BURNS & LEVINSON LLP

FOCUS

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THE ABC'S OF A PRODUCT RECALL

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Having a product that is regulated by the Food and Drug Administration (FDA) recalled can have devastating consequences. When the situation is not managed properly, in addition to harming the public, it can result in liability and injury to the company and brand. These problems can be needlessly magnified by a failure to timely and efficiently respond to defective products in the marketplace. Therefore, companies that manufacture or distribute products regulated by the FDA must put strategies and procedures in place to safely and effectively manage a product recall.

The proper management of a recall is top priority for protecting the public's health. Identifying and recalling the specifically affected products is often the most effective means for protecting consumers. If the cause of the defect is located promptly, the recall can be contained to only those products warranting such action. This prevents needless alarm among unaffected members of the public. In order to plan and execute a proper recall, companies should know the basics of a product recall (ABC's), and thereby avoid both unnecessary harm to consumers and costly missteps that can result in needless liability and costs.

A) Alert regulatory agencies promptly. The FDA must be notified as soon as possible, so the first step in any recall is to accurately identify and quantify the product being recalled. Understanding the origin of the defect in a product can contain the scope of the recall to those lots or expiration dates having the potential for problems. Having a proper quality control system using sufficient coding of regulated products makes it possible to positively identify, contain the scope of and facilitate effective recall of all faulty lots. Companies should prepare and maintain a current written contingency plan for use in initiating proper interactions with the FDA.

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lumenpulse™

A BRIGHT FUTURE FOR A COMPANY THAT IS LIGHTING UP THE WORLD

Greg Campbell, Senior Vice President & Chief Technology Officer, Lumenpulse Inc.

When Lumenpulse Inc. went public on the Toronto Stock Exchange in April, its $115 million public offering was substantially oversubscribed. That is probably because the Montreal-based company with a Boston-area technology development office racked up a compound annual revenue growth rate of 78 percent for the last three fiscal years, notching more than $62 million in sales in its most recent year. How are they doing it?

The company, which was founded in 2006, designs and manufactures high-performance lighting fixtures that enable the use of programmable, energy-saving, super-efficient LED bulbs that save money for clients while providing them with lighting effects and features never thought possible.

These fixtures, also known as luminaires, are paving the way for a revolution in architectural and commercial lighting,

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DELAWARE CORPORATE LAW BECOMES MORE USER-FRIENDLY

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One reason that Delaware law is attractive to corporations as a jurisdiction to incorporate in, is the fact that Delaware law is constantly evolving to make corporate governance matters as well as transactions easier from a corporate law perspective. In that regard, the 2014 amendments to the Delaware General Corporation Law did not disappoint. What follows is a summary of several of the more important recent changes.

Section 204 – Ratification of Defective Corporate Acts and Stock. Effective April 1, 2014, certain defective corporate acts and stock issuances that were improperly authorized or not authorized at all, and previously would have been either "void" or "voidable" under Delaware law, can now be ratified (i.e., retroactively validated) by a corporation's board of directors, in some cases following stockholder approval. Previously, Delaware case law had prohibited the ratification of certain defective acts which, depending on the circumstances, could have serious ramifications for corporations and their stockholders.

Defective corporate acts and stock issuances that can now be ratified include:

(i) The issuance of shares of stock in excess of the number of shares authorized to be issued, or the issuance of a share of a class of stock not authorized to be issued.

(ii) An election or appointment of directors that had not been authorized.

(iii) Any act or transaction taken by the corporation that would have been proper at the time it was effected had it been authorized.

Under all such scenarios, failure of authorization means the failure to authorize or effect an act or transaction in compliance with the Delaware General Corporation Law, the corporation's certificate of incorporation or bylaws, or any plan or agreement to which the corporation is a party.

