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Presentation Transcripts

INTELLECTUAL PROPERTY AND NANOTECHNOLOGY

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Editor's note: On February 28, 2003, The Journal hosted the Fourth Annual Intellectual Property Law Symposium. Dr. Newberger, an IP practitioner in all areas, has experience in preparing and prosecuting patents in areas such as carbon nanotechnology, fiber optic technology, field emission devices, and signal processing technology using wavelet transforms. The following is an edited transcript of Dr. Newberger's presentation.

It is a great pleasure to be here, and it has been a wonderful experience, starting with the dinner last night, as the previous speakers have noted. The speaker's gift is impressive, and I look forward to displaying it in my office.

My topic is nanotechnology and IP, which is a very broad topic. Selecting and choosing the subject matter, without knowing exactly who my audience was going to be, was an interesting task. And I hope my topic will be illuminating.

I am going to start out with a brief introduction to nanotechnology. Nanotechnology in general encompasses a wide range of concepts and individual perceptions may differ as to the "boundaries." Although nanotechnology is an emerging technology, there are things that fall within the general rubric of nanotechnology that are being commercially realized today. And they are important. There are also technologies that are on the horizon and I will mention some of those. And then, I will delve a bit into IP issues and nanotechnology, after all this is a symposium sponsored by the Intellectual Property Law Society and the Texas Intellectual Property Law Journal.

As a prelude, we heard this morning a very enlightening talk from Professor Louis Pirkey of The University of Texas School of Law, clearly one of this country's foremost experts in trademark law, about the doctrinal issues that are confronting the courts and practitioners in that area of intellectual property law. In contrast, there are no real doctrinal issues, certainly no burning doctrinal issues, in intellectual property protection and nanotechnology. But, there are interesting developments in the recent case law that bear the attention of practitioners, generally, but which may be of particular interest to practitioners working in emerging fields like ***650** nanotechnology. I will address these later in my talk. First, I will try to set the stage illustrating the current interest in nanotechnology.

What is the interest in nanotechnology? Why is it important? Probably high on the list is money. The sums that institutions, both public and private, are willing to invest are some measure, at least, of the importance of the subject. The National Nanotechnology Initiative (NNI), the federal government's "umbrella" nanotechnology program (which is within the National Science Foundation) invested $440 million in fiscal year 2001. The fiscal year 2004 budget proposal grows that to somewhat north of $700 million. And the current 2003 budget is about $100 million less than that. To put the numbers into a little bit of perspective--the annual budget in thermonuclear fusion research when I left the field to enter law school in 1994 was half the nanotechnology budget. That program supported several very large experimental facilities which have no analogue in nanotechnology at present, at least. So, the federal government is serious about nanotechnology, and, of course, money naturally attracts players in nanotech.

Another measure is IP activity. In 2001, the latest year for which I could find statistics, there were approximately 800 patents that had nanotechnology somewhere in the description or the title of the patent. So, the intellectual property protection in nanotechnology is important to those entities that are working in the field. That number is going to clearly go up, and, therefore, protecting intellectual property has to be on the radar screen of any entity, academic or private, that is working in the field. As an emerging technology, the opportunity for pioneering patents is now in. I will have more to say about that further down in my talk.

Let me now try to give some feel for what nanotechnology is about. Some people like to say it is what nature has been doing for billions of years, basically building structures on the molecular scale and larger, atom by atom. I think that is a bit narrow. In my opinion, a more practical definition is the application of science at the nanoscale. In particular, it is the application of science at the nanoscale that exploits the characteristics of materials that only just manifest themselves or become apparent at the nanoscale. In other words, characteristics that are particular to the nanoscale expression of materials. This definition paraphrases that which the NNI itself uses. Now "nano" is the prefix for a billionth, so the application of science at the "nanoscale," nanotechnology, is interested in the science and the application of that science to processes that are taking place on the scale of, say, 1 to 100 nanometers. That is a billionth of a meter up to one-hundred billionths of a meter.

I understand that is not very illuminating, and I will try to put that into perspective in a moment. And of course, there is the standard marketing hype, depending on whom you talk to, of nanotechnology as the "cure all." That is not surprising with perhaps $700 million at stake. But certainly, there are important nanotechnology applications, both now and in the future, that will improve computer display technology and the energy efficiency of batteries and fuel cells, either through lighter weight material or more efficient storage mechanisms. And researchers envision improved pharmaceuticals and medical procedures. Diagnostics and active research is ongoing in all these areas.

