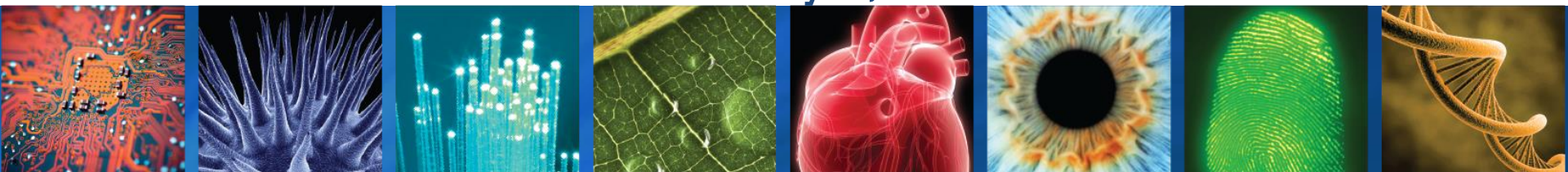


IP Protection of Medical Devices on the Global Stage

February 6, 2017

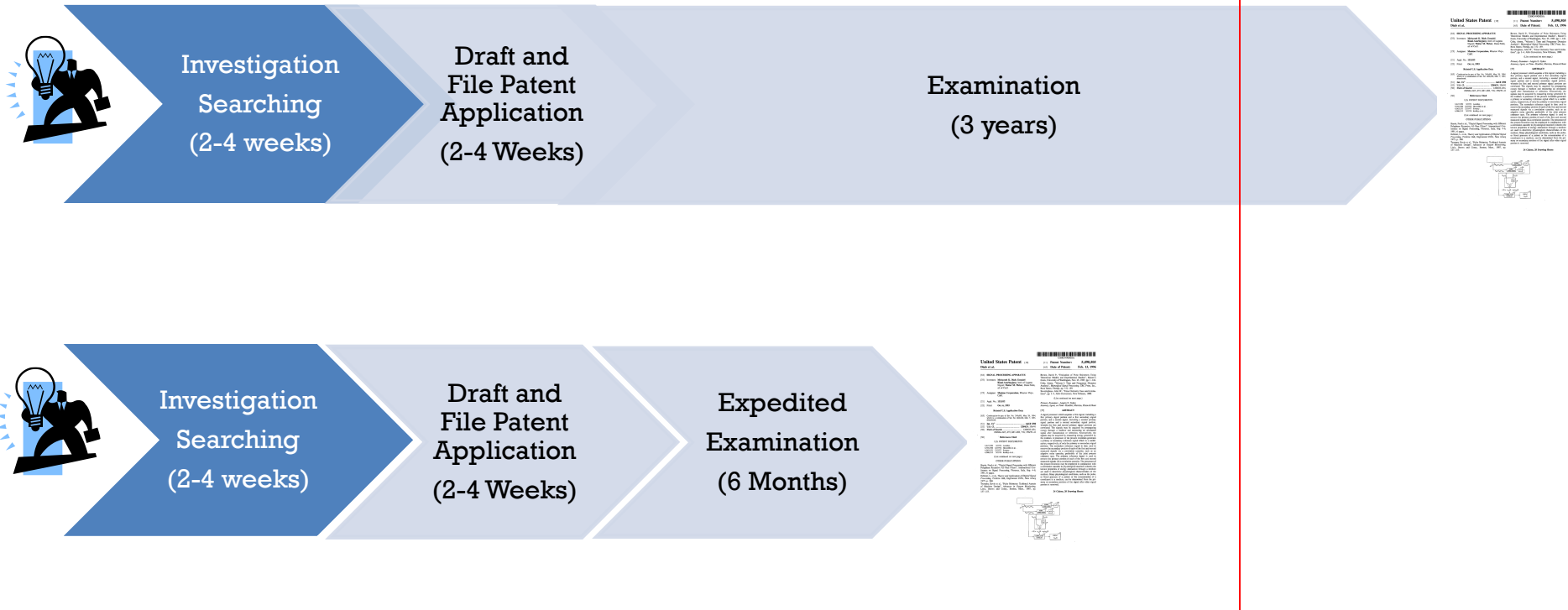


Issues re International Patent Rights

- Patent Timeline Overview
- The “30-Month” Window
- Compliance with Global Patent Laws
 - Ownership
 - Patentability
- Blocking Importations via International Trade Commission (ITC)

