

Rx

for Risk

In this Issue...

RECENT PATENT CASES OF NOTE

Patent cases that reach the U.S. Supreme Court and the Federal Circuit Court of Appeals bear close watching by the medical technology industry, as they can have long-term and wide-ranging implications. In our main feature, James Hill, MD, JD of McDermott Will & Emery LLP reviews three recent cases of note.

EARLY REPORTING WORKERS' INJURIES HELPS BOTH EMPLOYEE AND COMPANIES CONTROL COSTS

Given the challenges of the economy and the cautionary outlook for the workers' compensation industry, many CFOs are looking to reduce costs while maintaining appropriate insurance coverage and employee health and satisfaction. Using a strategy of timely reporting of claims, directing care for employees, and engaging in return-to-work programs, they can save money on insurance and give injured employees a better experience.

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UPCOMING EVENTS

September 16-18, 2009
BioPharm America 2009
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<http://www.ebdgroup.com/bpa/>

The Courts Weigh In: Recent Patent Cases Affecting Medical Technology Companies

by James Hill, MD, JD

In the last year, the U.S. Supreme Court and the Federal Circuit Court of Appeals – the appeals court for American patent disputes – decided a number of important cases that affect medical technology companies that own or license patents or that may be accused of infringing someone else's patent. Below is a summary of three of those cases. *(Editor's note: To learn more about these cases, please click on the embedded links.)*

When does a court have jurisdiction to determine a patent is invalid or not infringed?

Prasco v. Medicis Pharmaceutical¹

Bottom line: For a court to have jurisdiction to issue a *declaratory judgment* that a patent is invalid or not infringed, a company accused of infringing the patent must show it sustained an injury that is actual, concrete, or imminent.

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Viewpoint:

Early Reporting Workers' Injuries Helps both Employee and Companies Control Costs

by Joseph Coray

The cost of workers' compensation insurance, both premiums and losses, continues to be a significant component of the risk management expenses for medical technology and life sciences companies. Indeed, over 1.7% of total compensation costs go to workers' compensation premiums. Given the challenges of the economy and the cautionary outlook for the workers' compensation industry many CFOs are looking to reduce costs while maintaining appropriate insurance coverage and employee health and satisfaction. Using a three-part strategy of timely reporting of claims, directing care for employees, and engaging in return-to-work programs, they can save money on their insurance and give their injured employees a better experience.

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The Courts Weigh In: Recent Patent Cases Affecting Medical Technology Companies

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Details: If you're concerned your company may be infringing a patent, you have two alternatives: (a) wait to be sued for patent infringement by the patent owner, in which case your company is the defendant; or (b) sue the patent owner first, asking the court to render a declaratory judgment that your company does not infringe the patent or that the patent is invalid. In case (b), your company, the accused infringer, is the plaintiff. (A third choice, asking the Patent Office to reexamine the patent so as possibly to invalidate or narrow its claims, is available to you regardless of whether a lawsuit is filed.) But federal courts, having sole jurisdiction in patent cases, cannot hear every case in which a company thinks it may infringe, or wants to invalidate, a patent. The U.S. Constitution restricts federal courts to act only in instances in which there is justiciable case or controversy that arises under the Constitution, the federal laws of the United States, or its treaties.

The facts in this case are these: Prasco filed a declaratory judgment action against Medicis Pharmaceutical, seeking a declaration that one of its products did not infringe patents owned or licensed by Medicis. Medicis made and sold an acne medication called Triaz, and Prasco made a competing product, Oscion. Prior to this suit, Medicis did not know about the Oscion product. Instead, Prasco based jurisdiction for its declaratory relief action based on (1) Medicis having marked its Triaz product with patent numbers, and (2) Medicis having previously filed a patent infringement suit against Prasco and others on another patent covering an unrelated skin care product. Furthermore, after filing the suit, Prasco sent Medicis a sample of Oscion with an ingredient list and asked Medicis to provide a covenant not to sue. Medicis refused, and Prasco amended its complaint to allege this refusal.

