-sialylation of the enzyme of the invention lies in the higher stability in comparison to the non- $\alpha$ -2,6-sialylated enzyme form. However, decisive for the stability of the enzyme, which makes possible its use as medicament for the treatment of Fabry Disease, is apparently only that  $\alpha$ -2,6 sialylation is present, which results in inhibiting degradation in the body and in the enzyme remaining stable for a sufficient period of time to show its effect. This purpose, which is expressed in the description for example at page 62 of Exhibit K2, especially does not suggest that the absence of other sialylation forms on the enzyme according to the patent is of importance. This also corresponds to the wording of the patent claim, that only requires the  $\alpha$ -2,6 sialylation and neither stipulates its exclusivity nor contains negative features such as the lack of other forms of sialylation.

The analysis report of the laboratory M-Scan (Exhibit K11) and the expert opinion prepared by the company Coriolis Pharma (Exhibit K25), both provided by the plaintiff, confirm that the medicament Replagal contains at least enzymes with  $\alpha$ -2,6 sialylation. The defendant also did not deny this and in any case expressly admitted such in the oral hearing. Therefore Replagal contains enzymes in which Feature 2 has been realized.

2. Feature 3 ("contains mannose-6-phosphate") is also present.

According to Feature 3, the patent in suit stipulates that the  $\alpha$ -Gal A contains mannose-6-phosphate. The defendant has not denied that the  $\alpha$ -Gal A in the medicament in dispute contains mannose-6-phosphate. Because it follows from the expert opinion submitted as Exhibit 25 that this medicament contains, in particular, among the  $\alpha$ -2,6 sialylated  $\alpha$ -Gal A enzymes those that bear mannose-6-phosphate, the defendant has also admitted this fact.

3. The defendant responds to the accusation of patent infringement solely with the argument that Claim 3 of the patent in suit requires a product containing exclusively such  $\alpha$ -Gal A exhibiting the features specified in the patent claim. Only this "pure form" could be considered as a claimed invention, according to the understanding of the skilled person in view of the state of the art familiar to him. This however is not



convincing. The fact that Replagal, in addition to  $\alpha$ -2,6 sialylated  $\alpha$ -Gal A containing mannose-6-phosphate, also contains other forms  $\alpha$ -Gal A, does not prevent the utilization of the patent in suit. Claim 3 in effect simply protects an enzyme in the embodiment defined therein. This molecule is as such also protected even if it is not present within a quantity of several enzymes representing a "pure form" of this enzyme variation.

The wording of Claim 3 does not allow the conclusion that an entirety of several enzymes is being claimed, whereby each must individually exhibit certain features. Nor does the description give rise to such a limiting interpretation of the teaching of the patent in suit. It is obvious that in therapeutic use not only a single molecule or enzyme is employed, rather only a certain, optionally the largest possible amount can yield a significant benefit. However, the teaching of Claim 3 does not deal with this parameter. The teaching of the patent sets out with the problem, that sufficient enzyme suitable for therapeutic use was not available in the state of the art. However, the achievement claimed in Claim 3 of the patent is to provide a particular form of  $\alpha$ -Gal A that is especially suited for therapy, because it is effective and stable. A stable form, of course, also contributes to making sufficient amounts available for therapy. The patent claims, however, does not even begin to teach what amounts would be necessary for the individual applications. For this reason it apparently does not relate to a multitude of molecules for which homogeneity is of the essence. In addition, there is nothing that would make it evident why the *additional* presence of enzymes that are less effective or not effective at all should be detrimental for the therapeutic use of a medicinal product that contains the enzyme according to the patent.

Consequently, it is sufficient for the use of Claim 3 of the patent that the defendant under 1, by marketing its medicament Replagal, offers and places onto the market in particular those secreted human  $\alpha$ -Gal A molecules that contain mannose-6-phosphate and are  $\alpha$ -2,6 sialylated.

The defendants cannot offer a defence even by referring to an alleged novelty-destroying anticipation of such an enzyme which, to the skilled person, was either indirectly recognizable from the patent specification or known from his

common general knowledge. The state of the art referred to in the description can also be drawn upon to determine the meaning of the claims. In particular, the delineation from the state of the art made in the description can reveal what should not be the subject matter of the invention, provided the wording of the claim, which may not be read literally, allows for such an interpretation. The patent claim can in this manner be interpreted such that such subject matter is not included in the protection that is expressly specified in the description as being known in the state of the art (see BGH GRUR 2010, 123, Tz. 19 - *Escitalopram*). However, the present dispute differs from this situation. The description that may serve to interpret the teaching of Claim 3 of the patent does not lead the skilled person to recognize that the improvement was to be found in the higher concentration or purity of a substance (essentially) composed of the described enzyme, because this described enzyme was already known in the art in mixtures, but in insufficient concentration. It is also not apparent from the description that the effect in accordance with the invention should be based on the purity of a substance in the teaching. Rather, the description expressly emphasizes that for the first time secreted human  $\alpha$ -2,6 sialylated  $\alpha$ -Gal A that contains mannose-6-phosphate has been provided. It is not derivable from the description that an enzyme that was already known, but only of higher purity in accordance with the invention, was meant:

It is not derivable from the description that secreted human  $\alpha$ -Gal A was already known in a form containing mannose-6-phosphate. The description very obviously starts out from the assumption that mannose-6-phosphate-bearing  $\alpha$ -Gal A is generally not secreted, but transported to the lysosome. The description signifies the achievement of such secretion as "unexpected" (see Exhibit K2, top of p. 13, bottom of page 62). This does not contradict the introduction to the technical background at page 5 (middle) of Exhibit K2. There it is explained that a – presumably faulty – secretion of lysosomal enzymes was known in the art. That this was known, in particular for the human enzyme  $\alpha$ -Gal A, especially the  $\alpha$ -2,6 sialylated form, cannot be deduced from the disclosure of the patent in suit. This applies in particular to the content of the Ioannou doctoral thesis referred to in the description (Exhibit HL 10, therein Exhibit D8), from which the invention wants to set itself apart (see Exhibit K2, p. 6). That a skilled person can read into this prior

art knowledge of the designated enzyme as such cannot be assumed in view of the specific discourses in the description regarding the unexpected secretion of lysosomal  $\alpha$ -Gal A. This is particularly true because the cause for this secretion is mentioned in the description of the patent in suit, namely an over-expression of  $\alpha$ -Gal A (see Exhibit K2, in particular p. 6, 4<sup>th</sup> and 5<sup>th</sup> paragraph). Whether in the context of "normal" functioning of a human cell the enzyme form in accordance with the invention is secreted to a certain degree is not disclosed. Such information also cannot be deduced from the remarks on known experiments with purified  $\alpha$ -Gal A from the spleen and from plasma. Because in so far it is neither explained that the enzyme is secreted  $\alpha$ -Gal A, nor that the enzyme is  $\alpha$ -2,6 sialylated  $\alpha$ -Gal A or even in addition  $\alpha$ -Gal A decorated with mannose-6-phosphate.

At the same time, it is irrelevant whether human  $\alpha$ -2,6 sialylated  $\alpha$ -Gal A containing mannose-6-phosphate occurs in nature, because such natural existence of a substance would not contradict patentability, if its provision was not known in the prior art, or the substance exhibited unexpected effects (Benkard/*Meilulis*, PatG, 10. A., 2006, § 3 Rn 93; BPatG GRUR 1978, 238 - *Naturstoffe*). This is also in agreement with the disclosure of the patent specification, that it is claimed as the invention *at a minimum* that a certain substance, namely the enzyme as it is taught, has been recognized as being particularly useful in Fabry Disease and furthermore that for the first time a way of providing this form of enzyme has been found.

After all this, the designation of the enzyme in Claim 3, even in the overall context, cannot be interpreted restrictively such that exclusively a plurality of (numerous) individual enzymes, each with the specified features, in its pure form is taught. Consequently, in the case in dispute a realization of the teaching in Claim 3 is already present, because the medicinal product of the defendant contains the secreted enzymes of the patent, which are both  $\alpha$ -2,6 sialylated and contain Mannose-6-Phosphate, and the defendant thereby markets (inter alia) the enzymes in accordance with the patent.

