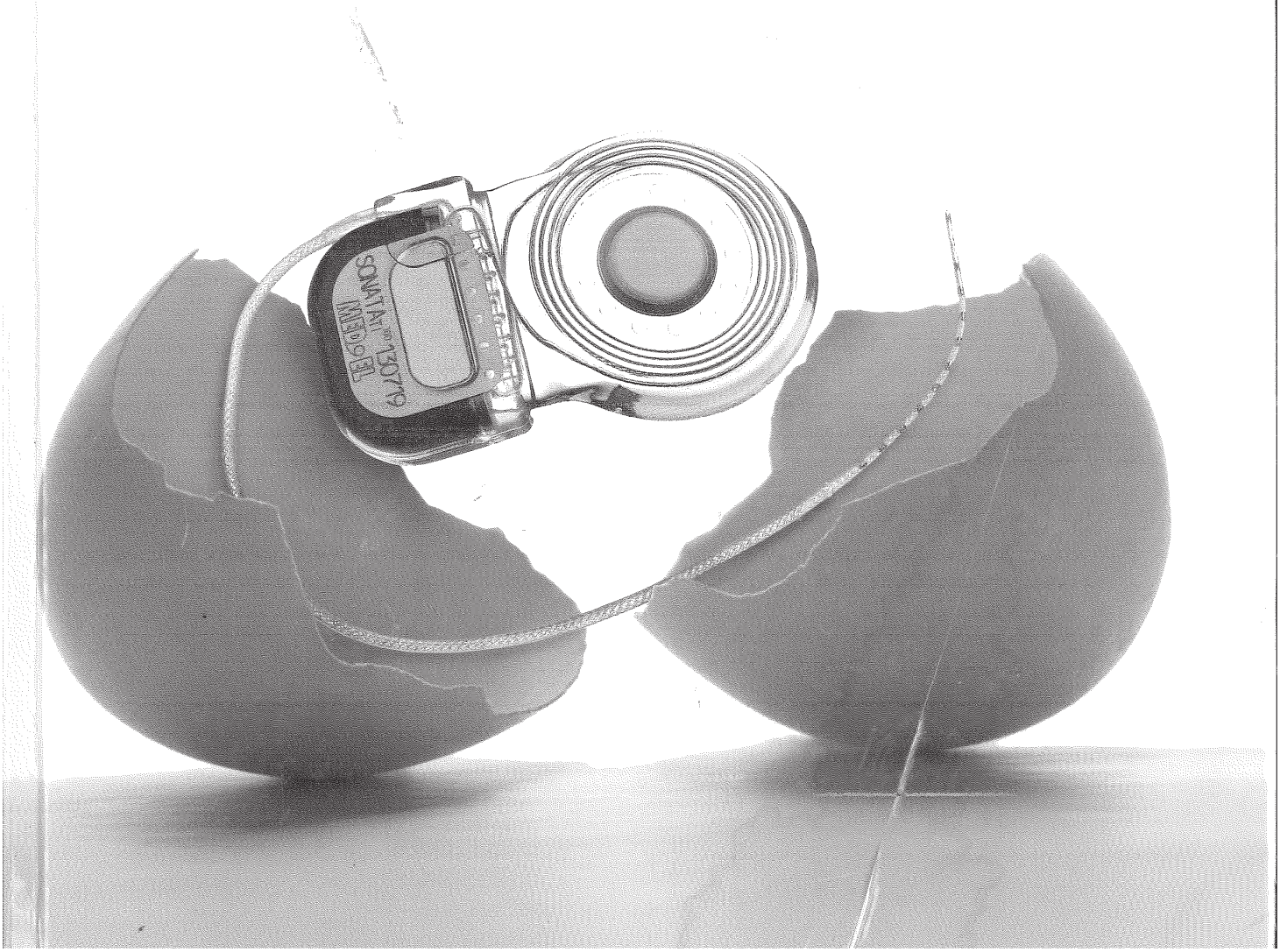
BIODESIGN

The Process of Innovating Medical Technologies

ZENIOS, MAKOWER, YOCK



WELCH ALLYN EXHIBIT 2010
iRhythm v. Welch Allyn
IPR2025-00378

Biodesign

The Process of Innovating Medical Technologies

Senior editors
Stefanos Zenios
Josh Makower
Paul Yock

Associate editors
Todd J. Brinton
Uday N. Kumar

Principal writer
Lyn Denend

Specialty editor
Thomas M. Krummel

Web editor
Christine Kurihara
(ebiodesign.org)

CAMBRIDGE
UNIVERSITY PRESS

CAMBRIDGE UNIVERSITY PRESS
Cambridge, New York, Melbourne, Madrid, Cape Town, Singapore,
São Paulo, Delhi, Dubai, Tokyo, Mexico City

Cambridge University Press
The Edinburgh Building, Cambridge CB2 8RU, UK

Published in the United States of America by Cambridge University Press, New York

www.cambridge.org
Information on this title: www.cambridge.org/9780521517423

Copyright © 2010 by the Board of Trustees of
the Leland Stanford Junior University. All rights
reserved. Used with permission from the
Stanford University Graduate School of Business.

