Working For A Good Clause: Canadian University Negotiates Global Access Licensing Deal For A Drug Reformulation That Could Save Thousands Of Lives

University of British Columbia

Whenever Mommy and Daddy start talking about work, 6-year-old John Paul Wasan is quick to quip, “Oh, no! Not that science thing again!”

But the tedious dinner conversation that Ellen and Kishor Wasan’s son is so eager to change is actually about an exciting discovery—the reformulation of a drug called amphotericin B (Amp B) that could save the lives of many little boys—as well as men, women and children around the world. And its journey is filled with all the elements of a good children’s story—unsung heroes, Lady Luck and kinship working together to stand up for the underdog and fend off evil intruders.

Only in this tale, the “bad guy” is Leishmania donovani, an insidious parasite that invades white blood cells, infiltrates vital organs and can ultimately lead to severe infection and death. And the good guys are the researchers, university staff and students, and licensee of the technology that are working together to ensure that, if the promising new

"science thing" that the Wasans are working on pans out, it could impact patients dealing with systemic fungal infections and the more than 350 million people from 88 countries—most of whom are in the developing world—affected by a deadly parasitic disease that causes visceral leishmaniasis.

The Perfect Storm

The story starts, in part, with a small band of idealistic students at the University of British Columbia (UBC) in Vancouver, Canada. In 2005, they formed a chapter of the Universities Allied for Essential Medicines (UAEM), an organization that works with student and faculty groups across the U.S., Europe and Canada to construct new approaches to developing and delivering public health goods.

This fledgling group of approximately 20 students, many of whom were doing graduate work in life sciences and medicine, started its charge by approaching the University-Industry Liaison Office (UILO) at UBC to discuss ways to enhance global access to the university's technologies.

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Their timing was impeccable, according to Ian Bell, a technology transfer manager at UBC's UILO, because, as it so happened, the conditions were ripe for developing global access principles—guidelines for how the university provides global access to its technologies—and, eventually putting them into practice with a licensing deal that included a global access clause for Amp B.

"The licensing deal for Amp B was the result of a perfect storm in a way," recalls Bell. "Just as this group was forming on campus, we had an associate director, Barbara Campbell, who was more than willing to champion the cause."

Another stroke of luck, says Bell, was that the university had recently appointed a new president and vice chancellor—one with a keen interest in social justice—Stephen J. Toope, Ph.D., a former international law professor, with a strong human rights and humanities background.

"He was very open and receptive to the ideas," recalls Bell. "It meant that we could undergo a philosophical paradigm shift. We realized that while we couldn't sacrifice deals or shun traditional commercial avenues, we could still look at ways to go beyond that."

Campbell began work with the students to get the go ahead from the president's office before leaving for a new post as associate director of Industry Liaison and Innovation at Dalhousie University in Halifax, Nova Scotia, Canada. After about a year of writing and consultation with industry and university administration, UBC became the first Canadian university to formally adopt global access principles.

(A copy of "Principles for Global Access to UBC Technologies" is available on UBC's Web site at http://www.uilo.ubc.ca/global.asp.)

Family Fortunes

Meanwhile, serendipity was at work in UBC's lab. Kishor and his team had stumbled across something that they had thought was impossible: that Amp B, which he had been working with for more than two decades, could be reformulated from its current intravenous form to one that could be administered orally. This breakthrough would make the drug much more practical for treating two conditions: systemic fungal infections—which often afflict immunosuppressed individuals such as cancer and AIDS patients—and leishmaniasis—which is mostly prevalent in

India, Bangladesh, Nepal, Sudan and Brazil, but has cropped up in Mexico and the southern United States in the unsanitary conditions in the aftermath of hurricanes.

“Amp B is the gold standard,” says Kishor, “but it can only be given as an injection which is impractical for many people, such as those who live in remote villages. It also has some toxicity issues that means it must be monitored carefully. Since I had been involved in developing the parenteral drug during my graduate work, I was sure an oral form was impossible. ...It sounds like it would be simple, but the science is actually quite complex.”

With so much time invested in the drug throughout his career, Kishor was ready to concentrate on other projects. But then, a set of experiments in the Wasan lab using Amp B as a negative control resulted in the discovery of a new way to mix the drug with a lipid—and that put an oral formulation within reach.

The lab data looked so promising, says Kishor, that he knew he had to go back to work on Amp B. However, he needed a formulation specialist on board. That’s when Lady Luck stepped in again, only this time in the form of his wife, Ellen, who possesses just the right expertise. (Ellen Wasan, Ph.D., is an adjunct professor on the faculty of pharmaceutical sciences at UBC and on the faculty at the British Columbia Institute of Technology in Vancouver.)

“My wife says, ‘Oh no! You aren’t dragging me into another one of your projects, are you?’” laughs Kishor. “I’m a pharmacist by training and I had the animal models I needed, but what I didn’t have was someone to bounce ideas off of about the best formulations. And there she was, right next to me.”

Under the Right Conditions

With the promising results in hand, Kishor contacted the UILO, which was able to negotiate its first tangible licensing deal using the newly developed global access principles.

“Originally, we were all thinking along the traditional commercial path,” recalls Bell. “Our initial consultations led us to believe there might be hesitancy from industry in agreeing to these global access principles.”

But Amp B was different. Because it was already approved by the FDA and in use in its intravenous form, it was a lower risk technology. But, more importantly, it could be used to treat two conditions each in a separate market, and, thus it was an easier sell. As it turns out, however, it was not difficult to find a licensing company at all, in fact, in yet another twist of fate, the licensing company found UBC.

“I’m slightly embarrassed to say that it was one of our shareholders who introduced us to this opportunity,” admits Andrew Rae, president and chief executive officer of iCo Therapeutics, a Vancouver-based reprofiling company focused on redosing or reformulating drugs with clinical history for new and expanded indications. “He had heard about this technology and asked us to go out to the university and have a chat,” Rae continues.

That chat eventually resulted in iCo acquiring the worldwide exclusive rights to iCo-009, iCo’s oral formulation of Amp B, in May 2008. In return for the worldwide right to develop and sell the oral formulation in the developed world as a treatment for blood-borne fungal infections, iCo Therapeutics agreed to ensure the availability and accessibility of a suitable formulation to countries in the developing world to treat leishmaniasis.

“This is basically a win-win,” says Rae. “The fact that the product really only requires a candy-wrapper lipid and has

been tested and approved makes it lower risk and fits our business model. Plus, it is suitable for two noncompeting markets."

Further, says Rae, because one of those markets is the developing world, additional funding for the reformulation may be available from what he calls the super philanthropies, some of which are targeting neglected diseases. But it's not all about money, says Rae, the true value of the product lies in its potential to impact society, and the good will that results.

"There is a natural inclination in the health care industry to do well," says Rae. "As health care providers, we are proud to see products improve the quality of life."

A Chance of a Lifetime

And no one is prouder than Kishor, who is quick to point out that Amp B still has a ways to go before actually going to market. (The reformulation is currently undergoing preclinical testing in animal models, where it is showing a greater than 99 percent eradication of leishmaniasis.) However, it is possible to advance the formulation to market on an accelerated development schedule, given the existing safety data on Amp B. Still, Kishor says, he can't help but dream of a day when he can visit his parents' birthplace, India, and help his physician uncle actually administer the drug to some of the many people infected with the parasite in that country.

"I know I have been lucky," says Kishor. "It's such a unique situation that I fell into almost by mistake. But I am embracing the moment because this is such a wonderful opportunity to make a difference."

For now, says Kishor, that's enough to make his story have a happy ending. And maybe, just maybe, give millions of other people a chance to live out their happily ever-afters.

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