

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.  
Petitioners,

v.

TELEFLEX INNOVATIONS S.A.R.L.  
Patent Owner.

---

*Declaration of Dr. John J. Graham, MB ChB, MRCP (UK)*

**TABLE OF CONTENTS**

	Page
I. INTRODUCTION .....	1
A. Qualifications .....	2
B. Materials Considered.....	4
II. LEGAL STANDARDS .....	5
A. Claim Construction .....	6
B. Anticipation .....	7
C. Obviousness.....	8
III. SCOPE OF OPINIONS .....	9
IV. PERSON OF ORDINARY SKILL IN THE ART .....	11
V. BACKGROUND ON THE USE OF GUIDE EXTENSION CATHETERS IN PCI.....	13
A. Complex PCI.....	18
B. Various Methods for Solving the Backup Support Problem in the 1990s and 2000s Were Unsuccessful.....	23
VI. THE GUIDELINER DEVICE.....	33
A. Use of the GuideLiner .....	36
B. Benefits of the GuideLiner Inventions.....	40
1. Enhanced backup support .....	40
2. Ability to safely deep seat.....	42
3. Rapid exchange functionality .....	43
4. Advancing the full array of interventional cardiology devices into the guide extension catheter while the guide extension catheter was inside the guide catheter.....	44
VII. THE MEANING OF CERTAIN TERMS USED IN THE CLAIMS OF THE ‘413 PATENT.....	46
A. “Interventional Cardiology Device” .....	46

B.	The Claimed Method Steps Require that an Interventional Cardiology Device Must be Inserted into the Standard Guide Catheter After the Coaxial Guide Catheter .....	50
VIII.	THE STATE OF THE ART AT THE TIME OF INVENTION OF THE GUIDELINER PATENTS .....	53
A.	The General Knowledge of an Interventional Cardiologist at the Time of the Invention .....	53
B.	Itou (Ex. 1007) .....	56
1.	The “protective catheter 5” disclosed in Itou is not an “interventional cardiology device” as defined by the GuideLiner patents.....	59
2.	Itou does not disclose a configuration capable of receiving stents/stent catheters.....	62
3.	Inserting an interventional cardiology device into Itou’s suction catheter after suction without first flushing the suction catheter outside the body would be dangerous.....	63
C.	Ressemann (Ex. 1008) .....	65
1.	Ressemann teaches a non-coaxial evacuation lumen .....	67
2.	Ressemann does not disclose a proximal side opening with two inclines .....	70
D.	Kontos (Ex. 1009) .....	75
1.	A POSITA would not expect Kontos to provide more than trivial backup support .....	76
2.	Kontos discloses a funnel structure to account for the proximal gap created by the configuration of its body 12 and to avoid problems with device hang-up on its proximal opening.....	77
3.	A POSITA would not extend Kontos’ body entirely out the distal end of the guide catheter .....	77
4.	Kontos’ lumen would not accept stents or stent catheters.....	78
E.	Kataishi (Ex. 1025) .....	79
F.	Adams (Ex. 1035) .....	81

G.	Takahashi (Ex. 1010) .....	85
IX.	AN INTERVENTIONAL CARDIOLOGIST PRACTICING AT THE TIME OF THE INVENTION WOULD NOT BE MOTIVATED TO COMBINE THE INVENTIONS DISCLOSED IN THE PRIOR ART .....	86
A.	Itou + Ressemann and Knowledge of a POSITA .....	86
1.	An interventional cardiologist at the time of the invention would not look to Ressemann to modify Itou.....	86
2.	An interventional cardiologist practicing at the time of the invention would not modify Itou’s proximal opening with Ressemann’s support collar 2141 .....	90
B.	Kontos + Adams and Knowledge of a POSITA .....	95
C.	Kontos + Ressemann and Knowledge of a POSITA .....	103
1.	An interventional cardiologist at the time of the invention would not replace Kontos’ funnel with Ressemann’s angled opening.....	103
2.	An interventional cardiologist practicing at the time of the invention would not modify Kontos’ funnel with Ressemann’s support collar 2141 .....	106
D.	Kontos in View of Takahashi and Knowledge of a POSITA Combinations.....	108
E.	Combinations Using Kataishi (Ex. 1025) and Knowledge of a POSITA .....	109
X.	OPINIONS ON OBJECTIVE EVIDENCE OF NON-OBVIOUSNESS ...	112
A.	Nexus and Clinical Success.....	112
B.	Long-Felt Need.....	114
C.	Industry Praise.....	116
D.	At Least Two Competitors Have Launched Products that Are Substantially Similar to GuideLiner.....	121
1.	Medtronic’s Telescope Guide Extension Catheter .....	121
2.	Boston Scientific’s Guidezilla Guide Extension Catheter.....	124

I, John J. Graham, hereby declare and state as follows:

## **I. INTRODUCTION**

1. My name is Dr. John J. Graham, MB ChB, MRCP (UK). I make this declaration based on my own knowledge. I am an interventional cardiologist at St. Michael's Hospital in Toronto, Canada. I am also an Assistant Professor, Division of Cardiology, at the University of Toronto. I have over 20 years of experience in interventional cardiology. I have performed thousands of percutaneous coronary intervention (PCI) procedures, including many hundreds of complex procedures using a guide extension catheter.

2. I have been retained by the Patent Owner Teleflex as an independent expert to provide my opinions as a practicing interventional cardiologist on certain issues. I have been asked to provide my independent expert opinions and testimony in connection with the *Inter Partes* Review proceedings initiated by Medtronic, Inc. and Medtronic Vascular, Inc. ("Medtronic" or "Petitioner") against Teleflex concerning U.S. Patents 8,142,413 ("the '413 patent"), and RE46,116 ("the '116 patent"). I understand these proceedings have the case numbers IPR2020-01341, IPR2020-01342, IPR2020-01343, and IPR2020-01344. I have also previously provided opinions in connection with the prior eleven IPR proceedings, which I understand have the case numbers IPR2020-00126, IPR2020-00127, IPR2020-00128, IPR2020-00129, IPR2020-00130, IPR2020-00132,

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.