PREVENTING INADVERTENT FORFEITURE OF PATENT RIGHTS

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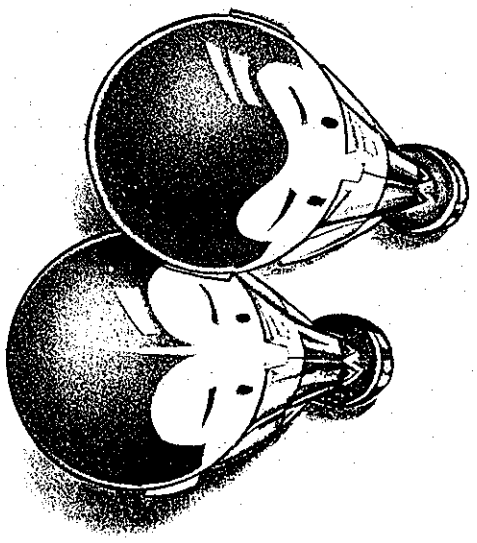
Imagine you are an inventor, or a businessman working with an inventor. Some months ago you demonstrated your new product to a customer. The customer tested it, and gave you a small order. Then a big one. Flushed with success, you rushed to the Patent and Trademark Office to file a patent application. But the door was locked. Furthermore, the door remained locked for your new product, because you *forfeited* your right to secure a patent for your invention. Do you know how this calamity occurred? Do you know how to avoid it? This article will give you some pointers.

Filing Time Limits

A popular misconception is that the patent system is merely intended to reward invention. In actuality, however, it seeks to reward the *prompt disclosure* of inventions to the public. Recognizing that an inventor may be tempted at first to commercially exploit his invention in secret and only belatedly file for a patent when other researchers are "hot on his heels," thus achieving an inordinately long period of exclusivity, Congress requires inventors to seek patent protection within a year of placing their inventions "on sale," lest they forfeit their right to secure a patent. This one year grace period is considered a reasonable amount of time for an inventor, having placed his invention on sale, to determine whether a patent is a worthwhile investment.

The Patent and Trademark Office is well equipped to research patent and technical literature, but is unlikely to notice the first murmurs of sales activity with regard to a new, patentable product. Consequently, it may well issue a patent that is invalid by reason of an on-sale bar. When and if this is discovered in subsequent infringement litigation, not only will the patent be invalidated but also the patentee may be ordered to pay the attorneys' fees of the accused infringer.

This is exactly what happened in *Trans-World Display Corp.* v. *Mechtronics Corp.* (1977). Eastman Kodak was the sole customer for film dispensers patented by



