

The biotech patent: to license or litigate?

The relative immaturity of the biotechnology industry and the still-developing law governing biotechnology patents, coupled with the marked rise in the number and type of untested biotech patents being granted, means that biotech is somewhat lacking in the relatively predictable modes and models of patent strategy that often prevail in more mature fields.

When confronted with adversely held biotech patents, companies must decide whether to take licences or risk litigation. As a company develops new technologies and considers whether to invest in new products, the ‘license or litigate’ question arises more frequently. This chapter considers various factors behind the answer.

Preliminary considerations

Before undertaking the expense of a detailed analysis of adversely held patents several initial questions should be answered. Does the patent realistically concern the proposed product or new technology at all? While all allegations of infringement should be taken seriously, some patent owners pursue a ‘mass mailing’ approach and send warning letters to all companies believed to be working in a certain field. Biotech has a particularly high level of such ‘background noise’ given the proliferation of patents, history of aggressive enforcement, and the distribution of patents among thousands of owners ranging from start-ups through traditional pharmaceutical companies to private and public universities. If it is determined that the patent may indeed apply, what is the term of the patent compared to the expected commercial launch of the product? A patent with only two years of remaining life poses little risk to a pre-clinical product. Might the company already have a licence under this patent? A series of mergers or acquisitions on either side can cloud the issue. This preliminary review will often determine that the patent is neither a threat nor an opportunity, and that no further action is required. Otherwise, a more in-depth analysis will be required to determine if a licence should be taken or if litigation should be risked.

Valuing a potential license v litigation

Ideally, the owner of every adversely held patent would be willing to grant a licence, each licence would be available on reasonable economic terms, and the total royalty

burden from licensing all such patents would not be prohibitive. In the biotechnology industry, this is rarely the case. A patent owner may simply refuse to grant a licence for any number of reasons. These range from the strategic (using its patents to acquire the product for itself instead of granting a licence), to the tactical (waiting to see if an early-stage product enters advanced clinical trials and then demanding much greater payments), to the mundane (not wanting to expend the resources required to investigate the licensee and negotiate a licence).

The patent owner may also demand a large up-front payment that is beyond the prospective licensee's means. Or, the multiplicity of relevant adversely held patents (frequently claiming different layers of patent protection) may render it commercially prohibitive to license them all, even if the price of each individual licence would be reasonable by itself. For example, an antibody-based product could be licensed under patents claiming the antibody itself, an agent attached thereto, a method of conjugating the agent, expression of the product in transformed cells, a particular expression system, cell culture conditions, purification methods, and therapeutic uses, as well as techniques used to develop and screen the selected antibody. If different companies own all these patents, it may be impossible to license them all.

Just as the patent owner's offer to grant a licence always carries with it (at least implicitly) the threat of litigation if a licence is refused, the prospective licensee should always consider both whether the threat of litigation is real and if litigation with a high probability of success may indeed be preferred to overpaying for a licence. There is no single way to determine the 'right' price for a licence, but various parameters should be considered.

Strength of the patent – infringement and validity

By some measures, as many as half of all patents that are litigated to final judgment are ultimately held to be invalid. For example, a recent report by the Federal Trade Commission found that generic drug companies had a success rate of more than 70% when challenging patents asserted by the innovator companies to cover the branded drug product. It is clear that litigation can be a viable option for a company accused of infringement. Thus, an informed evaluation of whether a licence is an economically rational choice requires an objective evaluation of the likelihood

of success if a licence is refused and the patent owner sues for infringement.

The principal issues in patent litigation are infringement and validity of the patent. A patent is infringed when the drug product is encompassed by the claims of the asserted patent. Patents are by law presumed to be valid, but may be invalidated by a court upon an adequate showing by an accused infringer. The two grounds of invalidity most pertinent to biotech patents are prior art and sufficiency of the specification.

