

## Maintaining Our Focus

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This past year started with a cautious optimism about the direction the economy was taking. Our clients were eager to move forward, our attorneys eager to help them. Everyone seemed to have plans to do new things, but then life took over. 2012 was filled with events which pulled us in many different directions – the yearlong political campaign which seemed to be divisive instead of uniting; hurricanes and tropical storms; terrorism at home and abroad; and an on-going war. It was easy to lose focus on what we are all striving for, on what is important.

Our clients are important; our staff and our families are important. Having challenging and interesting work is; doing good things in the community is. In spite of the international turmoil, at Burns & Levinson we were able to keep our focus this past year.

Many of our clients are doing exciting things, expanding in a variety of industries, including technology and life sciences, new media, digital technology, online and traditional commercial ventures, apparel, and wherever the economy is taking them. In 2012 we assisted them with finding and providing financing, buying and sometimes selling companies, taking them public, and helping them open new offices both domestically and internationally. Our private equity clients are putting money to work in the growing sectors of our economy, and our venture capital clients are financing cutting-edge science and technology start-ups led by some of the greatest entrepreneurs in the world.

In 2012 we helped colleges, universities and businesses navigate the challenging real estate environment and helped companies with their environmental concerns. We have helped our clients protect their intellectual property rights from infringement and have helped inventors take advantage of their new ideas. We have assisted our clients in standing up for their rights with employers and have helped companies protect themselves from attacks by others.

On the personal side of our practice, we have helped clients prepare for marriage with pre-nuptial agreements, have assisted families in getting through the loss of a loved one, guided families with special needs through the court systems, and have helped many address the ever-changing tax environment as our politicians brought us to the fiscal cliff.

Our attorneys and staff have also been active in the community. In 2012 we again volunteered at the Boston Food Bank, helped elementary school students learning how to read, and we offered inner-city high school students internship opportunities to learn about the business world. Our attorneys and staff volunteered with bar associations, community groups, music organizations; they played leadership roles in their churches and temples, in mothers' groups and professional organizations. During the year we contributed to a large number of charities selected by our staff, making the pledge to wear blue jeans to raise money for charity. We sponsored several

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charity events throughout the year benefiting students and others in need. We kept our focus on what we feel is important, and we hope that everyone benefits from this in some small way – and perhaps be inspired to give back in their own way.

In 2012, we were again extremely humbled and gratified by the recognition of our lawyers by their peers for their legal skills, leadership and community service.

We continue to be optimistic in the new year. In 2012 we welcomed many new people who brought their skills, experiences and enthusiasm to Burns & Levinson, continuing to add to the depth and breadth of our expertise, allowing us to continue to help our clients achieve their goals.

We plan to maintain our focus in 2013 in spite of whatever disruption the world brings us, whether it is a snowstorm or a hurricane, a new political race or a change in the tax code. Our focus is to help our clients, to maintain an environment where we can do challenging work and enjoy the people with whom we interact. We thank you for the opportunity to work together this past year, and we look forward to an exciting new year and the opportunity to work with you again.

Sincerely,

David P. Rosenblatt, Managing Partner

## Amazing Clients<sup>®</sup>

### Medical Miracles - The Age of Bionic Reconstruction Arrives



Magic Pixie Dust -- that is what the media calls it.

Doctors and researchers call it an extra-cellular matrix ("ECM") tissue graft derived from naturally occurring porcine urinary bladder, which acts as a scaffold for epithelial and progenitor cell attachment and proliferation.

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# Rethinking Today's "Fixed Income" Investments

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The volatile securities markets of recent years, coupled with an extended period of historically low interest rates, have presented particular challenges for investors seeking income from their portfolios. One noticeable result is that income-seeking investors have been led to or attracted by more unconventional and more complicated investment products that still offer an attractive income stream in the form of regular dividend or interest payments despite the current low interest rate environment. These vehicles, including such instruments as structured securities products, trust preferred securities and master limited partnerships, can be particularly appealing to retirees and senior investors because they generate income at rates typically more favorable than those offered by bonds. These instruments, however, are much more complex than typical corporate bonds and, in many cases, will behave more like equity or derivative investments and carry similar risks. While their regular stream of income may suggest a degree of safety, that safety may be an illusion.