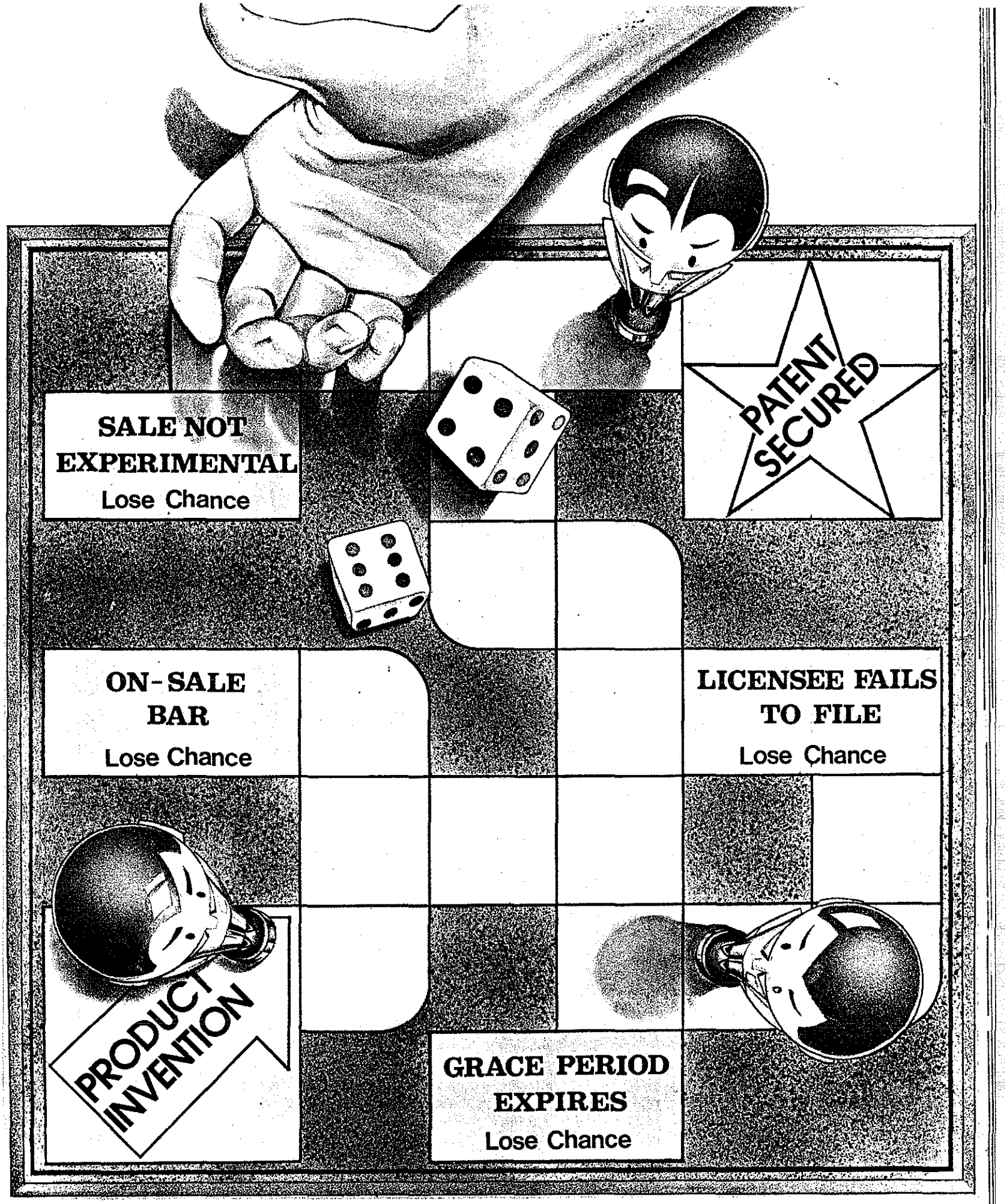


ILLUSTRATION BY KURZ AND KURZ

Trans-World and originally supplied by them. Mechtronics displaced Trans-World as sole supplier to Kodak. Before the critical date (one year prior to filing the patent application), Trans-World had demonstrated to Kodak a half-size, fully working dispenser and had given Kodak price and production cost estimates. Since these facts were not disclosed by Trans-World to the patent examiner, the court declared that Trans-World had brought suit with "unclean hands" and required Trans-World to pay Mechtronics' attorneys' fees.

If an inventor licenses or assigns his invention to an entrepreneur before a patent application is filed, the latter's failure to understand the legal significance of commercial activity may lead to a negligence suit by the inventor against the entrepreneur. In 1981, a North Dakota court held that a licensee, authorized by the licensors (the inventors) to file an application on their behalf, had negligently failed to cause an application to be filed in time to avoid an on-sale bar. Had the company properly informed its attorney of the date the product was first offered for sale (which the company's president could have determined by checking the sales records), the application would have been filed in time.

On-Sale Bar

Clearly, it is important that inventors and businessmen have a working knowledge of the on-sale bar. In reviewing the various factors that must be considered, prospective patentees should be aware that often the various federal courts, and even judges on the same court, differ as to which factors are most important, and the decided cases are not necessarily consistent. Therefore, consultation with a patent attorney is strongly advised should any of these considerations arise.

The one-year grace period starts as soon as a single unit is on sale. The unit need not be delivered, or even "on hand" for delivery, and the offer for sale need not be accepted. A sale to the government for use under cloak of secrecy is as effective as an ordinary commercial sale.

Perhaps the greatest peril for an inventor is in interpreting the on-sale provision as "sold." Under patent law, unsuccessful sales activity may place the invention on sale. As a Delaware court observed, a single offer for sale sent to a single customer, prior to any commercial production of the product, reciting only an estimated price and *not* leading to an actual sale, may be sufficient to start the on-sale clock ticking.

