IN THE SUPERIOR COURT OF THE STATE OF DELAWARE
IN AND FOR NEW CASTLE COUNTY

E.I. DU PONT DE NEMOURS AND COMPANY,	)	
Plaintiff,	)	
	)	
	)	**C.A. No. N10C-09-058-MMJ CCLD**
v.	)	
	)	
MEDTRONIC VASCULAR, INC.,	)	
Defendant.	)	

Submitted: November 26, 2012
Decided: January 18, 2013

On Motions for Summary Judgment

OPINION

Richard L. Horwitz, Esquire and John A. Sensing, Esquire, POTTER ANDERSON & CORROON, LLP, Wilmington, Delaware, John P. Donohue, Jr., Esquire, David J. Wolfsohn, Esquire (argued), Aleksander J. Goranin, Esquire, and Kevin M. Bovard, Esquire, WOODCOCK WASHBURN, LLP, Philadelphia, Pennsylvania, Attorneys for Plaintiff.

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JOHNSTON, J.

I. PROCEDURAL CONTEXT

Plaintiff E.I. duPont de Nemours and Company ("DuPont") filed this action against Defendant Medtronic Vascular, Inc. ("Medtronic") on September 9, 2010. DuPont asserted claims of Breach of Contract (Count I); Fraudulent Misrepresentation (Count II); and Negligent Misrepresentation (Count III). By Order dated November 26, 2012, the Court dismissed Counts II and III.

DuPont and Bard/Medtronic worked together to develop and market devices to be used in medical procedures. The device at issue in this case is a balloon catheter system, which is used in coronary angioplasty. DuPont and Medtronic's predecessor in interest, C.R. Bard, Inc. ("Bard"), entered into a Patent Assignment and Cooperative Agreement ("PACRA"). The overarching purpose of the PACRA was to establish a system of royalty payments to DuPont, for Products sold by Medtronic that utilize DuPont Materials and Technology.

The following summary judgment motions are pending:

(1) Medtronic's summary judgment motion on the issue of whether this action is barred by the applicable statute of limitations;

(2) DuPont's summary judgment motion on the issue of whether the January 1995 Amendment to the PACRA affects royalty provisions;

(3) DuPont's summary judgment motion on the issue of whether the April 1995 Amendment to the PACRA affects royalties on stents;

(4) Medtronic's cross-motion for summary judgment on the issue of whether the April 1995 Amendment to the PACRA waives royalties on stents;

(5) DuPont's summary judgment motion on the issue of whether a stent is "part" of a "Catheter" under the PACRA;

(6) Medtronic's cross-motion for summary judgment on the issue of whether a stent is a "Related Product" and a separate "Catheter" under the PACRA;

(7) DuPont's summary judgment motion on the issue of whether royalties under Paragraph 3 of the 1999 Amendment to the PACRA revert to the royalty rate after July 5, 2003;

(8) Medtronic's cross-motion for summary judgment on the issue of whether royalties under Paragraph 3 of the 1999 Amendment to the PACRA terminated on July 5, 2003;

(9) DuPont's summary judgment motion on the issue of whether the PACRA applies to Cordis sales;

(10) Medtronic's summary judgment motion on the issue of whether apportionment is applicable to Cordis sales; and

(11) Medtronic's summary judgment motion on the issue of whether Medtronic owes royalties on Abbott sales.

The Court heard oral argument on these motions on November 26, 2012. Trial is scheduled to begin on March 4, 2013.

II. FACTUAL SUMMARY

For purposes of these motions, the following facts are undisputed.

A. Background of the PACRA

In September 1982, Bard, a manufacturer of various medical devices, entered into a Collaborative Development and Supply Agreement ("CDSA") with DuPont.[1] Pursuant to the CDSA, DuPont agreed to provide Bard with access to its materials scientists to help Bard develop material for certain cardiovascular catheters. During this collaboration, DuPont provided Bard with research conducted by employee Stanley Levy, which concentrated on the use of balloon catheters in medical dilation procedures. Levy's research on balloon catheters led to the issuance of a patent referred to as the "Levy Patent."[2]

Finding that the CDSA did not adequately address the parties' existing relationship, Bard and DuPont elected to terminate the CDSA, and enter into a new agreement - the Patent Assignment and Cooperative Agreement ("PACRA") – on December 22, 1989.[3]

B. Relevant Provisions of the PACRA

Under the PACRA, DuPont assigned its rights under the Levy Patent and foreign counterparts to Bard.[4] The PACRA further provides that Bard and DuPont would collaborate on new projects supporting Bard's research and development

[1] MT Ex. 115. Citations to Medtronic's exhibits are cited herein as "MT Ex. ___ ," and citations to DuPont's exhibits are cited herein as "DP Ex. ___ ."

[2] MT Exs. 100, 101. DuPont is the assignee of the Levy Patent.

[3] MT Ex. 32.

[4] PACRA, Art. V(A).

efforts, with Bard receiving worldwide exclusive licenses on resulting products within the defined Field of Use.[5]

Article VII of the PACRA obligates Bard to pay DuPont royalties only on "Products." The term "Products" is limited to certain medical devices that utilize Material and Technology developed by DuPont[6] under the CDSA or the PACRA.[7] Specifically, Article II of the PACRA defines "Products" as:

> (i) any Catheter which utilizes a Material[8] or Technology[9]; (ii) any medical device or system, other than a Catheter, which is sold for application within the Field of Use and which utilizes a Material or Technology, except [for certain devices]; and (iii) any other device that the parties may mutually agree to in writing.

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[5] PACRA, Art. III. "Field of Use" is defined as: "(i) all actual or potential applications within the vessels and channels of the human body, including, but not limited to, the following: coronary, peripheral and neurological arteries; gastric and urological tracts; reproductive system, tear ducts and nerve centers for pain control; and (ii) any other medical applications that the parties may mutually agree to in writing." PACRA, Art. II(J).

[6] "Products" include material developed by DuPont individually or jointly with Bard under the CDSA or the PACRA. PACRA, Art. II(K).

[7] Conversely, medical devices that *do not* utilize Material or Technology developed by DuPont under the CDSA or the PACRA are not considered "Products," and therefore, Bard need not pay royalties on such devices.

[8] "Material" is defined as "any material developed by DuPont pursuant to the Collaborative Development and Supply Agreement as well as any material developed by DuPont individually or jointly with Bard pursuant to Article III [of the PACRA] or a material substantially corresponding in composition, properties and/or structure to any such material." PACRA, Art. II(B).

[9] "Technology" is defined as "any technology as developed by DuPont pursuant to the Collaborative Development and Supply Agreement as well as any technology developed by DuPont individually or jointly with Bard pursuant to Article III." PACRA, Art. II(L).

Relevant to the instant action is the definition of "Catheter," as set forth in Article II of the PACRA. A "Catheter" is defined as "any tubular medical device or parts thereof designed for insertion into the vessels and channels of the human body to permit injection or withdrawal of fluid or to occlude, dilate or keep a passage open."[10]

C. Calculating Royalty Payments on "Products"

Pursuant to the PACRA, Bard is obligated to pay royalties to DuPont for the sale of any "Product." Article VII sets forth the payment schedule for royalties:

> (A) Bard shall pay to DuPont, beginning June 1, 1989, the following fees, which shall not be returnable in any event, based on the cumulative Selling Price of all quantities of Products sold annually worldwide during the term of this Agreement by:
>
> (i) Bard,
> (ii) any sublicensee of Bard,
> (iii) any Affiliate of Bard, and
> (iv) any third party that has been given the right to do so by Bard or any sublicense or Affiliate of Bard,
>
> to any party other than any aforesaid party and DuPont and its Affiliates:
>
> - on the first Five Million Dollars ($5,000,000) in worldwide sales – ten percent (10%) of the Selling Price;
> - on the next Five Million Dollars ($5,000,000) in worldwide sales – seven percent (7%) of the Selling Price;

[10] PACRA, Art. II(A). Balloon catheters are used by angioplasty surgeons for the purpose of opening constricted blood vessels. During a balloon angioplasty, a catheter, with a small balloon attached at the tip, is inserted in the patient. The balloon is then inflated to push apart the plaque in the clogged arteries so as to improve blood flow. During another type of angioplasty procedure, a coronary stent is placed in the diseased area to help keep the artery open. The stent is mounted on a balloon catheter, which is inflated to expand the stent. Once the stent is fully expanded, the balloon is deflated and removed. The stent stays in place permanently.

- on the next Sixteen Million, Two Hundred Fifty Thousand Dollars ($16,250,000) in worldwide sales – four percent (4%) of the Selling Price; and,
- above Twenty-Six Million, Two Hundred Fifty Thousand Dollars ($26,250,000) in worldwide sales – three percent (3%) of the Selling Price.[11]

"Selling Price," as defined by the PACRA, is the invoice price charged on the sale of any "Product," less certain fees.[12]

D. Apportioning Royalty Payments on "Related Products"

Under the PACRA, Bard only is obligated to pay royalties on the sale of a "Product"[13] - that is, any medical device which utilizes Material and Technology developed by DuPont. In instances when a "Product" is sold in conjunction with a non-product, or "Related Product,"[14] for a single price, DuPont is owed royalty payments on only the fraction of the "Selling Price" attributable to the "Product." Article II provides a formula to calculate royalties due DuPont when a "Product" is sold in conjunction with a "Related Product":

$$\frac{\text{Product's Factory Cost}}{(\text{Product's Factory Cost}) + (\text{Related Product's Factory Cost})}$$

[11] PACRA, Art. VII(A).

[12] PACRA, Art. II(D).

[13] PACRA, Art. VII(A).

[14] A "Related Product" is defined as "any and all other materials or products sold by any party listed in Article VII(A)(i)-(iv) to any party other than a party listed in Article VII(A)(i)-(iv), DuPont or any of its affiliates in conjunction with a Product." PACRA, Art. II(I).

This ratio is then applied to the invoice price of the entire unit to determine the "Selling Price" attributable to the "Product."[15]

E. Quarterly Reports

Pursuant to Subsection D of Article VII, Bard is required to submit and maintain quarterly reports on the sale of Products:

> BARD shall report in writing to DU PONT within sixty (60) days next following December 31, 1989 and thereafter within sixty (60) days next following the end of each calendar quarter the cumulative Selling Price of all Products which were sold….
>
> BARD shall keep accurate records of the Selling Price of all Products for which it is required to render a report to DU PONT hereunder….
>
> If DU PONT requests an audit, BARD will permit DU PONT, at its sole expense, to have an independent auditor acceptable to BARD examine and make copies of appropriate records at such time as DU PONT may reasonably request in writing during normal business hours at the facility where BARD maintains such records.

F. Cordis Sublicense

In December 1993, Bard entered into a license agreement ("Levy License Agreement") with Cordis Corporation ("Cordis"), whereby Bard granted Cordis a non-exclusive license to make, use and sell products under the Levy Patent.[16] The Levy License Agreement obligates Cordis to pay royalties to Bard as follows:

> 3.01 For the rights granted under this Agreement, Cordis shall [ ]:

[15] PACRA, Art. II(D)(i)-(ii).

[16] MT Ex. 35.

> (a) pay to Bard the sum of $3,000,000 within 10 days of entering into this Agreement …
>
> 3.02 In addition, Cordis shall pay to Bard a royalty in the amount of eight percent (8%) of the Net Selling Price for each Licensed Product …

Pursuant to the Levy License Agreement, Cordis began paying royalties to Bard, which were then passed on to DuPont pursuant to the PACRA.

At some point in 1994, Cordis stopped making royalty payments to Bard. Bard moved to enforce the Levy License Agreement. Cordis and Bard ultimately reached a settlement agreement, and executed an Addendum to the Levy License Agreement ("Levy Addendum").[17]

G. Addendum to Levy License Agreement

In December 1996, the Levy Addendum was executed by Bard and Cordis. The Levy Addendum provided, in relevant part:

> It is further agreed that if Licensed Products are bundled with other goods, such as stents, or provided in kits, apportionment will be on a formula of:
>
> $$\text{Net Selling Price} = \frac{a}{a + b}$$
>
> where "a" is the Net Selling Price of the Licensed Products, and "b" is the net Average Selling Price of the unpatented portion of the bundle or kit.[18]

[17] MT Ex. 36.

[18] *Id.* at ¶ 6.