The district court granted Medicis' motion to dismiss the suit for lack of jurisdiction. The Federal Circuit affirmed the decision on appeal, holding that for declaratory judgment jurisdiction to exist, a dispute between parties must be "definite and concrete," "real and substantial," and have sufficient "immediacy and reality." To meet these requirements, an accused infringer must show it suffered an injury that is not merely hypothetical. Moreover, the injury cannot rest on a plaintiff's mere subjective perceptions; rather, it must be traceable to the defendant's conduct.

The court found accused infringer *Prasco had not suffered a real and concrete injury*. The mere existence of potentially adverse patents may create a fear of future harm, but subjective fear alone does not constitute an actual injury, the court said.

When does a method of doing something constitute patentable subject matter?

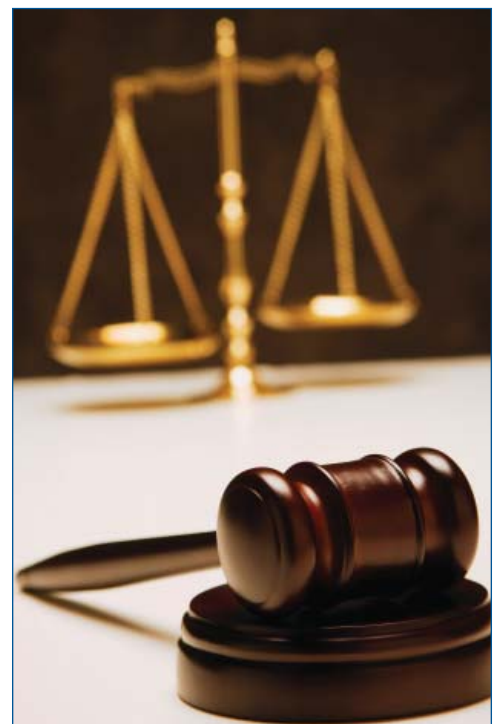
*In re Bilski*²

Bottom line: The "machine-or-transformation" test for subject matter eligibility of process (method) claims in a patent now applies. This test

requires that a method either (1) be tied to a particular machine or apparatus, or (2) transform a particular article into a different state or thing.

Details: U.S. law defines patentable subject matter as any new and useful process, machine, manufacture, or composition of matter.³ Under prior case law, if an invention fell into one of these categories, it was deemed patentable subject matter unless it fell under one of the Supreme Court's exceptions: laws of nature, natural phenomena, and abstract ideas. Some software and business method claims have been challenged as being mere abstract ideas and therefore unpatentable.

Previously, courts used numerous tests to determining the subject matter eligibility of patent claims. One test involved determining whether a claim recites a mathematical algorithm that is applied to physical elements or process steps. Another test required the claim to produce a useful, concrete, and tangible result. The facts: *Bilski* filed a patent application



¹ *Prasco, LLC v. Medicis Pharmaceutical Corp.*, 537 F.3d 1329 (Fed. Cir. 2008).

² *In re Bilski*, 545 F.3d 943 (Fed. Cir., 2008).

³ 35 U.S.C. § 101.

The Courts Weigh In: Recent Patent Cases Affecting Medical Technology Companies

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for a method of hedging risk in commodities trading. During examination by the Patent Office, the examiner rejected the application's claims as not directed to patentable subject matter because they were not implemented on a specific apparatus and were not directed to "technological arts." The Board of Patent Appeals upheld the rejection, finding that the claims did not involve a patent-eligible transformation, were directed to an abstract idea, and did not produce a useful, concrete and tangible result.

On appeal, the Federal Circuit also held that the claims were not directed to patentable subject matter, using a different rationale: The claims failed the machine-or-transformation test. The Federal Circuit left it for lower courts to work out the details of this test in the future.

Affecting patents in biotechnology, software, and business methods, *Bilski* is now on appeal to the U.S. Supreme Court.

