Battling infringement

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As more startups share competitive business information in their search for partners within big pharma or biotech, what legal protections are available if their intellectual property is infringed upon?

In the biopharmaceutical sector, in which large firms and small startups or universities often cross paths and frequently work together, a dispute over patent rights can be wildly unbalanced. In a David versus Goliath intellectual property (IP) battle, the large, well-financed Goliath can sometimes minimize or nullify David's hard-earned legal rights, thereby gaining freedom to operate. In fact, if a large company is willing to take risks, it's sometimes financially *beneficial* for the firm to just appropriate (rather than license) the technology.

In the following article, we expose some of the tactics used by large, well-established and well-financed companies to acquire a university's or small company's IP. We also offer suggestions that may be helpful in leveling the playing field, because if you're prepared, you may succeed in stopping the infringement and collecting damages.

Box 1 The consequence of eBay Inc. v. MercExchange, LLC

Before 2006, a university or a small company plaintiff forced out of business because of the delays in enforcing its patents could still have obtained a permanent injunction against the infringer. Permanent injunctions were usually granted to a patent holder after prevailing on liability (patent infringement and validity). The consequences of a permanent injunction were often so disastrous to an infringer that they served as a deterrent against egregious acts of intellectual property appropriation. Before 2006, driving the small company out of business did not eliminate this threat. That changed with the US Supreme Court decision of *eBay Inc. v. MercExchange, LLC*.

The eBay case was, in part, a reaction to the practice of patent enforcement by companies not competing in the marketplace. As a consequence of the eBay decision, injunctions prohibiting the manufacture, use and sale of infringing products are far less likely to be granted to companies not practicing the patented technology. If the company has been driven out of business because of the delays in enforcing its patents, then it clearly is not practicing the technology. In such circumstances, the courts may find that monetary remedies are sufficient to compensate for the injury caused by infringement. Namely, the small company can be totally compensated by money. Also, because the small company is no longer in business, the public interest may weigh against granting an injunction that shuts down an infringer. *eBay Inc. v. MercExchange, LLC* dramatically changed the risk profile for large, well-financed companies using technologies covered by patents from universities or small startups that have not yet commercialized the technology, and now the serious consequences to a large company of shutting down their manufacturing line and cutting off customers are less likely.

Exposing yourself

How does a large company find out about your technology anyway and decide to infringe it? The truth is, you can be exposed to the risk of IP appropriation through the normal process of seeking partners or financing your company. This is because at least some information must be disclosed in order for a prospective investor to perform due diligence—this can't be avoided. Companies seeking funding usually expect that a prospective investor will treat the information as confidential, sensitive business information, but the funding process presents inherent risks to confidentiality. And it's possible another company will act on the information it sees.

Many entrepreneurs think that if this does happen, a preliminary injunction can serve as a legal mechanism for protecting small companies in patent litigation. Although a court *can* grant a preliminary injunction, which would bar the defendant (in this case, the larger company) from making, using or selling the product before the full determination of the merits of a case, it is unlikely. In seeking a preliminary injunction, you need to demonstrate that there is a substantial likelihood of success on the merits of the case and that there is a threat of irreparable injury. Without a prior successful trial, it is difficult to demonstrate substantial likelihood of success.

It is also hard to establish the threat of irreparable injury, as the courts often conclude that any harm caused to you, the plaintiff, can be compensated with a monetary payment. Even if you were forced out of business, the harm can theoretically be compensated monetarily and thus is considered reparable.

There is a third thing working against you when seeking a preliminary injunction: the requirement for posting a bond. The bond is meant to compensate the defendant for financial losses if the defendant prevails. Perhaps you have the resources to post a multimillion-dollar bond, but few small startup companies or universities do.

If the court will not grant a *preliminary* injunction, then your goal is to secure a *permanent* injunction. This is the type of injunction

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that would be issued after a trial if you win. The problem for you as a small company is that, to get a permanent injunction, you must hit a proverbial home run. First, you need to be funded. Then, you need to work out the technical aspects of your technology, manufacture it, find a distribution channel and launch a product. (Although you can bring legal action, even without launching the product, you would have difficulty obtaining an injunction; see **Box 1**.) Next, you need to be awarded one or more patents with which to allege infringement. Finally, you need to actually win in court, at both the district and appellate levels. It's a lot; just your end of things that need to happen is a major uphill battle.