It is undisputed that the formula set forth in the Levy Addendum for apportioning the "Selling Price" – when a "Product" is sold in conjunction with a non-product – differs from the formula set forth in the PACRA. The Levy Addendum formula is based on relative selling price rather than relative manufacturing cost.

H. Amendments to the PACRA

On January 17, 1995, Bard and Dupont executed an amendment to the PACRA ("January 1995 Amendment"), which was intended to limit DuPont's product liability risk.[19] The January 1995 Amendment added the following provisions to the PACRA:

> (B) BARD will not use any Material in any medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues (where permanent means residing for more than 30 days).
>
> (C) BARD will indemnify DU PONT for all direct and consequential costs and damages caused to DU PONT due to a recall of a BARD product developed under a program of work described in Article III A, provided such recall is not a result of the negligence or willful misconduct of DU PONT, its agents or employees.[20]

On April 11, 1995, Bard and DuPont executed a second amendment to the PACRA ("April 1995 Amendment").[21] Under the April 1995 Amendment,

[19] MT Ex. 33.

[20] *Id.* at ¶ 2.

[21] MT Ex. 34.

DuPont agreed to waive certain royalties due under the PACRA. Paragraph 4 of the April 1995 Amendment provides:

> 4. DuPont and Bard had previously conducted work under the [PACRA] in the areas of stents and aortic aneurysm liners. DuPont agrees to waive any royalties due under the [PACRA] attributable to stents (unless bioresorbable) and aortic aneurysm liners.

Paragraph 6 of the April 1995 Amendment clarifies that such a waiver is specific to certain projects:

> 6. The waivers and reduction in royalties described above are specific to the projects enumerated herein. All other terms and conditions of the [PACRA] continue in full force and effect regarding these projects except where expressly modified herein. Moreover, the waivers and reduction in royalties described above do not constitute a loss of any other rights under the [PACRA] or applicable law, including without limitation the right to collect fees for other Products.

I. Medtronic's Acquisition of Bard's Coronary Catheter Business

On July 9, 1998, Bard sold its coronary catheter business to Arterial Vascular Engineering, Inc. ("AVE").[22] In the parties' Stock and Asset Purchase Agreement, Bard represented to AVE that Bard was not "in breach of or default in the performance of its obligations under any Business Contract," including the PACRA and the Levy Addendum.[23]

[22] *See* MT Ex. 139 (Bard and AVE Stock and Asset Purchase Agreement).

[23] *Id.*

On January 1, 1999, Bard assigned to AVE all of "Bard's rights and interest under the R&D Agreement [*i.e.,* the PACRA]" (the "1999 Assignment Agreement").[24] The 1999 Assignment Agreement provides, in pertinent part:

> Effective as of January 1, 1999, AVE assumes all of the liabilities and obligations of Bard under the R&D Agreement, except for the payment of fees with respect to (i) any sales of Products (as defined in the R&D Agreement) made prior to January 1, 1999, (ii) any sales of products made on or after January 1, 1999 by Bard or any Affiliate (as defined in the R&D Agreement) of Bard and (iii) any sales of Products made on or after January 1, 1999 by any party identified in clause (ii) or (iv) pursuant to a sublicense or other grant of right granted on or after January 1, 1999.[25]

"[C]lause (ii) or (iv)" refers to Article VII(A)(ii) or (iv) of the PACRA, which provide for royalties on sales by Bard's sublicensees or licensees.

J. Medtronic and DuPont Discuss Apportionment

On January 28, 1999, Medtronic, Inc. ("Medtronic") acquired AVE.[26] Following Medtronic's acquisition, DuPont and Medtronic engaged in a series of discussions regarding how to calculate royalties when a "Product" is sold in conjunction with a non-product. A March 25, 1999 email from DuPont's Kitty Knox to Mark Brister, Medtronic's Vice President of Research and Development,

[24] MT Ex. 37 (Assignment, Assumption and Consent Agreement).

[25] *Id.* at ¶ 2.

[26] MT Ex. 150 (SEC Form 8k); MT Ex. 151 (SEC Form 10k).

lists the "[c]alculation of royalty for balloons sold as part of a stent delivery package" as an issue that the parties discussed at a meeting the previous day.[27]

During a March 31, 1999 conference call between DuPont employee Charles Molnar and Medtronic in-house attorney Rick Klein, the parties discussed how to calculate royalties when a balloon catheter is sold with a stent.[28] Molnar's handwritten notes from the conference call reflect that royalties were only to be paid on the balloon catheter portion of the stent system.[29]

On April 13, 1999, Brister sent a letter to Knox, attaching a two-page spreadsheet reflecting projected royalties due DuPont from the sale of coronary

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[27] MT Ex. 44 (3/25/99 email from Knox to Brister).

[28] *See* MT Ex. 80 (Molnar's handwritten notes from 3/31/99).

[29] *Id.* Molnar's notes provide an example of how to calculate royalty when a balloon catheter is sold with a stent.

How to calculate royalty

Ratio of $\frac{\text{mfg cost balloon}}{\text{mfg stent}}$ $\frac{50}{50}$

\$1500 kit $\frac{50}{50}$ $\frac{750}{750}$

Royalty 750 x 1.5% = \$11.25

In Molnar's example, the kit, or stent system, sells for \$1500. This selling price is apportioned 50/50 between the balloon catheter and stent, so that royalty is only paid on the balloon portion of the stent system.

catheters.[30] Brister's projected royalty calculations were based on the average selling price of the balloon catheter only.

Thereafter, on April 16, 1999, Knox created her own spreadsheet from Brister's projections, whereby she apportioned the sales price of the stent system between the balloon catheter and the stent in calculating royalties.[31] Knox performed additional calculations to determine whether it would be more advantageous for DuPont to use the manufacturing cost or the average sales price for apportioning the sales price of balloon catheters in stent systems. Knox ultimately determined that DuPont's royalties would be higher if revenues were apportioned based on relative manufacturing costs.

K. The 1999 Amendment to the PACRA

On October 19, 1999, DuPont and Medtronic executed an amendment to the PACRA (the "1999 Amendment"), which established reduced royalty rates for certain medical devices.[32] As to balloon catheters being developed for future products, Paragraph 2 of the 1999 Amendment provides:

> 2. Article VII, Section (A) of the Research Agreement is hereby amended so that, with respect to the Product described in the immediately preceding Section (1), Medtronic AVE shall pay to Dupont, beginning the effective date of this Agreement a fee of one and one-half percent (1.5%), which shall not be returnable in any

[30] MT Ex. 38 (4/13/99 letter from Brister to Knox).

[31] MT Ex. 81 (Knox royalty calculations).

[32] MT Ex. 42 (1999 Amendment).

> event, based on the cumulative Selling Price of all quantities of such Products sold annually worldwide until July 5, 2003. Except as provided in Section (8) herein, no other fees shall be due with respect to any such Products.

With respect to balloon catheters presently sold, Paragraph 3 of the 1999 Amendment provides:

> 3. Effective January 1, 2000, catheters with nylon balloons presently sold under the names GX and LTX, and substantially equivalent or similar nylon balloon products or derivatives, will be deemed to be a Product under the Research Agreement, subject to a fee of one percent (1.0%), which shall not be returnable in any event, also based on the cumulative Selling Price of all quantities of such Products sold annually worldwide until July 5, 2003.

In consideration for the 1999 Amendment's "advantageous royalties," Medtronic agreed to pay DuPont a one-time fee of $1.75 million.[33] The 1999 Amendment further provides:

> Neither said fee nor the royalties provided in Sections (2) or (3) above constitute an admission of any kind by Medtronic AVE regarding the relationship of the GX and LTX balloons to the intellectual property identified in the Research Agreement.[34]

L. PriceWaterhouseCoopers Audit

In August 2000, DuPont engaged PriceWaterhouseCoopers ("PwC") to conduct an audit of Medtronic's royalty payments to DuPont under the PACRA for

[33] *Id.* at ¶ 8.

[34] *Id.*

the period of October 1, 1998 through June 30, 2000.[35] The parties' agreement, dated September 18, 2000, provided that the work performed by PwC was "only for the use and benefit of DuPont."[36]

By letter dated September 8, 2000, PwC advised Medtronic that it had been retained by DuPont to conduct a royalty audit under the PACRA, the 1999 Assignment and the 1999 Amendment.[37] PwC requested certain documents necessary for completion of the royalty audit:

> (1) Provide detailed description of the sales and royalty calculation systems;
>
> (2) Provide detailed description of methodology used to identify all royalty-bearing sales, as well as the procedures for calculating the relevant royalties under the [PACRA, 1999 Assignment, and 1999 Amendment];
>
> (3) Provide a list of all products offered through Medtronic's Vascular business unit. From that list, please identify the following: (i) all catheters and medical devices sold for application in the Field of Use that utilise a Material or Technology and thus, are royalty bearing Products under the [PACRA, 1999 Assignment, and 1999 Amendment] … and (ii) all catheters and medical devices in the Field of Use that don't utilise a Material of [T]echnology and thus, are excluded from the royalty calculation; …

[35] *See* MT Ex. 21 (audit engagement letter from PwC to DuPont). DuPont contends that the PwC audit was merely part of DuPont's initiative to audit its larger licensing arrangements, rather than in response to any particular suspicions of Medtronic's under-reporting.

[36] *Id*.

[37] MT Ex. 28.

> (10) Provide access to the following: (i) all sublicense agreements entered into by Medtronics (i.e., Cordis …); (ii) copies of royalty statements and checks submitted to Medtronics by sublicensees; and (iii) copies or any reports and/or correspondence obtained in connection with the examination of the books and records of any sublicensee.[38]

From October 15, 2000 through October 19, 2000, PwC was on-site at Medtronic's office, meeting with Medtronic employees and reviewing Medtronic's records. During the audit, PwC requested additional information from Medtronic.[39]

1. PwC October 2000 Memorandum

On October 25, 2000, PwC sent DuPont a memorandum outlining key issues uncovered by PwC during the audit.[40] According to PwC, Medtronic identified those products that were subject to the 1999 Amendment's reduced royalty rate of 1.5%, as well as those products subject to the 1999 Amendment's reduced royalty rate of 1.0%.[41] PwC also noted the following: "Based upon our examination, it

[38] MT Ex. 29.

[39] *See* MT Ex. 22 (memorandum listing issues to be discussed); MT Ex. 23 (memorandum listing items to be discussed).

[40] MT Ex. 30.

[41] *Id.* at ¶¶ 1, 2.

appears that Medtronics does not pay royalties relative to any products other than balloons and stents that incorporate balloons."[42]

2. PwC Final Report

PwC issued its Final Report on December 12, 2000.[43] The Final Report again identified those products that were subject to the 1999 Amendment's 1.5% reduced royalty rate, those products that were subject to the 1999 Amendment's 1.0% reduced royalty rate, and those products that were non-royalty bearing. The Final Report recommended that DuPont and Medtronic engineers meet to determine whether these products were, in fact, entitled to reduced royalty rates:

> PwC … recommends that DuPont and Medtronic AVE engineers discuss the underlying specifications of these products to determine whether application of the reduced royalty rate is appropriate. If application of the reduced royalty rate is not warranted, PwC shall calculate the amount of additional royalties due DuPont using the appropriate royalty rates.[44]

The Final Report found that Medtronic was apportioning the Selling Price of stent systems when calculating royalties. According to PwC:

> Pursuant to Article II (D)(i) of the [PACRA], "If any such Product is sold with any Related Product, Selling Price [i.e., the royalty base] means the amount obtained by multiplying the invoice price for such sale by a fraction, the numerator of which is the Factory Cost of such Product to Bard … and the denominator of which is the Factory Cost of such Product plus the Related Product sold in conjunction

[42] *Id.* at ¶ 3.

[43] MT Ex. 25 (PwC Final Report).

[44] *Id*. at DUP0000445.

> therewith." In connection with this engagement, we noted that Medtronic AVE applies this provision to the Selling Price of stent products. This appears reasonable given that stents include Related Products. Furthermore, based upon the testing performed in connection with this engagement, the factor Medtronics AVE applies to the Selling Price of the stents appears reasonable and in conformity with the terms of the [PACRA].[45]

With respect to the sublicense agreement between Medtronic and Cordis, the Final Report noted that PwC did not audit the royalty statements submitted by Cordis. Therefore, the Final Report made the following recommendation:

> Given the materiality of the net revenues included in the Royalty Reports relative to Cordis, it is recommended that DuPont suggest that Medtronic AVE perform a royalty examination of the reports submitted by Cordis under the sublicense agreement between Cordis and Medtronic AVE.[46]

PwC ultimately found that Medtronic owed DuPont an additional $2,083.00 as a result of unreported royalty bearing revenues.[47] Medtronic promptly paid this amount.