Patent Timeline

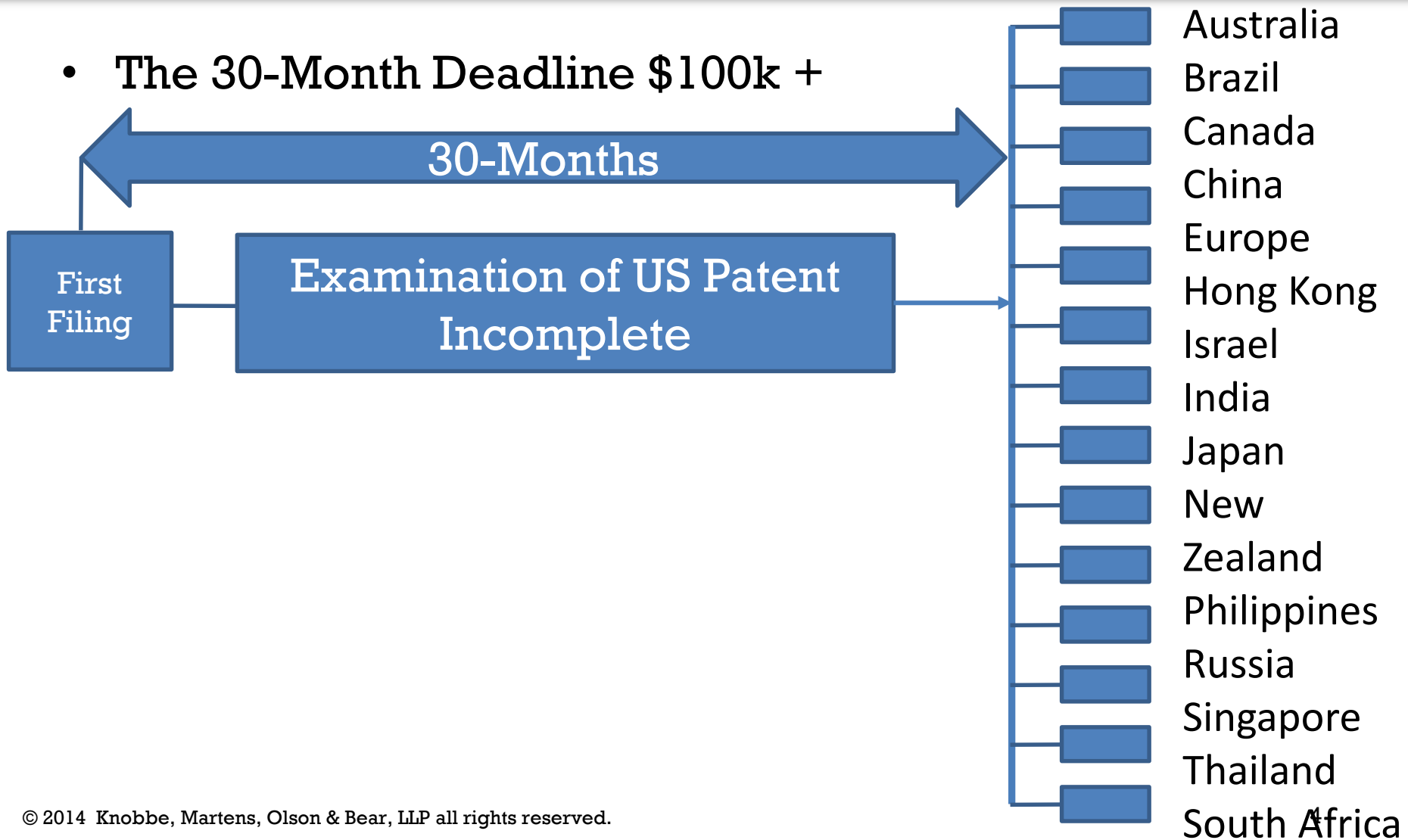
- Regular Speed v “Track 1” Expedited Examination \$1-4k



