

Intellectual Property at Fresenius Medical Care

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Innovation Center, Lexington, MA
21 Jan 2020

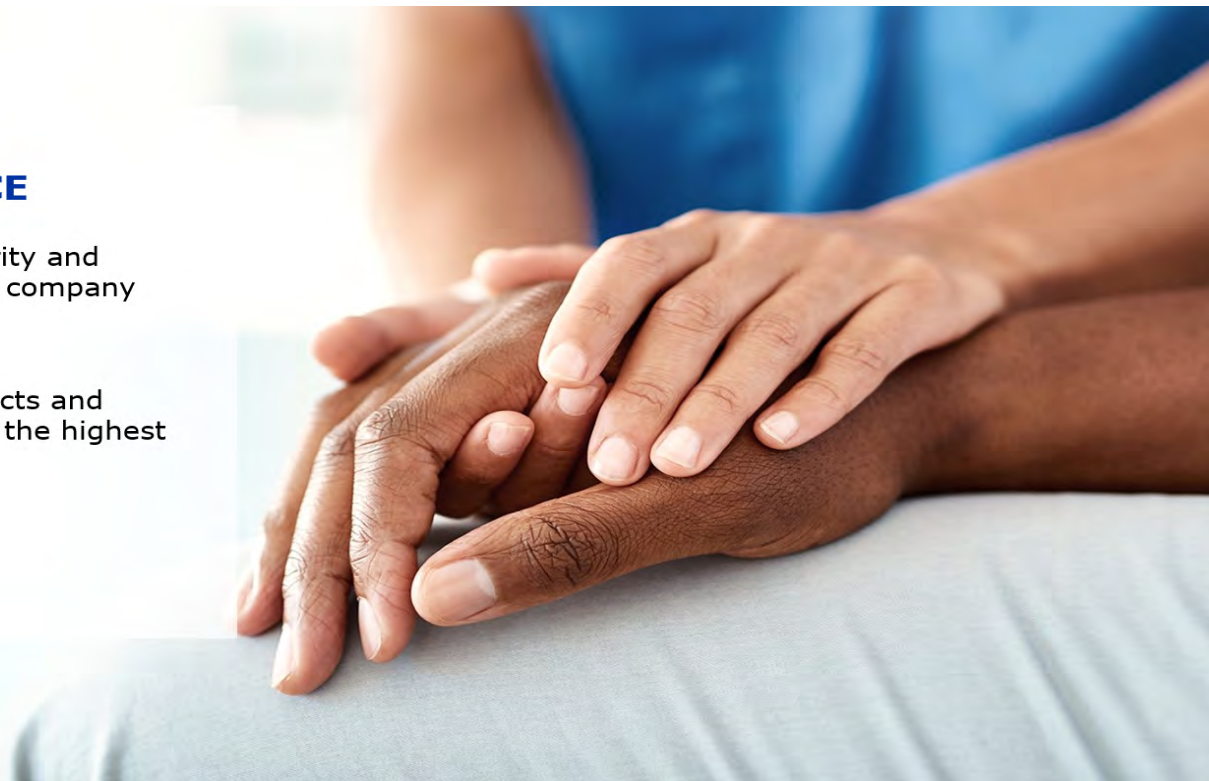


Compliance



WE ALL OWN COMPLIANCE

- We will conduct business with integrity and honesty in compliance with all laws, company policy, and our values.
- We are committed to produce products and deliver services that are safe and of the highest quality for our customers.



Agenda

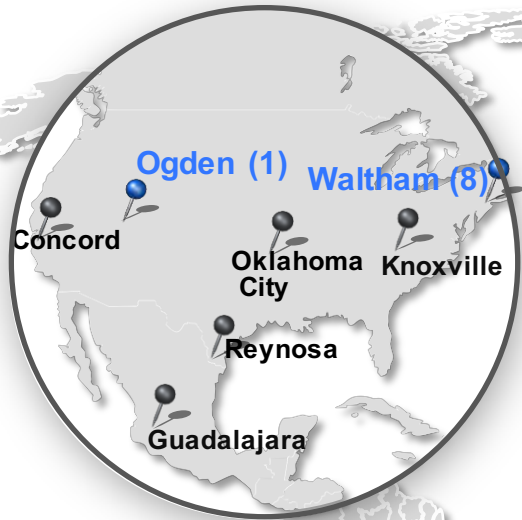
- 1) Global Intellectual Property (GIP) Department
- 2) Overview of IP rights
- 3) Process for Submitting Ideas and Obtaining Patents
- 4) Patent Benefits and Risks
- 5) Issue Spotting