M. DuPont's Internal Correspondence Regarding Apportionment

During the PwC audit and after issuance of PwC's Final Report, Blake Bichlmeir, DuPont's manager of the PACRA relationship at that time, sent several internal emails concerning royalty payments under the PACRA. Three separate

[45] *Id*. at DUP0000443.

[46] *Id.*

[47] MT Ex. 25.

emails, dated March 2, 2000,[48] June 1, 2000,[49] and September 1, 2000,[50] state that DuPont will benefit from the sales of a new line of Medtronic stent systems (S670 system) because "the nylon balloons, part of the S670 system, generate royalties to DuPont."

Thereafter, on June 29, 2001, Bichlmeir sent another internal email, attaching a rough draft of Medtronic's "Working Term Sheet."[51] The Working Term Sheet was intended as DuPont's proposed term sheet for a new licensing and development agreement with Medtronic on polymer coated stents. Under the heading "Payments," the Working Term Sheet describes several payment options for Medtronic, which Bichlmeir then contrasts with the current practice under the PACRA:

> We propose to change payments significantly from current practice. Under the old Bard angioplasty balloon agreement, compensation to DuPont depended solely on royalties on patents. Payments were based on a percentage of the cost of manufacture for the product sub-unit in question, in that case the balloon structure itself. **The calculation was based on the manufacturing cost of the balloon as a percent of the manufacturing cost of the total catheter system** times a stepped set of royalty rates.[52]

[48] MT Ex. 48.

[49] MT Ex. 63.

[50] MT Ex. 49.

[51] MT Ex. 66.

[52] MT Ex. 66 at DUP0011978.

(emphasis added).

N. Abbott Sales

On May 9, 2002, Medtronic and Abbott Laboratories ("Abbott") entered into an OEM Agreement, whereby Medtronic agreed to supply Abbott with balloon catheters to incorporate into Abbott's stent systems.[53] In 2005, Medtronic began selling Products to Abbott.[54] It is undisputed that Medtronic never paid any royalties to DuPont on Abbott's sales.

O. Termination of Royalty Payments

On July 5, 2003, Medtronic stopped paying royalties to DuPont on Medtronic sales.

Following Medtronic's July 2003 termination of royalty payments, DuPont disseminated several internal emails and/or notes regarding the termination of such payments. For example, handwritten notes by Craig Evans, DuPont's in-house counsel, dated August 28, 2003, state: "Mike Jaro [Patent and Intellectual Property Counsel for Medtronic] did internal check and says no more royalty due … no more products benefit … no more agmt due to no royalty."[55]

[53] MT Ex. 83 (OEM Agreement).

[54] DP Ex. JJJJ (Abbott Royalty Report); DP Ex. KKKK (Product List).

[55] MT Ex. 93 (Evans handwritten notes).

Thereafter, on September 8, 2003, Donald Loveday, Bichlmeir's successor at DuPont, sent an email, stating: "Mike Jaro believes that the Agreement with terminate with the termination of the Levy side-agreement [the 1999 Amendment]."[56] By email dated September 21, 2004, DuPont's William Cotreau confirmed that certain royalty obligations would end in July 2003.[57]

P. Medtronic's Quarterly Reports

On October 8, 2003, DuPont received the second quarter royalty report from Medtronic for the period of April through July 5, 2003.[58] The report reflects the total amount of royalty payments due DuPont on Medtronic sales.

On January 1, 2004, Medtronic produced the third quarter royalty report, for the period of July through September 2003.[59] The report shows no royalty payments due DuPont on Medtronic sales. Similarly, subsequent quarterly royalty reports sent to DuPont from Medtronic show that no royalties were being paid to DuPont on Medtronic sales after July 5, 2003.[60]

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[56] MT Ex. 51 (9/9/03 internal email from Loveday)

[57] MT Ex. 73 (9/21/04 email from Cotreau).

[58] MT Ex. 119 (DuPont Royalty Calculation: CY2003 Quarter 2 April –July 5, 2003).

[59] MT Ex. 96 (DuPont Royalty Payment Calculation: CY2003 Quarter 3 July – September 2003).

[60] MT Ex. 97 (DuPont Royalty Payment Calculation: CY2003 Quarter 4 October – December 2003); MT Ex. 98 (DuPont Royalty Payment Calculation: CY2004 Quarter 2 April – June 2004).

Q. Medtronic Advises DuPont that Royalty Payments Terminated

By letter dated December 30, 2005, Robert Allred, Financial Analyst for Medtronic, advised DuPont:

> As per the terms of the Amendment to Patent Assignment and Cooperative Research Agreement between DuPont and C.R. Bard dated December 22, 1989, all royalty obligations terminated upon expiration of the U.S. Levy patent, which occurred on July 5, 2004 [sic].[61]

R. Deloitte and Touche Audit

1. Purpose and Process

On October 13, 2003, DuPont retained Deloitte and Touche LLP ("Deloitte") to conduct a second audit of Medtronic.[62] The apparent catalyst for the second audit was DuPont's belief that Medtronic had decided on its own that certain products were not subject to the PACRA.[63] DuPont requested that Deloitte determine whether: (1) Medtronic owed any royalty to DuPont due to devices subject to the PACRA not included in a reported royalty calculation; (2) Medtronic owed any royalty to DuPont due to ongoing issues as noted in the 2000 PwC audit;

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[61] MT Ex. 91.

[62] Mt Ex. 87 (Deloitte audit engagement letter).

[63] MT Ex. 64 (Loveday email dated 11/04/2003). The email provides: "DuPont is not choosing to audit arbitrarily: our 2000 audit indicated that AVE had decided on its own that some renal catheter products were not 'subject to the agreement.' The audit firm (then, PriceWaterhouseCoopers) told DuPont that this did not appear to be correct, although DuPont did not bring this finding to the attention of AVE. Dupont feels that there exists a possibility of non-compliance just based on past experience and observation of PWC in 2000."

and (3) Medtronic owed any royalty to DuPont due to any other noncompliance on the part of Medtronic.[64]

By letter dated December 18, 2003, Deloitte advised Medtronic that it would be conducting a royalty inspection pursuant to the PACRA.[65] Deloitte requested that Medtronic provide specific information, including:

> (1) A description of the processes and sources of information used to generate the royalty reports submitted to DuPont by AVE.
>
> (2) A listing of all sublicensees of AVE and copies of royalty reports received by AVE from those sublicensees.

On December 24, 2003 Medtronic's Housman sent DuPont an email stating that although he did not believe an audit was necessary, he understood "the dynamics in light of the Amendment ending worldwide royalties on covered balloon products."[66]

2. Deloitte's Audit Report

On August 25, 2006, Deloitte issued its audit report.[67] With regard to apportionment, the report found:

> Based on our discussions with Mr. Housman and Mr. Jaro [Medtronic employees], we understand that AVE calculated royalties only on the

[64] *Id*.

[65] MT Ex. 75.

[66] MT Ex. 53 (12/24/03 Housman email).

[67] MT Ex. 61 (8/14/06 Deloitte Draft Report); MT Ex. 74 (8/25/06 Deloitte Draft Report).

> balloon portion of the stent sales. AVE allocated 44% of the sales price of the stent product (i.e., the POBA percentage) as the balloon portion of the sale, which was used as the basis for AVE's royalty calculation. We discussed this matter with DuPont and DuPont disagreed with AVE's interpretation of the Agreements ….
>
> In accordance with DuPont's interpretation of the Agreements, stents are considered Product [sic] and are thus royalty bearing in their entirety.

S. Tolling Agreement

On August 25, 2009, Medtronic and DuPont executed a Tolling Agreement.[68] The Tolling Agreement provides:

> From the date of the last signature of the parties executing this Agreement until either party terminates this Agreement as set forth below, the running of any statute of limitations, period of repose, or time within which to act in connection with any and all rights, claims, or causes of actions arising from or relating to the PACRA are hereby tolled.

III. STANDARD OF REVIEW

The standard of review on a motion for summary judgment in Delaware is well-settled. The function of the court when considering a party's motion for summary judgment is to determine whether genuine issues of material fact exist, but not to render decisions on those issues.[69] The court will grant summary judgment if, after viewing the record in the light most favorable to the non-moving

[68] MT Ex. 114 (Tolling Agreement).

[69] *In re Asbestos Litig.*, 2007 WL 2410879, at *2 (Del. Super.) (citing *Merrill v. Crothall-American Inc.*, 606 A.2d 96, 99-100 (Del. 1992) (internal citations omitted)).

party, no genuine issues of material fact exist and the moving party is entitled to judgment as a matter of law.[70] If an issue of material fact exists, or if the record has not been sufficiently developed to allow the court to apply the law to the factual record, then summary judgment will be denied.[71] The initial burden of demonstrating that the undisputed facts support its claims or defenses falls upon the moving party.[72] When the moving party meets its burden, the non-moving party then must show that there are material issues of fact for resolution by the fact-finder.[73]

"In the case of a motion for summary judgment based on a statute of limitations defense, the Court must grant the motion if the record reveals that no genuine issues of fact exist[] regarding the date on which the applicable statute of limitations began to run, the date to which the statute of limitations may have been tolled, and the date on which the plaintiff filed her complaint with the court."[74]

Where the parties have filed cross motions for summary judgment, and have not argued that there are genuine issues of material fact, "the Court shall deem the motions to be the equivalent of a stipulation for decision on the merits based on the

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[70] Super. Ct. Civ. R. 56.

[71] *Ebersole v. Lowengrub*, 180 A.2d 467, 470 (Del. 1962).

[72] *Moore v. Sizemore*, 405 A.2d 679, 680 (Del. 1979) (citing *Ebersole*, 180 A.2d at 470).

[73] *See Brzoska v. Olson*, 668 A.2d 1355, 1364 (Del. 1995).

[74] *Burrell v. Astrazeneca LP*, 2010 WL 3706584, at *2 (Del. Super.) (citation omitted).

record submitted with the motions."[75] Neither party's motion will be granted unless no genuine issue of material fact exists and one of the parties is entitled to judgment as a matter of law.[76]

IV. ANALYSIS

A. STATUTE OF LIMITATIONS

DuPont alleges that Medtronic breached its contractual obligations under the PACRA by: (1) discontinuing royalty payments on sales of its products as of July 5, 2003; (2) apportioning the selling price of stent systems between the balloon catheter and the stent, rather than paying royalties on the entire selling price;[77] (3) making royalty payments based on Cordis' "reduced" payment formula pursuant to the Levy Addendum; (4) misclassifying Products for purposes of royalty calculations; and (5) failing to pay royalties on Abbott Laboratories' sales.[78]

Medtronic contends that each of DuPont's purported breach of contract claims is time-barred. Medtronic further argues that the facts of the case do not warrant the application of a tolling doctrine to any of DuPont's claims. Medtronic

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[75] Super. Ct. Civ. R. 56(h).

[76] *Emmons v. Hartford Underwriters Ins. Co.,* 697 A.2d 742, 744-45 (Del. 1997).

[77] DuPont's apportionment claim concerns both Medtronic's product sales and Cordis product sales.

[78] In DuPont's Opposition Brief to Medtronic's Motion for Summary Judgment, DuPont withdrew its breach of contract claim stemming from Medtronic's alleged failure to pay royalties on world-wide Cordis sales. *See* DuPont's Brf. in Opp. at 2 n.1.

argues that there are no genuine issues of matter fact and that it is entitled to judgment as a matter of law.

1. Applicable Statute of Limitations

Under Delaware law, the statute of limitations for a breach of contract claim is three years.[79] The cause of action accrues "at the time of the wrongful act, even if the plaintiff is ignorant of the cause of action."[80] The wrongful act in a breach of contract claim is the breach and the cause of action accrues at the time of breach.[81] In this case, the parties entered into a tolling agreement on August 25, 2009. Thus, if DuPont's claims accrued before August 25, 2006, they are time-barred unless a tolling doctrine applies.

2. Tolling and Inquiry Notice

Under Delaware law, it is plaintiff's burden to plead facts to demonstrate that the statute of limitations was, in fact, tolled.[82] The statute of limitations can only be tolled until a plaintiff discovers, or by exercising reasonable diligence should have discovered, facts constituting the basis of the cause of action (*i.e.,* breach and injury).[83]

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[79] 10 *Del. C.* § 8106.