This publication is in copyright. Subject to statutory exception
and to the provisions of relevant collective licensing agreements,
no reproduction of any part may take place without
the written permission of Cambridge University Press.

First published 2010
3rd printing 2010
4th printing 2011

Printed in the United States at Edwards Brothers Inc., Ann Arbor, MI.

A catalogue record for this publication is available from the British Library

ISBN 978-0-521-51742-3 Hardback

Additional resources for this publication at www.cambridge.org/9780521517423 and ebiodesign.org

Cambridge University Press has no responsibility for the persistence or
accuracy of URLs for external or third-party internet websites referred to
in this publication, and does not guarantee that any content on such
websites is, or will remain, accurate or appropriate.

FROM THE FIELD iRHYTHM TECHNOLOGIES, INC.

Assessing the IP landscape and making preliminary filings

When Uday N. Kumar, John White, Kityee Au-Yeung, and Joseph Knight were fellows in Stanford University's Program in Biodesign, they began working on the need for *a better way to detect potential rhythm disturbances in non-hospitalized patients with suspected arrhythmias*. Arrhythmias are abnormal heart rhythms (atrial fibrillation, described at length in 2.1 Disease State Fundamentals, is one common type). Although some arrhythmias have few negative health consequences, others lead to serious heart disease, stroke, or sudden cardiac death.[35]

According to Kumar, a cardiologist specializing in cardiac arrhythmias, "The vast majority of people who have symptoms that could be due to arrhythmia first go to their primary care physician or an emergency room doctor. But physicians in those settings are not enabled fully to diagnose the problem since current cardiac rhythm monitoring technologies are complicated and have many drawbacks that limit their use by these doctors. So, many people never get assessed until they have a very severe presentation, such as passing out or experiencing a cardiac arrest. Unless something relatively serious happens, patients are often told, 'You had palpitations two days ago. But you look fine now. Let's wait and see if it happens again.'"[36] In contrast, if these patients were referred to a cardiologist, advanced monitoring technologies could be used to diagnose the problem and facilitate more proactive treatment, in many cases, before more serious symptoms occurred. "We figured out that enabling better diagnosis through more accessible and simple approaches was the key to getting more people into treatment earlier in the process," said Kumar.

Once the team understood the parameters of the need and the key need criteria (as articulated in the need specification), its members held a series of brainstorming sessions. Together, they generated dozens of potential solutions and screened them against the need. "After we had a solution that we thought would best meet the need spec," Kumar recalled, "we had to figure out if people had done this before so we conducted IP searches. Our focus was on patents that had already been issued as well as pending patent applications," he added. Importantly, the team did not spend too much time looking at medical journals and other general sources since, as a field, cardiac rhythm monitoring had not experienced a great deal of innovation in recent years. "There just weren't many recent publications out there talking about cardiac rhythm monitoring," Kumar recalled.

The initial patent searches were meant, in part, to establish the utility, novelty, and non-obviousness of the team's idea. Demonstrating the utility of a device designed to perform outpatient cardiac rhythm monitoring was not a primary concern. However, the team was intent on clearly identifying that its solution was novel and non-obvious. Kumar and his teammates performed many searches using a wide variety of search terms related to the description of the device concept, its functionality, appearance, interaction with the body, and links to the disease. Patents on existing cardiac rhythm monitoring therapies were also searched for relevant information. The team used different combinations of search terms to help ensure that the scope of the research was not too narrow and that nothing was inadvertently overlooked. "You have to be broad in your searches," said Kumar. "The information you uncover really depends on how you search. I used a thesaurus to figure out different ways to describe the same thing. People use different approaches, and you can miss a whole patent if you don't expand your thinking about search terms." The team also realized that being too broad in its search strategy led to many irrelevant results. Understanding the limitations of being too narrow or too broad allowed the team to develop a search strategy that gave them a good sense of what was out there.

