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Focus

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Do You Recall? The Consumer Product Safety Commission and Product Recalls

By Paul R. Mastrocola

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The "Recalls" section of *Consumer Reports* magazine recounts recent recalls for products as varied as automobiles, infant seats, children's toys, flashlights, scuba gear, boilers, and electric blankets, to list just a few. For the consumer, notice of a product recall may be viewed with a combination of surprise, relief, annoyance, and possibly anger. In this era of intense government consumer regulation, any company that manufactures, distributes, retails, imports or otherwise sells consumer products should be familiar with the rules and regulations governing consumer protection, and particularly, product recalls.

The Federal Consumer Product Safety Act (Act) established a set of stringent rules intended to compel companies to recognize potentially hazardous consumer products as early as possible, and to take remedial action to protect consumers from possible harm. The U.S. Consumer Product Safety Commission (CPSC) is the regulatory agency charged with the important responsibility of enforcing the Act and other Federal laws designed to protect the public from unreasonable risks of injury and death associated with consumer products. CPSC has jurisdiction over approximately 15,000 different types of products used in and around the home, schools, and in recreation. CPSC does not regulate products such as foods, drugs, cosmetics, medical devices, firearms, ammunition, automobiles, aircraft, boats, or tobacco.

The ample powers of CPSC can be brought to bear if it receives notice of a potential substantial product hazard. The Act defines a "substantial product hazard" as a product distributed in commerce that fails to comply with applicable consumer product safety rules, or that contains a defect, which creates a substantial risk of injury to the public. A defect could be the result of a manufacturing or design error, and could also occur in a product's components, finish, packaging, warnings or instructions.

CPSC is authorized to enter factories, warehouses, offices or other facilities to inspect the premises, products or any product components. Further, CPSC is entitled to access to and copies of documents relating to the production, inventory, testing, distribution, sale, transportation, importation or receipt of any suspect product or component. CPSC also may require company employees to sign affidavits, may issue subpoenas, take depositions and conduct hearings with sworn testimony.

A company is obligated to file a detailed report if it has knowledge of potentially hazardous products. It must notify CPSC "immediately" if it obtains information that "reasonably supports the conclusion" that a substantial product hazard exists. A company is deemed to have knowledge of product safety information when received by an employee who may reasonably be expected to appreciate its significance. A company may take a reasonable time to investigate whether information is reportable, but must do so diligently and expeditiously. The company should not wait to be absolutely certain of a substantial product hazard before reporting. The Act reflects Congressional intent to encourage widespread reporting of potential product hazards. Slow reporting will likely result in aggressive CPSC investigatory action.

Mandatory reporting requirements underscore the importance of proper and effective records maintenance. If a product recall is ultimately mandated, keeping accurate and thorough records is essential for a company to conduct an effective and economical recall. Among the critical records to maintain are records of consumer complaints, warranty returns, insurance claims, lawsuits, production, quality control, and distribution data.

Upon establishing that a substantial product hazard exists, CPSC implements a "corrective action plan" (CAP), which refers generally to any type of corrective action imposed upon a company. In addition, CPSC may seek injunctions, civil monetary penalties, and criminal penalties, including fines and imprisonment, for knowing and willful violations after receiving notice of noncompliance. Products deemed imminent hazards may be seized.

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An Overview of a Patent

By Trevor D. Arnold

Business is all about competition. While traditional business concerns focus on physical assets and financial planning, the core of a technology oriented company lies in its intellectual property resources. It is therefore of great importance to understand the nature of these rights, how they arise, and how they are preserved and enforced. This article will briefly cover patent rights in the U.S.

The Nature of Patent Prosecution

Patents are governed by Federal law, and protect the new, useful and unobvious features of a product or process. A patent preserves to the owner, for a limited time, the right to exclude others from making, using or selling the invention.

A patent is obtained by filing an application with the U.S. Patent and Trademark Office ("PTO"). The patent application itself is a document of several pages that must contain a sufficient disclosure of the invention; the manner of making and using it, as to enable a person of ordinary skill in the art to practice the invention; and the "best mode" for carrying out the invention. The disclosure concludes with one or more "claims" which legally define the invention. The application procedure includes a substantive examination of the invention and a comparison with the "prior art," and can take a couple of years to complete.

During the pendency of a patent application, no substantive patent rights exist. However, while the patent application is pending with the PTO, the prospective patent owner may mark its product with the legend "Patent Pending" or "Patent Applied For." This designation may in fact yield a competitive advantage because a potential competitor may refrain from entering into the market with the possibility that a patent will issue at any time.

Patents May Be One of Three Types

(a) Utility Patents. A utility patent covers the functional aspects of a product or process, i.e. the manner in which it is constructed or functions to achieve a given result. A utility patent has a term extending from the date of

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issuance to 20 years after the application filing date, and may be obtained for any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof. A utility patent cannot be obtained for certain non-statutory subject matter, such as scientific principles, laws of nature or products of nature. However, the application of a physical law to produce a new and useful process or apparatus may be patentable.