Can a court issue a permanent injunction ordering a defendant not to sell a product that infringes a patent, if the patent's owner has already licensed the patent to other competitors?

*Acumed v. Stryker*⁴

Bottom line: Even if a patent owner has previously been willing to license its patent to other competitors, a new infringer may nonetheless cause irreparable harm to the patent owner. This irreparability is a key factor in persuading a judge to issue an injunction.

Details: In *eBay v. MercExchange*, the U.S. Supreme Court in 2006 held that a judge may grant a patent owner a permanent injunction against an infringer only if four conditions are met: (1) the patent owner has suffered irreparable harm; (2) money damages alone are inadequate to compensate for the harm to the patent owner; (3) the balance of potential hardships between the parties, if an injunction issues or not, warrants issuing the injunction; and (4) the public interest would not be harmed by the injunction.⁵

The facts: Acumed sued Stryker for allegedly infringing Acumed's patent on a nail for treating bone fractures. The jury found Stryker willfully infringed certain valid claims and awarded Acumed lost profits and royalty damages. The district court also granted Acumed's motion for a permanent injunction against Stryker.

The Federal Circuit affirmed. On the first two *eBay* factors – irreparable harm and lack of adequate money remedy – Stryker argued that prior to the lawsuit, Acumed had licensed its patent to two competitors. This demonstrated that Acumed would not suffer irreparable harm and that a royalty was an adequate remedy, said Stryker.

The court disagreed, finding that a patent owner's past licensing to others may indeed indicate to a court that a royalty also paid by a current infringer would adequately compensate for its patent infringement. This factor would

weigh against issuing an injunction. But past licensing behavior is insufficient by itself to establish a lack of irreparable harm to the patent owner, and this harm favors issuance of the injunction. A new competitor entering the market and infringing the patent may produce irreparable harm to the patent owner that prior licensees did not.

Acumed suggests a patent owner may license its patents to some competitors and nevertheless seek permanent injunctions against others.

Patent cases that reach the U.S. Supreme Court and the Federal Circuit Court of Appeals bear close watching by the medical technology industry, as they can have long-term and wide-ranging implications. Look for summaries of high-profile medical technology court cases in upcoming issues of *Rx for Risk*.

About the Author:



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James W. Hill is a partner in the law firm of McDermott Will & Emery LLP, based in the Orange County, California office. James is a member of the Intellectual Property, Media & Technology Department and focuses his practice on patent prosecution and litigation, strategic counseling, intellectual property due diligence and licensing in the areas of medical devices, biotechnology, pharmaceuticals, software, and signal and imaging processing.

⁴ *Acumed LLC v. Stryker Corp.*, 551 F.3d 1323 (Fed. Cir. 2008).

⁵ *eBay, Inc. v. MercExchange LLC*, 547 U.S. 388 (2006).

Viewpoint:

Early Reporting Workers' Injuries Helps both Employee and Companies Control Costs

(Continued from Cover)

Just the Facts

Let's review some information on the state of the workers' compensation market from NCCI Holdings, Inc., the nation's largest research and rating making organization supporting the workers' compensation industry.⁶ NCCI reported that 2008 accident year combined ratio, defined as incurred losses plus expenses divided by earned premium – is 100%, meaning that the workers' compensation industry as a whole is breaking even in this underwriting cycle. However, the cycle itself is entering a period of uncertainty as medical costs and indemnity claim costs rise faster than wages. In fact, the average indemnity cost per lost time claim rose to over \$20,000 in 2008 versus \$17,000 in 2002. In this scenario of a weaker economy, lower total payroll and higher cost of claims, there will likely be pressure to increase rate per payroll and ultimately the price of insurance in order to balance the cost of workers' compensation insurance. In the competitive world of medical technology, CFOs of life sciences companies do not want to pay more for workers' compensation insurance than necessary. Thus, implementing some cost management practices which can contain or even reduce the cost of claims can help mitigate the expense of this insurance. Just as most medical technology companies take steps to prevent injury, it is equally important to control claim costs. Below are three actions which can help in this endeavor.

