

PRODUCT CLEARANCE AND US PATENT OPINIONS

Several significant risks are implicated when a company prepares to launch a new product into the commercial market, particularly in the U.S. These risks can be mitigated with proper attention to patent clearance issues and a well-reasoned opinion from a trained U.S. patent lawyer. Below is set forth a discussion of the potential pitfalls and thought process for clearing significant products into the commercial market while reducing the risk of being sued for patent infringement or otherwise being forced to halt production or market entry.

Imagine a situation where your company has spent a few million dollars advertising its' dynamite new product and the release date is next Monday. Then imagine the cease and desist letter arriving. You can envision--or worse, have experienced--this scenario. But there are ways to manage and even minimize this risk by understanding U.S. patent law in the context of clearing new products to market, particularly in industries where the competition holds patent protection relating to the market.

THE PROBLEM: TREBLE DAMAGES

Under U.S. law, an infringer found to be willfully infringing a U.S. patent can be found liable for treble damages. As part of the damages phase of a patent infringement trial, the court has the discretion to increase the damages by up to three times the amount of damages found or assessed once infringement has been found to occur. 35 U.S.C. § 284. In exceptional cases, the court may award reasonable attorneys fees to the prevailing party. 35 U.S.C. § 285. In view of this, the strategy implemented can be critical to the eventual profitability of new products and processes.

When a company prepares to commercialize a new product or process, a great deal of corporate resources are expended to research, develop, market, and efficiently manufacture the new product or implement the new process. Clearly, the economics of any given product for market entry affects the corporate resources that should be invested in a clearance investigation and analysis. Thus, the intellectual property law aspect of new product release is one of the linchpin resources that should be considered before market entry.

THE DECISION: TO SELL OR NOT TO SELL

In making such preparations for market entry, we typically see a company select one of three courses of action. The first is to decide that too many patents or aggressive competitors exist in a particular field. A decision is made to avoid that particular market or avoid expending further resources on a particular product or process being prepared for commercialization.

The second course of action is where a company may or may not be generally aware of one or more patents in the field of potential commercialization. A few companies ignore the competitive landscape and simply conduct business while ignoring the patents that may be covering the proposed or actual product. Others deliberately choose to proceed to

market, often because there is no specific knowledge--particularly at the management level--of any potential infringement issues. This course of action runs the greatest risk of receiving a cease and desist letter sent by the owner of any relevant patent(s), or a lawsuit seeking a TRO or preliminary injunction barring further infringement. These heart-stopping events often occur shortly after the company has entered the new market. Alternatively, companies sometimes discover patents relevant to a new product some time after the new product has entered the market. Ultimately, this course of action tends to jeopardize the investments made up to that point, and can result in unnecessary legal fees in an attempt to obtain a rapid evaluation and possible assurance of non-infringement or invalidity.

Even worse, such corporate action--or inaction--often runs the greatest risk of a company being found not only liable for infringement, but liable for treble damages for the knowing, intentional (i.e., willful) infringement of a product or process known to be patented. Often, one manager may receive a cease and desist letter, while another may be making the decisions to proceed to market. Regardless of internal corporate politics, the patentee can seek an injunction to prevent further infringement, and a finding of willful infringement of a given patent tends to limit credibility of the accused infringer with respect to further rulings from that court in that field of endeavor.

THE SOLUTION: A CLEARANCE INVESTIGATION AND OPINION

The third, and preferred, course of action, is to have a careful evaluation and assessment conducted regarding such new products before their entry to market. In many cases, a written opinion of non-infringement, invalidity, or a combination of these, is the best way to reduce the risks involved in bringing a new product or process to market. A written opinion of non-infringement and/or invalidity by a patent lawyer registered to practice before the U.S. Patent & Trademark Office can provide a company with a reasonable basis to conclude that one or more patents of concern are not infringed or are otherwise invalid, thereby permitting a business judgment to allow the product to proceed to market with a reduced likelihood of an adverse injunction or other problems after market entry.