In evaluating whether it has a good case to litigate at trial, the accused infringer should consider the types of defences it has and whether or not they make a good 'story' to present to the trier of fact (particularly a lay jury, which may have difficulty understanding complex proofs). For example, the patent owner has the burden of proving infringement. On the other hand, an issued patent is presumed to be valid and the challenger must prove invalidity by a high 'clear and convincing' standard of proof. Hence, a strong non-infringement position is generally preferred to an invalidity defense.

The issue of infringement is often determined by the court's decision with regard to 'claim construction', which refers to resolution of any dispute between the parties concerning the meaning of words or phrases in the patent claims. The judge decides such claim construction issues, and their resolution commonly permits the question of infringement to be decided on summary judgment. However, if there is a genuine factual dispute as to whether the product satisfies all the elements of the properly construed claim, infringement will be determined at trial (before a jury if this has been requested by either side).

With respect to prior art, a claim may be invalid as 'anticipated' (based on a single piece of prior art that discloses each claim element) or 'obvious' (based on a combination or modification of prior art). The patent specification should also be reviewed to see if it only describes a general class of biologics (eg proteins or antibodies) without identifying or fully describing the biological drug of interest (by DNA sequence or deposit, for example, or the amino acid sequence of the expressed and purified protein drug). Early biotech patents, in particular, may be invalid if their claims are broadly construed to cover

the disputed drug product because they fail to provide a sufficient ‘written and/or enabling’ description under the current biotechnology law.

A legally and technically sound conclusion that a patent is invalid or not infringed does not necessarily mean that the issue would be favourable to litigate. For example, because the patent owner may rebut a claim of obviousness by showing ‘secondary considerations’ such as commercial success, long-felt need, and copying by others – all of which allow the patent owner to impress the judge or jury with its scientific and business achievements – anticipation is generally easier to prove at trial because such evidence is irrelevant to anticipation.

Other factors not formally related to infringement and validity may also have a bearing on the likelihood of success. Is the patent owner a well-known research hospital with a sterling reputation in the community? If the patented drug is a successful product that has saved lives and reduced human suffering, or if the disputed technical issues are highly complex, will the trier of fact (particularly a jury) be willing to reverse the Patent Office’s decision to grant the patent? Conversely, might the public controversy over the cost of pharmaceuticals sway a jury toward stripping away patent protection that impedes the introduction of a competing product? Were there dealings between the parties that would make the patent owner’s claim look like a case of sour grapes? Is there a credible claim that the company’s product was actually derived from work done by the patent owner, as where the company’s scientists came from the lab of the inventor of the patent? In what jurisdiction is the litigation likely to occur? Does the company have access to credible fact and expert witnesses who will be able to convey its positions clearly and compellingly? While companies are sometimes overly influenced by these factors, even to the point where they come to believe that the actual merits of the case are of little concern, they should not be ignored when assessing the likely outcome of litigation.

Type and scope of patent

Different types of patents have different licensing value. For example, patents may be directed to products *per se*, to methods of using a product, manufacturing processes, or research tools. Clearly, a patent that claims a manufacturing process is of limited value if the company either does not use

that process or can economically change to a different, noninfringing process. The value of a patent that claims a method of using a product can be substantial if it broadly claims the intended use, such as a method of using an antineoplastic to treat cancer, or minimal if it narrowly claims an insignificant use, for example, a method of using an arthritis drug to treat a rare neurological disease that afflicts ten patients each year.

Biotechnology companies are frequently faced with the decision of whether to license a patent directed to a ‘research tool’. Such patents, which are ubiquitous in this field, claim methods of drug discovery or generally applicable laboratory techniques, but neither the actual therapeutic product nor a method of manufacturing or using that product. Licences under these patents may be offered on very reasonable terms – particularly if the licensee agrees to buy the materials for practising the patented method from the patentee – or may include a demand for significant ‘reach through’ royalties on sales of any product discovered through use of the patented method. The enforceability of such royalties is an open question. Another question is whether the general exemption in the patent statute for conduct directed to obtaining information for submission to the FDA for receipt of regulatory approval applies to basic drug discovery. At least one trial court has essentially held that virtually all drug-discovery research is immunised from claims of patent infringement, but the issue is far from settled.