Implement an Early Reporting Process

First, life science companies can implement an early reporting process. The quicker a company reports workers' compensation injuries to their insurance carrier, the lower the claim costs are likely to be. In a five year study, The Hartford Financial Services Group, one of the nation's top providers of workers' compensation insurance, found that claims filed a month or more after the injury occurred cost an average of 32% to 48% more to settle than those reported in the first week. The study reviewed over 41,000 lost time resulting from injuries typical to a medical technology company – back injuries, carpal-tunnel syndrome and other nerve disorders, and miscellaneous injuries other than open wounds, fractures, and dislocation. The Hartford's analysis showed that reporting these types of claims within the first week saves money in both medical costs, as well as lost wages, since prompt reporting initiates the appropriate treatment sooner. This includes offering case management services which assist the injured employee in gaining access to treatments and medications as appropriate. Many larger businesses do report worker injuries quickly and have established injury reporting protocols as part of their employee health and safety practices. However, smaller business, including emerging growth life science companies, often have fewer worker injuries and are less likely to have an early reporting procedure in place. This offers an opportunity for improvement.



Most workers' compensation insurers have procedures to help insureds report claims quickly and easily. Most employers require that any workplace injuries be reported to the employee's supervisor and through communication protocols to human resources or risk management staff who notify the insurers. While reporting injuries can be completed through fax or website, the most reliable method is simply calling the insurer using their toll-free claims service number, which in most states has to be posted in the workplace. Prior to calling the insurer to report a workplace injury, the employer should gather some pertinent information which allows the insurer to understand the incident and effectively manage the claim, including the care of the employee. Account information, including policy number and location, are very helpful to quickly confirm coverage. Additional

⁶ See summary of proceedings at <https://www.ncci.com/nccimain/Events/MinutesPresentationsMaterials/Pages/NewsfromAIS09.aspx>

Viewpoint: Early Reporting Workers' Injuries Helps both Employee and Companies Control Costs

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information about the injured worker, such as name, address, age, phone number, etc., allows the carrier to make prompt contact with the employee or their family. Further, providing pertinent details of the incident, such as when the accident occurred, how it occurred and was reported, what type of injury, etc., facilitates the investigation process. Small business owners can get assistance in establishing an early reporting process from their workers' compensation carrier.

Use Preferred Medical Network Providers

Second, using preferred medical network providers often supports the injured employee's treatment while containing costs. Medical expenses account for over 54% of workers' compensation claims costs. Many insurers work closely with nationwide networks of healthcare providers in handling workplace injuries and helping injured employees get back to work. Network healthcare professionals are experienced in treating work-related injuries, often having multiple specialties and services in convenient locations with easy accessibility, including diagnostic, therapeutic and pharmacological services. Negotiated network discounts allow insurers to provide the best care for every healthcare dollar. Many states allow employers to direct employees to specific healthcare providers for treatment of work related injuries. In addition, most carriers employ healthcare professionals for case management and quality audits to support the injured employee, as well as regular billing reviews as part of their approach to comprehensive claims service. Such practices, combined with network providers, reduce ultimate costs of claims significantly. Life sciences companies are encouraged to ask their insurers and agents for information on their provider networks and case management.