***651** Let me now return to the question of nanoscale in perspective. On the nanoscale scene, the human hair is enormous in size. [Editor's note: In the following, Professor Newberger makes references to a visual presentation.] It is 80,000 nanometers. That is an electron micrograph of somebody's hair. So, things on that scale are not nanotechnology by any stretch. Getting a little smaller is a human red blood cell--that's a scanning electron micrograph, a beautiful one from Utah State University.[1] 'The human red blood cell is about a thousand nanometers or one micro-meter. Again, that is large on the nanoscale. I am getting a little smaller going down by a factor of 10--that's an adenovirus. It is a hundred nanometers and now the first example that we have that is approaching the nanoscale. Viruses are organisms on the nanoscale. And continuing on the one nanometer scale-- probably the poster child, if you will, of nanotechnology and nanoscience--is carbon nanotube, which is about one nanometer to two nanometers in diameter. These are illustrations of the chemist's model of the carbon nanotube. These have been decorated with different proteins, I believe, in the three views. A carbon nanotube ("CNT") may be understood as a strip cut from single sheet of graphite and rolled into a tube until the cut edges join. The end caps are hemispheres of a carbon-60 molecule, commonly called a "buckeyball." By "cutting" the strip at different angles, different nanotube morphologies are produced and give rise to nanotubes with different physical properties, such as the ability to conduct electricity. This in turn makes CNTs an interesting candidate for applications in materials technology. The proteins have been attached to the outer surface of the nanotube. This is an example of one of the major areas of research--a kind of pioneering research--in which a substantial amount of intellectual property protection is being pursued: namely, how you attach things to carbon nanotubes without destroying the carbon nanotubes. The realization of nanotechnology-based therapeutics may turn on discoveries in this research. Solving the problem of attaching molecules, such as proteins, to carbon nanotubes is a step in developing CNT-based mechanisms for targeted delivery of pharmaceutical agents.

Now let's look at nanoscale materials in commerce today. In my view, this area of nanotechnology has been driven by new methods for reliably producing commercial quantities of nanoscale particles. Nanoscale particles have been around for a long time. The difficulty in commercializing them is producing them reliably and in controlled sizes. If fact, astronomical observations show nanoscale particles in the media between stars and galaxies but producing the whole spectrum of sizes from 10 nanometers up to the 1 micron scale. For commercial purposes, one needs to have controlled distribution of the sizes of the particles and in several areas that technology has been developed. One of the most intriguing to me--we are looking at nanosilver. That is a scanning electron micrograph of silver clusters. The typical diameter of those is about 22 nanometers. Silver has been known since the time of ***652** the ancients as an anti-microbial. Nanosilver is proving to be a highly superior form of silver as an anti-microbial agent. There are studies investigating its use in bandages to dress, for example, burn wounds. And they see superior healing properties, less pain to the patient on the change of the dressings, and other advantages. If that product is not on the commercial market now, I am sure it will be very soon. I understand Dr. Alan Bard, a professor of chemistry here at The University of Texas, has been involved in some of that research. And I first learned of this use of nanotechnology from him.

Also in the area of nanoscale particle production is a company here in Austin called Nanotechnology, Incorporated. I understand this company arose from work done at the UT Applied Research Laboratories here in Austin, and it is also producing nanoscale particles. This picture shows nanoscale aluminum, about 50 nanometers in diameter. Again, this is a kind of picture that only geeks can love and I put it here mostly to show the uniformity of the size of the particles. There is a great deal of interest in nanoaluminum to enhance propellants for projectiles, such as rockets and high explosives.

You are probably tired of seeing pictures of nanoparticles. This picture is titanium dioxide--well, not exactly titanium dioxide--but Ipanema Beach in Brazil, where the use of sunscreen is the order of the day. Now titanium dioxide is the pigment in white paint, not highly desirable as a sunscreen. But a company in Oklahoma City figured how to make nanoscale titanium dioxide. Now nanoscale titanium dioxide makes a great sunscreen. It is a very effective scatterer of UV radiation, but it is invisible because it does not scatter visible light very well. In July of last year, they sold that technology, its IP, to Dupont. Thus, there is room in this emerging technology for innovative startups with a solid IP portfolio.

Another example, again in the realm of new ideas and methods for producing nanoscale particles, is a chemist in California who came up with techniques for combining nanoscale synthetic polymers and polymers from natural textiles. These produce textiles that, for example, have the feel of cotton but are highly wrinkle and stain resistant. You have probably seen the ad, I think it is Dockers, where the guy takes off on a spree to Las Vegas for about twenty-four hours and reappears on his doorstep in a rather disheveled state--but his pants are in perfect condition. That is the product of NanoTex LLC, now acquired by the textile manufacturer, Burlington Industries.

