Moveable pieces

Janice V Rice and **Tamara Fraizer** discuss recent developments in US law that should be considered in IP due diligence

A wide range of assessments may fall under the rubric of intellectual property (IP) diligence – from mere tabulations of registered rights, to informed assessments of viable and pertinent rights, to rigorous valuations based upon legal review of those rights. Well-informed patent diligence is particularly important for life sciences companies, where the value of a marketable innovation may depend on the quality of the patent rights encompassing it. Because new developments in the law may render issued patents vulnerable to challenges, a savvy assessment will not only identify actual and potential IP of relevance, but also account for vulnerabilities in that IP and value the portfolio appropriately in view of them. In this article, we discuss several recent developments in US patent law that should be considered in IP diligence involving life sciences companies.

Subject matter (in)eligibility

What constitutes subject matter that is eligible for patenting under 35 USC § 101 is particularly important for life sciences companies. In the 2012 *Mayo v Prometheus* decision,[1] the Supreme Court of the United States ("SCOTUS") set forth a two-step test: first, consider whether a claimed invention is directed to a patent ineligible concept such as a law of nature, product of nature, or natural phenomenon. Secondly, consider whether there is significantly more to the claim than the patent ineligible concept. The courts have struggled to assess eligibility under this test.

For example, detection of paternally-inherited fetal DNA in a mother's blood for prenatal diagnosis and, more recently, confirming presence of Mycobacterium tuberculosis by detecting certain genetic sequences, were both found not patent-eligible.[2] In a welcomed decision, *Vanda Pharmaceuticals Inc v West-Ward Pharmaceuticals Int'l Ltd,*[3] now on appeal to the SCOTUS, the Federal Circuit Court of Appeals ("Federal Circuit") found that a claim to a method for treatment based on a biological correlation is eligible subject matter. In this case, claims to a method of treating a schizophrenia patient with iloperidone by determining whether the patient is a poor metaboliser of the drug based on genotype, and administering a specific dosage accordingly, were deemed patent eligible subject matter.

Given such continuing changes in the law of eligible subject matter, assessments of patents relating to diagnosis and treatment of disease deserve special consideration. Importantly, if the SCOTUS reverses the Federal Circuit in the *Vanda* case, then patents with claims directed to methods of treatment based on biological correlations are of questionable validity and value.

On-sale bar

While much can be gathered from public sources about the viability of a patent portfolio, some such information may be secret or difficult to identify. This is information for which an acquiring company should ask and that the target company should be prepared to provide. Of paramount importance are public uses or sales of inventions prior to the filing of patent applications.

In the US, a commercial sale or offer to sell an invention may bar a patent if the application was filed more than one year after the sale or offer to sell. Revisions to the patent laws in 2013 suggested that prior secret sales might not bar a patent. However, a recent SCOTUS decision, *Helsinn Healthcare v Teva Pharmaceuticals*,[4] confirmed that a prior sale or offer to sell does not have to make the details of the invention publically available to trigger the on-sale bar. Helsinn, a Swiss pharmaceutical company, licensed out the right to promote, market, and sell a pharmaceutical in the US, and also agreed to supply it to the licensee for sale in the US. Helsinn filed a patent application nearly two years after this activity. Helsinn's sale was held to be prior art for the subsequently filed patent application.

In IP diligence, careful review of existing agreements is therefore needed to determine whether the invention has been commercially sold before a patent application was filed on it – thereby jeopardising its validity. It is worth noting that a sale or purchase made primarily for purposes of experimentation may not be a "commercial" sale, depending on the evaluation of numerous factors.[5] For example, an on-sale bar may not be triggered where a company contracts with a third party to supply the company with material to do preclinical or clinical testing of their potential drug, which has not yet received marketing approval.

Patent term and double patenting

Life sciences companies need patents to recoup costs from the extended testing and approval processes, which on average take 12 years in the US.[6] A key consideration in diligence is whether the patent life of a product or clinical candidate has been fully maximised and whether the patent estate will withstand scrutiny in litigation.