Experimental Sales

The only exception to the rule that a sale starts the clock ticking against the inventor is when the sale is for an experimental purpose, i.e., when the inventor makes the sale primarily to obtain information on how the unit performs under field conditions or simulated field conditions, with a view toward redesigning the unit. The proper way in which to allow a customer to use a device for experimental purposes is illustrated by *Norfin, Inc.* v. *IBM* (1980). Norfin's collator was shipped under documents indicating that it was "being shipped on a memo billing for test and evaluation," that it was consigned "for trial or loan at no charge," and that it was "to be returned to seller" on a specified date. The jury found that this was not a "public use or sale," and awarded Norfin $7,500,000 in damages by virtue of IBM's patent infringement.

On the other hand, in *Racal-Vadic, Inc.* v. *Universal Data Systems* (1980), actual sales were made at full price, the customers were not told that the sales had an experimental purpose, and they were not required to report back test results. The patent was held to be invalid. While neither of these cases involved medical devices, they are significant interpretations of the on-sale clause and are applicable to patents for any products, including medical devices.

A "sale" is more likely to be considered experimental in intent if:

1. the customer was told that the items were for experimental purposes
2. the customer was testing the items at the behest of the manufacturer
3. the items were provided free-of-charge, at cost, or at a reduced price of some kind
4. the manufacturer devised the tests to be performed by the customer, or at least participated in their formulation
5. the customer was asked (or better, required) to report back test results
6. the manufacturer provided the customer with reporting forms
7. the customer was reimbursed for expenses of the test
8. the inventor witnessed the customer tests
9. the items were "on loan" only, and were returned after testing was completed
10. the customer had special testing facilities or expertise which the inventor lacked
11. the item was redesigned in the light of the results of the tests.

In general, when the customer tests a unit merely to ascertain that it is suitable for him, this is not considered to be for inventor's benefit and will not render the sale "experimental."

The sale of a device to an investigator under an IDE appears to be the kind that can be characterized as experimental in intent. The device must be labeled "investigational." The investigator is testing the device at the behest of the sponsor, indeed, pursuant to an agreement satisfying certain administrative standards. The manufacturer, in obtaining an IDE, must explain to FDA why the sale does not constitute commercialization of the device, i.e., show that the price does not exceed cost. The manufacturer, as sponsor, develops the investigational plan to be followed by the investigator, who, in turn, reports back the test results. The investigational plan must include a monitoring procedure, and return of unused items may be required. The

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investigator generally has special expertise and facilities. The device may well be redesigned in light of the test results. Thus, a sale under an IDE appears to bear most of the 11 indicia of an experimental sale as listed above.

Product Demonstration

Frequently, the demonstration of a unit to a possible customer, is considered an "offer for sale" which places the unit on sale. In the garment industry, new lines are customarily marketed by having the clothes modeled and then making samples available to buyers. In the "Tall Trousers" case, *Merry Hull & Co.* v. *Hi-line Co.* (1965), a design patent for overalls was invalidated as their demonstration of the design constituted placing it on sale. Similarly, in *Kalvar Corp.* v. *Xidex Corp.* (1977), the Ninth Circuit Court of Appeals declared that the distribution of film samples in order to generate sales was in itself sufficient reason to invoke the on-sale bar. A demonstration or examination is more likely to be considered an offer for sale if:

1. the demonstrator's sales personnel or the prospective customer's purchasing personnel are present
2. the inventor is not present
3. exact prices, delivery time, and quantities available are quoted
4. the demonstrator refused to demonstrate the device without charge
5. the item was referred to as a production item or as undergoing final testing
6. the performance of the item was guaranteed to be in accordance with specifications
7. the demonstration was referred to as being "successful"
8. no significant design changes were made subsequent to the demonstration.

Particular cases usually involved one or more but not all of these factors. Each case presents a unique situation which should be analyzed thoroughly to avoid possible forfeiture of rights.

Conclusion

Possibly by now, if you are an inventor or a businessman dealing with an inventor, and you are ready to demonstrate a prototype unit to a prospective customer, you are now aware of the pitfalls, and you will make sure that your patent attorney receives your invention disclosure, as well as a detailed description of whatever may be considered sales activity, in time to file an application within the grace period. If you give or sell a customer a sample unit for testing, you will know how to structure the arrangement so that the on-sale clock is not set ticking prematurely. This time, if the new product is commercially promising, you will be waiting on the Patent Office doorstep one morning, and the door will be unlocked. □