Establish a Return-to-Work Program

Finally, life sciences companies, large and small, should consider a return-to-work program as part of workers' compensation cost management. A return-to-work (RTW) program aims to get injured employees back to work in the shortest time possible, increasing productivity, employee morale, and reducing overall claims costs. On average, the cost to employers of employee lost time is \$81 per day. And studies have shown that injured employees who are out of work for more than 12 weeks have less than a 50% chance of ever returning to work. Since the length and resulting cost of a claim can have a significant effect on future premiums, it is vital to help injured employees get back on the job as quickly as possible and as soon as medically appropriate. Components of successful RTW programs include early collaboration between the injured employee, the employer, the healthcare providers and the insurer. This teamwork approach focuses on regularly assessing the health of the employee and identifying and offering transitional work which is both productive to the life science company and engaging to the employee returning to their job. Employees who feel valued are more productive, dedicated and likely to deliver quality results which can contribute to a win-win situation for all parties involved. It is always better for an employee to return to their same job, yet this is not always possible given the situation



of the injured employee. However, if an employer can offer suitable transitional work, the employee is more motivated to recover and to do so more quickly. Smaller companies may have more challenges in identifying and providing meaningful transitional assignments, however, most workers' compensation carriers have vocational or ergonomic specialists who, working with case managers and network healthcare providers, can assist the employer in designing and creating transitional work opportunities.

Start Your Three-Part Strategy to Reduce Workers' Compensation Expenses Today

Given all the challenges of the present economy for medical technology or life sciences companies, managing the costs of workers' compensation can seem overwhelming. Through working with their insurer and agent, most companies can reduce their costs using a three-part strategy of implementing early reporting procedures, utilizing medical provider networks, and offering early return-to-work opportunities. This approach can benefit the company through lower insurance premiums while supporting the health and well-being of their employees. For more information on this topic, please contact The Hartford at medtechlifesci@thehartford.com.

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ALLIANCE Q&A:

Q&A with Fran Stockwell, Chief Underwriting Officer, Medmarc

In this interview, we speak with Fran Stockwell, Medmarc's Chief Underwriting Officer about developing customized insurance solutions for life sciences and medical technology companies, both large and small.

Q: Medmarc works with small, emerging companies all the way to multi-national organizations. How do these companies differ from your perspective?

A: Since our founding 30 years ago, Medmarc has worked with companies from the very smallest emerging start-ups to large multinational organizations. We have an impressive "membership roll" across that entire spectrum. Having been with Medmarc for over twenty years now, I've been able to witness the remarkable growth of some of our policyholders – from \$10 million in revenue years ago to being multi-billion dollar companies today. That kind of success requires skillful maneuvering around and through many business obstacles.

Our largest clients have upwards of 50,000 products in their portfolio. In these cases, it's critical for Medmarc to understand the blend of risk these companies are facing, on both the liability side as well as the "people" side of the business.

Having dealt with so many companies and products, I can draw upon that experience to predict possible claims and the lost cost that these companies may confront. In addition to that, we have to learn the personality of the company and appreciate and respect what their tolerance for risk is. Once we understand that, we find out what makes them most comfortable and begin the process of putting together a program and service plan.



Q: What kind of pressures are these large companies facing?

A: Large companies are trying to achieve steady growth. They have demanding shareholders and they need to demonstrate value. And of course, they have to be able to invest enough in R&D to maintain a strong pipeline of innovative products.

Large companies also have to worry about threats to their reputation and their products' reputations – as large companies that sell many products, they are more often targeted by plaintiff's attorneys. When a claim happens, it can be a major distraction to the executive team, can be very expensive, very disabling, even to the point of threatening corporate existence. When this happens, Medmarc works aggressively on behalf of the policyholder to protect both financial well-being and the corporate reputation so that we can help the company maintain market confidence.

Q: In contrast, what do you have to keep in mind when you work with small, emerging companies?

A: Small companies are often trying to preserve cash and are very focused on clinical research and creating momentum – and they want to avoid any interruption to that momentum. They often don't want to get distracted about things that may not appear to pay immediate dividends such as loss prevention efforts.

For these companies, time is of the essence. They may have only one product and they face intense competition. They've got to outsell the larger, more established companies. As a result, we need to be incredibly responsive and move quickly when putting together a coverage plan.

Q: What are some of the milestones that small companies will pass through that would trigger the need to re-evaluate coverage or how they approach risk management?

