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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:
BERGHEIM *et al.*
Appl. No.: 10/831,770
Filed: April 23, 2004
For: **Delivery System for a Stentless Cardiac Valve**

Confirmation No.: 1421
Art Unit: 3738
Examiner: PELLEGRINO, Brian E.
Atty. Docket: P0039854(1737.4040000)

Payment of Fees Under 37 C.F.R. § 1.28(c)(2)

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Small entity status was established in the above-captioned application in good faith, and small entity fees were paid in good faith. However, it has recently been discovered that small entity status may have been maintained in error but in good faith, and that small entity fees therefore may have been paid in error.

The potential deficiency owed is calculated as follows:

	Type of Fee	Small Entity Fee Paid	Date of Small Entity Fee Payment	Large Entity Fee (current schedule)	Deficiency Owed
1.	Claims in Excess of 20[1]	$725.00	04/26/2007	$1508.00	$783.00

[1] On April 26, 2007, Applicants filed an Amendment adding claims 27-55, including 26 claims in excess of 20 and 1 independent claim in excess of 3 that were not previously paid for. Applicants mistakenly, however, indicated that 13 claims in excess of 20 and 2 independent claims in excess of 3 were not previously paid for in the Electronic Patent Application Fee Transmittal and charged the amount of $325 for claims in excess of 20 (a $400 fee deficiency), and $200 for independent claims in excess of 3 (a $100 overpayment), to a deposit account. Subsequently, the USPTO charged the $400.00 fee deficiency for claims in excess of 20 to the deposit account as indicated in the Sales Receipt for Accounting, dated May 1, 2007. In the table above, the indicated amount for the Small Entity Fee Paid for Item 1 is the sum of the $325 payment as indicated in the Electronic Patent Application Fee Transmittal and the $400

	Type of Fee	Small Entity Fee Paid	Date of Small Entity Fee Payment	Large Entity Fee (current schedule)	Deficiency Owed
2.	Independent Claims in Excess of Three[1]	$100.00	04/26/2007	$220.00	$120.00
3.	Extension for Response (second month)	$225.00	04/26/2007	$490.00	$265.00
4.	Claims in Excess of 20	$100.00	08/09/07	$208.00	$108.00
5.	Independent Claims in Excess of Three	$100.00	08/09/07	$220.00	$120.00
6.	Request for Continued Examination	$405.00	01/11/2008	$810.00	$405.00
7.	Extension for Response (third month)	$555.00	10/03/2008	$1110.00	$555.00
8.	Request for Continued Examination (RCE)	$405.00	04/09/2009	$810.00	$405.00
9.	Extension for Response (first month)	$65.00	04/09/2009	$130.00	$65.00
10.	Request for Refund (RCE filed)[2]	$405.00	02/03/10	$810.00	$405.00

fee deficiency charged to the deposit account by the USPTO. In an abundance of caution, however, the indicated amount for Item 2 is the amount of $100.00 for 1 independent claim in excess of 3 as indicated in the Patent Application Fee Determination Record, not the actual payment of $200 resulting in an overpayment of $100.

[2] An RCE was filed on January 27, 2010, and the RCE fee in the amount of $810 was charged to the deposit account. Applicants, again in good faith, subsequently filed a Request for Refund Under 37 C.F.R. § 1.26 on February 3, 2010, seeking a refund in the

	Type of Fee	Small Entity Fee Paid	Date of Small Entity Fee Payment	Large Entity Fee (current schedule)	Deficiency Owed
Total Owed:					**$3231.00**

Payment of these fees is to be treated under 37 C.F.R. § 1.27(g)(2) as a notification of loss of entitlement to small entity status. 37 C.F.R. § 1.28(d).

Applicants properly established small entity status when the above-captioned application was filed and properly paid small entity fees up to the point in time small entity status may have been erroneously maintained. A brief summary of the circumstances surrounding the discovery of the possibly erroneous maintenance of small entity status is provided below.

3F Therapeutics, Inc., the assignee of the above-captioned application, entered into a license agreement with Edwards Lifesciences PVT, Inc. ("Edwards") on June 2, 2005. This license agreement may have provided Edwards with a license to the above-captioned application. A redacted copy of the license agreement is attached as Exhibit A.

The current owner of the above-captioned application acquired ownership of the above-captioned application and many other patents and patent applications through a recent transaction which closed on or about August 12, 2010. During a recent review of the acquired patent and patent application assets, the current owner discovered the payments of small entity fees. Because the better practice would have been to pay large entity fees, the current owner is hereby submitting the possibly deficient fees.

Applicants respectfully request that the United States Patent and Trademark Office excuse this possible error and correct the entity status to be that of a large entity. Early notice to this effect is respectfully requested.

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amount of $405.00 as being a small entity. The overpayment was credited to the deposit account on February 18, 2010. The amount indicated for Item 10 for the Small Entity Fee Paid is the effective amount Applicants were charged for the RCE in view of the credited refund.

The Commissioner is authorized to charge the total amount owed of $3231.00 to Deposit Account No. 01-2525. The Commissioner is authorized to charge any deficiencies or credit any overpayments to our Deposit Account No. 01-2525.

The USPTO is invited to telephone the undersigned attorney at (763) 505-8426 to discuss any outstanding issues in this case.

Respectfully Submitted,

Date: Dec. 9, 2010

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EXHIBIT A

Exhibit 10.4

NON-EXCLUSIVE LICENSE AGREEMENT

This LICENSE AGREEMENT ("**Agreement**"), dated as of June 2, 2005 (the "**Effective Date**"), is by and between 3F Therapeutics, Inc., a Delaware corporation ("**3F**"), on the one hand, and Edwards Lifesciences PVT, Inc., a Delaware corporation ("**Edwards PVT**"), on the other hand. Each of 3F and Edwards PVT may be referred to herein individually as a "**Party**" or collectively as the "**Parties.**"

RECITALS

WHEREAS 3F is the owner of certain patents, patent applications, and know-how relating to heart valves and catheter-delivered heart valves;

WHEREAS Edwards desires to obtain a non-exclusive license to such patents, patent applications, and know-how; and

WHEREAS 3F is willing to grant such license under the following terms and conditions.

AGREEMENT

NOW, THEREFORE, in consideration of the covenants and agreements set forth herein, which constitutes good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. **Definitions**. The following definitions shall apply to the following terms:

1.1 "3F" shall have the meaning set forth in the preamble.

1.2 "**Affiliate**" shall mean, with respect to any specified Person, a Person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the Person specified.

1.3 "**Agreement**" shall have the meaning set forth in the preamble.

1.4 "Edwards PVT" shall have the meaning set forth in the preamble.

1.5 "Edwards" shall mean Edwards PVT and its Affiliates.

1.6 "**Effective Date**" shall have the meaning set forth in the preamble.

1.7 "**Excluded 3F IP**" shall mean the patents and patent applications listed on Exhibit A hereto.

1.8 "**Fields of Use**" shall mean the Surgical Field of Use and the Percutaneous Field of Use.

1.9 "**PVT Product**" shall mean the the Cribier-Edwards percutaneous heart valve, existing as of the Effective Date, including (i) any modifications or alterations to such valve that are made prior to the first approval by the United States Food and Drug Administration ("FDA") of a premarket approval ("**PMA**") application submitted on such valve in the Percutaneous Field of Use, (ii) any modifications or alterations that are made to such valve to adapt it for use in the Surgical Field of Use prior to the first approval by the FDA of a PMA application submitted on such valve in the Surgical Field of Use, and (iii) any modifications or alterations that are made to the FDA approved valves described in (i) and (ii) that do not require submission of a new PMA application.

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