30-Month Deadline

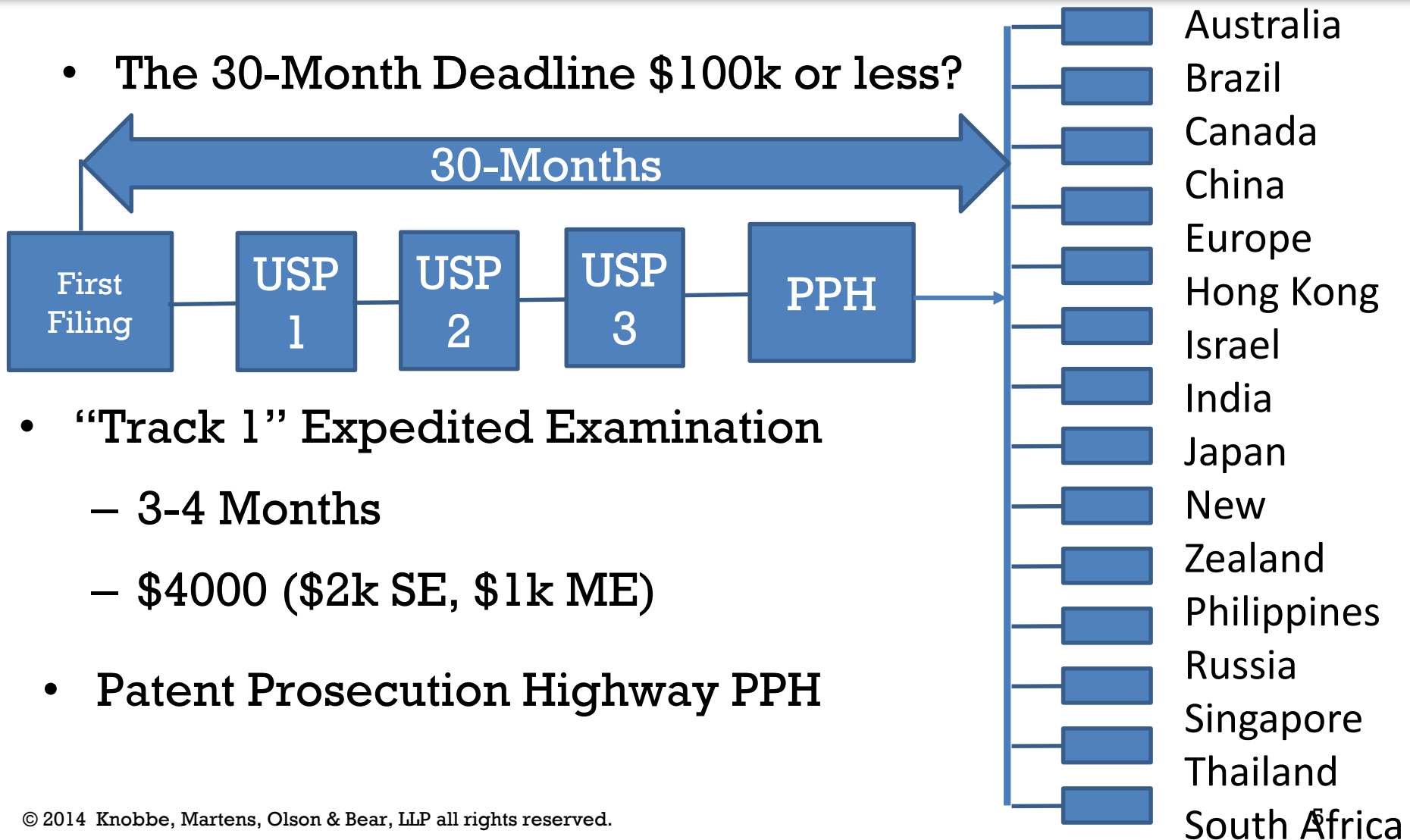
International Patent Timeline – Regular Speed

- The 30-Month Deadline \$100k +



International Patent Timeline – Expedited

- The 30-Month Deadline \$100k or less?