If any patent claims are ultimately held to be valid and infringed, a well-written opinion can help overcome the patentee's allegation that the infringement was willful. Thus, such an opinion can help preclude a finding of willfulness, thereby avoiding potentially trebled damages. When such opinions are prepared by registered patent lawyer practitioners experienced in patent law and in making such determinations of relevant fact and law, there is a much greater chance that a court will give the well-considered opinion due weight if and when the willfulness charge is made.

More importantly, a skilled patent practitioner reviews the claims of an issued patent in view of the prosecution history before the US Patent Office, along with a careful analysis of the prior art. This can lead to suggestions or recommendations of how to design (or change the design) of a particular product to create very strong non-infringement arguments. Recent decisions from the U.S. Court of Appeals for the Federal Circuit, the appellate court that hears all appeals of patent infringement cases from the U.S. District Courts, have established a

trend toward certainty of analysis of patent claims with respect to opinion preparation. This has been accomplished by requiring the patent drafter to be more clear as to the most far reaching aspects of the scope of the claims, and if these decisions are not followed a company may not realize that the patents they own are unduly limited. The critical analysis of issued patent claims to identify these “weak links” is a common way to determine the types of design modifications that are inarguably outside the valid scope of those claims. As we face this type of challenge when preparing patent applications, we are in a unique position to evaluate issued patent claims to ascertain where these weak links are.

Not all new products, however, require a written opinion. Typically, it is necessary to determine the scope of the investigation based on the level and breadth of patent protection in the field of the proposed product, as well as based on the importance of the proposed product to the company's proposed revenue stream. Either the company can provide all the related prior art to us for consideration, or can provide one or more references of concern. If not, or if the importance of the project warrants it, a clearance search or supplementary clearance search can be arranged by the patent lawyer preparing the opinion to obtain the closest patents in force for consideration. Any relevant file histories are typically ordered from the U.S. Patent Office at this stage.

The patents uncovered are then analyzed, along with the file histories where applicable, to arrive at a preliminary determination as to claim interpretation and possible avenues of non-infringement. If a patent is significantly far afield from the proposed product or process, a verbal opinion can be sufficient. If one or more patents are sufficiently close to the proposed product or process such that reasonable minds might differ on the infringement question, a written opinion should be prepared as long as a reasonable non-infringement position exists. As previously noted, such opinions can provide comfort to the company that it can proceed with its commercialization plan, and remains in the vault for use in an infringement trial should it become necessary. Moreover, design changes can be identified that can help move the client's products further away from the valid scope of the patent claims to further insulate the company from liability. The important point here is that a company needs to consider the patent landscape relating to a new product to increase the confidence that their marketing, sales and production will not be unexpectedly interrupted by legal action.

On occasion, there are times where a redesign is too costly, too time consuming, or simply impossible or not economically feasible. In those situations, the validity of the patent claims must be carefully evaluated, since an invalid patent claim cannot be infringed. An invalidity analysis is typically more involved than a non-infringement analysis. Often, a company knows the technology best and can provide such invalidating prior art to us for consideration. Otherwise, an additional and more detailed search, often called an "invalidity search," is implemented to locate prior art references that disclose or suggest the invention recited in any given patent claim of concern. Once suitable invalidating prior art is uncovered, the invalidity analysis can be conducted and a written opinion prepared.

In the event no reasonable position exists with respect to non-infringement or invalidity regarding a client's proposed product or process, it may be prudent to enter

negotiations to license the patent(s) of concern. Once a license is in place, commercialization can proceed with another risk resolved in advance.

While these points relate primarily to product clearance and market entry, many of the same intellectual property issues are implicated when our clients seek to acquire a product, a manufacturing plant, and/or a new line of technology. In fact, when acquiring a new line of commercial technology, these clearance issues can significantly affect the value of an acquisition target--and potential infringement liability can even render some too costly for further consideration. Please contact one of our trained patent lawyers if you seek legal advice regarding these or related issues.

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