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Have You Reviewed Your Royalty Agreements Lately?

Law360, New York (December 22, 2009) -- Intellectual property attorneys in the drug and medical device field need to understand the serious penalties, both civil and criminal, that can result from failing to consider Anti-Kickback, Stark and False Claims laws in their practice.

IP attorneys may be unknowingly exposing a company, physician and even themselves to liability. Compliance officers should be following up with their IP attorneys to better understand these complicated laws and regulations.

It is a familiar scenario that is repeated over and over in the medical device and pharmaceutical industry: A physician is retained by a company to develop a new drug, device, or new use of either. A consulting or development agreement is executed. The agreement is reviewed by corporate compliance. The hourly rate, time commitment and royalty rate appear reasonable.

Development of the product lasts 3-5 years. During this time the physician participates in several meetings with company R&D people. A decision is made to file a patent application and the physician is named as an inventor. The physician then begins to receive royalties based on sales of the product.

Depending on the amount and accuracy of development documentation, whether problems arose during preparation and prosecution of the patent application, there could be numerous potential violations of the federal and state Anti-Kickback and Stark Statutes and the federal False Claims Act.

How could this be true when the agreement was a fairly standard agreement? The answer is simple — patent law.

Background of the Health Care Laws at Issue

Anti-Kickback Statutes

The federal Medicare and Medicaid Anti-Kickback statute prohibits the offering, payment, solicitation or receiving of certain remuneration in return for referrals for or recommending purchase of devices, drugs, supplies and services reimbursable under federal government health care programs such as Medicare and Medicaid.[1] Numerous states have similar anti-kickback statutes.

The Anti-Kickback Statute is quite broad. There are, however, "safe harbor" rules identifying specific types of activities not subject to enforcement actions under the Anti-Kickback Statute.[2]

With regard to physicians, the safe harbor rules state that fair market value payment(s) made by a company to a physician as compensation for their legitimate, commercially reasonable services shall not be a violation of the Anti-Kickback Statute if certain additional guidelines are met.

Violations of the federal Anti-Kickback Statute constitute a felony, punishable by fines of up to \$25,000, jail terms of up to five years for each violation or a combination of both. There are also significant civil monetary penalties.[4]

Stark Law (Ethics in Patient Referrals Act)

The Stark Statute states that if a physician (or an immediate family member of such physician) has a financial relationship with an entity, then —

A) The physician may not make a referral to the entity for the furnishing of designated health services ("DHS") for which payment otherwise may be made under this subchapter, and

B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third-party payor, or other entity for DHS furnished pursuant to a referral prohibited under subparagraph (A).[5]

The Stark law is intended to prohibit physicians from profiting from their own referrals. It is a strict liability statute, i.e. no requirement to show knowledge or intent.

For the most part, Stark issues do not directly arise with medical device and drug companies because the companies do not seek payment from Medicare or Medicaid (subparagraph B) for their products and services.

It is important to note, however, that the Centers for Medicare and Medicaid Services solicited comments in its Fiscal Year 2009 Inpatient Prospective Payment Systems (FY 2009 IPPS) proposed rules whether physician-owned implant and medical device companies should be included under the definition of a DHS.[6]

Regardless, Stark claims can be raised against a drug or device company if there is collusion or conspiracy with a physician regarding self-referral.

Violations of the Stark law can result in denial of payment for the prohibited transaction, require refunding of payments, monetary penalties ranging from \$15,000 to \$100,000, and exclusion from participating in the federal program.[7]

False Claims Act

The False Claims Act provides criminal and civil penalties for presenting a false claim for payment against the United States.[8] The False Claims Act has been extended to include the submission for reimbursement/payment of false or fraudulent Medicare or Medicaid claims.[9]

The qui tam provisions of the act allow whistleblowers to file False Claims Act lawsuits against companies and individuals that defraud the government. Several states and the District of Columbia have state false claims acts.

Numerous federal False Claims Act actions have been filed based on violations of the Anti-Kickback and Stark statutes.[10] A defendant is potentially liable for up to three times the damages suffered by the government and between \$5,500 to \$11,000 for each claim.[11]

So Where Are the Problems Lurking?

Inventors

Before the patent application is filed: If royalty payments are being made based upon a physician being named as an inventor on a patent application, it is imperative that proper inventorship be ascertained.