## III.

The supply difficulties mentioned by the defendant of Genzyme Corporation, licensee of the plaintiff, with respect to its medication Fabrazyme, does not justify utilization of the patent.

The legal policy of justified necessity pursuant to Sec. 904 of the German Civil Code may be referred to in justifying use of a third party patent (see BGH GRUR 1992, 305, 309 - *Heliumspeisung*). However, such "influence" on the rights granted by the patent can only be used pursuant to Sec. 904 of the German Civil Code for warding off present danger if it is necessary, that is, if there are objectively no other equally suitable and less aggressive means at hand, and the risk of damage is disproportionate to any damage arising from exercising influence on the patent rights. Regardless whether, in the case at hand, supply shortages lead to present danger for life and limb of the patients suffering from Fabry Disease - such danger causing much more damage than non-licensed use of a patent - the conditions for Sec 904 of the German Civil Code are not present here.

That is to say, it is not evident that there were and are no other, less intrusive and objectively similarly suitable means for warding off danger caused by supply shortages of Genzyme. Even if the plaintiff should not be prepared to quickly grant a license, there would have been other means for warding off danger that would appear to make interference in the plaintiff's exclusive right of offering, marketing and introduction in the Federal Republic of Germany pursuant to Sec. 9 of the German Patent Act. The defendant under 1. could turn over the enzyme, produced by its affiliate in Sweden, directly to the plaintiff or its licensees, for import, supply and marketing in Germany.

This admittedly less profitable possibility for the defendant under 1. must be considered as the less severe means. Sec 904 of the German Civil Code restricts the power of the holder to exclude others from influencing things belonging to him and satisfy thereby the purpose of protection of the legal position of endangered third parties (see Münchener Kommentar zum *BGB/Säcker*, 5. A., 2009, § 904 Rn 1). Protection of the individual infringing the legal position of another is not the purpose of this rule. Therefore, the issue of equal suitability of other means should be judged from the point of view of the endangered individual. The patients affected (endangered) by supply

shortages for Fabrazyme could be just as effectively helped if the defendant under 1. were to turn over the production output of the alternative medication Replagal at its disposal to the plaintiff or its licensees and let these authorized entities market the medication. Even if this possibility is not economically reasonable for the defendant and perhaps does not correspond to traditional practice of the trade, it is still a measure that intrudes less on the legal standing of the plaintiff yet is equally effective. From the point of view of the patients, it is immaterial whether the alternative medication is marketed by the plaintiff, its licensees, or the defendant under 1.

It is not evident that such warding off of danger should contradict pharmaceutical regulations, as the defendants claimed in the hearing. Even if the required medication approval is linked to the product for bringing the medication into circulation, such that the licensee of the plaintiff would not be permitted to market the medication Replagal based on the approval for its medication Febrazyme, the defendant under 1. would be in a position to allow a marketing of the product by the plaintiff or its licensees in order to ward off danger. The defendant itself pointed out in its comments after conclusion of the hearing that at least a conclusive assignment to the licensee of the approval for bringing Replagal into circulation was a possibility. In this respect, it also is irrelevant under the aspect of Sec. 904 sentence 1 of the German Civil Code whether these means were economically reasonable. The fact that marketing of Replagal by a licensee of the plaintiff bears certain economical disadvantages and liability risks also does not hamper its qualification as the less severe means. The defendants did not state that the licensee of the plaintiff would not actually accept the Replagal provided by the defendant under 1 and the approval, especially as there is no such offer by the defendants. It also does not appear to be a remote possibility that the economic advantages to the licensee of the plaintiff of marketing Replagal would dominate, and that it would therefore accept the offer.

In view of this, it is no longer decisive that the question begs to be asked why the defendant did not accept any time prior to the hearing the undisputed offer from the plaintiff to discuss the issue of perhaps granting a license to the patent in suit. To this extent it may also remain unanswered whether early "licensed" means for warding off danger could have been made possible by this. In particular it is not necessary to go into detail as to whether in a certain case – not this one – in which *solely* the use of the

patent by the defendant itself is suitable for warding off danger, the defendant has a justified objection only if an acceptable license fee offer of the defendant were available, and insofar as the principles on the antitrust law defense that a compulsory license should have been granted within the meaning of the ruling "Orange-Book-Standard" of the Federal Court of Justice (GRUR 2009, 694) can be applied.

#### IV.

The plaintiff is entitled to the claims it has made on the grounds of the acts of patent infringement committed by the defendants, whereby the application of the following causes for the complaint are based on Art. 64 of the EPC.

1. The claim for injunction follows from Sec. 139 (1) of the Patent Act. The acts of infringement that have already been committed justify the danger of repetition.

As patent holder, the plaintiff has the right to sue. It can be assumed that the license granted to Genzyme Corporation is an exclusive license. The patent or utility model holder basically is entitled to assert a claim for injunction against the infringer, if it has granted an exclusive license to the property right (BGH GRUR 2008, 896 - *Tintenpatrone*, amtlicher Leitsatz zu 1). Even if the Federal Supreme Court, in the ruling issued (a.a.O., Tz. 24), justifies the right to sue of the plaintiff involved in that such retained the (exclusive) right to *produce* the protected subject matter, the Chamber interprets the ruling such that as a rule, the patent holder also remains entitled to claim injunction even if it has granted a completely exclusive license. This must also apply as long as the holder's legal position can be impaired by infringement of its property rights. This is regularly the case if the property right loses economical value, if it is no longer acknowledged by the market, and whenever the patent holder is interested in maintaining the value of his property rights in case of termination of the exclusive license agreement.

It is immaterial at this point whether and which requirements are to be met in determining to what degree a patent holder is affected in the case of an exclusive

license, in order to determine claims for injunction. At least they cannot extend beyond the conditions for such patent holder's own claims for damages. These conditions however are present in a dispute (see below, number 2.).

There is no need to discuss further the defendants' objection regarding alleged nullity of the license agreement on the grounds of alleged formal defect. This objection is insubstantial, because in the case of nullity of the license agreement the plaintiff's right to sue, as holder of the patent, would especially be justified.

In addition to the defendants under 1., their managing directors are also obligated to cease and desist.

2. The claim for compensation of damages follows from Sec. 139 (2) of the Patent Act.

Assuming an exclusive license of Genzyme Corporation, the declaration of claims to compensation of damages presupposes that nevertheless a certain probability of occurrence of damages to Plaintiff exists, as patent holder, which however does not necessarily have to be high, if according to experience of daily life such occurrence can be expected with some certainty. In the case of grant of an exclusive license, it can be generally assumed with sufficient probability that damage will be incurred by the licensor, if it participates economically in the exercise of the license by the licensee. If the license parties have agreed to a turnover or a quota license, there is usually the not too remote possibility that damage to the licensee also means damage to the holder of the property right, which is caused by the fact that the holder would have received higher license fees from the licensee if the licensee had granted a sub-license to the infringer or, due to the lack of competition infringing property rights, would have had higher sales. A reduction in license fees due to this poses replaceable damage (see BGH a.a.O. - *Tintenpatrone*, Tz. 26 f.).

This possibility of damage is present in this dispute. The license of Genzyme Corporation is linked strongly to turnover, such that the level of the license fees due is tied to a percentage of the actual (net) income from sales of the subject matter of the patent. Even if a reduction in sales of Genzyme Corporation in the time period in dispute should be excluded because the supply shortage allowed it to sell all of

its supply capacity, despite offers of the competing defendants, reductions in license fee income are not unlikely. The smaller the available supply on the market, the higher the price that Genzyme Corporation can achieve, which in turn affects the level of license fees. In addition, there is the likelihood of damage with respect to the special provision on the guarantee of exclusivity in the license agreement between the plaintiff and Genzyme Corporation. The excerpt from the agreement provided on this issue (Exhibit K12) proves that the availability at third parties of the subject of the license in the agreement region reduces the amount of license fees due (see Art. 4, No. 4.1, sentence 2 of the agreement). According to the Chamber, this can also be deduced without a doubt even from the excerpts of the agreement. In particular, no good reason can be ascertained to assume that by "third parties" within the meaning of the mentioned clause of the agreement only those third parties are meant that received a sub-license from Genzyme Corporation. Of course, the corresponding provision in Art. II, no. 2.1 speaks of the right "to sublicense third parties". Here, however, "third parties" also has no other meaning than the designation of third parties not a party to the agreement. These can receive a sub-license from the licensee, which however does not make them "third parties". It is also not comprehensible from the content why the reduction in license fees should be linked exclusively to the legitimate supply by sub-licensees of Genzyme Corporation, especially since this would lead to higher income for Genzyme Corporation and – in contrast to supply by infringers that hindered – does not represent an comprehensible reason for a reduction in licensee fee obligations.