Identity of the patent owner

The type of company or institution that owns the patent can profoundly affect the availability and value of a licence (as well as its terms). Although recent years have seen an increased aggressiveness by universities in enforcement of their patent rights, universities lack both the resources and the mandate to develop and commercialise drug products, and will usually grant licences on reasonable terms to companies that have the ability to do so. At the other extreme, large, well-funded biotech or pharmaceutical companies may leverage their patent portfolios to acquire (at a discount) potentially infringing products for their own pipeline. In between are companies that have the ability and resources to develop the product but are not interested in doing so because it is outside their current business focus.

An aggressive patent owner that perceives a clear imbalance of risks may also seek what the company perceives as extortionate licensing terms. For example, a patent owner who asserts a patent that is not protecting its own product and not generating any licensing income risks only the expenditure of its attorneys fees if it loses the case, while an accused infringer that has spent hundreds of millions of dollars to develop a product risks the loss of its entire investment if it is enjoined from selling the product. By contrast, a patent owner who is receiving substantial royalty income from a patent risks losing that income if a prospective licensee challenges the patent and obtains a ruling that it is invalid. Similarly, if the patent protects its owner's commercial product and the accused infringing product is not directly competitive, the patent owner may tolerate some level of infringement or grant a reasonable licence rather than risk a judicial ruling that the patent is invalid.

Licensing terms and anti-stacking provisions

Provisions in a company's existing licences may ease the sting of additional licences. For example, licences in the biotechnology field often include 'anti-stacking' terms that permit the licensee to deduct some portion of the royalties paid to others from the amounts due under the licence. For example, royalties may be fully or partially creditable to a set 'floor' rate. The licence may also set a ceiling or maximum royalty to be paid out to all licensors by the product developer. In any event, obtaining anti-stacking protection wherever possible is of particular importance in this field because of the substantial likelihood that a company will require multiple licences from different patent owners in order to commercialise a product.

It should be noted that there are other options (beyond the scope of this chapter) besides licensing or litigating. These include, for example, designing around the patent and

proceedings such as interferences or reexaminations that may be initiated in the US Patent and Trademark Office.

Although this chapter addresses the decision to license or litigate, they are often not mutually exclusive. A company that takes a licence on a particular patent is generally not precluded from challenging the validity or scope of that patent in litigation. Indeed, a licensee can usually keep the licence in force as a type of 'insurance policy' while it litigates (so long as it continues to pay royalties).

Also, once a company decides not to license a particular patent, its exposure to damages if litigation results can be minimised by receipt of an opinion letter prepared by competent patent counsel concluding that the patent is not infringed and/or invalid. The reasonable reliance on such an opinion may prevent an award of treble damages and attorneys' fees if the patent owner ultimately prevails in litigation. Such an opinion must be rendered by a qualified patent attorney and is preferably rendered by outside counsel.

Conclusion

Taking a licence under an adversely held patent largely eliminates the risk and expense of litigation on that patent in the future. However, the existence of many different, layered patents can preclude the possibility of licensing all potentially relevant patents or lead to prohibitive stacking royalties (not to mention up-front fees and milestone payments), making development of the drug product no longer commercially viable. Yet, if a required licence is not taken and the outcome of the litigation is a finding of infringement and validity, the entire investment in the product may be lost. Biotechnology companies must have a rational method to value potential licences, balance the risk and expense of litigation against the cost of taking a licence, seek and aggressively negotiate licences when appropriate, and be prepared to litigate when licences are not available or are not taken.

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Ms Somerville counsels clients on the validity, scope, enforceability and transfer of intellectual property rights. She actively guides clients in introducing new products and in developing intellectual property strategies and portfolios. While successfully procuring commercially significant patents, she has supervised the drafting of applications and their prosecution, including interferences, reissues, protests, re-examinations and oppositions. She also negotiates licenses and conducts due diligence for major corporate transactions. In addition, Ms Somerville has considerable experience in patent litigation before the federal courts.

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