

9. JACK A. SINGER

It was a typical clinic day in the small town of Randolph, Vermont back in June 1993, when a certified letter arrived from a lawyer in Washington, D.C. When I opened the envelope I thought I was having a bad dream. I simply could not believe what I was reading... that an ophthalmologist in Arizona was serving me with a lawsuit claiming patent infringement of a cataract incision method, and inducement of infringement for teaching the method to other eye surgeons. Samuel Pallin of Arizona was seeking, through litigation, royalties of up to \$10,000 per year which could be increased annually at his discretion, and damages for the thousands of surgeons that were using the patented incision as a result of my scientific presentations and publications. In addition, Pallin also sought an injunction to stop me from using the patented method. I had no prior warning to cease using and/or teaching the incision. On the contrary, my only communication with Pallin was a brief face-to-face conversation at an annual ASCRS meeting a few months after he received his patent. I asked him what he planned to do with the patent, and he replied that he had no intentions of enforcing it and was interested in donating it to a non-profit organization.

At the March 1990 ASCRS meeting in Los Angeles, while viewing Steven Siepser's 10 minute film festival video on an innovative technique called Radial-Transverse incision, I conceived of an incision method that would allow the insertion of any size PMMA IOL with single horizontal stitch closure and minimal surgically induced astigmatism. On March 20, 1990, one week after returning from L.A., I used the newly conceived incision, which worked perfectly. Postop keratometry was identical to preop keratometry following implantation of a 6 mm optic PMMA IOL. I knew that I had discovered something useful... nothing less than the elimination of the universal cataract surgery complication of surgically induced astigmatism! I immediately began a study to determine short and long term surgically induced

astigmatism using this incision with 6 and 7 mm optic PMMA IOLs. I also sent videotapes of my first two cases to Bob Osher for publication in his video journal, and submitted a brief article on the new incision method to Ocular Surgery News.

The incision that I had conceived and developed was basically a modified scleral tunnel that was curved opposite the corneal limbus. Since it appeared like a frown in the surgeon's view I named it the Frown Incision. Its configuration permitted watertight closure with one horizontal suture (an astigmatism neutral wound closure method described by John Shepherd for use with foldable IOLs), and acted like a suspension bridge that minimizes corneal flattening and against-the-wound astigmatism. It was not until January 1991 that I began using an internal corneal lip, described by Paul Ernest, which produced a watertight wound without a suture.

For the next 5 years I freely shared the Frown Incision with colleagues nationally and internationally at numerous symposiums, meetings, live surgery demonstrations, and publications. The first article I wrote was published in the August 1990 issue of Ocular Surgery News, and the Frown Incision video of my first case was published in the September 1990 issue of the Video Journal of Cataract and Implant Surgery. Other cataract incision methods were also published in the August 1990 issue of Ocular Surgery News, including an article from Pallin on the Chevron Incision which diverged from the corneal limbus in two linear segments. This was the first time I became aware of the Chevron Incision. Unlike the Frown Incision, Pallin claimed that the Chevron Incision was self-sealing without suture closure *and* without an internal corneal lip.

Although I was the only ophthalmologist in Randolph, Vermont when Pallin served his patent suit on me, I was employed by The Hitchcock Clinic, Inc., a multispecialty group of several hundred physicians, and worked full time in one of their regional offices doing business as Hitchcock Associates of Randolph. The Hitchcock Clinic Board of Trustees decided to defend the lawsuit as a matter

of principle, as it was seen to be a threat to the free exchange of medical and surgical knowledge. We believed that Pallin's lawyers were hired on a contingency basis. During depositions, it was clear that Pallin was unaware that I was employed by a large multispecialty group that had the resources and will to defend a costly patent litigation. Pallin made it clear that I was the first in a long line of eye surgeons to be sued for patent infringement. He claimed that all sutureless scleral cataract incisions infringed his patent, including those incorporating significant advances described by others before Pallin ever used or sought to obtain exclusive rights to the incision described in his patent.

The suit quickly became the focal point of a national debate over the patenting of medical and surgical methods, and catapulted me into the spotlight of an issue that goes to the heart of the way in which our society disseminates medical knowledge for the benefit of patients. In addition, such patenting has significant implications for containing health care costs.