The defendant under 1. is responsible for the compensation of damages incurred, because in connection with the patent infringement activities already committed, its decision-making bodies are in any case guilty of negligence. In addition, the defendants under 2. to 6. also are liability jointly and severally, because they are obligated as managing directors to prevent property right infringements by companies they represent (see OLG Hamburg, GRUR-RR 2002, 240 - *Super Mario*; Hass in: Festschrift für Schilling, 2007, S. 249 ff., 252, 261 f.; see also BGH GRUR 2009, 1142, 1145 - *MP3-Player-Import* – on negligent patent infringement). The managing directors of the defendant under 1. apparently did not fulfil the strict duties of care to be applied with respect to the observance of property rights.



The plaintiff is currently not in the position to determine the amount of the claim for damages; this justifies the petition for declaration.

3. In order to be able to quantify in the future the damage it incurred, Plaintiff has the right to information pursuant to Sec. 242 of the German Civil Code regarding the actions leading to liability for compensation of damages that have taken place since 14 Mai 2010. Furthermore, pursuant to Sec 140b of the Patent Act, the defendants are obligated to provide information regarding the origin and distribution path of the infringing products for the period starting on the day of the publication of the grant of the patent, 14 April 2010. The Chamber does not have the same reservations as the defendants regarding the appropriateness of the request for multiple evidence (order slips, order confirmations, invoices, delivery slips and customs documentation).
4. The plaintiff is entitled to claims for destruction, recall and removal pursuant to Sec. 140 (1), (3) of the Patent Act. There are no apparent circumstances that would indicate that the plaintiff's request is an inappropriate intrusion in the interests of the defendants.

#### B.

The dispute could not be stayed until the judgment was pronounced in the opposition proceedings against the patent. The judgment regarding opposition is pre-determinative within the meaning of Sec. 148 of the Code of Civil Procedure. However, the Chamber has utilized the discretion afforded to it by this rule to the extent that the infringement proceedings will not be stayed.

The Chamber exercises great caution in ordering a suspension, in order to avoid the situation where, as a consequence of the suspension, the interdiction right granted to the holder following the granting of the patent, also binding on the courts, is suspended for a considerable period of time. In order to prevent misuse, infringement proceedings may only be stayed according to case law if it is highly probable that the patent in suit will be revoked or voided on grounds of an opposition or revocation proceedings (BGH

GRUR 1987, 284 - *Transportfahrzeug*). Accordingly the mere possibility of the revocation of the right to bring suit in property right matters is not sufficient for a suspension. To the contrary, the Chamber usually stipulates that the probability of the success of the opposition must predominate.

These aspects that describe the interests of the plaintiff prevail in the case at hand over the defendants' interest in a stay of the lawsuit. In the case at hand, the Chamber cannot state that the opposition is more likely to succeed than to fail.

1. First of all, it must be stated that the Chamber cannot determine with sufficient certainty that Claim 3, added to the current divisional application during prosecution of the patent, constitutes an inadmissible amendment, and therefore cannot project that the grounds for revocation pursuant to Art. 123 (2) EPC will be confirmed in the opposition proceedings.

An amendment to a patent claim is considered inadmissible if it involves an object that would not be considered by a skilled person, based on the original disclosure, to have also been included in the requested scope of protection from the beginning. In making a decision regarding the stay of the proceedings it is important to consider that the admissibility of an amendment is part of the examination procedure of the granting process, such that a grant of the amended patent already includes an expert opinion of the examiner to the effect that the amendment is within the bounds of admissibility. The Chamber usually avoids replacing the opinion of the examiner with its own opinion, because it usually does not have better knowledge regarding what the skilled person would consider to be part of the invention based on the application documents. This also applies in the case at hand.

The priority document submitted by the defendant in Exhibit HL 7 was submitted during the entire hearing in English, as was the European parent application in Exhibit HL 8, which is why it is difficult for the Chamber to determine any deviations between the content of the patent in suit, in particular of Claim 3, and these documents. However, even submission of the German translation of the original application in Exhibit HL 19 after the closing of the oral hearing does not change the

opinion of the Chamber. In particular, it can basically be assumed that, especially in the case of amendments of patent claims, in particular whenever new claims are brought into the application process, the examining division of the European Patent Office will examine very carefully the original disclosure. It is therefore not apparent where in the case at hand the Chamber should draw the inference, based on the documents submitted, that the opinion of the examining division with respect to the disclosure in the original application was incorrect. In particular, Claim 3 only contains features that are also discussed in the description. The Chamber is not moved to experience strong doubts as to whether a skilled person would comprehend a substance with exactly this combination of features to be subject matter of the originally disclosed invention.

2. The plaintiff's concerns regarding a sufficient disclosure of the invention of the patent in suit are according to the Chamber also provide few grounds for justifying the assumption of errors on the part of the granting agency. This is particularly true because the description also applies to a manufacturing process for the enzyme claimed in Claim 3 and in the patent in suit various examples for manufacturing are described. It is therefore difficult in the opinion of the Chamber to comprehend why the defendants' objection that the manufacture of the enzyme is not sufficiently disclosed in the documentation, despite numerous examples, should be grounds for the success of the opposition.
3. Finally, the Chamber also cannot determine that the objections of the defendants to the patentability of the subject matter of Claim 3 will most likely defeat this claim.
  - a) The Chamber cannot recognize a novelty-destroying anticipation.

In particular the objection over D4, which the defendants emphasized does not sufficiently project a revocation or limitation of the patent in suit. The prior knowledge relating to Claim 3 appears dubious because nowhere in the objection is there mention made of an enzyme that is both  $\alpha$ -2,6 sialylated and contains mannose-6-phosphate. Insofar as the opposition brief uses the passages from the description of the patent in suit in order to prove the prior knowledge of certain possible features of  $\alpha$ -Gal A, (not however of the complete

combination of features according to Claim 3), this speaks against the success of the opposition. That is to say, if the description should even hereby demonstrate the allegedly relevant state of the art, an incorrect decision by the granting agency is improbable.

The documents D3 and D5 additionally referred to as novelty-destroying do not provide justification for a stay of the proceedings. The defendants do not point out where D3 discloses the features of  $\alpha$ -2,6 sialylation and the presence of mannose-6-phosphate. Prior knowledge of mannose-6-phosphate in lysosomal  $\alpha$ -Gal A enzymes can be deduced from D5. The disclosure of the combination of this feature with  $\alpha$ -2,6 sialylation, and in addition in secreted enzymes at that, is not demonstrated by the defendants, at least the Chamber cannot discern as much.

Apart from that, the fact that the documents cited by the defendants as being novelty-destroying were acknowledged already in the description of the patent in suit or in any case were known in the granting process as evident from the cover sheet, speaks against the success of the opposition.

- b) The defendants' challenges to the degree of inventiveness of Claim 3 also do not lead to suspension of the lawsuit.

The defendants claim lack of inventive step in view of D4; however, to this extent the Chamber does not have sufficient doubt regarding the inventiveness of Claim 3 of the patent for staying the infringement proceedings. Objections to inventiveness do not usually justify suspension if solely the state of the art acknowledged in the granting process is referred to. This is also the case in the case at hand.

The Chamber cannot without a doubt ascertain from the opposition brief what should have indicated to a skilled person to use a  $\alpha$ -2,6 sialylated enzyme as a more stable form of  $\alpha$ -Gal A as a medicament. To this extent, the defendants have not sufficiently proven to the Chamber to what extent D11 or D12, which would need to be added according to the defendants' view and which were available only in English, should be of further assistance. It is furthermore

unclear whether this would make the other features, in particular Feature 1.2 and Feature 3, more obvious. Therefore, especially with regard to the inventive step of the patent it cannot be projected that the expert assessment of the granting agency will be assessed as incorrect in the opposition proceedings, even though the agency was aware of the objections.