(b) Design Patents. A design patent covers any new, original and ornamental design of a product. Design patents are particularly well adapted for protecting certain types of products, such as those in which the design is the basis for product appeal (e.g. furniture, toys and jewelry). However, a design that is dictated by purely functional requirements is not protectable by a design patent. A design patent has a term of 14 years from the date the patent is granted.

(c) Plant Patents. A plant patent may be obtained by one who invents or discovers, and asexually reproduces, any distinct and new varieties of plants.

Infringement of any of the patent types occurs if another makes, uses, imports or sells a product or process that falls within the scope of the patented invention. The remedy for patent infringement is by civil action in Federal court.

Requirements for Patentability

The patentability of an invention is judged as of the date the invention is made. The date of invention is established when the invention has been conceived and "reduced to practice." Reduction to practice refers to the actual making of the invention and demonstrating its operability under normal conditions. However, there is no requirement that an invention actually has been made before filing a patent application. Instead, the law provides that the filing of a patent application constitutes a "constructive" reduction to practice. Thus, the date of invention may be established either by actually constructing the invention or by filing a patent application. The date of invention may also be established as the date the invention was conceived if there is diligence between the date of conception and the actual or constructive reduction to practice.

Patentable subject matter must be new, useful and unobvious. Utility is readily established in most instances. Utility is lacking if the invention is illegal or if it doesn't work, i.e. the classic example being perpetual motion devices. Novelty and unobviousness are more difficult to assess, and must be determined by comparing the invention with the "prior art." (i.e. that which is (1) known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant or (2) patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the U.S.).

If the identical subject matter to be patented existed in the prior art, then the subject matter lacks novelty, and is said to have been "anticipated" by the prior art. Even if the subject matter sought to be patented is not anticipated, it will not be patentable if the differences between the subject matter and the prior art would have been obvious at the time the invention was made to a person having ordinary skill in the art. For example, an invention consisting of a screwdriver with a rubber grip is not patentable if screwdrivers and hammers with rubber grips already exist and it would have been obvious to combine the rubber grip from the hammer with a screwdriver.

Too often, the procedures and legal structures to protect the intellectual property rights of the business are absent. Without this framework, disaster may strike or the business may eventually fail. Businesses must be constantly vigilant to both identify and protect their intellectual property assets. Only then will a business be able to take full advantage of its research, development and manufacturing capabilities.

When is an Offer to Purchase Real Estate a Contract?

by Shepard Davidson

Shepard Davidson serves as Of Counsel in the Firm's Business Litigation Group. He concentrates his practice in the areas of complex business torts, contract claims, real estate disputes and disputes involving closely held corporations.

In Massachusetts, the usual first step in a residential real estate transaction is for the buyer and seller to sign a one-page document entitled Offer to Purchase Real Estate. These Offers to Purchase generally are pre-printed forms on which one or both real estate brokers fill in various terms with a pen. Moreover, and perhaps because realtors often refer to these documents as "binders," buyers and sellers rarely consult any attorney before signing. What most people do not realize, however, is that ***in most instances Offers to Purchase are legally binding <u>contracts</u> for the purchase and sale of real estate.*** Indeed, an Offer to Purchase may be enforceable as a contract in a court of law even if it expressly states that the parties' rights and obligations are contingent upon the execution of a Purchase and Sale Agreement and no such Purchase and Sale Agreement is executed.

The key issue is whether or not an Offer to Purchase contains all of the "material" terms of the contemplated transaction. If it does, then the Offer to Purchase is a binding contract; if it does not, then the Offer to Purchase is not enforceable. Unfortunately, while it has been established that the names of the parties, the purchase price and the closing date are material terms of the transaction, this is where general guidance ends. Indeed, in one case it was implicitly held that a request by the buyer for a hazardous waste indemnification was ***not*** material, even though the property at issue abutted a known hazardous waste dumping ground.

Although buyers and sellers may be disheartened by such uncertainty, there is a way to avoid it – skip the Offer to Purchase stage and go immediately to the Purchase and Sale Agreement. There is no legal requirement that an Offer to Purchase be executed before a Purchase and Sale Agreement can be negotiated, and the vast majority of states, other than Massachusetts, do not use Offers to Purchase. In fact, some attorneys have been known to tell their clients never to sign an Offer to Purchase due to the inherent ambiguities in such documents.

While there almost always is more certainty that a transaction will be completed once a Purchase and Sale Agreement is signed, there are some circumstances (such as when you are a buyer in a sellers' market) in which it may be advantageous to execute an Offer to Purchase first. Accordingly, potential buyers and sellers are best advised to consult with an attorney before signing any document that may commit them to buy or sell a house.

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Do You Recall?