Global IP (GIP) is part of Global R&D (GRD)

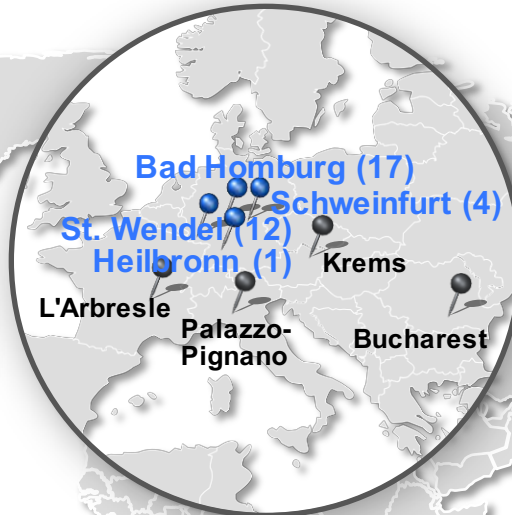


GIP is a Global Team...

North America



Europe



Asia/Pacific



GIP provides many levels of IP Support

- Inventions and Patents
- Freedom to operate (FTO) analyses
- IP landscape analyses
- Confidentiality/NDA agreements
- Licensing agreements
- Due diligence for deals
- Trademarks
- Copyrights
- IP disputes / litigation