The threshold question in determining inventorship is who conceived the invention.[12] Each joint inventor must generally contribute to the conception of the invention.[13] One who merely suggests an idea of a desired result rather than how to accomplish it, is not a coinventor.[14]

Improper inventorship has always been a concern with regard to validity of a patent, but intentionally misrepresenting inventorship for purposes of paying a royalty could create a serious problem under the Anti-Kickback, Stark and False Claims Act Statutes.

Practice Tip: Patent counsel should be asking at least the following questions regarding physician inventorship:

- Is there significant documentation?
- If multiple inventors, do all agree that each is an inventor?
- Will all inventors still agree years later or if no longer employed with the company?

- Does the physician agree he/she is an inventor or simply state he/she was told by employees that he/she is an inventor?
- Did the engineers or scientists merely add the physician to the invention disclosure because he/she attended the meetings?
- Are you asking the co-inventors both collectively and individually?

Pay extra attention to patent applications naming many inventors. It is human nature to want to name everyone involved on a project as inventor, regardless of their contribution.

After the patent application is filed. Patent counsel standard practice is to verify inventorship after a notice of allowance is received.

During the course of patent prosecution, claims that originally contained inventive concepts contributed by the physician may have been amended out of the issuing claims. A coinventor must make a contribution to at least one claim to be considered an inventor.[15]

Where there is no evidence of contribution to a claim, the physician should be removed as an inventor. The likelihood of having to remove inventors tends to increase with the number of original inventors, i.e., smaller individual inventive contributions.

Inventorship, where there was no deceptive intent, can be corrected.[16] Because of this, many patent attorneys do not carefully review final inventors believing they can amend at a later time.

Practice Tip: Invalidity due to false inventorship applies to all inventors. If this has occurred, royalties should not be paid where the agreement calls for a valid and enforceable patent.

This very issue of alleged questionable inventorship was raised in a False Claims Act whistleblower case U.S. ex rel. Poteet v. Lenke,[17].

The relator, Jacqueline Kay Poteet, alleged in her complaint that 120 spine surgeons and eighteen medical device distributors defrauded the federal government by accepting kickbacks from medical device manufacturer Medtronic Inc. and Medtronic Sofamor Danek U.S.A. Inc. (MSD) in exchange for promoting MSD's medical products.

On March 20, 2009, the case was dismissed on the grounds of prior public disclosure.[18]

Notwithstanding the dismissal, it is important to note that in the complaint,[19] Poteet alleged that four physicians receiving royalties from MSD had received a total of 41

patents since 1998, but had received none prior to 1998 in their 61 years of collective practice.[20]

Poteet alleged that 1998 was the date of inception of the clinical investigations of the MSD product INFUSE, the primary product in question in the complaint.[21] Poteet further alleged that a single doctor received 79 patents after 1998.[22]

The same doctor having allegedly earned only two patents in the preceding 19 years of his practice.[23] The relators contended that the patents in question named Medtronic engineers as co-inventors and that the physicians should not have been named inventors on the patents.[24]

Such allegations and concerns are not limited to Poteet. A 2007 Non Prosecution Agreement (“2007 NPA”) entered into between Stryker Orthopedics and the U.S. Attorney’s Office for the District of New Jersey states:

The company shall establish processes for reviewing individual Consultant contributions to determine whether Intellectual Property has been provided to the Company, such processes shall be approved by the Monitor.[25]

The 2007 NPA is similar to the 2007 Deferred Prosecution Agreements entered into between the U.S. Attorney’s Office for the District of New Jersey and Biomet, DePuy Orthopedics, Zimmer, and Smith & Nephew.

Practice Tip: Concerns about proper inventorship and documentation should not be limited to patent applications. It is also applicable to other situations involving development and intellectual property.

Similar potential compliance problems will arise if there is not proper documentation showing the contribution made by a physician where, for example, the work is maintained as a trade secret or protected as copyright.

Simply put, failing to properly evaluate inventorship or bowing to corporate political pressure to name a physician as an inventor could have dire consequences.

Patent Claims

The patent application may have a specification that describes the eventual commercial device, but the claims that issue and are being paid royalties on may not cover the commercial product.

There needs to be claims covering the device or drug, if the royalty agreement calls for royalties to be paid only if claims cover the commercial device.

Practice Tip: Some patent holders, when faced with uncertainty as to whether a patent covers a product or not, utilize language on the product or packaging along the lines of, “This product is covered by one or more of the following patents ...”