Under Section 204, the board now can adopt a resolution ratifying the act or issuance (the resolution must provide certain details as required by Section 204) and submit the resolution to the corporation's stockholders for adoption. Stock approval is not required if neither the Delaware General Corporation Law nor the corporation's certificate of incorporation or bylaws would have required stockholder approval either at the time of the defective corporate act or when the board resolution is adopted, and the defective act did not result from a failure to comply with Delaware General Corporation Law Section 203 ("Business Combinations with Interested Stockholders"). In any case, however, whether or not stockholder approval is required, the corporation must notify stockholders of the adoption of the resolution ratifying the act or stock issuance.

Section 141(f) – Written Consents of Directors to be Placed in Escrow. Section 141(f) has historically provided that board or board committee actions or votes can be taken without a meeting if all members of the board or committee sign a written consent in favor of such action or vote. This provision allows boards and board committees to act outside of actual board or committee meetings, which is important for time-sensitive matters that arise between regularly scheduled meetings. Effective July 1, 2014, Section 141(f) was amended to allow director consents to be signed but become effective at a future time or upon the happening of a future event (no later than 60 days after the consent is given). The amended section even allows the signing of such a consent by someone who is not a director at the time the consent is given but who will be a director at the time the consent is later effective. Any such consent must be revocable by the person signing it, however. Amended Section 141(f) makes it easier to document and complete complicated corporate transactions that involve multiple corporate votes/actions taking place in a particular sequence and/or at specific times.

Section 228(c) – Written Consent of Stockholders to be Placed in Escrow. Similar to board consents under Section 141(f), Section 228 allows stockholders to take action outside of a stockholder meeting if the requisite number of stockholders required to approve the action sign a written consent to such action. Effective July 1, 2014, Section 228(c) was amended to allow stockholder consents to be signed but become effective at a future time or upon the happening of a future event (no later than 60 days after the consent is given). Unlike director consents, however, a stockholder consent can be made irrevocable by the person signing it. Amended Section 228(c) works hand in hand with amended Section 141(f) (as discussed above) in facilitating multi-step corporate transactions.

Amazing Clients®

A BRIGHT FUTURE FOR A COMPANY THAT IS LIGHTING UP THE WORLD

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providing precise levels of brightness, shades of color, and programmable energy-saving functions. These features enhance the conference rooms, presentation screens, hallways, and lobbies of offices and hotels, and they dramatically change the possible lighting options available for museum displays, concert and entertainment venues, as well as sports stadiums.

That is why Boston's Langham Hotel, Montreal's Museum of Contemporary Art, General Motors headquarters, Soldier's Field in Chicago, and the 87-story Shard in London have already converted to Lumenpulse products.

"We understand specific lighting challenges that different clients face, and we work on technologies to solve their particular problems," says Greg Campbell, Senior V.P. & Chief Technology Officer for Lumenpulse. "Our customers are mostly lighting designers, architects and engineers who tell us what they need. They inspire the applications we develop, and they construct our vision for the future."

By way of example, Campbell points to his company's Lumendrive luminaire products, which power, dim and control LEDs directly from the AC mains. This eliminates the need for a conventional power supply inside the fixture, while simultaneously, providing superior efficiency and precise levels of brightness.

"With LEDs, you can use just 10 watts to get 60-watt performance in terms of lumens [a measure of brightness] but the challenge has been how to enable LED lighting through existing architectures of wires and circuits that were not designed with advanced technology in mind," Campbell says, noting that the transformers or "power bricks" inside of conventional fixtures do not enable optimal utilization of LEDs.

"By eliminating the traditional AC to DC power supply, Lumendrive modulates the power so that the LEDs and the fixtures can be warranted for 10 years instead of the five years, which is currently the industry standard," Campbell adds, noting that Lumendrive fixtures can easily be dropped into existing architectures without any expensive upgrades to wiring or circuitry.

Greg Campbell, Senior Vice President & Chief Technology Officer, Lumenpulse Inc.

He also points to Lumentalk technology as another popular innovation in Lumenpulse fixtures, enabling existing wires to communicate with LED smart bulbs so that lighting can be programmed for superior features and energy savings. "We put microprocessors inside the fixtures to translate programmed instructions to the lights, making it easy to adapt and perfect for existing offices."