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The CAP usually includes a recall, the key remedial measure employed by CPSC. The objective of a recall program is to communicate information to the public, and retrieve as many hazardous products from the distribution chain and from consumers as possible. The specifics of a recall program are tailored to the particular circumstances. Generally, the recall program establishes a system for the consumer's return of a product to the company in exchange for a refund, replacement, or repair. A critical element of any CAP is public notice of the nature of the hazardous product and the corrective actions. Recall information is often communicated by means such as a joint company and CPSC news release, company web sites, direct notice to consumers known to have the product, notices to dealers, retailers and others in the distribution chain, paid media advertisements, and point-of-purchase posters. A company that is the subject of a recall should set up a dedicated toll-free telephone number for consumers for the recall. CPSC closely monitors a recall and requires periodic progress updates. Designating a company official to serve as a recall coordinator is a useful step to effectively oversee recall operations.

Reporting a product to CPSC and the initiation of a CPSC investigation does not necessarily result in a substantial product hazard determination or a product recall. Companies typically work in conjunction with CPSC to determine if corrective action is warranted, and if so, to develop an appropriate recall program. It is imperative that the company has accurate information about the product defect and that the information is supplied to CPSC to determine the proper classification of the hazard level and intensity of the recall. Key factors include the number of defective products distributed in commerce, the severity of risk, and the likelihood of injury. If the substantial product hazard designation is not contested, it may be prudent for a company to work closely with CPSC to design a recall program with agreed terms. This approach allows the company to initiate a voluntary recall, and to avert the potentially onerous recall terms that could be ordered by CPSC. A voluntary recall usually enables the company to retrieve hazardous products in the most practical, cost efficient manner possible.

It is unavoidable that a CPSC product recall will involve substantial expense, inconvenience and some measure of bad publicity. Nevertheless, a successful and reasonable recall can result in renewed consumer confidence and continued consumer support for the company.

Capacity to Sign Wills and Advance Directives

By Lisa Madeleine Cukier

Lisa Cukier is an Associate in the Firm's Probate Litigation Group. She concentrates her practice in all aspects of probate litigation, guardianship, mental health law, elder law and domestic relations.

Competent adults can make dispositions of their property by Will and they can designate people to serve as their decision makers under advanced directives such as a Health Care Proxy and a Durable Power of Attorney. All adults are presumed competent by law unless adjudicated incompetent, even if suffering from physical disabilities, advanced age, mental retardation, or mental health issues. An individual, however, may be presumed competent by law, yet be functionally incapable of executing a Will and advanced directives. If a person's functional mental capacity is questionable when she signs these documents, the documents may later be legally attacked. What mental capacity does the law require of the person signing?

In order to execute a Will, a person must have testamentary capacity. This requires the person signing the Will to understand the nature and situation of her property and her relationships with people who she would naturally choose to benefit under her Will. It requires the person signing the Will to have the mental capacity to understand the contents of the Will and how the Will operates upon death. Capacity, however, may vary from day to day. So long as the person signing the Will has testamentary capacity at the moment of signing, the fact that she may lack capacity at other times is irrelevant.

A competent adult can appoint, in advance of incapacity, a surrogate decision maker to later make health care decisions on her behalf in the event of subsequent incapacity pursuant to a Health Care Proxy. The person signing is called the Principal, and the person(s) appointed are called Agents. The Agent(s) become legally recognized decision makers for the Principal. The Health Care Proxy does not take effect until and unless a physician certifies that the Principal has become incapacitated. The document directs health care professionals, family, and friends to honor the Agent's decisions. At the time the Principal signs a Health Care Proxy, the Principal does not necessarily need to have capacity to weigh risks and benefits of the actual types of medical treatments that might potentially be needed in the future. It is sufficient that the Principal have mental capacity to understand the effect of designating an Agent to weigh risks and benefits and make health care decisions in her stead should she later become incapacitated.

A competent adult can also sign a Durable Power of Attorney as part of an estate plan. A Durable Power of Attorney is a document that appoints an Attorney-In-Fact to make financial decisions on behalf of the Principal. Depending on the language in the document, financial decision making authority can be granted immediately upon signing the document, or it can take effect upon the subsequent incapacity of the Principal. In order to sign a Durable Power of Attorney, the Principal must have enough mental capacity to understand and appreciate what it means to designate another person to handle her finances on her behalf. It requires that the Principal, at the time of signing, understand the nature of her financial affairs and understand what it means to relinquish control of management of those finances to the Attorney-In-Fact.

Unfortunately, some people do not plan in advance to execute Wills and advanced directives. Sometimes people delay execution of Wills and advanced directives until they are already of questionable mental capacity. When this happens, disputes might later arise in connection with the Principal's mental capacity to sign these important documents.

If signing a Will or an advanced directive occurs at a time when, or under circumstances in which mental capacity is questionable, it is best practice to obtain a written narrative from a physician that speaks to the issue of the Principal's present capacity to execute the particular estate planning and advance directive documents. Since competence can vary from day to day and indeed from moment to moment, it is critical in many cases for a physician to document proof of capacity to execute these documents at the same time the documents are executed. This will help to establish the Principal's then capacity if the documents are later attacked or questioned at a time when the Principal lacks capacity.

Focus

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