[80] *Wal-Mart Stores, Inc. v. AIG Life Ins. Co.*, 860 A.2d 312, 319 (Del. 2004) (per curiam).

[81] *Wright v. Dumizo*, 2002 WL 31357891, at *2 (Del. Super.).

[82] *Burrell*, 2010 WL 3706584, at *4.

[83] *Wal-Mart*, 860 A.2d at 319.

"Inquiry notice does not require a plaintiff to have actual knowledge of a wrong, but simply an objective awareness of the facts giving rise to the wrong."[84] Inquiry notice is determined objectively.[85] The Court must find that the facts known to the plaintiff would have "clearly and unmistakably . . . led a prudent person of ordinary intelligence to inquire," and if pursued, would have led to discovery of the elements of the claim being asserted.[86]

DuPont asserts two theories to support tolling the statute of limitations in this case: (1) inherently unknowable injuries; and (2) fraudulent concealment. Under the "inherently unknowable injury" doctrine, also known as the "discovery rule," the statute of limitations is tolled "where it would be practically impossible for a plaintiff to discover the existence of a cause of action" and "the claimant is blamelessly ignorant of the wrongful act and the injury complained of."[87]

The statute of limitations also will be tolled if a defendant engaged in fraudulent concealment of the facts necessary to put a plaintiff on notice of the truth.[88] Fraudulent concealment requires an affirmative act of concealment or

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[84] *Sunrise Ventures, LLC et al. v. Rehoboth Canal Ventures, LLC et al*., 2010 WL 363845, at *7 (Del. Ch.).

[85] *Id.*

[86] *Coleman v. Pricewaterhousecoopers LLC*, 854 A.2d 838, 842 (Del. 2004).

[87] *Cent. Mortgage Co. v. Morgan Stanley Mortgage Capital Holdings LLC*, 2012 WL 3201139, at *22 (Del. Ch.) (citations omitted).

[88] *Albert v. Alex. Brown Mgmt. Servs., Inc*., 2005 WL 5750601, at *19 (Del. Ch.).

some misrepresentation by a defendant that prevents a plaintiff from gaining knowledge of the facts.[89] Mere nondisclosure is not enough to toll the limitations period.[90]

3. Medtronic's Termination of Royalty Payments

a. Parties' Contentions

Medtronic argues that DuPont's breach of contract claim based on Medtronic's termination of royalty payments is time-barred. Medtronic contends that in 2003, DuPont was informed multiple times that Medtronic's obligation to pay royalties on sales of its Products would terminate as of July 5, 2003. On that date, and in accordance with the 1999 Amendment, Medtronic discontinued its royalty payments. Because Medtronic's November 30, 2003 royalty report reflected that cessation in payments, Medtronic contends that DuPont's purported claim accrued no later than November 30, 2003.

DuPont concedes that it had actual notice that Medtronic intended to, and in fact, did, terminate royalty payments on July 5, 2003, upon expiration of the Levy Patents. However, DuPont contends that its claim did not accrue until issuance of

[89] *Id*.

[90] *Ruger v. Funk,* 1996 WL 110072, at *7 (Del. Super.).

Deloitte's Final Report in September 2006, when DuPont could "learn whether or not there were any damages as a result of this breach."[91]

b. Actual Notice

The Court finds that DuPont's claim as to Medtronic's July 5, 2003 termination of royalty payments is time-barred. The undisputed evidence demonstrates that DuPont had actual knowledge of Medtronic's termination of royalty payments by the end of November 2003. Medtronic's royalty report for July through September 2003 showed no royalties due to DuPont on Medtronic sales.[92] All subsequent royalty reports provided to DuPont likewise showed no royalties due DuPont on Medtronic sales.[93] In light of Medtronic's royalty report for April through July 5, 2003[94] (the last royalty report provided to DuPont which reflected any royalties due DuPont on Medtronic sales), DuPont clearly was on notice that Medtronic intended to stop, and in fact, did stop, paying royalties on Medtronic sales.

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[91] *See* DuPont's Brf. in Opp. 39.

[92] MT Ex. 96 (DuPont Royalty Payment Calculation: CY2003 Quarter 3 July – September 2003).

[93] *See* MT Ex. 97 (DuPont Royalty Payment Calculation: CY2003 Quarter 4 October – December 2003); MT Ex. 98 (DuPont Royalty Payment Calculation: CY2004 Quarter 2 April – June 2004).

[94] MT Ex. 119 (DuPont Royalty Calculation: CY2003 Quarter 2 April –July 5, 2003). DuPont received that document in October 2003.

Moreover, there is record evidence of ongoing discussions between Medtronic and DuPont beginning in August 2003, and continuing through December 2005, regarding Medtronic's termination.[95] The Court need not address inquiry notice on this issue because DuPont had actual knowledge of Medtronic's intention to stop paying royalties, and Medtronic's subsequent failure to pay.

Further, DuPont's argument – that its cause of action did not accrue until it learned whether or not it had been damaged – is inconsistent with Delaware law. In Delaware, the cause of action accrues at the time of the wrongful act, "even if the plaintiff is ignorant of the cause of action."[96] The claim does not arise only after the plaintiff suffers a loss.[97]

DuPont was aware as early as November 2003 of Medtronic's decision not to pay royalty payments after July 5, 2003. The doctrines of inherently unknowable injury, and fraudulent concealment, do not apply when the plaintiff

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[95] *See, e.g.*, MT Ex. 93 (8/28/2003 internal notes by Evans noting that Medtronic did an internal check and decided no royalty payments were due any more); MT Ex. 51 (9/8/2003 internal Dupont email explaining that Medtronic informed DuPont that royalty payments would end with the termination of the Levy Patent); MT Ex. 138 (12/3/2003 email within Medtronic regarding DuPont's position that royalty payments were still due); MT Ex. 53 (12/24/2003 email from Medtronic's Housman to DuPont's Loveday stating that the 1999 Amendment ends worldwide royalties on the covered balloon products); MT Ex. 91 (12/30/2005 letter from Medtronic to DuPont stating that all royalty obligations terminated on July 5, 2004 [sic] with the expiration of the Levy patent). *See also* MT Ex. 118 (internal Medtronic meeting agenda notes for July 31, 2002 meeting with DuPont noting the expiration of the Levy patent as one topic to discuss).

[96] *Wal-Mart*, 860 A.2d at 319.

[97] *Albert*, 2005 WL 5750601, at *18.

has actual knowledge of the breach and potential injuries to follow. DuPont's suggested application of the rule – allowing a plaintiff to accrue more damages over time before filing an action – would, in effect, defeat the purpose of a statute of limitations for a breach of contract claim.[98]

4. Medtronic's Royalty Apportionment on Medtronic's Sales and Quarterly Reports

Medtronic's alleged breach of the PACRA by apportioning the sales price between the balloon catheter and the stent system occurred by March 1999, when Medtronic first apportioned its royalty payments to DuPont in that fashion. The breach of contract accrued no later than June 1999 when DuPont received a royalty report for that quarter, reflecting the apportionment. This claim is barred unless DuPont can prove the statute of limitations is tolled. Unlike DuPont's 2003 termination claim, the Court finds genuine issues of disputed fact about whether DuPont had actual knowledge of Medtronic's royalty apportionment. Therefore, the Court must analyze the application of tolling doctrines.[99]

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[98] The Court rejects DuPont's argument that "even if the statute arguably ran on this claim, DuPont would still be entitled to recover any royalties that became due for three years before the parties' tolling agreement was signed - in other words, any royalties due from August 25, 2006 on." DuPont provided no case law in support of this proposition, and the Court is not aware of any such support.

[99] *See* DP Ex. G, Knox Dep. 302:22-303:17 (explaining that she would have found Medtronic's decision not to pay royalties on stents in stent delivery systems "unacceptable"); DP Ex. F, Bichlmeir Dep. 54:9-13 (explaining that he did not have an understanding of Medtronic's royalty payments while he was licensing manager); MT Ex. 3, Brister Dep. 75:11-77:8 (explaining that he told Ms. Knox before April 1999 how Medtronic was going to interpret the PACRA); DP Ex. H, Evans Dep. 182:24-183:11 (explaining that he first found out how Medtronic apportioned

a. Fraudulent Concealment Standard

Fraudulent concealment requires that the plaintiff show an affirmative act of concealment by defendant to put the plaintiff off the trail of inquiry or to prevent the plaintiff from gaining knowledge of the facts.[100]

b. Medtronic Complied with the PACRA's Reporting Provisions

DuPont's main assertion of fraudulent concealment is that Medtronic purposefully doctored its quarterly reports so that DuPont would not realize how it was paying royalties.[101] Specifically, DuPont contends that Medtronic made a "hefty deduction before calculating royalties on the 'net sales' of stent systems," "scrubbed the [royalty calculation] spreadsheet of any incrimination information," and then "sent the tampered version to unsuspecting DuPont."[102]

The Court finds no record evidence to support DuPont's allegations. Rather, the evidence establishes that Medtronic provided DuPont with quarterly reports as required under the PACRA. Pursuant to Article VII(D), Medtronic was required to "report in writing to DuPont . . . within sixty (60) days following the end of each calendar quarter the cumulative Selling Price of all Products which were sold by

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royalty payments on stent delivery systems in Deloitte's prelimary report to DuPont); DP Ex. MMM, Koopmans Dep. 30(b)(6) 35:14-24 (explaining that Medtronic's royalty reports did not specifically include the percentage deducted from its payments to DuPont).

[100] *Burrell*, 2010 WL 3706584, at *7; *Smith v. McGee*, 2006 WL 3000363, at *3 (Del. Ch.).

[101] *See* DuPont's Brf. in Opp. at 30-33.

[102] *Id.* at 31.

the parties listed [therein]."[103] The PACRA did not require Medtronic to provide calculations or more detailed reports. Medtronic disclosed the data required, based on its interpretation.[104] There is no indication of an "affirmative act of actual artifice" that led DuPont away from the truth.[105] Based on the evidence, the Court finds that no reasonable juror could find that Medtronic's failure - to give more detailed reports than was required by the PACRA - constitutes fraudulent concealment.[106]

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[103] PACRA, Art. VII(D).

[104] *Compare* DP Ex. UUU *with* DP Ex. TTT. DuPont's argument that Medtronic should have sent more detailed reports, as requested by Bichlmeir in October 1999 (*see* DP Ex. SSS), is of little significance. The evidence indicates that DuPont requested more detailed reports after it received one such report and did not identify the underlying "problem" with Medtronic's apportionment within that report. *See* DP Ex. SSS (describing revenue for "RELY *on* Stent Products" - - where RELY is a balloon catheter) (emphasis supplied).

[105] DuPont points to the fact that Medtronic drafted a letter explaining its position on royalty payments of stents, which was never sent, as an indication that Medtronic was hiding its position. The Court does not find that this act rises to the level of fraud, especially in light of the evidence that shows DuPont had inquiry notice of Medtronic's royalty apportionment.

[106] *See, e.g.*, *SmithKlineBeecham Pharm. Co. v. Merck & Co.*, 766 A.2d 442, 450-51 (Del. 2000) (affirming the Court of Chancery's finding that "while there may have been some acts of concealment committed, . . . there was no evidence of fraudulent concealment presented"); *Ruger*, 1996 WL 110072, at *7 ("[F]raudulent misrepresentation for pur[poses] of tolling the statute of limitations requires an affirmative act. The argument that a fiduciary's silence tolls the statute has been specifically rejected . . . ."). Had DuPont wanted to inquire into Medtronic's calculations, the PACRA provided ways to do so. *See* Art. VII(D) (requiring that Medtronic keep accurate records of the Selling Price of all Products for two years from the date of the report and allowing DuPont to audit Medtronic).

c. Apportionment Discovered

There is ample record evidence that Medtronic and DuPont discussed apportionment of royalty payments between the balloon catheter and the stent throughout 1999 and into 2000.[107]

d. No Evidence of Fraudulent Concealment During Audits

DuPont's only other allegation of fraudulent concealment stems from the two audits performed by PwC and Deloitte on behalf of DuPont.[108] DuPont argues that: (1) Medtronic hid information from PwC about apportioned payments; and (2) Medtronic intentionally prolonged the Deloitte audit so that DuPont could not learn the facts of its claims before the running of the statute of limitations.