Looking to the future, we have carbon nanotubes, the nanomaterial that my colleagues at Winstead are involved with. We have a practitioner in our Houston office who got his Ph.D. from Rice and came up with the technique in his dissertation for attaching molecules to the sidewalls of carbon nanotubes. I previously mentioned that attaching proteins to carbon nanotubes is a precursor to pharmaceutical applications. Again, the underlying issue here is producing commercial-scale quantities of these carbon nanotubes. This issue touches on the topic that Steve discussed so well in his talk. [Dr. Steve Nichols spoke at the Symposium on the topic of Technology Transfer. Dr. Nichols is an engineering professor at The University of Texas and an expert on design and manufacturing systems.] Carbon ***653** Nanotechnology, Inc. (CNI), is a company that spun out of Rice University. CNI has a pilot plant in Katy to exploit techniques for producing carbon nantoubes on a commercial scale, based on technology licensed from Rice University. Once commercial-scale sources of carbon nanotubes become available, a spectrum of applications becomes accessible. These include conductive plastics, advanced composites, displays that exploit the field emission properties of carbon nanotubes, and eventually, systems for the target delivery of pharmaceutical agents. An area that is receiving attention is the application of carbon nanotubes as a medium to store hydrogen as the preferred fuel to power fuel cells. One of the targets of President Bush's energy policy is a hydrogen-based energy economy.

These examples illustrate that nanotechnology has interesting applications today. What we are going to see in the near future--the two- to ten-year time frame--may well be the core technology, underpinning the gamut from a renewable energy economy to fundamentally new mechanisms for attacking diseases. Whatever the application, capturing the IP will be a necessary part of the process.

I now turn to the IP protection in the nanotechnology context. Of the traditional IP protection regimes--patents, trade secrets, copyrights, and trademarks--patents and trade secrets are the most germane. With respect to trademarks, branding issues are common to companies and businesses generally. There is nothing particular about that with regard to nanotechnology, and I will not discuss trademarks further. Similarly, copyright is not particularly relevant to nanotechnology IP. There may be an exception with respect to maskworks as applied to MEMS (micro-electromechanical systems). Although MEMS, in their own right, are an important area of technology innovation, they fall outside the common rubric of nanotechnology.

Trade secret protection of nanotechnology IP may be a viable option in some circumstances. Trade secret protection offers the advantages of avoiding the expense of preparing and filing patent applications, but it is not "free." It requires an investment to put into place trade secret protection policies and measures, and continuous diligence is required. Slip-ups can destroy your protection, and once it's gone, it's gone. Trade secret protection has the advantage of a potentially indefinite duration, subject to reverse engineering. I think in the environment in which nanotechnology is emerging, as I will discuss in a moment, I am not sure that the applicability of trade secrets is that great. But, it may be that in some circumstances, it may be suitable. I'm not really going to talk much about trade secrets because it is going to be fact-dependent. And really, I think the only potentially useful case is where you have a process where the real novelty is in the process and it is not really subject to reverse engineering.

Patents, are the primary regime for IP protection with respect to nanotechnology. Patents provide strong IP protection. The down-side is cost. It is expensive to prepare and prosecute patent applications. After issuance of the patent, there are maintenance fees. And as patent protection typically only obtains within the boundary of the issuing country, it may be desirable to seek foreign patent protection as well. This can increase the cost of IP protection substantially.

***654** Unlike other technologies that have been recently emergent, there are no doctrinal issues that need to be worked through. Nanotechnology falls squarely within the present, and indeed historical, IP protection regime. By contrast, the emergence of computer software technology, and then the Internet starting in the 1980s through the dot.com era, raised doctrinal issues particularly in the area of patentable subject matter. Software itself was not an emerging technology, and computer programming in high-level languages for scientific and business applications had been around for thirty years or more. And as the technologies emerged, the doctrine evolved. With respect to nanotechnology, we are talking about products in the traditional sense, items of manufacture, and processes of manufacturing nanotech-based materials.

What makes IP issues interesting with regard to nanotechnology? My take on it lies in the mix of players here and the substantial government presence, particularly the federal government. This also gets to the heart of the topic that Steve was talking about so eloquently and really drives home the point well. We have a mix of players, and a lot of the interesting nanotechnology is rising in academia. Government is the 800-pound gorilla here, because they've got the money and everybody is going to be playing for it. I tried to do a quick mental calculation from one of Steve's viewgraphs on the fraction of UT sponsored research that came from the federal government. It is clearly the majority of the funds that they get--I am going to estimate 60% or 65%. And in nanotechnology, that is going to be major driving force, I submit. Some fraction of the new ventures in nanotechnology, and perhaps a significant fraction, will be companies that are spun out of academic institutions in the way that Steve described. Nanotechnology arising in academia certainly have significant impact on Winstead's IP practice in this area.