- c) Even when considering the expert opinion submitted by the defendants, prepared by Dr. Conradt (Exhibit HL 16a), the Chamber can still not predict sufficiently probable success of the opposition. In any case, this expert opinion does not contain any compelling indications for such an event.

### C.

The Chamber also refrains from the stay of the lawsuit until conclusion of the compulsory licensing proceedings before the Federal Patent Court.

It is immaterial whether such a stay of the proceedings can be considered at all, as according to prevailing opinion the granting of a compulsory license pursuant Sec. 24 of the Patent Act would only apply to the future (see Benkard/Rogge, PatG, 10. A., 2006, § 24 Rn 28), (for this very reason negative: Benkard/Rogge, PatG, 10. A., 2006, § 139 Rn 109). Regarding any discretionary decision it should at least be taken into consideration that a stay of the proceedings can only be considered in particular exceptional cases, in order not to suspend the assertion of the holder's claims already at instigation of compulsory license proceedings. A condition for a stay of the proceedings must have at least strong probability of success of the petition for compulsory license, which is not demonstrated by the case at hand. The defendants demonstrated in the brief they submitted after conclusion of the hearing neither the conditions pursuant to Sec. 24 (1), (5) of the Patent Act, nor to Sec. 24 (2) of the Patent Act, rather refer sweepingly to the draft of the claim for compulsory license.

Beyond this, the Chamber sees no need, within its discretion, for a stay of the proceedings because the defendants did not refer to the possibility of a claim for compulsory license until after conclusion of the hearing, and, possibly, have instigated

such proceedings, however, did not accept the plaintiff's offer of negotiations for a license during the entire hearing.

**D.**

The determination of costs follows from Sec. 92 (2) No. 1 of the Code of Civil Procedure. The determination on provisional enforceability is issued pursuant to Sec. 709 sentences 1 and 2 of the Code of Civil Procedure.

The Chamber sees no need to not link the determination of the security to the amount in dispute. The cap on the security of 100 million EUR as requested by the defendants is not imperative, because the defendants do not give detailed information as to why damages in case of enforcement would amount to this sum. The abstract reference to the non-quantified "number of patients currently treated with Replagal" is neither sufficient nor comprehensible, especially since the defendants denoted this number of patients in the same brief of 10 December 2010 as "small", and pointed to a moderate sales trend.

The petition for exemption from judicial execution pursuant Sec. 712 of the Code of Civil Procedure is unsuccessful. A decision granting the petition of the defendants would stipulate that the execution would lead to economic disadvantage that could not be compensated by them as debtors (Sec. 712 (1) sentence 1 of the Code of Civil Procedure) and a preponderant interest of the plaintiff as creditor does not oppose the exemption from judicial execution (Sec. 712 (2) sentence 1 of the Code of Civil Procedure). In the case at hand there is already a lack of demonstration of the first condition. The defendants have not demonstrated any irreplaceable disadvantages they would incur as a result of enforcement. Sec. 712 of the Code of Civil Procedure does not serve the purpose of protecting third parties, who would be the endangered patients in this case, according to the defendants.

**E.**

The brief of 10 December 2010 submitted by the defendants after conclusion of the hearing contains no new information of substance for the judgment, as is the case regarding the brief of 17 January 2011, and for that reason provided no justification for reopening the hearing at the discretion of the court pursuant to Sec. 156 (1) of the Code of Civil Procedure.

Dr. Kircher  
Regional Court  
Presiding Judge

Gauch  
Regional Court Judge

Lehmeyer  
Judge

Copied by:

[seal of the court]

[illegible signature]  
Records clerk of the Court Registry

Tab B (English translation  
of 11/19/11 letter)

[letterhead JD Munich]

Dear colleague Dr. v. Falck,

We refer to your letter dated December 9, 2010, and the reference therein to statements made by our client to NIH.

Our client has assured the NIH that our client would not seek to enforce an injunction against the marketing and sale of Replagal during any period of an existing or future shortage of Fabrazyme. Our client has repeatedly reaffirmed this position, and has also repeatedly clarified that the welfare of the patients is Mount Sinai's first priority. Nevertheless, in view of the judgment of the Regional Court of Mannheim dated January 18, and to facilitate the continued efforts of our client to reach a settlement of the dispute, our client has asked us to provide you with comfort on the enforcement of the German judgment as a confirmation of goodwill from our client's side.

Our client expects that in the second half of 2011, the shortage in the supply of Fabrazyme will have been resolved. Our client therefore undertakes, as a first step, not to enforce any injunction issued against your client or its customers concerning the drug Replagal in Germany before September 30, 2011; to be extended as set out below. The same commitment for non-enforcement shall apply for the rights relating to destruction of stock of Replagal and recall of Replagal from the distribution channels.

Our client will closely monitor the supply situation for Fabry drugs. Should it become apparent that the current shortage of Fabrazyme will extend beyond the first half of 2011, our client will, at the latest three months prior to September 30, provide you with a further undertaking of non-enforcement. The same applies, should any update on a further extension of a shortage of Fabrazyme occur thereafter. We invite you to remain in close contact with our client and exchange information on the supply situation for Replagal, to ensure that any assessment on the shortage of Fabry drugs is made on a correct factual basis.

This commitment is not to be construed as a license and is entered into without recognition of a legal duty, but shall nevertheless be legally binding. We trust that it will allow the parties to continue their discussions to reaching a settlement agreement.

Yours sincerely,



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LG Mannheim, 2 O 75/10

Sehr geehrter Herr Kollege Dr. von Falck,

nachdem das Landgericht Mannheim gestern das Urteil zu Gunsten unserer Mandantin verkündet hat, kommen wir zurück auf Ihr Schreiben vom 9. Dezember 2010 und die darin enthaltene Anfrage bezüglich der Stellungnahme unserer Mandantin gegenüber dem NIH.

Unsere Mandantin hat dem NIH versichert, dass unsere Mandantin nicht beabsichtigt, einen Unterlassungstitel gegen den Verkauf und den Vertrieb von Replagal während einer Phase einer bestehenden oder zukünftigen Knappheit von Fabrazyme zu vollstrecken. Unsere Mandantin hat diese Position wiederholt bestätigt und dabei auch jeweils klargestellt, dass an erster Stelle der Prioritäten für unsere Mandantin das Wohl der Patienten steht.

COMMERZBANK MÜNCHEN · KONTO-NR. 660601600 · BLZ 700 400 41 · IBAN DE23 7004 0041 0660 6016 00 · BIC COBADEFFXXX · UST/VAT REG NO DE 112010330

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Schreiben an Hogan Lovells  
vom 19. Januar 2011

Im Hinblick auf das Urteil des Landgerichts Mannheim hat uns unsere Mandantin gebeten, etwaige Bedenken Ihrer Mandantin hinsichtlich der Vollstreckung aus dem deutschen Urteil auszuräumen. Dies geschieht als Bestätigung des guten Willens unserer Mandantin und zur Förderung ihrer anhaltenden Bemühungen, eine gütliche Beilegung der Auseinandersetzung zu erreichen.

Unsere Mandantin erwartet, dass der Lieferengpass für Fabrazyme in der zweiten Jahreshälfte des Jahres 2011 behoben sein wird. Unsere Mandantin verpflichtet sich daher in einem ersten Schritt, vor dem 30. September 2011 keinen Unterlassungstenor gegen Ihre Mandanten oder deren Abnehmer betreffend das Arzneimittel Replagal in Deutschland zu vollstrecken (Ziffer I.1. des Urteils). Diese Verpflichtung wird gegebenenfalls wie unten beschrieben verlängert und gilt ebenfalls für die tenorierten Rechte auf Vernichtung von Lagerbeständen (Ziffer I.3 des Urteils) und Rückruf und Entfernung von Replagal aus den Vertriebswegen (Ziffer I.4 des Urteils).