The United States is virtually alone among industrialized nations in granting exclusive ownership of medical procedures by allowing patents on pure methods of medical diagnosis and treatment. This cataract/IOL incision patent litigation is believed to be the first infringement action involving one physician suing another to enforce a pure medical method patent. For the medical profession, therefore, it put a very real face on the previously theoretical risk of being dragged into court for performing procedures thought to be freely available. For the average physician, medical method patents suddenly became ticking time bombs, just waiting to explode into a patent infringement action at any time.

Most methods of medical treatment evolve through the collaborative efforts of many physicians. Freely shared ideas build upon one another and improvements are discussed openly in medical journals and conferences. Many popular techniques are discoveries of existing principles or a renaissance of previous methods.

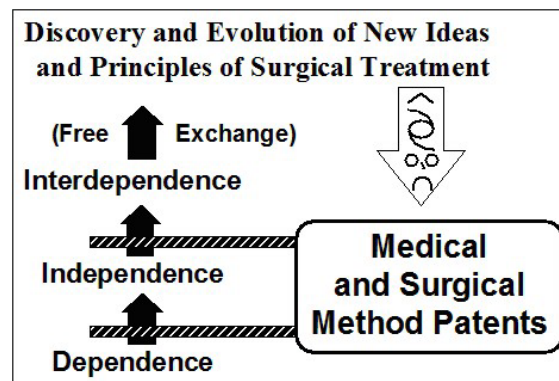


Fig. 1:

The following figure is worth a thousand words. It shows the maturity continuum of the *timeless way* of sharing medical and surgical knowledge, and the potential for abuse of the patent system when 'quote inventors' can skim off the vast pool of freely exchanged medical knowledge to claim ownership and exclusive control over new procedures that others have developed and previously shared freely with all qualified physicians. In short, the medical profession's culture of openness offers a virtual gold mine of free information for undeserving inventors to claim ownership of procedures developed by others who have chosen to apply the principles of Hippocrates and A.M.A.'s code of medical ethics.

Three years of my professional and personal life were largely consumed with defending this suit and working to preserve the free exchange of medical knowledge. I received an outpouring of support from colleagues and professional organizations, including the ASCRS and AAO. Following my testimony at the 1994 AMA Delegates Conference, the AMA Council on Ethical and Judicial Affairs prepared a detailed report which concluded that it is unethical for physicians to seek, secure or enforce patents on medical procedures. The ASCRS led a coalition of over a dozen medical specialty societies, including the American College of Surgeons, to lobby the US Congress for federal legislation to prohibit the enforcement of medical method patents. In October, 1995 ASCRS president Charles Kelman and I

testified before the US House of Representatives Committee on the Judiciary, Subcommittee on Courts and Intellectual Property.

In December, 1995 the ASCRS announced its commitment of significant financial and legal resources towards my defense of this patent infringement lawsuit as the case moved toward the trial phase. Esteemed colleagues Richard Kratz, I. Howard Fine, and Paul Ernest volunteered to serve as expert witnesses on my behalf. Drs. Fine and Ernest testified along with Pallin and I at a hearing in the Federal District Court of Vermont in March, 1996. That hearing concluded when a Federal Judge issued an order invalidating all of the patent claims at issue, and prohibiting Pallin from enforcing any aspect of the patent against any physician, health care provider, hospital, clinic, teaching institution or any entity or person of any kind. The Judge also declared that neither Hitchcock Clinic nor Jack Singer infringed the patent in any respect.

Pallin consented to this order after we presented overwhelming evidence that other physicians, including myself and many others, developed and used the patented incision before Pallin allegedly invented it. This baseless lawsuit was more than just a battle over a patent that never should have been

issued. Although the task of defending a patent infringement action seemed overwhelming, we felt compelled to defend the timeless principles of Hippocrates, and the free exchange of medical knowledge for the benefit of our patients and our profession. It seemed as if the sky were falling and we had the enormous task of holding it up. However, by defending this action we have effectively brought the issue of medical procedure patents to the attention of our profession, Congress and the public.

In October, 1996 federal legislation was passed prohibiting enforcement against physicians and their related health care entities of all medical procedure patents issued after the effective date of the legislation. Dr. Charles D. Kelman, President of ASCRS, hailed the enactment of the enforcement ban as a victory for patients. "This legislation will help ensure that new medical discoveries will be freely shared within the medical profession and widely available to our patients."

Just as the founding fathers of ASCRS fought for and gained acceptance of intraocular lens implantation 22 years ago, our resounding victory in this case should serve as an example of what can be achieved when we stand unified on principles which benefit our patients.