Take for example the structured securities product ("SSP") known as a reverse convertible note. On its surface, the reverse convertible note may look like a corporate bond, offering an investor the benefit of favorable, regular coupon payments. The underlying mechanics of the note, however, are structured to resemble the sale of a put option on corporate stock. Over time, the note behaves more like an equity derivative than a bond and carries similar risks. For example, the put option component of the note effectively caps the investment's upside in a favorable market while leaving the investor fully exposed to the downside.

Before buying a reverse convertible note, an investor essentially must consider whether the note's enhanced stream of income justifies the risk presented by selling a put option in the underlying stock. Complicating matters further is the fact that the reverse

convertible note (along with many enhanced-income products) is illiquid and, therefore, cannot be readily sold if the investor needs to access his or her investment capital.

Despite their complicated nature and often obscure risk factors, enhanced income products are appearing more frequently in individual investor accounts – a trend that has caught the attention of government and industry regulators. Regulators have raised concerns about whether SSPs are suitable investments for certain individual investors, particularly seniors, and whether financial advisors within the securities industry have sufficient knowledge and training about the inner workings of and risks presented by such investments.

The SEC's Office of Compliance Inspections and Examinations, for example, issued a report last year that reviewed sales of a number of different SSPs, including principal protected notes, enhanced-income notes, performance/market participation notes, leveraged/enhanced participation notes and reverse convertible notes. The SEC found "numerous" instances where the sale of more-risky SSPs did not coincide with investors' stated investment objectives and investment profiles. The SEC also noted instances where SSPs were inaccurately classified on customer account statements as preferred securities or preferred stock, possibly leading to confusion about the true nature and risks of those investments.

In light of the growing retail market for these complex investments, at a minimum, investors need to adjust their thinking. The traditional notion that income-generating investments are relatively safe and stable is no longer appropriate in many cases. The income stream that makes an SSP an attractive investment should also be read as an indicator of the investment's inherent risks. An investor should always assume that an attractive income stream corresponds with a higher level of risk somewhere in the investment. A financial advisor or the seller of the product should be able to identify and explain where those risks lie. Until the source and extent of those risks are understood, however, an investor should proceed with caution. ☒

## Can Gray Market Goods Be Stopped?

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The Supreme Court will soon issue an important decision, in the case of *Kirtsaeng v. John Wiley & Sons, Inc.*, regarding whether "gray market" goods can be sold in the United States. Manufacturers, distributors and retailers are awaiting the decision because it will help to answer the question of whether copyright law can be used to stop the unauthorized importation and distribution of foreign products into the United States. Many organizations and companies have filed amicus briefs with the Supreme Court on this case, including eBay,

Costco, various software publishers, movie companies, computer dealers, book publishers and art museums.

What are gray market goods? They are genuine goods manufactured for sale in a foreign market but, instead, are imported into the United States without the manufacturer's permission. The goods are often sold on the Internet by unauthorized wholesalers or at off-price stores.

How large is the gray market? It amounts to hundreds of billions of dollars. The accounting firm KPMG estimates that gray market merchandise costs the information technology industry more than \$40 billion in sales per year. The gray market affects countless products, including Pepsi-Cola, iPhones, cameras, pharmaceuticals, personal care products and auto parts, to name a few.

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## Amazing Clients®

### Medical Miracles -

### The Age of Bionic Reconstruction Arrives

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Bottom line: It works. ECM heals wounds and helps to regenerate skin, muscle, tendons and other living tissue. ECM products from various manufacturers have been successfully used on humans to heal surgical wounds, diabetic ulcers, and damaged muscles and ligaments. The products have even been used to facilitate reconstruction of urinary tracts, rotator cuffs and other anatomical surfaces.

Furthermore, they have been successfully used on animals to treat extremely serious injuries, such as significant burns and degloving (which occurs when large areas of skin are sheared or torn off completely).