Unsere Mandantin wird die Liefersituation für Fabry-Medikamente beobachten. Sollte unsere Mandantin zu dem Schluss kommen, dass sich ein Fortdauern der gegenwärtigen Knappheit von Fabrazyme über dieses Datum hinaus abzeichnet, wird unsere Mandantin Ihnen spätestens drei Monate vor dem 30. September 2011 eine weitere Zusicherung der Nichtvollstreckung zukommen lassen. Gleiches gilt jeweils, falls sich danach eine weitere Verlängerung der Knappheit von Fabrazyme abzeichnen sollte. Wir regen an, dass Ihre Mandantin in engem Kontakt mit unserer Mandantin bleibt und Informationen über die Liefersituation für Replagal austauscht, um sicherzustellen, dass eine Beurteilung der Knappheit von Fabry-Medikamenten auf einer zutreffenden Tatsachengrundlage vorgenommen werden kann.

Diese Verpflichtung ist nicht als Lizenz oder Verzicht auf sonstige Rechte betreffend diesen Zeitraum auszulegen und wird ohne Anerkennung einer Rechtspflicht abgegeben, ist aber gleichwohl rechtsverbindlich. Wir gehen davon aus, dass sie es den Parteien erleichtert, ihre Gespräche zum Erreichen einer gütlichen Einigung fortzusetzen.

Mit freundlichen kollegialen Grüßen



Dr. Christian Paul  
Rechtsanwalt

**BANK GUARANTEE No. ....**  
**for execution of foreclosure**

In the proceedings

**Mount Sinai School of Medicine of New York University, One Gustave Levy Place, New York, NY 10029-6574, USA**

(hereinafter referred to as „Plaintiff“)

Legal representatives: Attorneys at Law & colleagues at JONES DAY,  
Prinzregentenstr. 11, 80538 Munich

versus

1. **Shire Germany GmbH**
2. **Leonhard Terp**
3. **Dr. Werner Föller**
4. **James Nicholas Bowling**
5. **Gian Piero Reverberi**
6. **Mark Andrew Rothera**

all located c/o Shire Germany GmbH, Friedrichstr. 149, 10117 Berlin, Germany

(hereinafter referred to as „Defendants“)

Legal representatives to 1-6: Attorneys at Law & colleagues at Hogan Lovells,  
Kennedydamm 24, 40476 Duesseldorf

Defendants are ordered by judgment of Mannheim Regional Court – 2<sup>nd</sup> Civil Division – of January 18, 2011 in the case 2 O 75/10, cipher I. 2., to provide information and to submit an accounting.

The judgment concerning the order to provide information and to submit an accounting is, according to cipher I.V., provisionally enforceable for the Plaintiff against a surety in the amount of EUR 100,000.00.

That being said, we [bank, address], herewith assume absolute, unconditional and irrevocable suretyship with respect to the Defendants for an unlimited period of time, up to the maximum amount of

**EUR 100,000.00**

**(in words: EURO one hundred thousand)**

for all damage compensation claims that may be incurred by the Defendants in the event of revocation or modification of the aforementioned judgment by enforcement or by a service rendered to forestall enforcement. This surety shall also extend to claims for repayment on the part of the Defendants against the Plaintiff, up to the aforementioned maximum amount, arising because of an enforceable court settlement.

The claim deriving from this surety shall be due as soon as the announcement of a rescinding or modifying judgment in the second instance with the availment has been verified. The same shall apply on conclusion of the lawsuit by an enforceable court settlement.

Any claims and rights arising from this bank guarantee can only be assigned with our prior written approval.

Our surety shall expire when a court decision under § 109 paragraph 2 ZPO is brought to our attention or when the original of this deed of suretyship has been returned to us by the beneficiary of the surety – or by a third party with the consent of said beneficiary.

[Place, date]

**PROZESSBÜRGSCHAFT Nr. 7F7S-713531**  
zur Durchführung der Zwangsvollstreckung

In dem Rechtsstreit

**Mount Sinai School of Medicine of New York University, One Gustave Levy Place, New York, NY 10029-6574, USA**

(nachstehend „Klägerin“ genannt)

Prozessbevollmächtigte: Rechtsanwälte von JONES DAY und Kollegen, Prinzregentenstraße 11, 80538 München

gegen

1. **Shire Deutschland GmbH**
2. **Leonhard Terp**
3. **Dr. Werner Föller**
4. **James Nicholas Bowling**
5. **Gian Piero Reverberi**
6. **Mark Andrew Rothera**

alle geschäftsansässig c/o Shire Deutschland GmbH, Friedrichstr. 149, 10117 Berlin, Deutschland

(nachstehend „Beklagte“ genannt)

Prozessbevollmächtigte zu 1 - 6: Rechtsanwälte Hogan Lovells und Kollegen, Kennedydamm 24, 40476 Düsseldorf

sind die Beklagten durch Urteil des Landgerichts Mannheim – 2. Zivilkammer – vom 18. Januar 2011, Aktenzeichen 2 O 75/10, gemäß Ziffer I 2. des Urteils zur Auskunft und zur Rechnungslegung verurteilt worden.

Das Urteil ist für die Klägerin bezüglich der Auskunft und Rechnungslegung gemäß Ziffer I.V. des Urteils vorläufig vollstreckbar gegen Sicherheitsleistung in Höhe von EUR 100.000,00.

Dies vorausgeschickt, übernehmen wir, J.P.Morgan AG, Junghofstrasse 14, 60311 Frankfurt am Main, hiermit den Beklagten gegenüber die selbstschuldnerische, unbedingte, unwiderrufliche und unbefristete Bürgschaft bis zum Höchstbetrag von

**EUR 100.000,00**  
**(in Worten: EURO einhunderttausend)**

für alle Schadensersatzansprüche, die den Beklagten im Falle der Aufhebung oder Abänderung des vorgenannten Urteils durch die Vollstreckung oder durch eine zur Abwendung der Vollstreckung erbrachte Leistung etwa entstehen sollten. Die Bürgschaft erstreckt sich bis zum vorgenannten

J.P. Morgan AG • Junghofstrasse 14, 60311 Frankfurt am Main, Germany  
Telephone: +49 (0) 69 7124 -0 • Facsimile: +49 (0) 69 7124 2209

HRB 16861 Frankfurt am Main • Bankleitzahl 501 108 00 • Swift Address CHASDEFX  
Vorstand: Thomas Meyer (Vorsitzender) • Oliver Berger • Burkhard Kübel-Sorger  
Aufsichtsratsvorsitzender: Mark S. Carvin

**PROZESSBÜRGSCHAFT Nr. 7F7S-713531**

Höchstbetrag auch auf Rückzahlungsansprüche der Beklagten gegen die Klägerin, die aufgrund eines vollstreckbaren Prozessvergleichs entstehen.

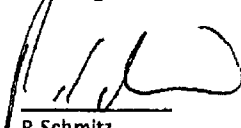
Der Anspruch aus dieser Bürgschaft wird fällig, sobald uns mit der Inanspruchnahme die Verkündung eines aufhebenden oder abändernden Urteils in zweiter Instanz nachgewiesen wird. Entsprechendes gilt bei Beendigung des Rechtsstreits durch vollstreckbaren Prozessvergleich.

Ansprüche und Rechte aus dieser Bürgschaft können nur mit unserer vorherigen schriftlichen Zustimmung abgetreten werden.

Unsere Bürgschaft erlischt, wenn uns eine gerichtliche Entscheidung nach § 109 Abs. 2 ZPO nachgewiesen wird oder wenn wir diese Bürgschaftsurkunde im Original vom Sicherheitsberechtigten – oder mit dessen Zustimmung von einem Dritten – zurückerhalten haben.