- “Track 1” Expedited Examination

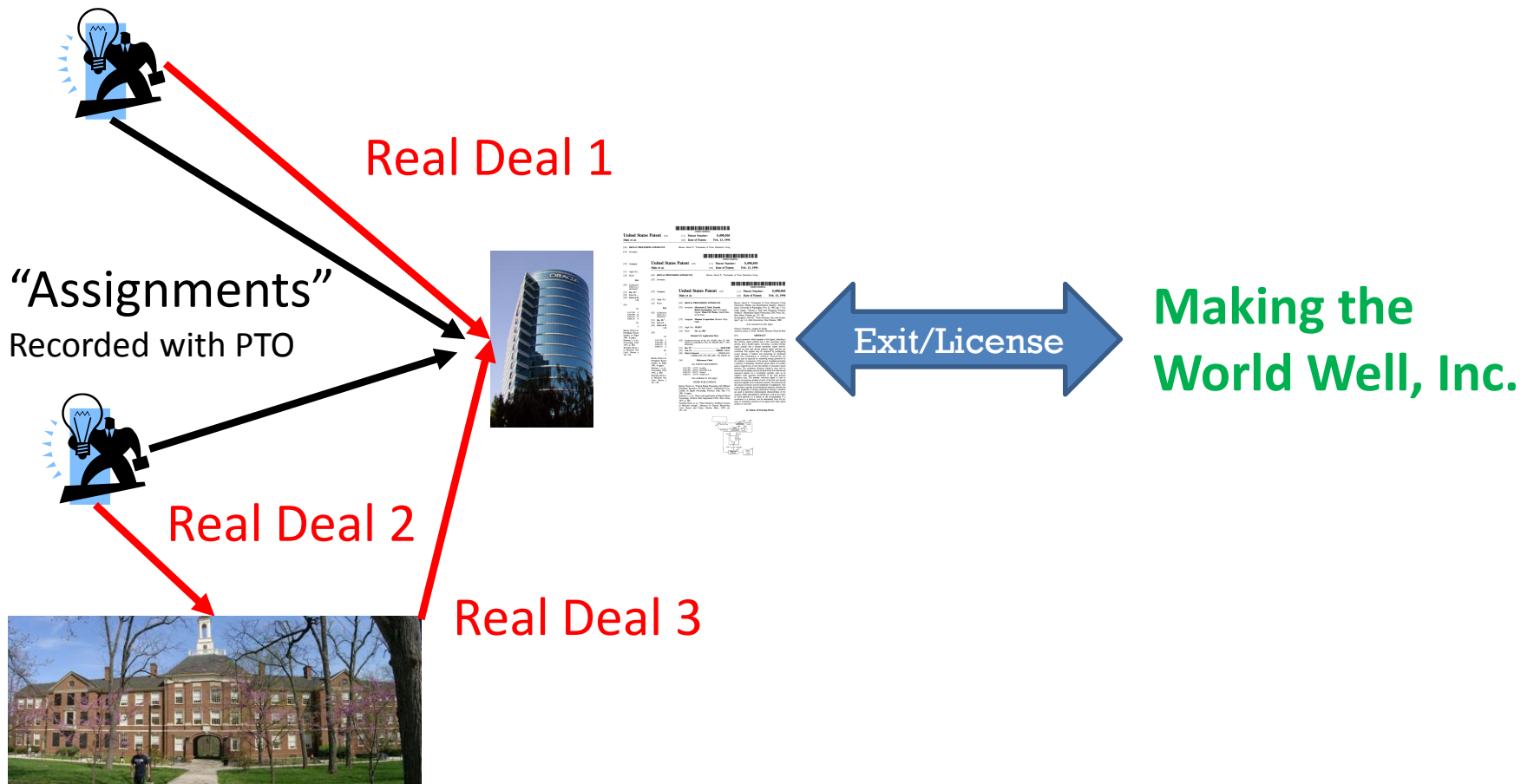
- 3-4 Months

- \$4000 (\$2k SE, \$1k ME)