The emergence of a new technology, a pioneering technology, creates issues and opportunities in perfecting IP rights. The absence of prior art affords the opportunity for broad patent protection. On the other hand, patent examiner inexperience complicates focusing issues early in prosecution. And the mix of players also affects IP protection strategies. For example, the focus in the academy has historically been, and remains, on early disclosure. Steve clearly pointed out publication, and not patenting, is the traditional measure of academic performance and a necessary component in the preparation of graduate students. Nevertheless, as Steve so well described in his talk, universities are now focusing attention on the importance of university-generated intellectual property. In the present budget-tightening climate, IP represents a potential source of revenue. Generally, the private sector has been more concerned with IP protection; however, there is a tension between maintaining confidentiality pending the filing for patent protection and the need to raise capital. With government participation, particularly as a source of research and development money, disclosure issues may also arise. Additionally, government participation may implicate other issues in view of recent case law with respect to the experimental use of patent technology. I will discuss each of these further.

In an environment where early disclosure of research results is important, the tension between these requirements and the necessity to avoid the preclusion of IP ***655** protection is apparent. The academy is a paradigm of such an environment. "Publish or perish" is still the name of the game. The ultimate reward for a researcher is predicated on the rapid and wide distribution of research results. When I was in academia and actively participating in research, the pressure was to write things up and distribute them to your colleagues. Part of your measure of performance is how many times your work is cited by somebody else. So researchers want to distribute their work widely. Obviously, in such an environment, reliance on trade secrets is of no value.

When dealing with academic clients, which we do in our nanotech practice, it is important that the institution have in place IP policies and procedures. In particular, mechanisms to ensure that researchers, the generators of IP, are cognizant of the need to protect the IP must be implemented. Additionally, mechanisms that facilitate early interaction between researchers and IP counsel are advisable. These policies also need to be harmonized with institutional policies and procedures respecting sponsored research. In particular, this arises in the interplay between government sponsorship and IP ownership.

Under the Bayh-Dole amendments to the Patent Act, small business entities and non-profits like universities can retain IP ownership rights in federal government sponsored research.[2] Acquisition of these rights requires that certain formalities be complied with. The government, however, retains a royalty-free license to any patented technology, and for reasons to be discussed, this may be beneficial in view of recent case law. Also, the institution must be cognizant of reporting requirements that are part of the sponsored research. These could raise disclosure issues, depending on the manner in which such reports are disseminated. For example, one issue is whether the reports will be maintained in confidence.

IP policies and procedures must reflect these considerations. The emergence of nanotechnology as a major national research initiative sharpens these issues as institutions--historically not primarily research institutions--become participants in this initiative.

In the private sector, the need to raise capital can impose its own pressure to disclose. Ideally, such disclosure may be protected by confidentially agreements. However, as a practical matter, securing such agreements from sources of capital may be difficult in some circumstances. Because IP may be a nanotechnology company's primary (if not its only) asset, getting external funding may require the disclosure of that IP.

One strategy that we have been using makes use of provisional application filings in conjunction with international applications under the PCT. Provisional applications may be used to balance the preservation of IP rights against pressures, driving early disclosure. The care you have to take here, and it should be no surprise, ***656** is that the provisional applications provide enabling disclosure. Provisional applications have to satisfy the requirements of 35 U.S.C. § 112, first paragraph. This may be more critical if you are looking at a retrospective filing. In other words, when a public disclosure of IP is pending, suppose the client sent a report to a funding agency and that report is going to be publicly available. To prevent that from being used against you as prior art, a provisional patent application may be filed. In a new field such as nanotechnology, there may be little prior art, and your own work may be the best art with respect to your later-developed IP. Consequently, diligence is required to preserve your IP rights. However, if the provisional does not satisfy the requirements of Section 112, first paragraph, with respect to the later claimed subject matter, you cannot rely on that filing to claim priority. At least, the provisional application should include the documents to be disclosed, on the ground that such a provisional can be no less enabling than the disclosed material itself. (In a pioneering field such as nanotechnology, obviousness rejections may be more difficult to sustain.) In particular, with respect to retrospective filings, support in the provisional for later claimed subject matter is essential. This is driven home in the recent decision in New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.[3] in which claims in a utility application were held to be unsupported by the disclosure in a provisional application, invalidating the claims because of sale of the claimed device prior to the filing of the provisional.[4] Consider filing multiple provisionals as the subject matter is further developed, or to make sure that you have the coverage needed. A utility application may rely on multiple provisionals, provided the utility is timely filed based on the earliest provisional relied upon.