Frankfurt am Main, 9. Februar 2011

J.P.Morgan AG

  
R. Schmitz

  
M. Causera

Tab D

## JONES DAY

REGULATED BY THE SOLICITORS REGULATION AUTHORITY  
21 TUDOR STREET • LONDON EC4Y 0DJ • DX 67 LONDON/CHANCERY  
TELEPHONE: 020.7039.5999 • FACSIMILE: 020.7039.5999

Your Ref L-178417/N Jones/Y Liyanage  
Ref/CAM AJM/702827-600009  
E-mail ameculloch@jonesday.com  
Direct 020 7039 5219  
Date 20 January 2011

Linklaters  
One Silk Street  
London EC2Y 8HQ

BY HAND

Dear Sirs

**Shire Pharmaceutical Contracts Ltd v Mount Sinai School of Medicine of New York University  
Mount Sinai School of Medicine of New York University v Shire Plc (t/a Shire Human Genetic Therapies)**

We enclose by way of service our client's Defence. We also enclose a Part 20 Claim Form, Particulars of the Part 20 Claim (which are attached to the Defence), extracts from the website [www.replagal.com](http://www.replagal.com) referred to in the Particulars and a response pack.

Please confirm that you are instructed to accept service of the Part 20 Claim and Particulars on behalf of Shire Plc (t/a Shire Human Genetic Therapies) and that service be deemed to have occurred today.

You will see that the Part 20 Defendant is Shire Plc (t/a Shire Human Genetic Therapies). It is clear that infringing acts in relation to the Replagal product are being performed in the United Kingdom and, from our research, it appears to us that this is the company and business unit within the Shire group that is performing those acts. Please confirm by return that our understanding is correct and that, within the Shire group, it is Shire Plc (t/a Shire Human Genetic Therapies) that is carrying out the acts complained of. If our understanding is incorrect, please confirm by return the identity of the correct Shire entity/entities and we will amend our client's Part 20 Claim Form and Particulars of Claim accordingly.

A LIST OF PARTNERS AND THEIR PROFESSIONAL QUALIFICATIONS IS AVAILABLE AT

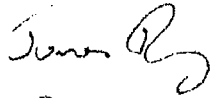
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You will also see that our client is seeking an injunction. For the avoidance of doubt, this is not intended to override our client's affirmation to the NII that it will not seek to enforce an injunction against the marketing and sale of Replagal during any period of an existing or future shortage of Fabrazyme.

Yours faithfully



**Jones Day**



# JONES DAY

REGULATED BY THE SOLICITORS REGULATION AUTHORITY  
21 TUDOR STREET • LONDON EC4Y 0DJ • DX 67 LONDON/CHANCERY  
TELEPHONE: 020.7039.5959 • FACSIMILE: 020.7039.5999

Your Ref L-17841/N Jones/Y Liyange  
Ref/CAM AJM/702827-600009  
E-mail amcculloch@jonesday.com  
Direct 020 7039 5219  
Date 17 February 2011

Linklaters  
One Silk Street  
London EC2Y 8HQ

Dear Sirs

**Shire Pharmaceutical Contracts Ltd v Mount Sinai School of Medicine of New York University**  
**Mount Sinai School of Medicine of New York University v Shire Pharmaceuticals Ltd and Shire plc (t/a Shire Human Genetics Therapies)**

As we have not heard from you in relation to our request as to whether you are instructed to accept service on behalf of Shire plc, we are proceeding to serve the Amended Part 20 Claim Form and Amended Particulars of the Part 20 Claim directly on Shire plc.

In relation to Shire Pharmaceuticals Ltd, we enclose by way of service:

1. Amended Part 20 Claim Form;
2. Amended Particulars of the Part 20 Claim; and
3. response pack

Kindly acknowledge service.

You will see that our client is seeking an injunction. For the avoidance of doubt, this is not intended to override our client's affirmation to the NIH that it will not seek to enforce an injunction against the marketing and sale of Replagal during any period of an existing or future shortage of Fabrazyme.

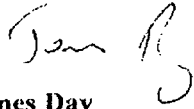
A LIST OF PARTNERS AND THEIR PROFESSIONAL QUALIFICATIONS IS AVAILABLE AT  
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With regard to the court's permission for the additional claim against Shire Pharmaceuticals Ltd, we propose that this is addressed by an appropriate term in the directions.

Yours faithfully



**Jones Day**

Tab E  
Confidential

[Date]

Federal Patent Court  
– Third Senate –  
P.O. Box 900253  
81502 Munich

DR. ULRICH MEHLER  
Munich Office  
Secretariat: Mrs. Jung  
Tel. 089-206042-257  
Our Ref.:  
702827-600187

## OBJECTION

### Case No. 3 Li 1/10 (EP)

In the case of

**Shire Deutschland GmbH**

versus

**Mount Sinai School of Medicine**

---

on behalf of and with the full power of the Defendant, we are herewith submitting our

**objection**

to the petition for grant of a compulsory license to the German part of the European Patent EP 1 942 189 B1 (DE 693 34 327.3, "patent-in-suit").

Objection to the Federal Patent Court  
of March 15, 2011, Case No.: 3 Li 1/10

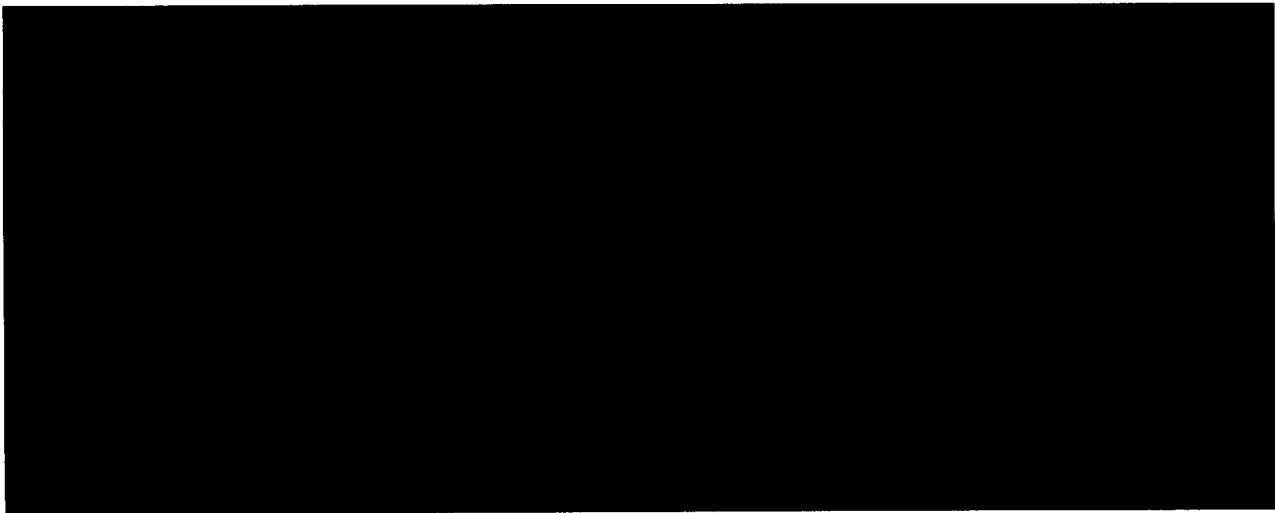
We notify the court that in addition to the attorneys-at-law Dr. Christian Paul, Dr. Ulrich Mehler and Dr. Christian Fulda of the law firm JONES DAY, the patent attorney Dr. Martin Weber of the law firm JONES DAY, Prinzregentenstrasse 11, 80538 Munich, will be contributing to these proceedings on behalf of the Defendant.

We respectfully ask the court to grant the Defendant a period of time within which to reply in detail to the Plaintiff's submission. This period of time should not end before May 31, 2011. At the present time, we already point out the following in advance:

The infringement of the patent-in-suit has been confirmed by the Landgericht Mannheim. Since the date of filing the infringement complaint, Defendant has repeatedly offered the Plaintiff's corporate group ("Shire") a license to the patent. Nevertheless, Shire is attempting to instrumentalize various court proceedings to avoid paying an equitable royalty.

This goal is also obviously also being pursued by the present action. Neither the prerequisites of § 24 paragraph 1 in combination with paragraph 5 nor the prerequisites of § 24 paragraph 2 PatG are met here:

The Plaintiff has not even attempted, during an appropriate period of time as required by § 24 paragraph 1, to obtain a license to the patent-in-suit, neither itself nor through its corporate group. It has to be emphasized in this context that the Defendant was from the beginning and continues to be willing to grant a license to the patent-in-suit under equitable conditions. Despite concrete offers on the part of the Defendant since November 2010, Shire has sought only a negotiation meeting with the Defendant directly in advance of the foreseeable infringement ruling by the Mannheim Regional Court of 18 January 2011 (case no. 2 O 75/10).