Types of Intellectual Property

Patents

Trademarks

Copyrights

Trade Secrets

Types of Intellectual Property

Patents

Trademarks

Copyrights

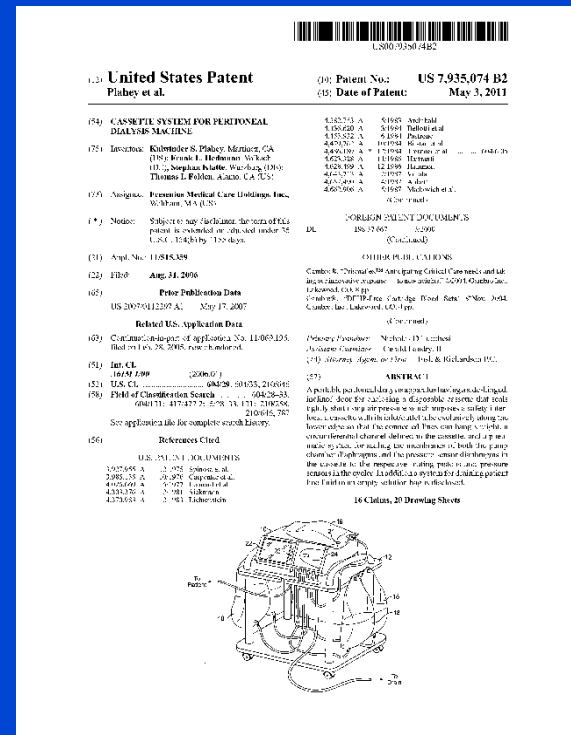
Trade Secrets

Utility Patents

Inventions that are useful,
new, and non-obvious

Process, machine, object of
manufacture, or composition
of matter

Term: 20 years from first US
utility filing



Types of Intellectual Property

Patents

Trademarks

Copyrights

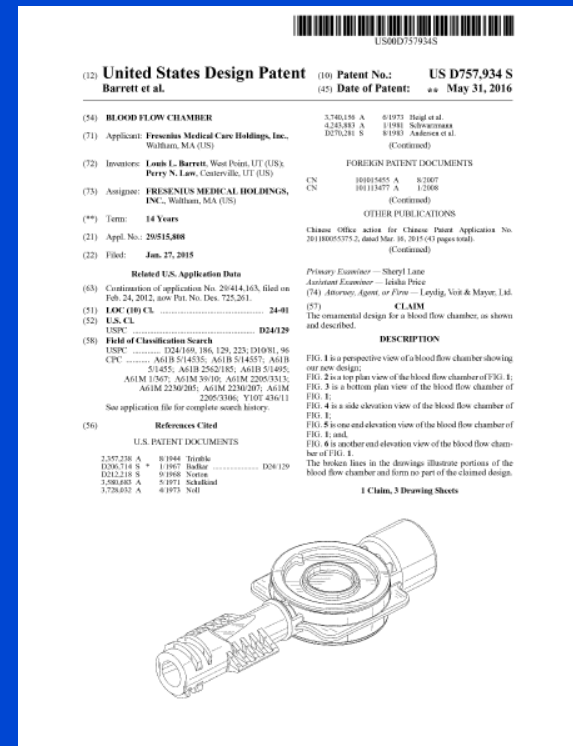
Trade Secrets

Design patents

Ornamental designs that are new and non-obvious

Covers aesthetics, not function

Term: 15 years from issue



Types of Intellectual Property

Patents

Trademarks

Copyrights

Trade Secrets

A patent grants an **exclusionary right**, allowing the patent owner **to exclude others** from making, using or selling the invention in that country during the life of the patent.



FMCNA Patent Marking Statement (for product labels):

Patents apply, visit www.fmcna.com/patents

Types of Intellectual Property

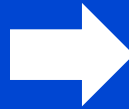
Patents

Trademarks

Copyrights

Trade Secrets

Exclusionary rights are conveyed by the numbered "claims" at the end of a patent



Inventorship: Anyone who has made an "inventive" contribution to any of the claims

What is claimed is:

1. An apparatus for pumping fluids between a peritoneal dialysis machine and a patient in order to perform peritoneal dialysis on the patient, comprising:
 - a disposable cassette for routing PD solution,
 - a cassette compartment defined by a deck and a door hinged from the side so as to close in parallel over the deck and enclose the cassette within the compartment, wherein the deck has openings for valve actuators and piston heads, and when the apparatus is resting on a substantially horizontal surface during use, the deck lies in a plane inclined from the vertical by 10 to 35 degrees, and the apparatus comprises two substantially mushroom head shaped piston heads that travel back and forth through two of the openings in the deck when reciprocated.

Types of Intellectual Property

Patents

Trademarks

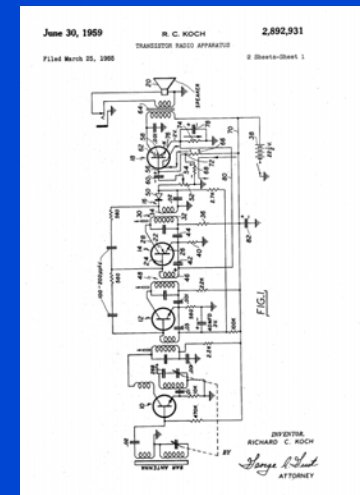
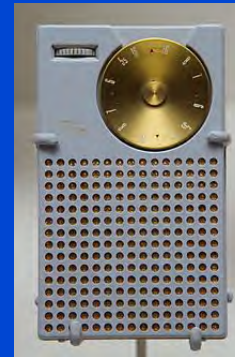
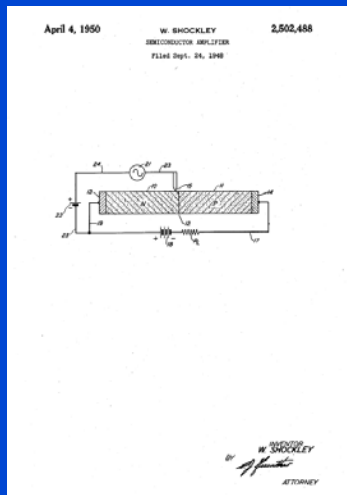
Copyrights

Trade Secrets

A patent grants a right to exclude others – NOT a right to practice an invention (restrictions from statutory, regulatory, other IP etc.)

1950 – Transistor (Bell Labs)

1954 – Transistor radio (Tx. Instr.)



Types of Intellectual Property

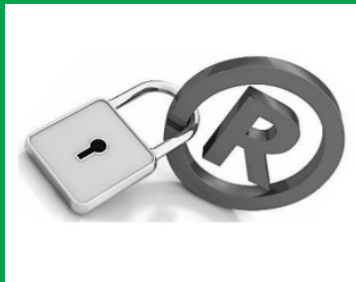
Patents

Trademarks

Copyrights

Trade Secrets

Words and symbols
that associate origin
of goods/services



 **FRESENIUS**



FMCNA trademark attribution statement:

Fresenius Medical Care, the triangle logo...[etc.] are trademarks of Fresenius Medical Care Holdings, Inc. or its affiliated companies. All other trademarks are the property of their respective owners.