The climb steepens

Unfortunately, besides the hurdles you face on your own, there are many tactics a large company can use to stop a small company patent owner along the way. The first is financial. Until the trial, if the competing large company copies and markets essentially the same technology, then there will be two similar product offerings available to customers. The large company will likely enjoy brand-name recognition and lower distribution and service costs because, as an established company, it probably also handles other products. For these reasons, the large company will probably outsell you and might be able to bleed you dry (**Box 2**).

Once the litigation has started, the defendant might hire an aggressive law firm to generate large numbers of legal motions, document discovery requests and deposition notices. This will force your law firm to respond, driving up your legal bills and increasing your rate of cash burn. The entry fee—the absolute minimum a lawsuit is likely to cost to get to trial (not including appeals and a potential second trial for determining damages)—is about $1 million. More commonly, the figure is several million dollars. If the infringer hires an aggressive law firm, the number is likely to be even higher.

An additional tactic of a larger company is to simply find reasons to push the trial date out as far as possible, giving the large company more time to sell its product and drain your finances. Often, the judicial process moves at a glacial pace. A 2008 study of patent litigation measured the time to trial among 394 trials in 65 US federal districts. The national median time to a first trial, for assessing liability, is 2–3 years[1]. From start to finish, the process can take a decade. For a small company, the years required for enforcing IP can be lethal. Until an injunction is issued, the large, entrenched competitor may be dominating the market with the technology initially developed by you—and you may go out of business in the interim.

Another delaying tactic is to file a reexamination request with the US Patent and Trademark Office (USPTO), which undertakes reexamination of issued patents (35 U.S.C. 302). Patent reexaminations were intended to provide an inexpensive mechanism for challenging issued patents without requiring a court proceeding. Because it is inexpensive relative to litigation, the reexamination process is designed to provide an even footing for both small and large companies. There is, however, an alternative use for a patent reexamination that has little to do with its original purpose. It is possible to use it to delay court proceedings.

Within 3 months following the filing of a reexamination request, the USPTO will determine whether the requestor has raised a substantial new question of patentability. The threshold for this determination is not necessarily high. Often, that threshold can be met by the identification of new prior art, not considered by the patent examiner during the original prosecution, that creates a question as to novelty or obviousness of the patent claims.

If these conditions are met, then the USPTO will reopen the patent examination.

Once the reexamination is started, the large company defendant can file a request with the court to stay, or place on hold, all legal proceedings pending the reexamination's outcome. There is no guarantee that the court will agree to a stay, but the argument can be compelling from the standpoint of judicial efficiency. Courts are not inclined to spend judicial time and resources if there is a chance the patent will not survive reexamination. Reexaminations can take at least 1 year—and often several—which for a stayed case can be a substantial delay.

A reexamination can also be filed even if the plaintiff already won at trial. If the reexamination request is filed after the determination of patent validity, then it may seem to the small company or lone inventor patentee like a sort of judicial double jeopardy. The defendant gets a second chance, with the same or similar arguments, to try to invalidate or narrow the patent claims. The fact that an invalidity argument was already adjudicated at trial has little weight in the reexamination. Juries are instructed to view issued patents with a presumption of validity unless proved otherwise. No such presumption of validity exists during a reexamination proceeding. The two different standards justify subjecting the patent holder to two routes for challenging patent validity.

Even if the defendant is ultimately found liable for infringement, the damages awarded may be relatively small compared with the potential upside in value appreciation the small company might have seen had the infringement never occurred. Patent law (35 U.S.C. 284) allows you to recover only damages adequate to compensate for the infringement but not less than a reasonable royalty. A lost-profits calculation is one possible basis for damages that usually yields a higher number than a reasonable royalty calculation. However, it only applies to companies that are in business and selling the product. If your company did not survive during the years of litigation, then you may have to settle for a reasonable royalty. Because universities are not in the business of manufacturing and selling the product, they cannot be awarded lost profits, only a reasonable royalty. This means that the defendant's worst-case outcome is that the damages will cost only what they would have paid anyway. In this case, there is no penalty to the large company for appropriating, rather than licensing, the IP other than the cost of litigation.