Other innovations include Lumensmart, Lumencool, Lumendim and Lumenlife technologies, which can combine to perform a stunning array of tasks.

Campbell points to the New England Aquarium as an illustration of the full potential of Lumenpulse technologies.

"Biology studies have found that an exact mix of blue-green and cool white lighting can hinder algae growth in an aquarium tank. We can combine and control those colors with precision, saving the aquarium money while keeping their tank clean," he says, adding that "we can also mimic the passing over of clouds and create other reality effects with our lighting."

Campbell also notes that "the penguins need a certain white light effect for sunrise and sunset to set their biorhythms," adding that "we provide that control for the aquarium through microprocessors inside of our fixtures, and we can adjust for the seasons or time of day."

He foresees a day when light systems will do far more than just provide light, much as cell phones have become much more than calling devices.

"People will routinely adjust and measure room color, brightness and even temperature through their lighting systems. They will track lights that are out and flag them for replacement, and their lights will automatically go on and off when someone enters or leaves a room," he suggests.

In fact, forecasters predict that 60 percent of retailers will have switched to "smart" LED lighting systems by the year 2020, whereas only 8 percent have done so to date. Lumenpulse is already well-positioned to ride the crest of that transitional

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THE ABC'S OF A PRODUCT RECALL

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The FDA needs to know:

- An estimate of the amount of recalled product in the marketplace.
- The lots affected by the recall.
- Information regarding the distribution pattern of the product.
- The reason for the recall.
- The nature of the defect.

Finally, the recalling firm is required to provide an assessment of the health risk associated with the deficiency and an outline of the recall strategy.

B) Be transparent with the public. Alerting the public to a product recall should be the highest priority and done promptly. In a situation where the product may pose a significant health hazard and is in the hands of consumers, a press release approved by the FDA is required. Particular consideration should be taken regarding potential future liability. In addition, all customers in the distribution chain should be notified of the recall in writing that provides the necessary actions needed to effectively remove the product from sale, or procedures for product correction or destruction. A quality control system should also include product distribution records so that it is easy to locate the products being recalled.

C) Check the effectiveness of the recall. It is the recalling firm's responsibility to assure that the recall is effective. Effectiveness checks should be conducted to verify that notification letters were received, read and understood and that instructions were followed accurately. An effectiveness check should also verify that a recall reached the appropriate level in the distribution chain. Any proper contingency plan should include contact information for outside regulatory professionals that can help the company navigate the regulatory and legal considerations of a product recall. A recall is considered complete after all of the company's corrective actions are reviewed by the FDA and deemed appropriate.

In addition to potentially being harmful to consumers, a recall can also be disruptive to a company's operation and business. With prior planning, prudent businesses can minimize many of these risks. In case of a product defect, remember your ABC's: **A**lert regulatory agencies promptly, **B**e transparent with the public, and **C**heck the effectiveness of the recall.

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wave of innovation, thanks in part to their 25 patented technologies and more than 50 patents that are pending.

"We chose Joe Maraia at Burns & Levinson to help us with our patent strategy, technology and trademark protection in part because he is an electrician who understands both the intellectual property issues and the product applications," says Campbell, noting that Lumenpulse selected Maraia after extensive interviewing of other lawyers at other firms.

Campbell not only likes that Maraia has a degree in electrical engineering and holds master and journeyman electrical licenses, he loves that Maraia "knows what is really important to us and will pursue neither too few nor too many patents associated with our technology."

"We are a customer driven, product development organization, not an academic science lab. Joe gets that we are focused on developing particular technologies to solve particular problems and our IP program needs to match the specific needs of our business," Campbell says.

"Our company is also focused on people and culture, and Joe is a 'fit' for us in that way too. He is level-headed and has a laid back temperament, but he is very smart and can execute quickly to accommodate our rapid growth. He is sharp and fast, but easy-going. That is the kind of person we look for, and we are very happy with Joe," Campbell concludes.

- John O. Cunningham, freelance writer/editor

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