As to DuPont's first claim, the Court has not found any record evidence to support DuPont's contention that Medtronic hid information from PwC. The PwC auditors testified that they were not under the impression that anyone at Medtronic was "hiding the ball" or was dishonest.[109] Further, Medtronic's 30(b)(6) deponent, Barbara Crandell, remembers being part of the discussion with PwC about calculating the Plain Old Balloon Angioplasty ("POBA" – *i.e.*, an angioplasty

[107] *See* discussion *infra* A.4.e.

[108] *See* DuPont's Brf. in Opp. at 32-33.

[109] DP Ex. OO, Swan Dep. 79:18-80:16.

procedure using a balloon catheter without a stent) percentage, which PwC's report then describes.[110]

With regard to the Deloitte audit, the evidence shows a general lack of availability and unresponsiveness by Medtronic.[111] However, even DuPont understood this as pushback from Medtronic because of the disruption the audit was causing Medtronic's business.[112] In the end, Deloitte and DuPont received the information requested. DuPont has not pointed to any affirmative acts of concealment that could constitute fraudulent concealment.

e. Inquiry Notice Evidenced by DuPont's Internal Correspondence about Apportionment

The Court finds undisputed record evidence of inquiry notice by 1999.[113] In April 1999, during negotiations over whether Medtronic's nylon balloons were

[110] MT Ex. 6, Crandell Dep. 79:6-80:25.

[111] *See* DP Ex. ZZ (7/15/2003 letter from Bahl to Housman with a list of failures to cooperate); DP Ex. YY, Bahl Dep. 152:14-155:24.

[112] *See* DP Ex. XX, Loveday Dep. 83:11-15 ("My understanding from Medtronic was they were -- their key objection was the disruption to the ongoing business, that an audit could not [sic] be onerous or a disruption to business.").

[113] DuPont argues that the evidence prior to June 1999 may not be considered by the Court as evidence of inquiry notice because its claim against Medtronic had not accrued at that time. Although the Court agrees that the discovery rule does not place a duty on prospective plaintiffs to inquire into possible future wrongful conduct, the Court sees no reason why it may not consider pre-accrual evidence of DuPont's knowledge of royalty apportionment within the broader "mix of information" known to DuPont in the case. The post-accrual evidence in light of the pre-accrual evidence shows clearly that "red flags" existed as early as June 2000 which would have led a prudent person to inquire about facts sufficient to then enable the plaintiff to discover the basis of its claim.

covered by the Levy Patent and therefore fell within the PACRA, DuPont considered whether it would benefit from *apportioning* the balloon portion of the assembly based on manufacturing cost (as is stated in the PACRA) or *apportioning* the balloon portion of the assembly based on selling price. The relevant documents do not discuss whether the stent system would be apportioned, but how it would be apportioned.

Specifically, during the 1999 negotiations, DuPont's Kitty Knox requested sales projections for Medtronic's nylon balloons.[114] In response, Medtronic provided projections for DuPont royalties for the next five years.[115] Subsequently, Knox broke down the spreadsheet provided by Medtronic and internally calculated the apportionment of the sales price of stent systems based on two methods: the manufacturing costs of the balloon and stent (noted as DuPont's calculation) and the average sales price (noted as Medtronic's calculation).[116] In May 1999, Knox wrote to Mark Brister, Medtronic's Vice President of Research and Development, suggesting that the royalty base calculation remain as it was in the PACRA [*i.e.*,

[114] MT Ex. 44 (3/25/99 email from Knox to Brister).

[115] MT Ex. 38 (4/13/99 from Brister to Knox enclosing sales projection report).

[116] MT Ex. 81.

based on manufacturing cost] until January 1, 2001, at which time it would be reduced to two-times the average selling price.[117]

Thereafter, beginning in March 2000, Blake Bichlmeir, DuPont's Licensing Manager, disseminated three internal emails concerning royalties on the balloon portion of the stent systems. These emails, dated March 2, 2000,[118] June 1, 2000,[119] and September 1, 2000,[120] state that DuPont will benefit from the sales of a new line of Medtronic stent systems because "the nylon balloons, part of the S670 system, generate royalties to DuPont."[121]

Perhaps most compelling to the Court is the draft term sheet for a new licensing and development agreement written by Bichlmeir in the hope of replacing the PACRA. Bichlmeir forwarded the document internally to others at DuPont on June 29, 2001. The proposed term sheet states:

> We propose to change payments significantly from current practice. Under the old Bard angioplasty balloon agreement, compensation to DuPont depended solely on royalties on patents. Payments were based on a percentage of the cost of manufacture for the product sub-unit in question, in that case the balloon structure itself. The

[117] MT Ex. 39 (5/4/1999 letter from Knox to Brister)

[118] MT Ex. 48.

[119] MT Ex. 63.

[120] MT Ex. 49.

[121] MT Ex. 48 (3/2/2000 email regarding 1999 fourth quarter royalty payments); MT Ex. 63 (6/1/2000 email regarding 2000 first quarter royalty payments); MT Ex. 49 (9/1/2000 email regarding 2000 second quarter royalty payments).

> calculation was based on the manufacturing cost of the balloon as a percent of the manufacturing cost of the total catheter system times a stepped set of royalty rates.[122]

During his deposition in this litigation, Bichlmeir testified that this draft sheet was a mistake and that he later corrected the statement.[123] The Court, however, cannot ignore the fact that this document shows that Bichlmeir, DuPont's own Licensing Manager, acknowledged that apportionment between the balloon part of the assembly and the stent part of the assembly was one method for calculating royalties.[124]

The Court finds that Knox's calculations and the discussions in 1999 concerning different ways to calculate apportionment, along with the later statements of Bichlmeir, show indisputably that DuPont was aware that apportionment of royalty payments was at least a viable option for calculating royalty payments beginning in 1999. DuPont's knowledge should have led a prudent person to inquire as to how Medtronic calculated its royalties on stent systems.

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[122] MT Ex. 66 at DUP0011978.

[123] Ex. BB, Bichlmeir Dep. 87:24-90:14, attached to DuPont's Reply in Support of Partial Summary Judgment.

[124] *See also* MT Ex. 118 (internal Medtronic meeting agenda for July 31, 2002 meeting with DuPont noting the basis for royalties to DuPont as one topic to discuss).

f. Diligent Inquiry Would Have Uncovered Alleged Breach

The final question is whether diligent inquiry by DuPont should have uncovered facts sufficient to assert a breach of contract claim.[125] The Court must consider what information a diligent inquiry would have uncovered in light of efforts that were undertaken and what information the plaintiff would have had access to.[126]

The record shows that Bichlmeir first attempted to get more fully-detailed royalty reports in 1999, but failed. DuPont conducted an audit of Medtronic in 1999, and again in 2006. DuPont argues that nothing in the audit reports explained how Medtronic was calculating its royalties.

The Court finds DuPont's suggested interpretation of the undisputed evidence unpersuasive. The 2000 Final Report by PwC states that Medtronic applied Article II(D)(i) of the PACRA, or the "Related Product" apportionment formula, to "the Selling Price of stent products" which "appears reasonable given that stents include Related Products."[127] The Report continues: "Furthermore, based upon the testing performed in connection with this engagement, the factor Medtronics AVE applies to the Selling Price of the stents appears reasonable and

[125] *Coleman*, 854 A.2d at 842-43.

[126] *Id.*

[127] MT Ex. 25.

in conformity with the terms of the Bard Agreement."[128] The Court finds that the 2000 PwC Final Report reflected that Medtronic was apportioning royalties to some extent on stent products.

In 2006, DuPont was again put on notice. The Deloitte royalty audit draft report, dated August 4, 2006, states that "AVE calculates royalties on 44% of the stent sales to quantify balloon portion of the stent sales."[129] According to the report, this finding was discussed with DuPont and DuPont disagreed with AVE's interpretation of the Product.[130]

A second draft report, dated August 25, 2006, reiterates that DuPont had been advised of AVE's apportionment of Selling Price and disagreed with that finding.[131] The report further states: "In accordance with DuPont's interpretation of the Agreements, stents are considered Product and are thus royalty bearing in their entirety."[132]

In sum, the evidence shows that on multiple occasions, DuPont was presented with data and calculations suggesting that Medtronic might not be paying royalties on the stent portion of a stent delivery system. The Court finds

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[128] *Id.*

[129] MT Ex. 61 (7/27/06 draft Deloitte audit report).

[130] *Id.*

[131] MT Ex. 74 (8/25/06 draft Deloitte audit report).

[132] *Id.*

that DuPont was at least on inquiry notice prior to August 25, 2006. With diligent inquiry, DuPont should have had sufficient grounds to raise a breach of contract claim before the statute of limitations expired.

5. Cordis Payments

DuPont has raised two breach of contract claims that derive from Medtronic's treatment of Cordis sales. First, DuPont contends that Medtronic erroneously calculated royalties on Cordis sales pursuant to the formula set forth in the Levy Addendum, as opposed to the PACRA formula. Second, DuPont argues that Medtronic improperly apportioned the Selling Price on sales of Cordis products.

Medtronic argues that both claims are time-barred. As to the calculation of royalty payments per the Levy Addendum, Medtronic contends that DuPont had actual notice in 2000 following issuance of PwC's Final Report. With respect to apportionment of Cordis sales, Medtronic argues that DuPont was on inquiry notice as early as December 2000.

a. Calculation of Cordis Royalties Pursuant to Levy Addendum

DuPont retained PwC in August 2000 to conduct an audit of Medtronic's royalty payments to DuPont under the PACRA for the period of October 1, 1998 through June 30, 2000.[133] Pursuant to the parties' agreement, PwC was to

[133] *See* MT Ex. 21 (audit engagement letter from PwC to DuPont).

undertake a multi-phase approach in conducting the royalty audit. The agreement expressly provided that PwC was to obtain DuPont's approval before performing certain work.[134] Additionally, PwC was to defer to DuPont on key issues. After a thorough review of the parties' express agreement and course of dealing, the Court finds the requisite amount of control to establish a principal-agent relationship between DuPont and PwC.[135]

During the 2000 audit, PwC requested and received, *inter alia*, a copy of the Levy License Agreement and the Levy Addendum, which set forth the formula for apportionment on Cordis sales. PwC's Final Report explicitly states that PwC reviewed the sublicense agreements (*i.e.*, Levy License Agreement and Levy Addendum) and relevant correspondence.[136] Under agency principles, PwC's notice and knowledge of the Cordis formula, as set forth in the Levy Addendum, is

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[134] *See, e.g., id.* The engagement letter provides: "After consultation with you and review of available documentation, we will work with you to determine the precise extent and nature of our procedures"; "Meet with DuPont or its representatives to determine expectations …"; "With DuPont approval, additional fieldwork as deemed necessary"; "[T]he work is performed only for the use and benefit of DuPont."

[135] *See Estate of Eller v. Bartron*, 31 A.3d 895, 897 (Del. 2011) ("As a general matter, '[a]gency is the fiduciary relationship that arises when a person (a 'principal') manifests assent to another person that the agent shall act on the principal's behalf and subject to the principal's control, and the agent manifests assent or otherwise consents so to act.'") (citing Restatement (Third) Agency, § 1.01 (2006).

[136] MT Ex. 25 at DUP0000443.

imputed to DuPont.[137] Knowledge is imputed regardless of whether such knowledge or notice is actually communicated.[138] Therefore, the Court finds that DuPont was on notice of the Levy Addendum formula for Cordis sales as early as 2000.[139]

b. Apportionment of Cordis Sales

The Court finds genuine issues of material fact as to whether DuPont had actual knowledge that Medtronic was apportioning the Selling Price on Cordis sales. Therefore, the Court must address the applicability of the inherently unknowable tolling doctrine.

c. No Inherently Unknowable Injury

DuPont contends that Medtronic's apportionment of Cordis sales was inherently unknowable and that DuPont was blamelessly ignorant of the cause of action. In support of this contention, DuPont points to the fact that neither the PwC audit nor the Deloitte audit discovered any "red flags" with respect to Cordis

[137] *See Wavedivision Holdings, LLC v. Highland Capital Mgmt. L.P.*, 2011 WL 5314507, at *15 (Del. Super.) ("Under agency law, knowledge of the agent generally imputes to the principal.").

[138] *See Abrose v. Thomas*, 1992 WL 208478, at *2 (Del. Super.).