4d



Moreover, there is no public interest demanding the grant of a compulsory license to the benefit of the Plaintiff. The Defendant has already agreed repeatedly not to enforce the injunctive judgment issued by the Mannheim Regional Court as long as the supply shortage of the drug "Fabrazyme" on the part of Genzyme Inc. persists. The parties have currently reached a binding agreement to a moratorium until at least 30 September 2011.

**Set of Exhibits B 1**

In view of this waiver of enforcement, adequate supply of German Fabry patients is ensured and a threat to health is out of the question, especially since the licensee of the Defendant has already significantly expanded their production capacities.

If the Plaintiff is attempting to give the impression that there is public interest in a grant of a permanent compulsory license because the switch (back) from "Replagal" to "Fabrazyme" will be associated with health risks for the patients affected, Shire itself has made statements to the contrary in negotiations with the Defendant concerning the predicted sales, namely that a significant number of the patients will be switched back to "Fabrazyme."

The prerequisites for the grant of a compulsory license under § 24 paragraph 2 PatG are not met either. The German versions of Shire's European Patents EP 0935651 (DE 69732 129.0) and EP 1163 349 (DE 600 38 104.8) do not depend on the patent-in-suit, and moreover the inventions thereby protected do not constitute a significant advance of substantial scientific importance, which the Plaintiff cannot utilize appropriately unless the compulsory license being sought is granted.

The Defendant will state its position in detail concerning these aspects as well as others as part of the substantiation of an opposition.

Objection to the Federal Patent Court  
of March 15, 2011, Case No.: 3 Li 1/10

Dr. Ulrich Mehler  
- Attorney-at-Law -

Dr. Christian B. Fulda  
- Attorney-at-Law -

## JONES DAY

RECHTSANWÄLTE · ATTORNEYS-AT-LAW

PATENTANWÄLTE

PRINZREGENTENSTR. 11

80538 MÜNCHEN

BUNDESREPUBLIK DEUTSCHLAND

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15. März 2011

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DR. MARTIN KOCK <sup>12</sup> <sup>13</sup>

DR. MARTIN WEBER <sup>18</sup> <sup>19</sup> <sup>110</sup>

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STEFANIE STÖHR <sup>12</sup>

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DR. HUMAN BEHFOROUZ <sup>12</sup>

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DR. JOHANNES ZÖTTL <sup>12</sup>

TED-PHILIP KROKE <sup>12</sup>

SABINE FELIX <sup>12</sup>

### Vorab per Telefax!

Bundespatentgericht  
– 3. Senat –  
Postfach 900253  
81502 München

Telefax-Nr. 089 / 69 937-5303

DR. ULRICH MEHLER  
Büro München  
Sekretariat: Frau Jung  
Tel. 089-206042-257  
Unser Zeichen:  
702827-600187

## WIDERSPRUCH

**Az. 3 Li 1/10 (EP)**

In Sachen

**Shire Deutschland GmbH**

gegen

**Mount Sinai School of Medicine**

COMMERZBANK MÜNCHEN · KONTO-NR. 860601600 · BLZ 700 400 41 · IBAN DE23 7004 0041 0660 601600 · BIC COBADEFFXXX · UST/VAT REG NO DE 112010330

<sup>11</sup>PARTNER-IN-CHARGE; <sup>12</sup>RECHTSANWALT; <sup>13</sup>ATTORNEY-AT-LAW; <sup>14</sup>STEUERBERATER; <sup>15</sup>FACHANWALT FÜR HANDELS- UND GESELLSCHAFTSRECHT;  
<sup>16</sup>FACHANWALT FÜR ARBEITSRECHT; <sup>17</sup>FACHANWALT FÜR GEWERBLICHEN RECHTSSCHUTZ; <sup>18</sup>PATENTANWALT; <sup>19</sup>EUROPEAN PATENT ATTORNEY;  
<sup>110</sup>EUROPEAN TRADEMARK & DESIGN ATTORNEY; <sup>111</sup>ADVOKAT (SWEDEN); <sup>112</sup>SOLICITOR (ENGLAND & WALES); <sup>113</sup>AVOCAT (FRANCE); <sup>114</sup>RECHTSANWALT (ÖSTERREICH)

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Widerspruch an das Bundespatentgericht  
vom 15. März 2011, Az.: 3 Li 1/10

legen wir namens und mit Vollmacht der Beklagten

### Widerspruch

ein gegen die Klage auf Erteilung einer Zwangslizenz an dem deutschen Teil des europäischen Patents EP 1 942 189 B1 (DE 693 34 327.3, „Streitpatent“).

Wir teilen mit, dass der Patentanwalt Dr. Martin Weber der Kanzlei JONES DAY Rechtsanwälte Patentanwälte Attorneys-at-Law, Prinzregentenstrasse 11, 80538 München für die Beklagte an dem Verfahren mitwirkt.

Wir bitten das Gericht, der Beklagten eine Frist einzuräumen, innerhalb derer sie im Einzelnen auf das Vorbringen der Klägerin entgegen kann. Diese Frist sollte nicht vor dem 31. Mai 2011 enden. Zum jetzigen Zeitpunkt weisen wir vorab auf folgendes hin:

Das Landgericht Mannheim hat die Verletzung des Streitpatents durch die Klägerin mit Urteil vom 18. Januar 2011 (Az. 2 O 75/10) bestätigt. Seit der Anhängigkeit der Verletzungsklage hat die Beklagte der Unternehmensgruppe der Klägerin („Shire“) mehrfach die Lizenzierung des Streitpatents angeboten. Shire hat demgegenüber durch die Instrumentalisierung verschiedener Gerichtsverfahren den Versuch unternommen, die Zahlung angemessener, marktüblicher Lizenzgebühren zu vermeiden.

Diesem Ziel dient ersichtlich auch die vorliegende Klage, mit der die Klägerin die deutsche Gerichtsbarkeit für ausschließlich kaufmännisch motivierte Zwecke instrumentalisieren möchte. Weder die Voraussetzungen des § 24 Abs. 1 i.V.m. Abs. 5 noch die Voraussetzungen des § 24 Abs. 2 PatG liegen vor:

Die Klägerin hat sich schon nicht während eines angemessenen Zeitraums um eine Lizenz an dem Streitpatent bemüht. Die Beklagte war von Anfang an und ist weiterhin bereit, der Klägerin die Benutzung zu angemessenen Bedingungen zu gestatten. Shire hat trotz konkreter Angebote der Beklagten seit November 2010 erst unmittelbar im Vorfeld des absehbaren Verletzungsurteils überhaupt um ein Verhandlungstreffen mit der Beklagten nachgesucht.





Widerspruch an das Bundespatentgericht  
vom 15. März 2011, Az.: 3 Li 1/10



Es existiert im übrigen kein öffentliches Interesse, das die Erteilung einer Zwangslizenz zugunsten der Klägerin gebietet. Die Beklagte hat bereits mehrfach zugesagt, die durch das Landgericht Mannheim ausgesprochene Unterlassungsverpflichtung nicht zu vollstrecken, solange die Lieferknappheit für das Arzneimittel „Fabrazyme“ der Firma Genzyme Inc. fort dauert. Die Parteien haben sich derzeit verbindlich auf ein Moratorium geeinigt, das bis mindestens zum 30. September 2011 dauert.

#### **Anlagenkonvolut B 1**

Angesichts dieses Vollstreckungsverzichts ist die ausreichende Versorgung der deutschen Fabry-Patienten gesichert und eine Gesundheitsgefährdung ausgeschlossen. Zudem baut die Lizenznehmerin der Beklagten bereits jetzt ihre Produktionskapazitäten spürbar aus.