ALLIANCE Q&A: Q&A with Fran Stockwell, Chief Underwriting Officer, Medmarc

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A: Certainly graduating from a clinical trial stage to new product launch. This is a time when we have to reassess the exposure to loss. When companies are in this phase, they have a great deal of zeal and sometimes rush to ramp up product sales. We keep a close watch on things like recruitment and hiring of a sales force and how they will be trained, and how hospital staff are trained on the use and care of equipment. When a product is about to launch, we focus on how the sales staff trains the technicians in the operating room. We advise companies on off-label use that might occur and what to do if a product is used for an indication or application for which it wasn't approved.

Another milestone would be a merger or acquisition or any significant reorganization within a company, as that may signal a change in focus. Similarly, if a company is migrating from a medical disposable enterprise into something more invasive or into therapeutic products, or expanding in terms of geography – that requires our attention.



When a company begins manufacturing a product, we have to pay close attention to and advise on contractual risk transfer – whether it be hospitals as the end-use consumers of products, wholesale distributors, or the suppliers of component parts.

For large companies, post-marketing surveillance is critical. It is a focus of the FDA and we watch very closely the diligence and ability of companies in managing adverse event reporting.

I would add that in all of these cases, our network of brokers contribute important client-oriented perspectives which serve to strengthen the communications link between our policyholders and Medmarc underwriters. The brokers are a first-line information source for tracking the evolution of our policyholders and assessing loss exposures. With their constant vigilance, our policyholders stay well-informed on matters that may impact their insurance and risk management objectives.

Q: Why should life sciences and medical technology companies consider Medmarc for their product liability needs?

A: Our staff is very experienced, very knowledgeable about the diversity of companies and products in this industry and the history of prior problems

and claims these companies have faced. We understand how coverage and risk management solutions vary depending on the size of an organization. This perspective and expertise allows us to provide unique, well-informed advice and offer the kind of analyses that our clients need to successfully navigate through the regulatory and legal liability environment.

Best efforts may not always result in avoidance of a claim or the elimination of a product recall. Our goal is to prepare policyholders so that if something does happen, they can emerge with less expense, less downtime, and an intact reputation. If a claim does happen, we are better positioned to address the situation and help companies through it.

Having been founded by the industry, we are committed to a stewardship role, we consider ourselves to be guardians of the industry.

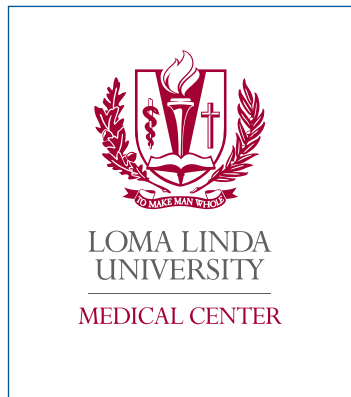


Fran Stockwell is Medmarc's Chief Underwriting Officer. His responsibilities involve the establishment of risk selection and pricing criteria, supervision of policy language design and modifications, oversight of foreign insurance placements as well as account management responsibilities for several key client relationships. Mr. Stockwell has been a commercial insurance underwriter for over thirty years. Fran can be reached at fstockwell@medmarc.com.

Industry Insights:

Editor's note: In celebration of Medmarc's 30th anniversary, this edition of Industry Insights highlights two of our long standing policyholders – Loma Linda University Medical Center and KOL Bio-Medical Instruments.

Protecting Leading Edge Technology at Loma Linda University Medical Center



Mark Hubbard, Vice President
Loma Linda University Medical Center

Loma Linda University Medical Center is a large tertiary teaching facility with over 900 beds providing care to more than 33,000 inpatients and a half million outpatients annually. The medical center operates some of the largest clinical programs in the U.S. in areas such as neonatal care and outpatient surgery and is recognized as the international leader in infant heart transplantation and proton treatments for cancer.