[139] In reaching this conclusion, the Court need not address DuPont's argument that Medtronic "hid" the Levy Addendum from DuPont or that DuPont had not way of obtaining such information.

payments. DuPont contends that "this fact … actually proves how hard it was for a reasonably prudent plaintiff to discover the basis for this claim."[140]

In its Final Report, issued in 2000, PwC noted: "Medtronic has never audited the [royalty] statements submitted by the Sublicensees [*i.e.*, Cordis]."[141] Therefore, PwC recommended that DuPont examine the royalty statements:

> Given the materiality of the net revenues included on the Royalty Reports relative to Cordis, it is recommended that DuPont suggest that Medtronic AVE perform a royalty examination of the reports submitted by Cordis under the sublicense agreement between Cordis and Medtronic AVE.[142]

DuPont, however, elected not to follow-up with PwC's recommendation.

The Court finds that PwC's recommendation, coupled with PwC's Final Report's finding that Medtronic was apportioning Medtronic's stent products in some capacity, should have raised DuPont's suspicions that Medtronic also may have been apportioning Cordis sales. Diligent inquiry by DuPont into the calculation of Cordis royalty payments should have uncovered facts sufficient to assert a breach of contract claim. Therefore, the Court finds that DuPont was on inquiry notice by December 2000 when PwC issued its Final Report.

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[140] DuPont's Brf. in Opp. at 26.

[141] MT Ex. 25 at DUP0000443.

[142] *Id*.

6. Misclassification of Products

DuPont contends that Medtronic breached the PACRA by misclassifying certain Products under the 1999 Amendment. According to DuPont, between 1999 and 2000, Medtronic miscategorized certain products as bearing a 1.0% royalty rate, as opposed to the correct royalty rate of 1.5%. Although Medtronic realized its mistake in 2001, DuPont contends that it was neither informed of the error nor paid for the underpayment in sales during the relevant time period.

Medtronic argues that this claim is time-barred because DuPont had actual notice as early as December 2000 when DuPont received a copy of PwC's Final Report. Medtronic contends that the Final Report provided DuPont with "lists of specifically identified products that Medtronic had classified as being subject to the 1999 Amendment's 1.5% royalty rate, or its 1.0% rate, or as not being subject to royalties at all."[143]

The record evidence demonstrates that DuPont had actual knowledge of Medtronic's classification of products in December 2000. During its 2000 audit, PwC reviewed Medtronic's product classifications. In its December 12, 2000 Final Report, PwC specifically identified those products subject to a 1.0% royalty rate and those subject to a 1.5% royalty rate.[144] PwC, however, acknowledged that it

[143] Medtronic's Op. Brf. at 40.

[144] MT Ex. 25 at DUP0000444-446.

did not have sufficient information to determine whether Medtronic's classifications were accurate, and therefore, recommended that DuPont speak with Medtronic:

> PwC … recommends that DuPont and Medtronic AVE engineers discuss the underlying specifications of these products to determine whether application of the reduced royalty rate is appropriate. If application of the reduced royalty rate is not warranted, PwC shall calculate the amount of additional royalties due DuPont using the appropriate royalty rates.[145]

It appears that DuPont and Medtronic never discussed these product classifications.

As it turns out, several of the product classifications identified in PwC's Final Report were erroneous. For example, the Final Report identified the following products as bearing a 1.0% royalty rate – X1S balloons, X2S balloons, D114s balloons, and Be2 RX stents. DuPont contends, however, that these four products (as well as several others) were miscategorized and actually subject to a 1.5% royalty rate.[146] Yet, DuPont never brought these alleged misclassifications to light until this litigation commenced, approximately ten years after receipt of PwC's Final Report. DuPont's apparent failure to adequately review PwC's Final Report, or to recognize the alleged misclassifications, does not provide a basis to invoke any tolling doctrine. Therefore, DuPont's breach of contract claim with respect to product misclassification is time-barred.

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[145] *Id.* at DUP0000445-446.

[146] *See* DuPont's Brf. in Opp. at 41.

7. Abbott Sales

DuPont argues that Medtronic breached the PACRA by failing to pay royalties to DuPont for Abbott sales. Although DuPont acknowledges that it was aware of the underlying OEM Agreement between Medtronic and Abbott, effective May 9, 2002, DuPont contends that it was never informed that Medtronic was selling Products to Abbott on which royalties were due. According to DuPont, it did not learn of Medtronic's breach until this litigation "when certain internal documents showed such sales had been made, apparently beginning in 2005, and which were subject to the PACRA."[147]

The undisputed record establishes that the alleged breach occurred in 2005 when Medtronic sold Products to Abbott but failed to pay any royalties to DuPont.[148] DuPont neither alleges that this breach was inherently unknowable nor fraudulently concealed by Medtronic. Rather, DuPont's entire argument hinges on the fact that Medtronic never revealed to DuPont that it began selling Products to Abbott in 2005. DuPont's ignorance, however, does not operate as a basis for tolling the statute of limitations.[149]

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[147] *See* DuPont's Brf. in Opp. at 42.

[148] *See* DP Ex. JJJJ (Abbott Royalty Report).

[149] *See* Discussion *supra* IV.A.1. *See also Burrell v. Astrazeneca LP,* 2010 WL 3706584, at *7 (Del. Super.) ("Mere ignorance of the facts by a plaintiff, where there has been no [fraudulent] concealment, is no obstacle to operation of the statute [of limitations].") (citing *In re Dean Witter P'ship Litig*., 1998 WL 442456, at *6 (Del. Ch.)).

The Court finds that the cause of action accrued in 2005, more than three years before the parties entered into the tolling agreement, and is therefore time-barred.

8. Conclusion

The Court finds that each of DuPont's breach of contract claims is time-barred. The undisputed record establishes that DuPont was on notice of facts sufficient to lead to the discovery of each of the alleged breaches prior to August 25, 2006 – more than three years before DuPont and Medtronic executed a tolling agreement. DuPont has failed to meet its burden in demonstrating that a tolling doctrine resurrects any of its claims. Therefore, Medtronic is entitled to summary judgment as a matter of law.

B. CONTRACT INTERPRETATION

This case is complicated. It would be an understatement to say that the record is extensive. The attorneys for both parties have provided the Court with excellent written briefs. Oral argument, held over three days, was extremely helpful. All attorneys demonstrated extraordinary advocacy before this bench.

Having exhaustingly reviewed the evidence, written submissions and transcripts, it seems appropriate to provide the parties with a fulsome analysis. Therefore, even having found that this case must be dismissed as barred by the

statute of limitations, by way of alternative holding, a discussion of the substantive claim follows.

1. Principles of Contract Construction

Where the language of a contract is clear and unambiguous, the Court must construe the contract terms by their ordinary and usual meaning.[150] "Contract terms themselves will be controlling when they establish the parties' common meaning so that a reasonable person in the position of either party would have no expectations inconsistent with the contract language."[151] Upon a finding that the contract clearly and unambiguously reflects the parties' intent, the Court must refrain from destroying or twisting the contract's language, and confine its interpretation to the contract's "four corners."[152]

A contract is not rendered ambiguous merely because the parties dispute the meaning of its terms.[153] "Rather, a contract is ambiguous only when the provisions

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[150] *GMG Capital Invs., LLC v. Athenian Venture Partners I, L.P.,* 36 A.3d 776, 780 (Del. 2012) (citing *Paul v. Deloitte & Touche, LLP*, 974 A.2d 140, 145 (Del. 2009)). *See also Rhone-Poulenc Basic Chems. Co v. American Motorists Ins. Co*., 616 A.2d 1192, 1196 (Del. 1992) ("Ambiguity does not exist where the court can determine the meaning of a contract 'without any other guide than a knowledge of the simple facts on which, from the nature of the language in general, its meaning depends.'").

[151] *GMG Capital Invs*, 36 A.3d at 780 (citing *Eagle Indus., Inc. v. DeVilbiss Health Care, Inc*., 702 A.2d 1228, 1232 (Del. 1997)).

[152] *Doe v. Cedars Academy, LLC*, 2010 WL 5825343, at *5 (Del. Super.); *O'Brien v. Progressive Northern Ins. Co*., 785 A.2d 281, 288-89 (Del. 2001).

[153] *GMG Capital Invs*, 36 A.3d at 780 (citing *Rhone-Poulenc*, 616 A.2d at 1195).

in controversy are reasonably or fairly susceptible of different interpretations or may have two or more different meanings."[154] "[W]here reasonable minds could differ as to the contract's meaning, a factual dispute results and the fact-finder must consider admissible extrinsic evidence."[155]

2. PACRA Amendment Signed January 17, 1995 Does Not Affect Royalties

DuPont and Bard signed the 1995 amendment to the PACRA on January 17, 1995.[156] The January 1995 Amendment addressed limitations of DuPont's product liability risk. The following language was added:

> (B) BARD will not use any Material in any medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues (where permanent means residing for more than 30 days.).
>
> (C) BARD will indemnify DUPONT for all direct and consequential costs and damages caused to DUPONT due to a recall of a BARD product developed under a program of work described in Article III A, provided such recall is not a result of the negligence or willful misconduct of DUPONT, its agents or employees.[157]

Medtronic argues that because the January 1995 Amendment prohibited use of any DuPont Material in stents, it is now inconsistent for DuPont to seek summary judgment on its entitlement to collect royalties on stents. DuPont

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[154] *Rhone-Poulenc*, 616 A.2d at 1196.

[155] *GMG Capital Invs*, 36 A.3d at 776.

[156] MT Ex. 33 (January 1995 Amendment).

[157] *Id.* at DUP0000359.

contends that this change to the PACRA does not pertain to any provisions relating to payment of royalties, or to the definition of "Catheter."

The Court finds that the January 1995 Amendment does not alter any definition of "Catheter" in the PACRA. Further, the clear and narrow intent of the January 1995 Amendment was to prohibit DuPont Material from being used in any product or component part that would be left in a human body for more than 30 days; and to add indemnification to DuPont should DuPont be found liable in connection with the recall of a non-DuPont product.

Therefore, the Court grants summary judgment to DuPont on this issue. The amendment signed January 17, 1995 has no bearing on Medtronic's obligation to pay royalties under the PACRA.

3. Interpretation of PACRA Amendment Signed April 13, 1995

In April 1995, the parties amended the PACRA to address royalties on certain products.[158] The explicitly stated purpose of the April 1995 Amendment was to codify the agreement reached following "a series of discussions relating to program direction and royalties due under the [PACRA]."[159] The first numbered paragraph lists 3 areas in which the parties intended to continue collaborative

[158] MT Ex. 34 (April 1995 Amendment).

[159] *Id.* at DUP0000361.

research and development.[160] The second paragraph involves new work statements to be executed.[161]

The third paragraph lists three projects for which no further work will be done - megalumen guide, balloon catheter shaft, and coated guide wire projects.[162] This paragraph further provides:

> The parties recognize that Bard presently offers products in these areas but elected not to incorporate certain developments made via these work statements. DuPont anticipated that these developments would be incorporated into these products to compensate DuPont for its efforts under the work statements. ***Nevertheless, in view of current Bard business circumstances, DuPont agrees to waive any royalties due under the [PACRA] on the presently offered products.*** This concession by DuPont is made despite considerable resources that were expended by DuPont under these work statements. In the event that Bard should at a later time offer a new product incorporating any features developed, proposed or suggested by DuPont pursuant to these work statements (whether individually or jointly with Bard), royalties will be due pursuant to the [PACRA].[163]

(Emphasis added).

Paragraph 4 contains the language most disputed by the parties:

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[160] *Id.*

[161] *Id.* at DUP0000361-362.

[162] *Id.* at DUP0000362.

[163] *Id.*

> DuPont and Bard had previously conducted work under the [PACRA] in the areas of stents and aortic aneurysm liners. DuPont agrees to waive any royalties due under the [PACRA] attributable to stents (unless bioresorbable) and aortic aneurysm liners.[164]

Paragraph 5 addresses the reduction on the royalty rate for a specific product referred to as "RELY polyurethane balloon."[165]

Paragraph 6 states:

> The waivers and reduction in royalties described above are specific to the projects enumerated herein. All other terms and conditions of the [PACRA] continue in full force and effect regarding these projects except where expressly modified herein. Moreover, the waivers and reduction in royalties described above do not constitute a loss of any other rights under the [PACRA] or applicable law, including without limitation the right to collect fees for other Products.[166]

In its motion for summary judgment, DuPont argues that the April 1995 Amendment was not a waiver of royalties on the stent parts of the catheter at issue in this litigation. Rather, the April 1995 Amendment waived royalties only on those materials or technology developed under five specific projects. DuPont claims that it is undisputed that the five projects concerned research done on (1) megalumens, (2) guide wires, (3) balloon shaft development, (4) aortic aneurysm devices, and (5) stents. According to DuPont, the stent components involved in

[164] *Id.* at DUP0000362.