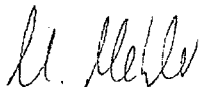
Soweit die Klägerin den Eindruck zu erwecken versucht, es bestehe ein öffentliches Interesse an der dauerhaften Erteilung einer Zwangslizenz, weil die (Rück)Umstellung von „Replagal“ auf „Fabrazyme“ mit gesundheitlichen Risiken für die betroffenen Patienten verbunden sei, geht Shire selbst in den Verhandlungen mit der Beklagten über die Umsatzprognose demgegenüber davon aus, dass ein signifikanter Teil der Patienten wieder auf „Fabrazyme“ umgestellt werden.

Auch die Voraussetzungen für die Erteilung einer Zwangslizenz nach § 24 Abs. 2 PatG liegen nicht vor. Die deutschen Teile von Shires europäischen Patenten EP 0935651 (DE

Widerspruch an das Bundespatentgericht  
vom 15. März 2011, Az.: 3 Li 1/10

69732 129.0) und EP 1163 349 (DE 600 38 104.8) sind nicht vom Streitpatent abhängig, und die damit geschützten Erfindungen stellen im übrigen keinen wesentlichen Fortschritt von erheblicher wirtschaftlicher Bedeutung dar, den die Klägerin ohne die Erteilung der begehrten Zwangslizenz nicht angemessen verwerten kann.

Die Beklagte wird im Rahmen einer Widerspruchsbegründung zu diesen und weiteren Aspekten ausführlich Stellung nehmen.



Dr. Ulrich Mehler  
- Rechtsanwalt -



Dr. Christian B. Fulda  
- Rechtsanwalt -





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September 7, 2011

Ms. Ann Hammersla  
Director, Division of Policy  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard  
Rockville, MD 20852  
(corrected copy, correcting the date of the oral hearing)

Dear Ms. Hammersla:

This letter shall serve as Mount Sinai School of Medicine's ninth monthly submission to the NIH pursuant to its request and Determination not to exercise its March-in-Authority. As we have specified previously, since virtually all of the requested information relates to Genzyme and the efforts it is making towards resolving the shortage of Fabrazyme, Genzyme is submitting an update directly to you.

With respect to the Compulsory License Proceeding in Germany, we received Shire's reply brief and we are in the process of obtaining an English translation of the German submission and will provide you with a copy. As mentioned in our previous submission, the oral hearing for this motion remains slated for February 14, 2012. Aside from these proceedings, we have not received any requests for a license to the 804 patent.

Finally and most importantly, as we have underscored in previous letters, Mount Sinai shares the NIH's consternation regarding the Fabrazyme shortage. We care deeply about the health of these patients; several of our physicians have devoted their entire careers to the treatment of Fabry patients and they seek the best outcomes for these patients. While we remain hopeful that Genzyme will secure FDA approval of its new Framingham plant as scheduled to alleviate the shortage, we remain available to work with the NIH during this interim period.

Please contact me if you would like any additional information.

Regards,

Sally Strauss

Cc: Dennis Charney, M.D., Dean, Mount Sinai School of Medicine  
Teri Willey, Vice President, Office of Technology and Business Development



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October 3, 2011

Ms. Ann Hammersla  
Director, Division of Policy  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard  
Rockville, MD 20852

Dear Ms. Hammersla:

This letter shall serve as Mount Sinai School of Medicine's tenth monthly submission to the NIH pursuant to its request and Determination not to exercise its March-in-Authority. As we have specified previously, since virtually all of the requested information relates to Genzyme and the efforts it is making towards resolving the shortage of Fabrazyme, Genzyme is submitting an update directly to you.

With respect to the Compulsory License Proceeding in Germany, we have now obtained a translated version of Shire's reply brief. We will provide you with our reply brief upon submission to the Court. (the Court has not yet set a due date for our reply). We note, however, that we strongly object to Shire's incorrect suggestion that Mount Sinai has wavered on its commitment not to seek enforcement of an injunction against Repligal in Germany during any period of shortage. We have done no such thing. Indeed, as an academic medical center committed to treating and improving the health of our patients, we would never consider pursuing actions that would exacerbate the shortage and deprive patients of access to treatment. We have made this commitment to the NIH and to the German Courts and steadfastly stand by it.

As a health care provider, patients remain our first priority. In this regard, throughout this shortage period, the physicians at Mount Sinai with expertise in Fabry's disease have been working closely with the Fabry community to provide guidance and support for alternative treatments. For example, Mount Sinai maintains a toll-free hotline offering assistance to Fabry patients and providers. We generally receive between twenty-five to thirty calls/emails each month from patients and/or providers all over the country with various treatment questions during the shortage, such as questions relating to pain management, nutrition, anti-platelet therapy, use of statins etc.; Our staff freely shares their expertise providing advice and appropriate referrals. Sinai also offers free genetic testing for Fabry disease to help family members discern the degree to which this genetic disease has penetrated their family tree. The program receives between twenty to thirty samples each month and provides extensive reports documenting the results for each individual. Sinai

staff has also volunteered their time and expertise at patient conferences and camps. Just two weeks ago one of our physicians spoke at such a conference hosted by the National Fabry Disease Foundation and she and a genetic counselor spent the weekend at the family camp to answer patient questions. These examples illustrate Mount Sinai's longstanding focus on caring for Fabry patients and our continued commitment to do so.

As we have tried to underscore in our prior communications, Mount Sinai 's mission is to treat patients; several of our physicians have dedicated their entire careers to the treatment of Fabry patients. As health care providers, we remain committed to do whatever we can to assist these patients and the NIH during this ongoing shortage. Please contact me if you would like any additional information.

Regards,

Sally Strauss

Cc: Dennis Charney, M.D., Dean, Mount Sinai School of Medicine (MSSM)  
Teri Willey, Vice President, Office of Technology and Business Development, MSSM



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November 1, 2011

Ms. Ann Hammersla  
Director, Division of Policy  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard  
Rockville, MD 20852

Dear Ms. Hammersla:

This letter shall serve as Mount Sinai School of Medicine's eleventh monthly submission to the NIH pursuant to its request and Determination not to exercise its March-in-Authority. As we have specified previously, since virtually all of the requested information relates to Genzyme and the efforts it is making towards resolving the shortage of Fabrazyme, Genzyme is submitting an update directly to you.

At this time there are no updates regarding the compulsory license proceeding in Germany; the hearing remains scheduled for February 2012 and we have reconfirmed our commitment not to enforce an injunction in Germany during any period of the shortage.

Mount Sinai continues to maintain its toll-free hotline to assist patients and providers during this period of shortage. With respect to treatment options for patients in the United States, we understand that just a few days ago, Shire resubmitted its Biologics License Application for Replagal and expects to obtain approval within the next six months. Given the progression of Genzyme's new manufacturing plant and the pending application of Replagal, it appears that an end to the shortage may indeed be in sight. As we progress towards this common goal, we remain committed to do whatever we can to assist Fabry patients and the NIH. Please contact me if you would like any additional information.

Regards,

Sally Strauss

Cc: Dennis Charney, M.D., Dean, Mount Sinai School of Medicine (MSSM)  
Teri Willey, Vice President, Office of Technology and Business Development, MSSM



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December 1, 2011

Ms. Ann Hammersla  
Director, Division of Policy  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard  
Rockville, MD 20852

Dear Ms. Hammersla:

This letter shall serve as Mount Sinai School of Medicine's twelve monthly submission to the NIH pursuant to its request and Determination not to exercise its March-in-Authority. As we have specified previously, since virtually all of the requested information relates to Genzyme and the efforts it is making towards resolving the shortage of Fabrazyme, Genzyme is submitting an update directly to you.

As we explained last month, there are no further updates regarding the compulsory license proceeding in Germany; the hearing remains scheduled for February 2012 and we have reconfirmed our commitment not to enforce an injunction in Germany during any period of the shortage.

We are encouraged by Genzyme's continued progress towards restoring full dosage to its patients (patients received four doses between November and December) and Shire's resubmission to the FDA of its BLA for Replagal which we understand has been fast tracked. Yet, until this shortage is truly over, we remain vigilant about doing whatever we can to assist Fabry patients and the NIH. Please contact me if you would like any additional information.

Regards,

Sally Strauss

Cc: Dennis Charney, M.D., Dean, Mount Sinai School of Medicine (MSSM)  
Teri Willey, Vice President, Office of Technology and Business Development, MSSM