Types of Intellectual Property

Patents

Trademarks

Copyrights

Trade Secrets

Original expression of ideas

But not underlying information
or ideas themselves



Examples: photographs,
written materials, software
code

FMCNA copyright statement:

© [YEAR] Fresenius Medical Care. All Rights Reserved.

Types of Intellectual Property

Patents

Trademarks

Copyrights

Trade Secrets

Technology that can be kept secret

Hard to reverse engineer

Examples: secret processes, formulas



Submit Ideas Using the Invention Disclosure Form

Available at:

FMCNA fmc4me: fmc4me.fmcna.com/intranet/Compliance/Legal/index.htm

FME International Intranet: fmc.intra.fresenius.com/29387.htm (NA form)

Submit to Global IP: GLOBALIPadmins@fmc-na.com

Company Confidential

IDEA / INVENTION DISCLOSURE

COMPLETE ALL AVAILABLE INFORMATION
INDICATE IF NOT APPLICABLE OR UNKNOWN PLEASE PRINT IDEA NO. []
(Assigned by Fresenius IP Dept.)

IDEA/INVENTION INFORMATION

Presenta Division: []

TITLE: []
(Select a Short Title That Describes the Main Feature of Idea/Invention)

Investor's Full Name	Dept.	Tele Ext.	Loc.	Investor's Full Name	Dept.	Tele Ext.	Loc.
[]	[]	[]	[]	[]	[]	[]	[]
[]	[]	[]	[]	[]	[]	[]	[]

Date Conceived: [] Date of First Document of Idea/Invention (Brief Summary and Date): []

Earliest Disclosure of Idea/Invention Made to the Following Employees (Other Than Witnesses of this Disclosure):

Name	Date	Name	Date
[]	[]	[]	[]
[]	[]	[]	[]

PRODUCT/PROJECT INFORMATION

What Project Number was Charged when Idea/Invention was Conceived?: []

Specific Product to which Idea/Invention Applied when Conceived?: []

Other Related and/or Unrelated Products that Idea/Invention may be used in?: []

Report Number/Memorandum Describing Idea/Invention (if None, so State)? []
(Please attach if available)

STATUS INFORMATION

Is Idea/Invention one of conception only?	YES <input type="checkbox"/>	NO <input type="checkbox"/>
Is Idea/Invention Being Studied, Built, or Tested?	YES <input type="checkbox"/>	NO <input type="checkbox"/>
Has the Idea/Invention Been Reduced to Practice?	YES <input type="checkbox"/>	NO <input type="checkbox"/>
Report Idea/Invention has Been and is Being Developed.		
Current Test Status:	Start Date: []	Comp. Date: []
Future Effort Planned:	Start Date: []	Comp. Date: []
Date of First Successful Test:		
Current Test Status:	Start Date: []	Comp. Date: []
Future Effort Planned:	Start Date: []	Comp. Date: []
Date of First Successful Test:		

EXTERNAL USE INFORMATION

First Sale Expected First Sale of Product Incorporating Idea/Invention: Date: []

Nature and Date of First Public Disclosure or Expected First Public: Date: []

Company Confidential

IDEA / INVENTION DISCLOSURE

Disclosure of Idea/Invention:
Name of any Non-Employees who are Aware of Idea/Invention: []

RETURN COMPLETED FORM DATA TO:
Fresenius Medical Care North America
Law Department, 920 Water Street
Waltham, MA 02451

IDEA NO. []
(Assigned by Fresenius IP Dept.)

This disclosure should be sufficiently completed in technical detail and appropriately illustrated, to provide a clear understanding of the Idea/Invention's nature, purpose, operation, and scientific characteristics. (See instructions below). This form and all additional sheets must be signed and dated by the inventor(s) and by two witnesses.

TITLE: []
(Select a Short Title That Describes the Main Feature of Idea/Invention)

DESCRIPTION AND SKETCHES
(attach if possible)

Explain to and understood by:
Witness: [] Signature: [] Date: []

Signature: [] Date: []

Signature: [] Date: []

Signature: [] Date: []

Signature: [] Date: []

INSTRUCTIONS TO INVENTORS

The following format is suggested to give the patent committee a better understanding of the Idea/Invention, and to assist in a timely review, but attached technical papers and/or descriptions are also acceptable.