"A large portion of the hospital's risk is self-insured. All the Loma Linda entities have pooled the risk on campus for those types of exposures that we feel comfortable assuming the risk on," notes Mark Hubbard, Vice President, Loma Linda University Medical Center. "With respect to the proton accelerator, this represented for us a unique exposure and on that we didn't feel confident that we should try to self-insure."

An alternative to conventional radiation therapy, high-energy protons were first used to treat patients with certain cancers in the 1950s. Proton beam therapy enables healthcare professionals to deliver full or higher doses of radiation to a tumor that might be impossible to get to via surgery while sparing surrounding healthy tissues and organs.

Research and laboratory applications continued to be developed over the next three decades but it was not until the opening of the proton treatment facility at Loma Linda University Medical Center in 1990 that the full benefits of proton treatment could be offered to patients with a wide variety of cancers. Loma Linda University's accelerator was the first hospital-based proton accelerator developed, built, and implemented in the United States and is the world's smallest variable-energy proton synchrotron. Designed to deliver a focused beam of energy sufficient to reach the deepest tumors in patients, proton treatment is valuable for treating localized, isolated, solid tumors.

Loma Linda University partnered with the U.S. Department of Energy's Fermi National Accelerator Laboratory.

"Because we developed this technology in partnership with Fermilab, we own the technology which means we also own the products liability exposure," noted Hubbard. "The litigation exposure from products liability is quite different from the traditional risks that we've typically self-insured. The proton accelerator represented a unique exposure for the hospital."

Loma Linda University Medical Center selected Medmarc to provide tailored coverage for this technology.

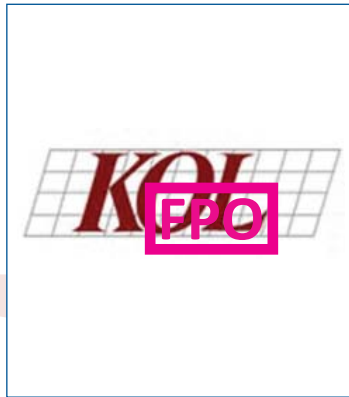
"Medmarc offers very specialized expertise and possesses knowledge about the specific risks that are associated with this type of technology," said Hubbard. "The accelerator really represents a new type of risk that we face and partnering with Medmarc helps us manage it."

With a vision of innovating excellence, Loma Linda University Medical Center continues to develop technologies to advance patient treatment and care. In turn, the medical center continues to rely on Medmarc to provide insurance protection and risk management solutions for these leading-edge advancements.

"Medmarc plays an important role in helping the Medical Center stay at the forefront of clinical innovation," notes Hubbard. "Medmarc's underwriters certainly understand this business and they understand the risks the Medical Center faces as a product manufacturer. Some of this new technology and the research that leads up to it may not be viable if we couldn't transfer the risks that are associated with these kinds of activities. If we had to bear this risk, we'd have to re-evaluate pursuit of product development. Without Medmarc, we would be unwilling to pursue certain ventures that represent too much exposure for us."

For more information on Loma Linda Medical Center's Proton Treatment and Research Center, please visit www.protons.com.

Protecting a Unique Approach at KOL Bio-Medical Instruments



Philip M. Reilly, Chief Financial Officer
KOL Bio-Medical Instruments

Founded in 1971 in Fairfax, Virginia, KOL Bio-Medical Instruments is a specialty distributor committed to bringing emerging medical technologies to the market. KOL partners with innovative client manufacturers who share a strong desire to enhance the healthcare value chain by improving patient health and/or dramatically reducing costs in the system. Among the companies that are, or have been represented by KOL, are Clinical Innovations, Megadyne, Charter Medical, Angio Systems, WIT, SpaceLabs, St. Jude Medical, Pall Corporation, Fresenius, and Becton Dickinson. KOL currently has a sales force of about fifteen and it sells directly in twenty-two states in the eastern United States. In addition, it markets and sells three lines nationally via other distributors. KOL is a certified Service Disabled Veteran-Owned Small Business.

