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### Zamboni says no conflict in applying for MS patents



Brett Gundlock/National Post Files

Tom Blackwell | Apr 2, 2011 – 7:00 AM ET | Last Updated: Apr 1, 2011 10:03 PM ET

The Italian doctor behind a furiously debated theory of multiple sclerosis treatment applied for several patents to protect his discoveries long before they became widely known, and has worked closely with a company marketing an MS ultrasound machine built according to his specifications.

Dr. Paolo Zamboni's patent requests and corporate connections add a new twist to what is often characterized as a clash between entrenched, Big Pharma interests and a scientific renegade with forward-thinking ideas.

The neurologists who traditionally treat MS patients have been among the harshest critics of the new hypothesis; Zamboni supporters accuse them of being blinkered to non-pharmaceutical alternatives, citing the funding many receive from drug companies whose products are currently the chief MS treatment. The Italian physician himself has said he was personally motivated to explore multiple sclerosis by his own wife's struggles with the illness.

Experts on intellectual property and bioethics say it is not unusual or unethical for academic researchers like Dr. Zamboni to apply for patents around their inventions, but note that it normally means the inventor or someone else wants to make money off the discovery, and suggest he should have pro-actively disclosed any commercial interests.

Many medical journals now require that study authors reveal patent applications around their research, as well as industry ties, a policy encouraged by the World Association of Medical Editors in its ethics guidelines. At least three of Dr. Zamboni's major MS papers list competing interests as "none."

"You would expect that if this was really being done in the public interest, that he would announce it. He would say, 'Yes, I have these patents, I obtained them on purpose, in order to facilitate access,'" said Richard Gold, an intellectual property expert at the McGill University law school.

"The fact he hasn't said anything and it was uncovered, it wasn't him who uncovered it, would indicate it's likely for profit, and one should question his motives in the same way one should question anyone's motives who is both publishing research and commercializing a product."

Medical scientists take out patents for a number of reasons, including simply to ensure that their discovery can one day be developed by a company and aid mankind, said Jonathan Kimmelman a bio-ethicist at McGill who specializes in ethics of health research. Accumulating patents can also bolster academic standing, he said. It's wrong to believe, though, that only drug company ties influence researchers, he added.

"I think it's an absolute error of reasoning to suggest there is no financial interest in non-pharmaceutical approaches to treating disease, including multiple sclerosis," said Prof. Kimmelman.

Dr. Zamboni, however, said it is "ridiculous" to suggest his patent applications and work with Esaote S.p.A., the ultrasound manufacturer, represent anything like the conflicts of researchers who receive money from drug companies.

Esaote has merely provided equipment to his lab and funded professional training, and he has no plans to commercialize the inventions described in the patents, he said in an emailed response to questions.

"Scientific passion is my more relevant conflict of interest," said the vascular specialist.

In fact, one prominent Italian neurologist who is highly skeptical of Dr. Zamboni's ideas dismissed as insignificant any commercial interests the surgeon might have. What is important is completing a slew of studies now under way that should answer whether the theories hold water or not, said Dr. Giancarlo Comi of Milan's San Raffaele institute.

Love for his wife gives Dr. Zamboni a "strong personal motivation," said Dr. Comi in an interview. "This is really more than any economic motivation."

Medicine has never pinned down the cause of multiple sclerosis but the prevailing theory is that it involves an auto-immune response, where the body's defences essentially turn on itself. Treatment now involves a range of drugs — which earn manufacturers billions of dollars a year — but their effectiveness is limited, and the side effects can be miserable.

Dr. Zamboni triggered a massive upheaval in the MS world with his theory that the illness is caused by a narrowing of veins in the neck, dubbing the condition chronic cerebrospinal venous insufficiency (CCSVI). That constriction, he said, causes blood draining from the brain to back up, creating iron deposits and setting off the brain inflammation that is key to the disease. He proposed using angioplasty, where a tiny balloon is threaded into the vein and inflated to open up the narrowing — or stenosis — and has published studies suggesting it works.

Glowing media coverage of Dr. Zamboni's findings in late 2009 caught the imagination of MS patients, even as their specialists warned that the evidence was preliminary at best. Hundreds of Canadian patients have travelled to foreign countries to undergo the so-called "Liberation" treatment, which is not available here, and many say it has transformed their lives. One Canadian man, though, died after a blood clot formed during repeated treatments in Costa Rica.

Those initial media reports talked of Liberation as a possible cure, and quoted Dr. Zamboni as saying it "could be a revolution for the research and diagnosis" of MS and that "I am fully convinced that this is very, very important."

In the two years before those reports, applications were filed for several patents covering Zamboni inventions at offices in Europe, the U.S., Canada and other countries.

One details a "system for diagnosing multiple sclerosis," which includes using a doppler ultrasound machine to detect blood flows and a personal computer to analyze the results. Others are for devices designed to better treat CCSVI, though some experts worry those inventions might increase the risk of internal bleeding and other complications.

In early 2010, just as excitement about the Zamboni ideas was building, Esaote, based in Genoa, Italy, launched MyLab Vinco, a doppler ultrasound system touted in the company's online brochure as "the only product designed for the diagnosis of CCSVI."

Mariangela Dellepiane, a spokeswoman for Esaote, said the company has worked with Dr. Zamboni and his centre for vascular diseases at the University of Ferrara for years, and developed MyLab Vinco according to his research. The firm pays Dr. Zamboni's centre to train its customers on use of the system, but provides no other payment linked to its sales, she said in an emailed response to questions.

Several of the clinics worldwide offering CCSVI diagnosis and Liberation treatment advertise that they have bought MyLab Vinco, stressing its connection to Dr. Zamboni.

Ironically, the largest stake in Esaote is held by Switzerland's Bertarelli family, which until a few years ago controlled the pharmaceutical giant Serono. Its top selling drug, with worldwide 2010 sales of \$2-billion, is Rebif, one of the MS drugs that Zamboni's supporters often decry. As well as Esaote, the Bertarellis' company — Ares Life Sciences — owns two drug firms.

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