- Patent Prosecution Highway PPH

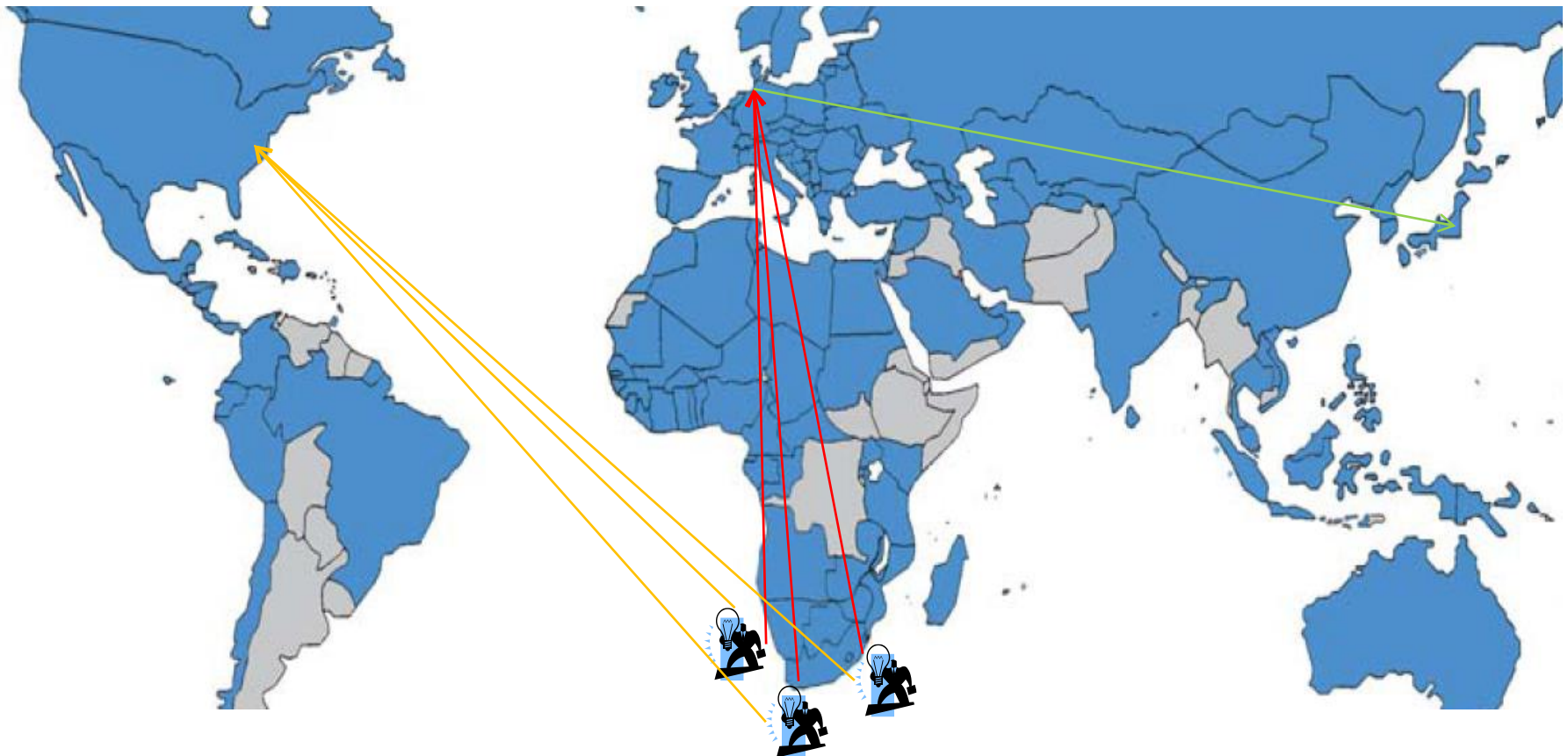
Patent Chain of Title - Basic

- Patent Rights Start at Invention



International Patent Rights Complications

- Compliance with Local Laws at Location of Invention



South African Technology Laws

- Form South African Technology Co./Own Rights
- Submit Valuation and Apply to SA Reserve Bank for Export