As the team reviewed patent documents it became increasingly clear that their solution had several important elements that made it unique. To address the non-obviousness of the device, they spent significant time and energy figuring out where the cardiac rhythm monitoring field was trending. "If you understand where the field is heading, you can determine how you fit in," Kumar commented. "If we're going in one direction and everyone else is going another, it shows that we're on a different path, which makes it difficult for the patent office to say that what we're doing is really obvious."

At that point, in parallel with other activities in the biodesign innovation process, the team was eager to seek input and opinions about its solution from other people in the field, "so we filed a provisional patent application," said Kumar (see Figure 4.1.11). "It wasn't just a paper napkin with a sketch. It had a detailed background section and drawings." It also included a single claim the team believed captured the device's utility. Filing a provisional application secured a priority date in the patent office and protected the team from third-party disclosure (see Figure 4.1.11).

As biodesign fellows during this preliminary IP assessment, the team did not have the financial means to engage an IP attorney. However, upon completing the program, "I made the decision to start a company," said Kumar. "That's when I knew it was time to get a patent attorney involved." To prepare for his interactions with an IP lawyer, Kumar revisited the team's early IP assessment and initiated a more detailed review of the prior art. "I spent a lot of time going back to the original patents we had examined. I also did more searching, brushed up on what else was out there, and dived much more deeply into the analysis of specific claims," he remembered. Kumar and team had started a claims analysis but realized they needed outside expertise to complete it. For this reason, they decided to file the provisional application and come back to claims analysis later, if any of them decided to pursue the project beyond graduation. "At the end of the day, the claims are what matters," Kumar note. "In the first instance, it can be discouraging to read descriptions and see figures in another patent that look similar. But 'similar' doesn't mean 'the same.' You have to closely examine and interpret the claims, especially the independent claims, to determine whether a potential problem exists." Kumar looked at both device and method claims, since his product and business model were directed towards a monitoring device and an approach for using the monitoring technology.

Based on his preliminary claims analysis, Kumar narrowed the list of patents to those that were closest and most relevant to the proposed solution. "Then, I went back to look at the text to understand the arguments that were made to support the claim sets. This also helped me think about and refine my own arguments for why the solution

FIGURE 4.1.11
The team with its first provisional patent filing (courtesy of Uday N. Kumar).

FROM THE FIELD iRHYTHM TECHNOLOGIES, INC.

Continued

was novel and non-obvious compared to what was already out there."

With his own analysis complete, Kumar was ready to engage an attorney. As a fellow, he had been introduced to Ben Glenn, who regularly volunteered time to be an "IP coach" to teams in the Program in Biodesign. "I recalled meeting Ben and the positive experience our team had in talking with him. He had deep knowledge and experience in medtech, so I sought his help," said Kumar. He shared his assessment with Glenn as the first step in establishing a close and highly collaborative relationship." Over time, I spent countless hours with Ben, really explaining exactly what we were doing and bringing him up to speed. This way he could help direct how I could be most helpful as we parsed up the work. Even with a great IP lawyer, the innovator really has to stay involved and understand what's happening because you know better than anyone else what the technology is intended to do." In addition to validating the team's assessment of the IP landscape, Glenn orchestrated a conversion of the provisional application that emphasized the differences and advantages of the device and the method of use. The result was an IP foundation with three utility patent applications (covering the device and associated methods), as well as a PCT application. "In the end, it's hard to overstate the importance of having an experienced IP lawyer such as Ben on my side. He definitely spent a great deal of time trying to understand the space so that he could thoughtfully put together claims and send them to me. He'd ask, 'Is this really what you mean?' and we'd go back and forth, trying to define different elements or combinations of elements to distinguish over the prior art. Being pushed and questioned by Ben was the key to developing claims that really got to the essence of what was patentable about the solution," Kumar explained.

One important tool that Kumar recommended in developing a preliminary patent position was the USPTO Patent Application Information Retrieval system (or PAIR database), which allows users to access the status of current patent applications. "It gives you all of the history on what's gone on between a patent applicant and the patent examiner," he said. "By reading these interactions, you can see where applications have been rejected by an examiner, and for what reason. It shows you what claims were rejected, the prior art used in the rejection, and the rationale behind it. With Ben's help, I was also able to appreciate which of the many documents in the file for a given patent application really were significant. This information helped me to think more specifically about where Ben and I might expect push-back in the examination of our own applications, and it allowed us to realistically address these potential issues."

The company that Kumar founded around the IP that he worked on and licensed from Stanford became the foundation for iRhythm Technologies, Inc., based in San Francisco, California. In addition to developing the device and establishing the methods to use it, the company has continued to monitor the IP landscape to stay aware of salient new developments in the field and has also started to file additional patent applications.