There is no telling how many applications ECM products might have, as doctors and veterinarians have only started using them in recent years. But CNN, 60 Minutes, Oprah, Fox News, the BBC and more than 170 peer-reviewed papers have attested to the seemingly miraculous healing potential of ECM.

In fact, you can find literally dozens of published reports about the use of ECM in soldiers returning from battle or civilians who have had ligaments or fingertips mangled by bombs, chain saws, model airplane propellers and other devices. Patients with damaged fingers have even regrown their nails and fingerprints while recovering sensation.

When a 51-year-old Nebraska man lost the tip of his thumb in a chain saw accident, his doctor sent away for 20 powdered applications of the ACell MatriStem® ECM product. The patient described the result as miraculous. "The best one thousand bucks I ever spent in my life," he reportedly said after the finger grew back almost entirely.

Miles Grody, Senior Vice President and General Counsel for ACell Inc., says that the impressive performance of MatriStem technology "has made ACell one of the fastest-growing medical device companies in the country."

He explains that a MatriStem graft, which microscopically looks like complex webs of biological string, works by "providing a platform for recruitment of adult stem cells." These cells swarm to the ECM scaffolding at the injury or wound, "assisting in tissue growth and diversification into specialized cells of whatever kind is needed at the site."

ACell's MatriStem products, which are harvested from pig bladders (a waste item from the meat processing industry) and processed to isolate a discrete acellular tissue layer known as the epithelial basement membrane, are rich in laminin, biometric proteins, collagens, polysaccharide connective tissue and other growth factors that catalyze the growth of specialized living cells at the injury site.

"Because of these properties, MatriStem products promote rapid repair and remodeling of damaged tissue, can be totally resorbed by the body, and leave little or no scar tissue or calcification," Grody says, explaining the product's superior healing properties.

He notes that MatriStem products are currently cleared for human use in many applications, including general and plastic surgery, wound care (including diabetic ulcers) and esophageal reconstruction.

An application for human burn treatment is also being rolled out now, and orthopedic, cardiovascular and neurological applications are expected to follow, providing ACell with a total revenue opportunity that could potentially exceed \$40 billion in the U.S. alone.

Grody notes that it all began with the work of ACell's late founder, Dr. Alan R. Spievack, a surgeon, researcher and inventor who dedicated much of his life to regenerative medicine. Spievack conceived of an ECM composition featuring the epithelial basement membrane of pig bladders, which led to the creation of ACell in 1999.

Just a few years later, CEO James DeFrancesco jump-started the transition of Dr. Spievack's invention from laboratory research to commercial product with rounds of angel investor financing, but the initial applications of the product were largely in the veterinary field.

"This was obviously a safer place to launch it with less demanding hurdles on getting to market," Grody says, noting that ACell's ECM performed even better than expected in animals. "When race horses are injured, they rarely get back to form, but veterinarians injected a powdered form immersed in saline into lesions in the tendons and ligaments of racehorses, and they made a full recovery, returning to a high level of performance," Grody says, adding that more than 1,000 competitive jumping horses have been treated with ACell's ECM.

But Grody also recalls some dark days in the company's early history when it was battling for its life in the courts. He credits the survival of ACell's valuable patent portfolio largely to Dr. Ronda Moore, an intellectual property lawyer at Burns & Levinson, who procured and bullet-proofed the company's early patents for Dr. Spievack.

"Ronda helped us to obtain a broad patent portfolio to protect, enhancing our opportunity to commercialize a platform technology that has multiple applications," Grody says, adding that she also provided critical assistance during a three-year legal battle that resulted in a successful Federal Circuit appeal of an adverse patent infringement ruling.

"With her help, we were able to explain to the court how our invention includes material that was excluded from [the plaintiff's] patents," he adds.

Not long after the infringement battle concluded, an anonymous petition for re-examination of ACell's core patent was filed in the Patent and Trademark Office (the "PTO"), and Moore was called upon again. "She was the lead attorney who successfully persuaded the PTO examiner that our technology was both novel and non-obvious even though the petitioner had cleverly mischaracterized prior art references."