[165] *Id.*

[166] *Id.* at DUP0000363.

this case arose out of, or were related to, the stent project referenced in the April 1995 Agreement.

Medtronic counters that the April 1995 Amendment constitutes DuPont's waiver of any right to receive royalties on Medtronic's sale of any stents, other than bioresorbable stents. Additionally, unlike the other four projects for which DuPont was waiving royalties, Medtronic argues that there were no collaborative projects for stents other than the bioresorbable stent project. Medtronic contends that Paragraph 6 was not intended to apply to stents because other than bioresorbable stents, there were no other stent projects undertaken.

Reading the April 1995 Amendment as a whole, the Court finds the document to be unambiguous on its face. The Court need not refer to extrinsic evidence. Following negotiations, DuPont agreed, as set forth in Paragraph 3, to waive any royalties due under the PACRA on products offered as of the date of the Amendment. Paragraph 4 is DuPont's waiver of royalties on non-bioresorbable stents, to the extent work on those stents previously had been conducted under the PACRA. Paragraph 6 makes clear that the waivers and reduction in royalties are limited to the specifically-enumerated projects. All other terms and conditions of the PACRA continue in full force and effect. All rights to collect fees for other products are not affected.

The only reasonable interpretation of the April 1995 Amendment is that the waiver of royalties applies only to those non-bioresorbable stents, which were part of a product offered as of the date of the Amendment. It would be an overly-broad reading of the Amendment to find that the parties intended to waive royalties on ***all*** stents (other that bioresorbable): regardless of when the stent was developed; regardless of whether DuPont and Bard had previously conducted work under the PACRA in connection with a particular stent; or regardless of whether the stent was part of a product offered as the date of the Amendment.

4. Propriety of Apportionment of Royalties Under the PACRA

DuPont and Bard executed the PACRA on December 22, 1989.[167] Bard agreed to pay to DuPont certain fees. Article VII(A) states that such fees shall be "based on the cumulative Selling Price of all quantities of ***Products*** sold annually worldwide during the term of [the PACRA]." (Emphasis added).[168]

The PACRA defined a "***Product***" as: "any ***Catheter*** which utilizes a ***Material*** or ***Technology***."[169] "'***Material***' means any material developed by DU PONT... individually or jointly with BARD...."[170] "'***Technology***' means any

[167] MT Ex. 32.

[168] PACRA, Art. VII(A).

[169] PACRA, Art. II(K).

[170] PACRA, Art. II(B).

technology as developed by DU PONT...as well as any technology developed by DU PONT individually or jointly with BARD ...."[171] (Emphasis added).

The parties now dispute the definition of "***Catheter***." The PACRA provides: "'***Catheter***' means any tubular medical device or parts thereof designed for insertion into the vessels and channels of the human body to permit injection or withdrawal of fluids, or to occlude, dilate or keep a passage open."[172] (Emphasis added).

DuPont argues that the stent at issue in this case is "part" of the "Catheter." However, Medtronic did not pay royalties on the stent portion of the medical device. Therefore, according to DuPont, Medtronic underpaid DuPont by not calculating royalties on the full Selling Price of the "Catheters."

Medtronic contends that the stent and balloon catheter are separate. According to Medtronic, both the stent and balloon catheter are "Catheters," as defined by the PACRA. Although a stent would not be called a catheter "[i]n the real world," for purposes of the PACRA, a stent is a "Catheter" because it is a "tubular medical device or part[] thereof designed for insertion into vessels and channels of the human body to permit injection or withdrawal of fluids, or to occlude, dilate or keep a passage open." Because the stent is a "Catheter" that

[171] PACRA, Art. II(L).

[172] PACRA, Art. II(A).

does not use any DuPont Material or Technology, it is not a "Product" that generates royalties under the PACRA.

Nevertheless, Medtronic posits, it does not matter whether a stent is called a "Catheter;" a medical device other than a "Catheter;" an undefined catheter; or a stent. This is because a stent is a "Related Product." "Related Products" do not generate royalties.

The precise question before the Court on this issue is whether the stent is part of the total balloon catheter system - and thus subject to royalties; or whether the stent is either a separate "Catheter" or a "Related Product" - neither of which would generate royalties.

a. A Stent is not a "Catheter" as Defined by the PACRA

In its brief in opposition to DuPont's summary judgment motion, Medtronic conceded: "In the real world, a catheter is not a stent, and a stent is not a catheter, and confusing the two could be fatal for a patient."[173] Nevertheless, Medtronic posits:

> In the world that consists only of the four corners of the PACRA, and thus in this Court, a catheter still is not a stent, and a stent still is not a catheter. But within the four corners of the PACRA, and thus in this Court, a "Catheter" (with a capital "C") is an intentional creation of the PACRA drafters defined as "any tubular medical device or parts thereof designed for insertion into the vessels and channels of the human body to permit injection or withdrawal of

[173] Medtronic's Brf. in Opp. at 3.

> fluids, or to occlude, dilate or keep a passage open."...As a result, a catheter is a Catheter (with a capital "C") and a stent is also a Catheter (with a capital "C"). More importantly, and at the heart of the present dispute, within the four corners of the PACRA, and thus in this Court, a Catheter that uses a Material or Technology is a Product (with a capital "P") that generates royalties under the PACRA whereas a Catheter that does not use a Material or Technology is ***not*** a Product, but can be a Related Product (if sold in conjunction with a Product). A stent is a Catheter that does not use a Material or Technology. Thus, no royalties are due to DuPont on stents regardless of whether stents are called a Catheter, a medical device other than a Catheter, a catheter, or a stent, because a stent is a Related Product. And that distinction between a Product and a Related product, intentionally created by the drafters of the PACRA and used exactly in that manner for the 20 years since the PACRA's creation, is the critical distinction that DuPont all but ignores in its summary judgment briefing. That failure is fatal to DuPont's case.[174]

The Court is not persuaded by Medtronic's argument that the parties intended that a stent fall within the definition of "Catheter" for purposes of the PACRA. It strains reason and common sense to call a stent a Catheter. The parties to the agreement are highly sophisticated in the area of medical technology. If the definition of "Catheter" had been intended to include stents, the parties could have so stated. Such a clear definition would have been entirely consistent with the careful and scientifically-precise drafting reflected throughout the agreement. The PACRA simply cannot reasonably be read to reflect any joint intention of the parties that a stent is a "Catheter."

[174] *Id.* at 3-4.

The apparently purely-coincidental fact that a stent happens to be a "tubular medical device...designed for insertion into the vessels and channels of the human body...to occlude, dilate or keep a passage open" does not mean that the parties considered a stent a Catheter. The PACRA cannot reasonably be interpreted so as to convert a stent into a Catheter. Such an interpretation would require the type of convoluted and contorted analysis necessary to wedge a square peg into a round hole.

In any event, this finding is not dispositive on the issue of whether the stent is royalty-generating.

b. A Stent is not a "Part" of a Stent System Catheter Under the PACRA

The device at the center of this case is composed of a stent, balloon, proximal shaft, distal shaft, guidewire lumen, and proximal adapter. It is undisputed that only the balloon portion of the device utilizes DuPont Material and Technology. It is also undisputed that the stent does not utilize DuPont Material and Technology.

The type of catheter at issue in this litigation is used in coronary angioplasty. Angioplasty surgeons use catheters to open constricted or blocked blood vessels. Catheters are designed both with and without stents.

Without a stent, a tubular device is equipped with a balloon. The balloon end of the catheter is inserted into a blood vessel, and the balloon is inflated. The entire device then is removed from the body.

If a stent is used, it is mounted on the outside of the balloon portion of the catheter device. When the balloon is inflated, the stent expands with the balloon until the stent touches the blood vessel wall. The stent remains to hold the vessel open. The rest of the catheter device is removed from the body.

At the present time, the Medtronic catheter is sold as a single product. The tubular device, with attached balloon and mounted stent, are described in the Medtronic marketing materials, which advertise the stent system as a single unit. The catalog describes a single medical device - a "coronary stent...mounted on an extended pressure, semi-compliant, over-the-wire delivery system." One item number or product code applies to the entire catheter system. Customers may purchase the stent system in various sizes, however, the stent is mounted on other parts of the catheter. The catheter system is shipped in a single sterile package. The Food and Drug Administration approved the catheter system as a single device.

The packaging and marketing materials are informative for purposes of determining whether the stent is part of a Catheter. Nevertheless, Medtronic's

choice of the most advantageous means of selling the medical device is not determinative. The terms of the PACRA control this disputed issue.

i. Development of Stents

DuPont contends that at the time the parties negotiated and executed the PACRA in 1989, DuPont intended the term "Catheter" to cover stents. According to DuPont's Patrick Foley, although stents were not completely "evolved" at the time the PACRA was executed, DuPont nonetheless "anticipated [that] stents may play a role" in the development of balloon catheters.[175] Therefore, Dupont contends that it negotiated for a broad definition of the term "Catheter" so as to ensure that stents would be included within this definition.[176]

The Court is not persuaded by DuPont's argument. The undisputed evidence establishes that in 1989, at the time the PACRA was executed, DuPont was not manufacturing or selling stents.[177] Bard's product line did not include

[175] DP Ex. A, Foley Dep. 80:2-80:24 (explaining that DuPont "knew stents were going on, and [was] aware of [stents]" and therefore anticipated that stents may play a role in catheters). *But see* MT Ex. 13, Knox Dep. 62:1-64:10 (explaining that DuPont and Bard collaborated on the development of angioplasty balloons before the existence of stents).

[176] *See* DP Ex. A, Foley Dep. 80:23-80:25.

[177] DP Ex. A, Foley Dep. 79:23-80:19 (explaining that DuPont "knew stents were going on, and [was] aware of [stents]"); DP Ex. 13, Knox Dep. 62:3-65:17 (explaining that at the time Bard and DuPont collaborated on angioplasty balloons, stents were not yet in existence).

any commercial stent products at that time.[178] Indeed, stents were not even commercially available for use in coronary angioplasty procedures in the United States in 1989.[179] It was not until 1993 that the FDA approved the sale of coronary stents in the United States.[180] Therefore, at least initially, the angioplasty balloons developed as a result of the collaboration between Bard and DuPont did not include stents.[181]

ii. A Stent is a Separate Component

Balloon catheters have been commonly used for angioplasty procedures since at least the mid-1980s. Bard first began to sell balloon catheters mounted with stents in the 1990s. It is undisputed that a balloon catheter can be produced, sold and used as a medical device without a stent.

The parties have never disagreed that Medtronic owed royalties to DuPont on balloon catheters attached to balloons that were designed using DuPont Materials and Technology. Only the balloon piece of the catheter uses DuPont Materials and Technology.

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[178] *See* DP Ex. X, Brister Dep. 35:22-36:14 (Bard had no commercial sales of any stent products before AVE's acquisition); MT Ex. 43 (7/9/98 interoffice memorandum from Knox stating that Bard has not had a stent product to date).

[179] Housman Affidavit in Support of Medtronic's Op. Brief at ¶ 4 ("When C.R. Bard, Inc. ('Bard') entered into the PACRA in 1989, stents were not commercially available for use in coronary angioplasty procedures in the United States.").

[180] Housman Affidavit in Support of Medtronic's Op. Brief at ¶ 5.

[181] DP Ex. 13, Knox Dep. 62:3-65:17 (explaining that there was no expectation, early on, that angioplasty balloons would include stents).

With the advance of medical technology, the balloon catheter was repurposed for use, in part, as a stent delivery system. The stent slides onto the balloon portion of the catheter system like a sleeve, and then is compressed onto the balloon in preparation for insertion into the body. The balloon opens the vessel, the balloon catheter is removed, and the stent remains in the body to keep the vessel open.