Global Patentability

- **Exclusion of Medical Procedure Patents**
 - A medical procedure patent only confers rights over procedural steps and does not confer rights over any new devices.
 - Over 80 countries prohibit medical procedure patents.
 - Focus on Devices
- **Adhere to Most Stringent Requirements**
 - Country of Origin may be too lax!!
 - “Problem – Solution” Disclosure (Not Required in US, but Optional)

Masimo's Initial Patent Filing



United States Patent [19] [11] **Patent Number:** 5,490,505
Diab et al. [45] **Date of Patent:** Feb. 13, 1996

[54] **SIGNAL PROCESSING APPARATUS**
 [75] Inventors: **Mohamed K. Diab; Esmail Kiani-Azarbayjani**, both of Laguna Niguel; **Walter M. Weber**, Dana Point, all of Calif.
 [73] Assignee: **Masimo Corporation**, Mission Viejo, Calif.
 [21] Appl. No.: **132,812**
 [22] Filed: **Oct. 6, 1993**

Brown, David P., "Evaluation of Pulse Oximeters Using Theoretical Models and Experimental Studies", Master's thesis, University of Washington, Nov. 25, 1987, pp. 1-142.
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 Severinghaus, John W., "Pulse Oximetry Uses and Limitations", pp. 1-4, ASA Convention, New Orleans, 1989.
 (List continued on next page.)
Primary Examiner—Angela D. Sykes
Attorney, Agent, or Firm—Knobbe, Martens, Olson & Bear

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 249,690, May 26, 1994, which is a continuation of Ser. No. 666,060, Mar. 7, 1991, abandoned.
 [51] Int. Cl.⁵ **A61B 5/00**
 [52] U.S. Cl. **128/633; 356/41**
 [58] Field of Search **128/633-634, 128/664-667, 672, 687-688, 716; 356/39-41**

[57] **ABSTRACT**
 A signal processor which acquires a first signal, including a first primary signal portion and a first secondary signal portion, and a second signal, including a second primary signal portion and a second secondary signal portion, wherein the first and second primary signal portions are correlated. The signals may be acquired by propagating energy through a medium and measuring an attenuated signal after transmission or reflection. Alternatively, the signals may be acquired by measuring energy generated by the medium. A processor of the present invention generates a primary or secondary reference signal which is a combination, respectively, of only the primary or secondary signal portions. The secondary reference signal is then used to remove the secondary portions of each of the first and second measured signals via a correlation canceler, such as an adaptive noise canceler, preferably of the joint process estimator type. The primary reference signal is used to remove the primary portion of each of the first and second measured signals via a correlation canceler. The processor of the present invention may be employed in conjunction with a correlation canceler in physiological monitors wherein the known properties of energy attenuation through a medium are used to determine physiological characteristics of the medium. Many physiological conditions, such as the pulse, or blood pressure of a patient or the concentration of a constituent in a medium, can be determined from the primary or secondary portions of the signal after other signal portion is removed.