In years past, products liability coverage for specialty distributors was sometimes an afterthought. In many cases, these companies relied on their manufacturing partners to have the appropriate coverage. For KOL, securing its own coverage through Medmarc in the late 1980's made sense for a number of reasons notes Philip M. Reilly, Chief Financial Officer. "If a partner were sued, we could potentially be dragged into the courtroom as a co-defendant resulting from our role as seller. By having our own coverage, we are also buying defense. If we are sued, even if it isn't our fault, we want to have coverage as you've got to defend yourself even if you're totally innocent. Additionally, because some of our manufacturers are smaller emerging companies, they might have lower limits and, if faced with a lawsuit, could be forced into bankruptcy and we would be left standing there – which is something we want to avoid." The movement toward more aggressive credentialing by hospitals is an important factor in KOL's desire to maintain its own products liability coverage.

"Hospitals are under pressure from the JCAHO [Joint Commission on Accreditation of Healthcare Organizations]; they're under pressure as a result of new legislation; they're under pressure through the implications of HIPAA [Health Insurance Portability and Accountability Act]. There are a lot of external forces that are driving hospitals to be sure they are protecting themselves and they are very often demanding proof of insurance," says Reilly.

(Editor's note: Please visit <http://www.medmarc.com/Resources/Pages/Newsletters.aspx> to read more on the topic of credentialing.)

When it came to selecting an organization to provide KOL's product liability coverage, the choice was obvious.

"We wanted an insurance provider that understood our business," says Reilly. "One of Medmarc's advantages is that it was started by the Health Industry Manufacturers Association, now AdvaMed. We are in an unusual business where we represent manufacturers and yet we still have products liability exposure – the Medmarc team understands our unique situation and provides solutions that are customized to match our specific needs. They also understand situations that are peculiar to our industry, such as credentialing, and can advise us on those areas." Further, through its strategic alliance with The Hartford, KOL is able to obtain a comprehensive general liability, property, workers compensation and automobile protection.

"Very often as companies grow and become more successful, there are claims and there are problems," added Reilly. "Medmarc is more likely to be able to help you because the Company's underwriting, loss control and claims people are experts who understand the business. If something goes wrong, because of their specialty knowledge and years of experience in this industry, the people at Medmarc can assess a situation immediately and assess it better. And regardless of economic conditions, there is a continuing flood of new technologies, new companies, new approaches to healthcare and the device industry's role in it."

"Because Medmarc is devoted to device and device related coverages, it has a leg up on understanding the prospects, problems, hurdles and opportunities of these new entities, whether or not the leaders of those entities are old hands or new innovators. Additionally, because many of these entities grow, and become larger, Medmarc has the capability to understand the ramifications of growth in this industry. Larger insurers may take longer to understand what Medmarc knows intuitively."

To learn more about KOL Bio-Medical Instruments, please visit www.kolbio.com.

Product Liability: Strategies for Success when Life Science Companies Come Under Attack

Wednesday, September 30th

2:00 pm – 3:30 pm EDT



WHAT TO EXPECT WHEN YOUR PRODUCT IS IN THE CROSSHAIRS.

Personal injury lawyers are constantly on the hunt for the “next big thing”, advertising for plaintiffs, experts, and selling strategies. Your product could be next.

This webinar will provide practical advice on what medical technology and life sciences companies can do to better prepare themselves when faced with high stakes product liability claims and litigation.

Our panel of experts will provide insights on:

- What to expect when faced with litigation
- How to prepare your board
- What to expect from plaintiff attorneys
- What the litigation process is like and what the real costs are
- Finding the best legal talent
- What to expect during the discovery phase
- How to develop an appropriate exit strategy to achieve a win-win situation

Expert panelists:

Geoff Coan

Partner

Wilson Elser Moskowitz Edelman & Dicker LLP

Practice focuses on defense of mass torts

Megan Wynne, Esq.

Vice President and General Counsel
I-Flow Corporation

Cindy Khin

Chief Claims Officer
Medmarc



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