The stent is not glued, bonded, fused, or otherwise permanently attached to the balloon catheter. The balloon catheter functions as a delivery system for the stent, which remains in place after the balloon catheter is removed. A balloon catheter without a stent is a disposable device. The stent is a permanent implant in the body, and is not dependent on the balloon catheter to perform its continuing function. The stent is the only portion of the balloon catheter system that is not permanently attached, and that ultimately is separated from the other pieces of the catheter.

The Court finds that although used in conjunction with the balloon catheter, the stent is not "part" of the Catheter as defined in the PACRA. Viewing the PACRA in its entirety, the Court finds that the stent is a separate component designed for use with the royalty-bearing balloon catheter system.

iii. A Stent is a "Related Product" When Sold with a Balloon Catheter that Incorporates a "Material" or "Technology"

A "***Related Product***" is any material or product "sold in conjunction with a Product."[182]

The "***Selling Price***" is the invoice price, less certain costs, taxes and other allowances.[183] If a "***Product***" is sold with any "***Related Product***," the "***Selling Price***" is calculated by:

> (i) multiplying the invoice price for such sale by a fraction, the numerator of which is the Factory Cost of such Product to BARD or its Affiliate or sublicensee hereunder and the denominator of which is the Factory Cost of such Product plus the Related Product sold in conjunction therewith to BARD or such Affiliate or sublicensee....[184]

The clear purpose of the PACRA was to reasonably compensate DuPont for its contribution of DuPont Materials and Technology to Medtronic products.

It is undisputed that the balloon is the only piece of the Medtronic catheter system that utilized DuPont Materials and Technology. There is no dispute that stents contain no DuPont Materials or Technology. The remaining pieces of the catheter system, which are permanently attached to the balloon, are not the result of DuPont Materials or Technology.

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[182] PACRA, Art. II(I).

[183] PACRA, Art. II(D).

[184] *Id.*

There is no question that the entire Medtronic catheter system is sold together, and designed to be used at the same time, for the same medical procedure. Having found that the stent is not "part" of the balloon catheter as defined in the PACRA, the only rational conclusion is that the stent is a Related Product.

5. 1999 Amendment Terminated Royalty Obligations on Sales of Medtronic Products as of July 5, 2003

The 1999 Amendment to the PACRA established reduced royalty rates for certain medical devices. Specifically, as to balloon catheters developed for future use, Paragraph 2 provides, in pertinent part:

> 2. Medtronic AVE shall pay to Dupont, beginning the effective date of this Agreement a fee of one and one-half percent (1.5%), which shall not be returnable in any event, based on the cumulative Selling Price of all quantities of such Products sold annually worldwide until July 5, 2003. **Except as provided in Section (8) herein, no other fees shall be due with respect to any such Products.**[185]

(Emphasis added).

Similarly, Paragraph 3 provides for a reduced royalty rate for balloon catheters presently sold:

> 3. Effective January 1, 2000, catheters with nylon balloons … will be deemed to be a Product under the Research Agreement, subject to a fee of one percent (1.0%), which shall not be returnable in any record, also based on the cumulative Selling Price of all quantities of such Products sold annually worldwide until July 5, 2003.

[185] MT Ex. 42 (1999 Amendment).

Because Paragraph 3 does not contain the last sentence of Paragraph 2, DuPont contends that only fees on Paragraph 2 Products expired on July 5, 2003. As to Paragraph 3 Products, sold after July 5, 2003, DuPont claims that Article VII of the PACRA sets forth the appropriate royalty rate.

The Court finds that the clear and unambiguous language of the 1999 Amendment establishes that from January 1, 2000 until July 5, 2003, Paragraph 3 Products would be subject to a 1% royalty rate. Medtronic's royalty obligations, with respect to Paragraph 3 Products, then would terminate on July 5, 2003.

Contrary to DuPont's assertion, the 1999 Amendment is devoid of any language whatsoever suggesting that Medtronic would owe fees on Paragraph 3 Products after July 5, 2003, much less be subject to PACRA's heightened royalty rates. Had the parties intended for Paragraph 3 Products to be subject to royalties after July 5, 2003, such a provision should have been explicitly included in the parties' agreement. The Court declines to insert a new term into the parties' agreement.[186] The Court finds that pursuant to the 1999 Amendment, Medtronic's royalty obligations, with respect to Paragraph 2 and Paragraph 3 Products, terminated on July 5, 2003.

[186] *See Cincinnati SMSA Ltd. P'Ship v. Cincinnati Bell Cellular Sys. Co.,* 708 A.2d 989, 992 (Del. 1998) ("[I]t is not the proper role of a court to rewrite or supply omitted provisions to a written agreement…. In the narrow context governed by principles of good faith and fair dealing, this Court has recognized the occasional necessity of implying such terms in an agreement so as to honor the parties' reasonable expectations. But those cases should be rare and fact-intensive, turning on issues of compelling fairness.") (internal citations omitted).

6. PACRA Applies to Cordis Sales

In December 1993, Bard licensed certain patents to Cordis.[187] Cordis agreed to pay Bard royalties for licensed products. The PACRA provides that Bard was obligated to pay royalties to DuPont on Products sold by its licensees.[188] The royalty-calculation provisions under the PACRA differ in many ways from the method of calculating royalties in the agreement between Cordis and Bard.

It is undisputed that Medtronic succeeded to all obligations of Bard under the PACRA. As successor, Medtronic received royalties from Cordis pursuant to the license agreement. Some royalties were passed on to DuPont. Medtronic does not contest that it is obligated to pay DuPont royalties on Cordis sales pursuant to the terms of the PACRA - not pursuant to the terms of its license with Cordis. However, the parties dispute how such royalties should have been calculated under the PACRA. DuPont claims that it is entitled to royalties on stents. Medtronic contends that royalties should be apportioned.

Medtronic also argues that summary judgment should be denied because DuPont has failed to present evidence that Cordis' method of royalty calculations has resulted in any damage to DuPont. DuPont counters that it need not prove

[187] MT Ex. 35 (Levy License Agreement).

[188] *See* PACRA, Art. VII(A).

damages at this point because quantification of damages should take place during expert discovery.

On the record before the Court at this juncture, there simply is not sufficient evidence to determine whether or not royalties due to DuPont (from Cordis sales through Medtronic) have been calculated properly. Nor is there record evidence necessary for a finding of whether DuPont has been damaged.[189] There are genuine issues of material fact that cannot be resolved on this summary judgment record. In any event, the correct royalty calculation must be consistent with the Court's prior rulings on interpretation of the PACRA.

7. Abbott Sales

It is undiputed that Medtronic never paid royalties to DuPont on any sales of Catheters to Abbott. The parties, however, dispute whether DuPont was entitled to any royalties from these sales. Medtronic argues that pursuant to the 1999 Assignment Agreement, Medtronic was not obligated to pay royalties on sales by new licensees granted licenses after January 1, 1999. In response, DuPont contends that the PACRA requires Medtronic to pay royalties on any sales by sublicensees, which includes sales by Abbott.

Paragraph 2 of the 1999 Assignment Agreement provides, in pertinent part:

[189]The Court is not opining on the issue of whether DuPont has the burden at this stage in the proceedings to demonstrate the existence of damages.

> Effective as of January 1, 1999, AVE assumes all of the liabilities and obligations of Bard under the R&D Agreement, except for the payment of fees with respect to (i) any sales of Products (as defined in the R&D Agreement) made prior to January 1, 1999, (ii) any sales of products made on or after January 1, 1999 by Bard or any Affiliate (as defined in the R&D Agreement of Bard and **(iii) any sales of Products made on or after January 1, 1999 by any party identified in clause (ii) or (iv) pursuant to a sublicense or other grant of right granted on or after January 1, 1999.**[190]

(Emphasis added). "[C]lause (ii) or (iv)" refers to Article VII(A)(ii) and Article VII(A)(iv) of the PACRA, which provides for royalties on sales by Bard's licensees and sublicensees.[191]

Pursuant to the 1999 Assignment Agreement, AVE/Medtronic "stepped into the shoes"[192] of Bard and assumed all of Bard's obligations, liabilities, rights and interest under the PACRA and its amendments, with some exemptions.[193] As set forth above, Paragraph 2 of the 1999 Assignment Agreement exempts Medtronic from paying royalties to DuPont on any sales made by sublicensees of Bard (PACRA, Article VII(A)(ii)) or any third parties given the right to do so by Bard

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[190] MT Ex. 37 at ¶ 2.

[191] *See* PACRA, Art. VII(A) ("(A) Bard shall pay to DuPont, beginning June 1, 1989, the following fees, which shall not be returnable in any event, based on the cumulative Selling Price of all quantities of Products sold annually worldwide during the term of this Agreement by: (i) Bard, (ii) any sublicensee of Bard, (iii) any Affiliate of Bard, and (iv) any third party that has been given the right to do so by Bard or any sublicense or Affiliate of Bard ….").

[192] *See Price Auto Group v. Dannemann*, 2002 WL 31260007, at *8 (Del. Super.) (citing *Merck & Co. v. Smithkline Beecham Pharms. Co*., 1999 WL 669354, at *44 (Del. Ch.) ("[A]ssignee steps into shoes of the assignor.")).

[193] *See* MT Ex. 37 at ¶¶ 1, 2.

or any sublicensee or Affiliate of Bard (PACRA, Article VII(A)(iv)), if the sublicensee was granted on or after January 1, 1999.

However, by executing the 1999 Assignment Agreement, Bard relinquished all rights and obligations under the PACRA as of January 1, 1999. including Bard's right to grant sublicensees. Therefore, to give any meaning to Paragraph 2 of the 1999 Assignment Agreement, the Court must substitute "Medtronic" for "Bard" in Article VII(A) of the PACRA, and find that Medtronic is exempted from paying royalties on sales of Products made by sublicensees of Medtronic, or any third parties given the right to do so by Medtronic or any sublicensee or Affiliate of Medtronic, if Medtronic granted the sublicense on or after January 1, 1999.[194]

Abbott was granted a sublicense by Medtronic in 2002.[195] Therefore, pursuant to Paragraph 2 of the 1999 Assignment Agreement, Medtronic is exempt from paying royalties to DuPont on any of Abbott's sales of Products.

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[194] *See Sonitrol Holding Co. v, Marceau Investissments*, 602 A.2d 1177, 1183 (Del. 1992) ("Under general principles of contract law, a contract should be interpreted in such a way as to not render any of its provisions illusory or meaningless.") (citing *Seabreak Homeowners Ass'n, Inc. v. Gresser*, 517 A.2d 263, 269 (Del. Ch. 1986)).

[195] MT Ex. 83 (OEM Agreement).

V. CONCLUSION

The Court hold as follows:

(1) Medtronic's summary judgment motion on the issue of whether this action is barred by the applicable statute of limitations is hereby **GRANTED**.

By way of alternative holding, the Court finds as follows:

(2) DuPont's summary judgment motion on the issue of whether the January 1995 Amendment to the PACRA affects royalty provisions is hereby **GRANTED**.

(3) DuPont's summary judgment motion on the issue of whether the April 1995 Amendment to the PACRA affects royalties on stents is hereby **GRANTED**.

(4) Medtronic's cross-motion for summary judgment on the issue of whether the April 1995 Amendment to the PACRA waives royalties on stents is hereby **DENIED**.

(5) DuPont's summary judgment motion on the issue of whether a stent is "part" of a "Catheter" under the PACRA is hereby **DENIED**.

(6) Medtronic's cross-motion for summary judgment on the issue of whether a stent is a "Related Product" and a separate "Catheter" under the PACRA is hereby **GRANTED IN PART AND DENIED IN PART.**

(7) DuPont's summary judgment motion on the issue of whether royalties under Paragraph 3 of the 1999 Amendment to the PACRA revert to the royalty rate after July 5, 2003 is hereby **DENIED**.

(8) Medtronic's cross-motion for summary judgment on the issue of whether royalties under Paragraph 3 of the 1999 PACRA Amendment terminated on July 5, 2003 is hereby **GRANTED**.

(9) DuPont's summary judgment motion on the issue of whether the PACRA applies to Cordis sales is hereby **GRANTED**.

(10) Medtronic's summary judgment motion on the issue of whether apportionment is applicable to Cordis sales is hereby **DENIED**.

(11) Medtronic's summary judgment motion on the issue of whether Medtronic owes royalties on Abbott sales is hereby **DENIED**.

IT IS SO ORDERED.

/s/ Mary M. Johnston
MARY M. JOHNSTON, JUDGE

Original to Prothonotary
cc: All counsel via File & Serve