- A paragraph(s) describing the principle objective of the idea/invention
- A paragraph(s) summarizing the background of the idea/invention, including a statement of the problem solved.
- Describe the construction and operation of the idea/invention. Use sketches if possible and refer to numbered features on sketch in supporting text. Indicate any alternate methods of construction.
- A paragraph(s) stating the inventor's perception of novelty and improvement over prior art.



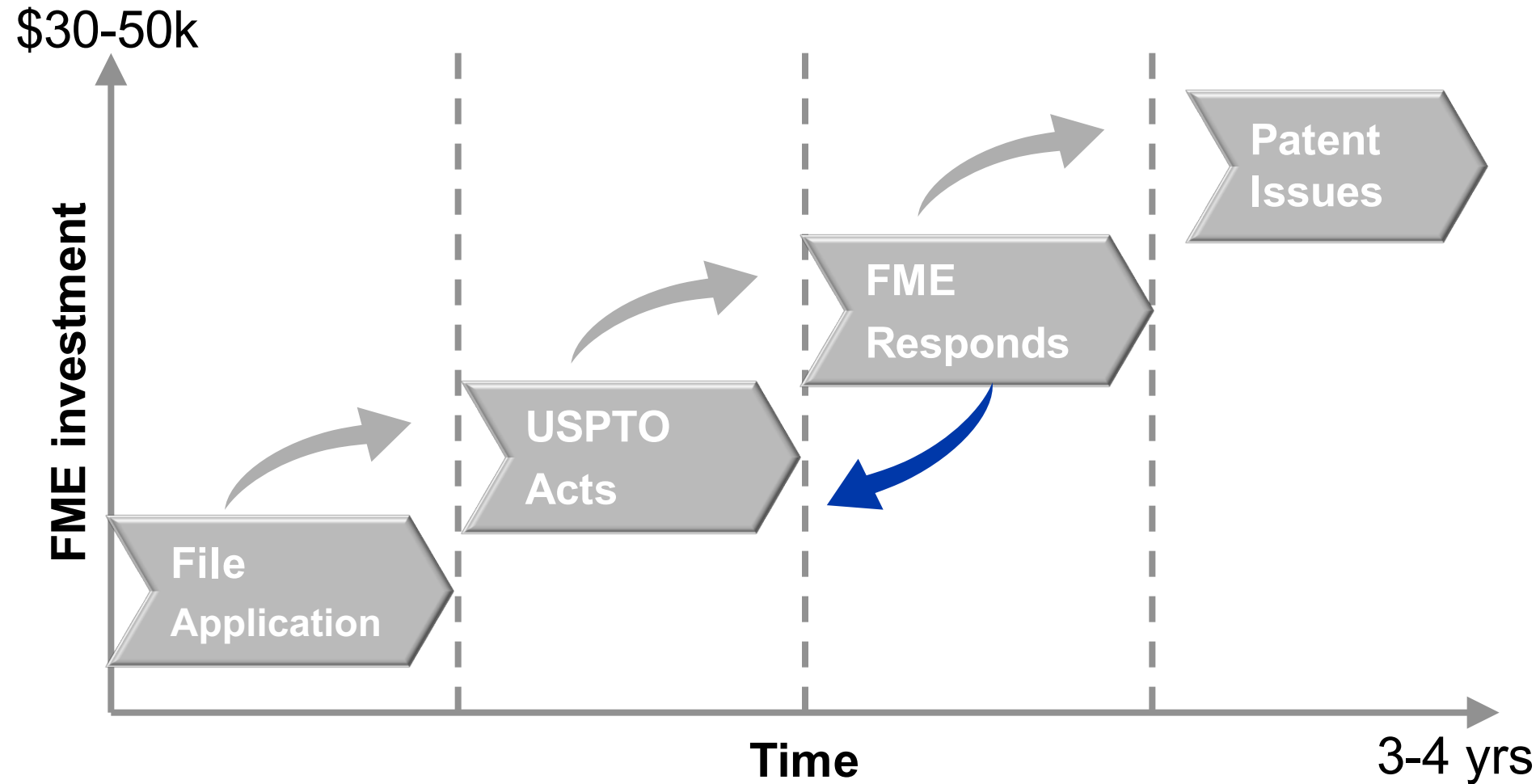
**GLOBAL
INTELLECTUAL
PROPERTY**

Inventions Are Valued and Carefully Reviewed for IP

Idea/Invention Review Process for IP at FMCNA

- **Inventor submits Idea to Global IP**
- **IP Review Committee (IPRC) Evaluates**
 - Quarterly Meetings
- **IPRC Decisions include:**
 - Not to pursue the idea / Keep it as a trade secret
 - Request more information on the idea
 - Conduct a search to evaluate patentability
 - Approve the preparation and filing of a patent application (with input from inventors on the invention)
 - Foreign filing decisions

The Patent Process Takes Time, Money and Effort...