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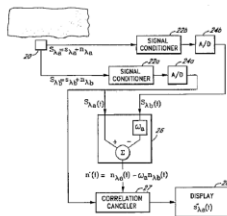
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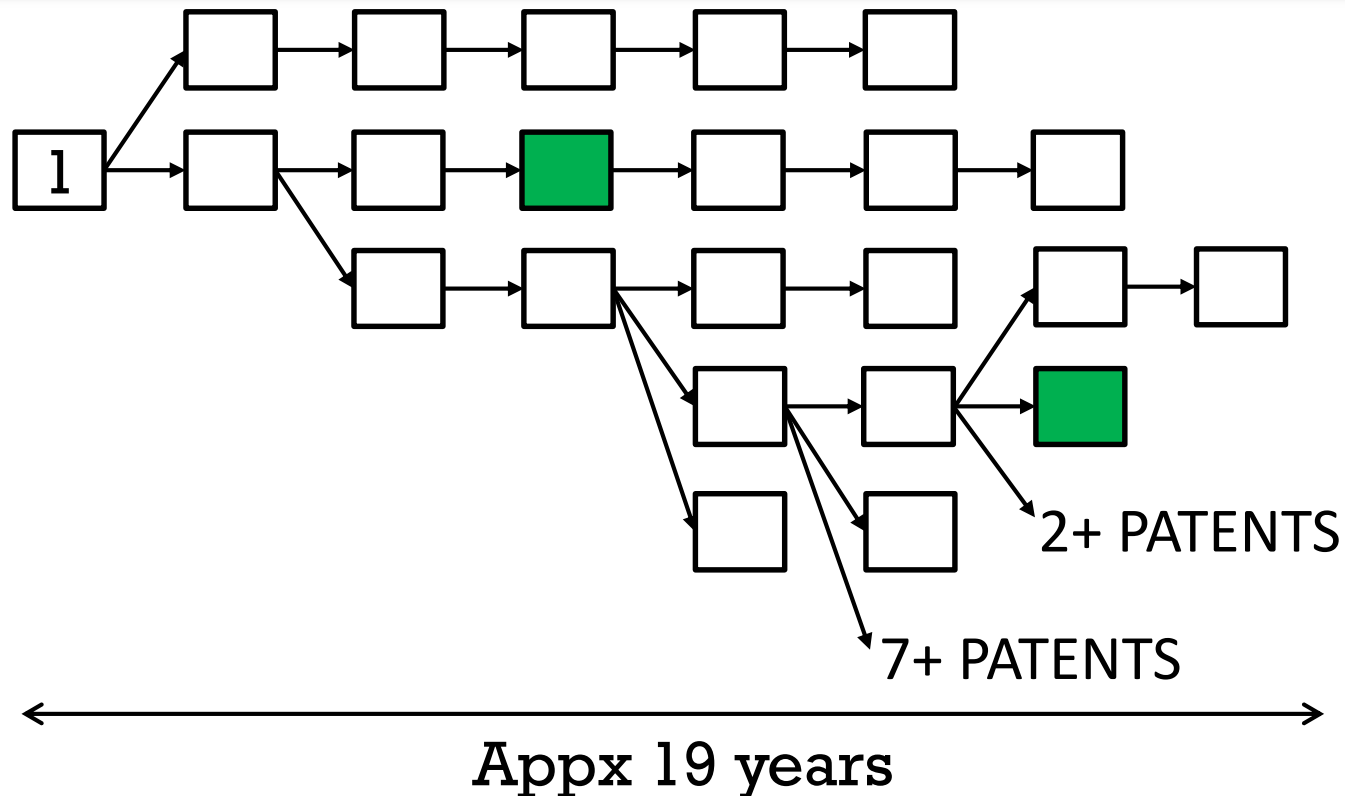
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 Rabiner, L. et al., *Theory and Application of Digital Signal Processing*, Prentice Hall, Englewood Cliffs, New Jersey 1975, p. 260.
 Tremper, Kevin et al., "Pulse Oximetry: Technical Aspects of Machine Design", *Advances in Oxygen Monitoring*, Little, Brown and Comp., Boston, Mass., 1987, pp. 137-153.

24 Claims, 20 Drawing Sheets



- **Pulse Oximeter**
 - 51 Pages
 - 40 Drawings
 - 50 Columns of text
 - Filed in 11 countries + EU

Masimo's Initial Patent Spawned 32 Patents



One of Masimo's Patent families, 31 "Continuations" of One patent application. Value = \$1B jury verdicts.

Blocking Importations

- International Trade Commission (ITC)
 - “Exclusion Order” 19 USC § 1337
 - Patent Infringement
 - Domestic Industry
 - \$2M-\$5M 12-18 Months



Summary

- **First Patent Filing Critical**
 - **Global Ownership and Patentability laws**
- **Investment / Alternative Billing for 30-Month Window**
- **Blocking Importation**



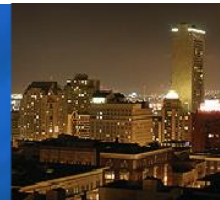
Orange County



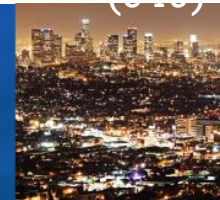
San Diego



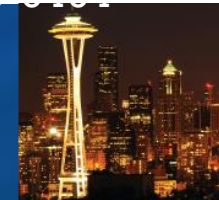
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Silicon Valley



Los Angeles



Seattle



Washington DC