Although I have focused primarily on issues respecting the protection of IP, given my practice as a prosecutor, IP enforcement issues may also be on the horizon as nanotechnology patents, broad in scope, are issued. While litigation issues in general are not particular to nanotechnology, the breadth of the field, and the opportunity for broad patent coverage, may create a tension between the monopoly rights of the "first comers" and ongoing research in the field. A recent decision in the Federal Circuit may be particularly troublesome. In Madey v. Duke University,[5] the Federal Circuit made clear that to the extent an experimental use defense[6] to patent infringement existed at all, that defense was very narrow.[7]

***657** By way of background, Dr. John Madey was a Professor at Stanford University and a pioneer in the field of free electron lasers (FEL).[8] Madey moved to Duke University in 1988 and continued his research there until he and Duke had a falling out. However, while at Stanford, Madey obtained sole ownership of several patents directed to FEL-related technology that were, allegedly, practiced by certain equipment in the FEL laboratory at Duke.

In the court below, among other defenses, Duke asserted the experimental use defense.[9] In remanding on this issue, the Federal Circuit held that the use cannot further the alleged infringer's legitimate business and must focus on whether the use was "solely for amusement, to satisfy idle curiosity, or for strict philosophical inquiry."[10] Under this standard, it is doubtful very much is left of the experimental use defense, as a practical matter. This may be a haven for the garage experimenter, but few others.

Nevertheless, there may be another avenue available to provide a shield in some circumstances. In its defense, Duke also asserted that, in effect, it had a license to practice the patents at issue on the government's behalf, in view of the government's rights in the patents and the use of the allegedly infringing devices in the performance of government sponsored research.[11] The Federal Circuit left this issue open in view of the lack of a record on appeal respecting this issue, noting that the parties could develop the issue on remand.[12] The "government license" defense may be particularly helpful to nanotechnology researchers in view of the substantial level of government sponsorship of nanotechnology. Recipients of government grants and/or contracts for nanotechnology research should, to the extent possible, expressly seek to claim as a third party beneficiary any rights retained by the government in patents springing from government sponsored research. Of course, this sword is double-edged--any IP rights secured under government sponsorship would be subject to the same "government license" defense to infringement.

In summarizing, I have tried to convey a sense that nanotechnology is an emerging technology with exciting prospects for IP, in both the near term and for many years into the future. The importance of IP and securing IP rights are recognized by the players, and the mix of players--particularly the role of government sponsorship, combined with the ever present time and cost constraints--may shape strategies for protecting nanotechnology IP.

Footnotes

[a1] Winstead Sechrest & Minick P.C.; B.S., Carnegie Mellon University; Ph.D., Princeton University; J.D., The University of Texas School of Law.

[1] William McManus, Red Blood Cell (image), at http:// bioweb.usu.edu/emlab/Galleries/animals/red%20blood%20cell.html.

[2] Codified at 35 U.S.C. §§ 200-212 (1994).

[3] 298 F.3d 1290, 63 U.S.P.Q.2d (BNA) 1843 (Fed. Cir. 2002).

[4] Id. at 1295-97, 63 U.S.P.Q.2d at 1846-48.

[5] 307 F.3d 1351, 64 U.S.P.Q.2d (BNA) 1737 (Fed. Cir. 2002).

[6] The experimental use defense to infringement should not be confused with the experimental use “exception” to anticipation under 35 U.S.C. §102. The experimental use defense may be analogized to a “fair use” defense, albeit a very narrow one. For a brief history of this defense, see Roche Prods., Inc. v. Bolar Pharm. Co., Inc., 733 F.2d 858, 862, 221 U.S.P.Q.2d (BNA) 937, 939 (Fed. Cir. 1984).

[7] Madey, 307 F.3d at 1361, 64 U.S.P.Q.2d at 1745.

[8] FEL is a device for producing intense electromagnetic radiation, typically in the infrared or visible spectrum.

[9] Madey, 307 F.3d at 1355, 64 U.S.P.Q.2d at 1741.

[10] Id. at 1362-63, 64 U.S.P.Q.2d at 1747.

[11] Id. at 1363-64, 64 U.S.P.Q.2d at 1747-48.

[12] Id.