...and Hopefully Results in an Issued US Patent



US010154097B2

(12) **United States Patent**
Wang et al. (10) **Patent No.:** US 10,154,097 B2
(45) **Date of Patent:** *Dec. 11, 2018

(54) **CONTROL OF HOME DIALYSIS MACHINES USING A NETWORK CONNECTED SYSTEM** (58) **Field of Classification Search**

(71) Applicant: **Fresenius Medical Care Holdings, Inc., Waltham, MA (US)**
CPC H04L 67/125; H04L 67/141; H04L 63/10; A61M 1/1601; G16H1 40/67; G06F 19/00; G06F 19/3418
See application file for complete search history.

(72) Inventors: **Aiyuan Wang, San Ramon, CA (US); Martin Joseph Crnkovich, Walnut Creek, CA (US); Fei Wang, Concord, CA (US); Sue-Jane Lee, Fremont, CA (US); David Yuds, Antioch, CA (US); Hak Kan Leung, Sunnyvale, CA (US); Jeffrey Tarn, Walnut Creek, CA (US)** (56) **References Cited**

(73) Assignee: **Fresenius Medical Care Holdings, Inc., Waltham, MA (US)**
U.S. PATENT DOCUMENTS
5,933,136 A 8/1999 Brown
5,987,519 A 11/1999 Peifer
(Continued)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.
This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/910,276**
FOREIGN PATENT DOCUMENTS
CN 101194278 6/2008
CN 101363843 2/2009
(Continued)

(22) Filed: **Mar. 2, 2018**
OTHER PUBLICATIONS
Wrzel et al., Networked development to drive new dialysis solutions, Aug. 2009, Portland International Conference on Management of Engineering & Technology, pp. 3018-3032 (Year: 2009).
(Continued)

(65) **Prior Publication Data**
US 2018/0191830 A1 Jul. 5, 2018
Primary Examiner — Kenneth W Cheng
(74) *Attorney, Agent, or Firm* — Fish & Richardson P.C.

Related U.S. Application Data
(57) **ABSTRACT**

(63) Continuation of application No. 15/446,084, filed on Mar. 1, 2017, now Pat. No. 9,948,720, which is a (Continued)
This disclosure relates to remote control of home dialysis machines, for example, using a network connected system including a network device. In an aspect, a dialysis system includes a network device, a dialysis machine configured to connect to the network device over a network, and a mobile device configured to connect to the network device over the network. The network device is configured for receiving, from the mobile device, through the network, a request to access the dialysis machine, receiving an authorization for the mobile device to access the dialysis machine, and after receiving the authorization, transferring, through the network, between the dialysis machine and the mobile device, information pertaining to one or more of an operation of the dialysis machine or the mobile device in accordance with the designation.
(Continued)

(51) **Int. Cl.**
H04L 29/08 (2006.01)
G06F 19/00 (2018.01)
(Continued)

(52) **U.S. Cl.**
CPC **H04L 67/125** (2013.01); **A61M 1/1601** (2014.02); **G06F 19/00** (2013.01);
(Continued)



What is claimed is:

1. A dialysis system comprising:
 - a network device located in a home of a patient;
 - a dialysis machine configured to connect to the network device over a network; and
 - a mobile device configured to connect to the network device over the network, wherein the network device is configured for:
 - receiving, from the mobile device, through the network, a request to access the dialysis machine;
 - receiving an authorization for the mobile device to access the dialysis machine, wherein the authorization is based at least in part on an identity of one or both of the mobile device or a user of the mobile device;
 - receiving a designation of a level of access among a plurality of levels of access to the dialysis machine granted to the mobile device, wherein the level of access allows one or both of monitoring or controlling of the dialysis machine; and
 - after receiving the authorization, transferring, through the network, between the dialysis machine and the mobile device, information pertaining to one or more of an operation of the dialysis machine or the mobile device in accordance with the designation.