Grody calls Moore "one of the greatest assets we have at ACell," noting that "she not only has the needed expertise in patent law, but as a certified veterinary pathologist she understands both the science and the law relating to our products."

"Ronda treats our company like it is her own, and I have no doubt that she has the company's interests foremost in her mind at all times," Grody adds. "She helped position us for rapid growth and gave us an opportunity for multiple shots on goal."

If ACell can score on all of its goals, there will be new and potentially unbounded hope for patients with serious injuries, wounds and organ defects. ■■■

*- John O. Cunningham, freelance writer/editor*

## Can Gray Market Goods Be Stopped?

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The *Kirtsaeng* case involves an enterprising graduate student who subsidized his education by selling foreign textbooks on eBay. He obtained the textbooks from his native Thailand, where the textbooks sold for less than similar textbooks in the United States. The foreign textbooks were marked with a legend "Authorized for sale in Europe, Asia, Africa and the Middle East only," and were manufactured with lower-quality paper and ink than the versions intended for sale in the United States.

The publisher sued Kirtsaeng for copyright infringement because it is unlawful to import a copyrighted work acquired abroad without the permission of the copyright owner. Kirtsaeng argued that the "first sale doctrine," which permits the owner of a lawfully purchased work to resell it without the permission of the copyright owner, barred the publisher's copyright claim. The publisher asserted that the first sale doctrine does not apply to products manufactured abroad and was, therefore, inapplicable in this case.

This is not the first time that the Supreme Court has faced this issue. The much-publicized case of *Omega v. Costco* in 2008 involved a suit by the watchmaker against Costco for importing and selling foreign Omega watches in Costco stores. Omega asserted that parts of the watches were protected by copyright and that Costco had violated copyright law by selling them in the United States. As a result of Justice Kagan's recusal from the case, the Supreme Court split 4-4 and no decision was reached. Legal scholars and practitioners are watching the *Kirtsaeng* case to see whether the narrow split prevails and on which side the deciding vote will be cast.

What are the implications of the *Kirtsaeng* case? If the publisher prevails, a wide variety of retailers could be affected. Internet retailers such as Amazon.com and eBay, and large discounters such as Costco sell many types of gray market goods, including car parts, electronics, apparel, cosmetics and personal care products. If a manufacturer has a copyright on part of the product or its packaging, the manufacturer may be able to stop the unauthorized sale of the gray market product.

The *Kirtsaeng* case will surely be an important copyright decision that will have great impact. But manufacturers do not have to wait for the decision to take action against gray market imports. United States trademark law has, for more than 20 years, provided manufacturers an effective remedy to address gray market imports. Under trademark law, manufacturers may stop the unauthorized sale of their foreign product if they can show a "material difference" between their foreign product and its United States version.

What does material difference mean? It means a difference that could be important to a consumer, including differences in quality control, packaging, flavor or ingredients. For example, Perugina chocolates from Venezuela differed from the United States versions of Perugina in quality control, the layout of chocolates in the box, packaging and price. Due to these material differences, the manufacturer of Perugina was successful in stopping the sale of the foreign version in the United States.

Recently, the maker of the popular energy drink Red Bull won several cases against unauthorized imports of Red Bull in the United States. The material differences shown by Red Bull included different information printed on the foreign can, such as the use of British English spellings and a high caffeine warning, which is

required by British law. Red Bull did not have to show a difference in flavor or ingredients in order to win the case.

Similar victories based on the material difference rule have been won by other companies such as Nestlé, Novartis, Kia Motors, Pepsi-Cola, Davidoff, Bayer and others.

The Supreme Court is likely to decide the *Kirtsaeng* case in the next few months. The issue in *Kirtsaeng* is whether copyright law can be used against unauthorized gray market imports. Knowledgeable manufacturers, however, should be aware that they already have a potent weapon against gray market imports of their products by using existing trademark law. They can use the material differences between their domestic and foreign products as the lever to stop the unauthorized importation of their foreign products into the United States, regardless of how the Supreme Court decides *Kirtsaeng*. ☺



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