Keep in mind that such practices will likely create tenuous situations when physician inventors are instructed that they will not receive a royalty on sales of a product even though the patent is listed as possibly covering the device.

Validity, Enforceability and Protection

This question seems obvious, but Is the patent at issue still valid or enforceable? Was there a litigation, Opposition, Re-examination or Reissue proceeding that resulted in an amendment or cancelling of the claims covering the commercial product? Has the patent expired or become abandoned?

Practice Tip: Periodic audits should be performed with the department responsible for paying royalties to make sure the corresponding patent and relevant claims are still valid and enforceable.

Prior art issues. What if prior art is uncovered that suggests invalidity of the patent? If it appears that the patent is likely invalid, royalties should not be paid on the patent until a Reissue or Reexamination confirms the validity of the pertinent claims.

If, after uncovering strong prior art, a company makes the strategic decision not to file a Reissue or Re-examination, it should, at the very least, acquire a written validity opinion from competent patent counsel.

Practice Tip: Know your documentation. It could be a very troubling situation if there is significant documentation such as emails or opinions stating the patent in question is likely invalid, but royalties are continuing to be paid to a physician.

Similarly, if evidence is found suggesting that the patent is invalid or unenforceable due to, for example, prior use, on sale bar or misrepresentation under 37 CFR 1.56, the continued payment of royalties is likely not appropriate.

Alternatively, if there is uncertainty, a competent written opinion of validity and enforceability should be ascertained from patent counsel.

Practice Tip: Although not a guarantee, it would appear that such precautions such as, for example, a written opinion, where royalties are being paid, would suggest a lack of intent to violate anti-kickback statutes. Once again, however, intent is not required to be in violation of Stark.

Sales in nonpatent-protected countries. Depending on the language in the royalty agreement, the place of manufacturer, assembly or use of the product, and the type of

claim, e.g., apparatus, method-of-use, method of manufacture, etc., royalty payments to physician inventors in non patent-protected countries may not be appropriate.

For example, if the agreement states that royalties will only be paid on products covered by a valid and enforceable patent in the country of ultimate sale and there is no patent coverage in that country, then royalty payments should not be made on sales in that country.

Conclusion

Intellectual property attorneys in the drug and medical device field need to understand the serious penalties, both civil and criminal, that can result from failing to consider Anti-Kickback, Stark and False Claims laws in their practice.

In addition, compliance officers need to become as educated as possible in patent law and licensing so that they can easily spot patent and development issues as they relate to inventorship, contribution, scope, validity and enforceability.

Finally, consideration should also be given to the practice of patent law and the voluntary codes of conduct adopted by, for example, members of the Medical Device Manufacturers Association, Advanced Medical Technology Association and Pharmaceutical Research and Manufacturers of America.

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[1] 42 U.S.C. § 1320a-7b

[2] 42 CFR 1001.952

[3] 42CFR 1001.952(d)

[4] Ibid. 1

[5] 42 U.S.C. § 1395nn

[6] 73 Fed Reg 48434–49084 (2008)

[7] Ibid. 5

[8] 31 U.S.C. §§ 3729-3733

[9] U.S. v. Bank of Farmington, 166 F.3d 853, 857 (7th Cir. 1999)

[10] See United States ex rel Pogue v. Diabetes Treatment Centers of America, 565 F.Supp.2d 153 (D. D.C. 2008)(False Claims Act filed by relator could properly be pursued based on violations of Federal Anti-Kickback Statute).

[11] Ibid. 8

[12] Fiers v. Revel, 984 F.2d 1164, 1168, 25 USPQ2d 1601, 1604-05 (Fed. cir. 1993).

[13] Manual of Patent Examining Procedure §2137.01 (2008)

[14] Ibid. 13

[15] Ibid.

[16] 35 USC §256

[17] U.S. ex rel. Poteet v. Lenke, No. 1:07-CV-10237-RGS (D. Mass.).

[18] Ibid., 604 F.Supp.2d 313 (2009), 2009 U.S. Dist. LEXIS 24342 (March 20, 2009).

[19] Ibid 18. Original Complaint at paragraphs 292 – 298

[20] Ibid.

[21] Ibid.

[22] Ibid.

[23] Ibid.

[24] Ibid.

[25] 2007 Non Prosecution Agreement entered into between Stryker Orthopedics and the U.S. Attorney's Office for the District of New Jersey.