Remember:
The legal rights of a utility patent are conveyed by the numbered paragraphs at the end

Term: 20 years from first US utility filing
Maintenance fees due at: 3.5, 7.5, 11.5 years



Obtaining and Protecting IP is a Strategic Necessity for Fresenius Medical Care



- Exclusive rights
 - Patents grant FME exclusive IP rights in inventions.
- Strengthen market position
 - Through these exclusive rights, we are able to prevent others from commercially using the patented invention.
- Opportunity to license or sell the invention
 - If we chose not to exploit the patent ourselves, we may sell it or license the rights.
- Increase in negotiating power
 - Our patent portfolio can enhance our bargaining power in negotiating cross license arrangements.
- Positive image
 - Business partners, investors and shareholders perceive patent portfolios as a demonstration of the high level of expertise, specialization and technological capacity within FME.

Patent Awards

FMCNA Patent Award Policy

- Application Filing Award - Each named inventor is eligible for an award of **net \$500** when a patent application has been filed on an invention disclosure. The award applies only for original patent application filings in the country of origin.

- Patent Grant Award - Each named inventor is eligible for an award of **net \$1000** when the patent application has been granted. The award applies only for a patent granted in the country of the original filing.

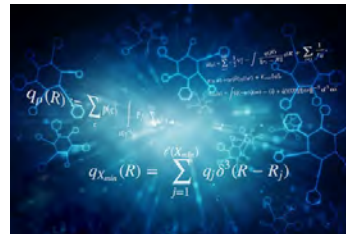
Two award periods: (i) Dec 1 - May 31 and (ii) Jun 1 - Nov 30

This policy applies to Employees and Contractors!

Types of technology pursued for IP at FME

What types of technology?

- Dialysis machines/devices
- Dialyzers
- Disposable blood lines and cassettes
- Dialysis fluid solutions
- Pharmaceuticals
- Methods of manufacture/use/treatment
- Care coordination / "Home" technologies
- Connectivity / Cybersecurity
- Software / Data analytics
- Interfaces / VR / AI



IP Directly Impacts R&D Project Development

PROJEX – Executing Development Projects Globally

DEVELOPMENT PROCESS MAP



Intellectual Property	PREPARATION OF CONCEPT & FEASIBILITY	PLANNING OF PROJECT & DESIGN INPUTS	DESIGN DEVELOPMENT & VERIFICATION	DESIGN TRANSFER & VALIDATION	COMMERCIALIZATION	CLOSING OF PROJECT
	search for relevant IP	define IP strategy for protection of development result	identify inventions, match to IP strategy, file where appropriate	file remaining applications before product publications	continuously evaluate IP and update cIPRA	
	review concept against existing 3rd party patents	define 3PP competitive landscape	prepare current IP risk assessment (cIPRA)	file trademark reg. if applicable		
			continuously evaluate IP and update cIPRA	continuously evaluate IP and update cIPRA		
			review potential names of trade mark			

3rd Party Patents Also Need To Be Considered

- **Risks**

- Injunctions



- Monetary damages

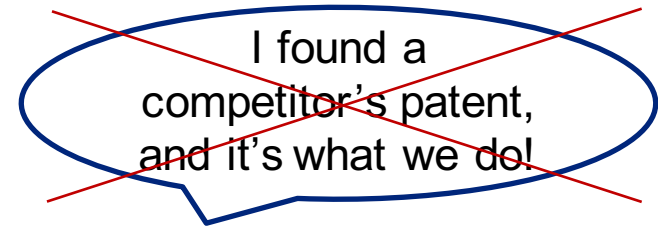


- **GIP Activities**

- Continually monitor 3rd party IP landscape
- Perform project-specific IP search and analysis
- Assess risk
- Actively oppose 3rd party IP
- Approach and negotiate favorable license terms
- Advise internal clients
 - Provide risk analysis during product development
 - Assess “design around” options for problematic IP
 - Develop invalidity positions

Issue Spotting

- **Publications, Posters, Presentations, Communications/Meetings with 3rd parties**
 - Is a new technology being discussed? If so, consult with GIP
 - May need to revise content and/or file application before disclosure/meeting
 - May need NDA
 - Unprotected disclosure can prevent FME from obtaining patents
- **If you become aware of 3rd party patent that might be relevant to FME business...**
 - Confer with GIP
 - OK to review patent, but do not make or communicate legal conclusions
 - Patent claim interpretation is a complex legal issue
- **New ideas that could be patentable**
 - Submit an invention disclosure to GIP (early and often!)



Thank you!

Questions?



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781-699-9208