If the defendant is found to have willfully infringed, then that can result in greater damages. Many assume that the risk of double or treble damages will discourage large companies from aggressively appropriating

Box 2 Why litigation delays are lethal to small companies

Litigation battles that stretch 2 years or longer can cripple a small company. The enterprise is hemorrhaging cash and the court appears to be unconcerned with its plight by not moving the matter to a quick resolution. What should have been an innovative new product technology is now, because of the infringement, a me-too product. A small company may try to publicize the fact that they have the patent rights and are suing for patent infringement, but customers are often not concerned with the patents and IP ownership. On the other hand, the infringing, larger company might tell prospective customers that the small company may be out of business soon, further compromising potential reputation and sales. With no near-term solution in sight, the small company might exhaust its cash on the litigation battle and end up being acquired at a fire-sale price. This is an opportunity for the competitor or a third party to acquire the small company's IP rights at a steep discount—effectively driving the small company out of business.

a small company's (or university's) IP. Recent appellate court decisions, however, make it more difficult than ever to prove intent, rendering a finding of willful infringement an unlikely outcome.

Suggested steps

None of this looks particularly easy, and spending all this time enforcing your IP rights would detract from your real focus of running a business. Certainly, the concerns of the marketplace might seem a long way away if you're just launching your company with preclinical data. But there are steps you should take early on to mitigate risks, secure defensible patents and preserve confidentiality while seeking business partners or funding.

First, maintaining confidentiality early in the process is important. When providing a business plan to potential venture capital investors, obtaining a written confidential disclosure agreement is unlikely. Instead, document the recipient's existing confidentiality policy (it may be posted on its website). It may state that the information will be kept within the firm and its pre-established group of advisors. If there is no written policy, ask.

Second, boldly print or stamp the word "confidential" on each page of the business plan, not just on the front page.

Third, print the business plan on paper that does not allow clean copies (for example, Boise BEWARE security paper).

Fourth, do not provide a digital file of a business plan because it is easy to copy and retransmit.

Fifth, insert on each business plan page a discreet code linked to the business plan number. Retain a master list of the codes/business plan numbers so that even isolated pages from the document can be traced back to the recipient and you'll know where a leaked document page came from.

Sixth, minimize the number of business plans that you send out. Too many creates the appearance that the documents are in the public domain and increases the risk of disclosure by one recipient. Disclosure of the underlying information from a single recipient to an innocent third party can destroy the confidentiality of the information.

Seventh, avoid sensitive information in your business plan. That's easily done if the sensitive information is limited to a secret formula, but when it can be a new, previously unappreciated market opportunity, avoiding it becomes much harder.

Eighth, to the extent that confidential information is patentable, it is important to protect your IP rights as best you can before sending out business plans. So make sure you have complete and well-drafted patent applications filed before you disseminate business plans due to the possibility of a breach of confidentiality that could interfere with subsequent patent filings.

Ninth, enforcing IP also depends on the strength of your patents. This is an area in which the relationship to your patent counsel can be of paramount importance. Maintaining a continuation application pending throughout the enforcement period is a practice that has been criticized by some, but it can help balance the practices of infringers. If you have a continuation patent application pending, you can present newly cited prior art for consideration by the examiner without the limiting procedural requirements of reexamination. A continuation also enables the patent owner to tweak the claims as required in response to unexpected interpretations of claim language by the courts or redesigns by infringers attempting to avoid a lawsuit while copying the essence of the invention. A close and continuing relationship between an inventor and patent counsel can be the difference between success and failure in the patent enforcement process.

And finally, many of the constraints that the US legal system places on small companies and universities (in trying to enforce their IP) can be overcome by partnering with a large company against the infringer. In fact, this is an area in which your interests may align quite well. A large-company partner will have the financial resources to see the litigation through to the end. Because the partner is selling the product, it can obtain an injunction and argue for damages from lost profits rather than from a reasonable royalty. From the partner's standpoint, it has the opportunity for an exclusive license to your technology. The fact that a large competitor is infringing somewhat validates the market opportunity.

Conclusions

For universities and small companies, enforcing IP presents many unique challenges that large-company plaintiffs are unlikely to encounter. Part of the solution may be the creation of a new mechanism for prompt adjudication. Dragging the litigation out for up to a decade makes patent enforcement out of reach for many small businesses, and this can ultimately stifle competition and drive small companies out of business—both contrary to the general interests of the United States, if this happens to be where your company is located. Unfortunately, the only way to have a meaningful solution to this problem is with an act of US Congress. In the meantime, entrepreneurs should do all they can to keep infringers at bay.

1. Levko, A., Torres, V. & Teelucksingh, J. A closer look: 2008 patent litigation study: damages awards, success rates and time-to-trial. PwC <http://www.pwc.com/en_US/us/forensic-services/assets/2008_patent_litigation_study.pdf> (2008).

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