US statutory and judicial doctrines prevent a patent owner from extending the life of a first patent to an invention with further patents on the same invention (double patenting), or obvious variants of it (obviousness-type double patenting or ODP). ODP is commonly used to challenge patents for what may be perceived as an unfair extension of the patent life of a pharmaceutical. One way to overcome

ODP, but not double patenting, is to file a terminal disclaimer. However, any terminal part of the patent's term is dedicated to the public, defeating one goal of filing follow-on applications.

In what some perceive as an expansion of the ODP doctrine, the Federal Circuit in the 2014 *Gilead Sciences, Inc, Natco Pharma Ltd* decision, held that:

> An earlier expiring [but later issued] patent can qualify as an obviousness-type double patenting reference for a later-expiring [but earlier-issued] patent... In [such] cases... a terminal disclaimer can preserve the validity of the later-expiring patent by aligning its expiration date with that of the earlier-expiring patent. *That disclaimer will most effectively enforce the fundamental right of the public to use the invention claimed in the earlier-expiring patent and all obvious modifications of it after that patent's term expires.* (emphasis added)

In light of the *Gilead* decision, portfolios should be reviewed carefully for potential ODP issues that may arise in a patent after it has issued, when closely-related patents issue thereafter, and for whether additional terminal disclaimers should be proactively filed.

After the *Gilead* decision, questions arose about how far the courts might extend the public's "fundamental right" to use an expired patent. Fortunately for patentees in the pharmaceutical industry, a recent case shows there are limits. In *Novartis AG v Ezra Ventures LLC*,[7] the Federal Circuit ruled that it is a permissible consequence that an earlier-expiring patent cannot be practised during the term extended under 35 USC § 156 (PTE).[8] The court also held that the earlier-expired patent does not invalidate, under an ODP theory, the PTE-extended patent. Given the importance of ODP issues to the length of patent life of a drug, diligence activities should include a thorough evaluation of the patent portfolio for potential ODP issues and the effect and scope of any terminal disclaimers.

Unenforceability

An issued patent can be found unenforceable based on legal doctrines of equity, eg, the doctrine of inequitable conduct. This doctrine traditionally required that material information was withheld from the US Patent and Trademark Office (USPTO) during prosecution of the patent application and that such withholding deceived the USPTO – with some balancing of these factors allowed.

Almost a decade ago, in *Therasense, Inc v Becton, Dickinson & Co,*[9] the Federal Circuit found the doctrine to be overused and tightened the standards, requiring proof by clear and convincing evidence that the patentee had a "specific intent to deceive" the USPTO in withholding information and, separately, proof that the information withheld was "but-for material", such that the patent would not have issued but for its withholding. These higher standards made findings of unenforceability less likely.

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More recent opinions suggest the impropriety of the patentee's behaviour – both in prosecution and litigation of those rights – may still jeopardise the enforceability of its patents. In *Gilead Sciences, Inc v Merck & Co*,[10] the Federal Circuit affirmed the trial court's finding that prosecution counsel improperly used information obtained from another company to amend the patentee's application. Applying the equitable doctrine of unclean hands, it barred the patentee from obtaining any recovery for infringement of this patent. In the case of *Regeneron Pharmaceuticals v Merus*,[11] the court issued an adverse inference of specific intent to deceive the USPTO based upon counsel's alleged conduct in litigation.

These decisions demonstrate that misconduct of patent counsel in prosecution and/or litigation can jeopardise the enforceability of a patent. In conducting diligence, it is therefore advisable to consider the practices of a company's patent attorneys, including polices, to ensure proper disclosures of information to the USPTO and to prevent improper use of confidential information during prosecution.

Summary

At every step of the life of a patent – from eligibility to validity and enforceability – there are pitfalls that can trap the unwary. While this article has focused on some issues arising from recent US case law, legally informed assessments are important in all aspects of defining a company's viable patent rights. In particular, fundamental issues related to inventorship and ownership,[12] as well as patent quality, must not be overlooked. For the best result, target companies should work closely and openly with IP counsel to identify and address potential issues with their IP. Those that seek to invest in them should beware the perils of this challenging and changing legal landscape.

Footnotes

1. 566 US 66 (2012).
2. *Ariosa Diagnostics v Sequenom*, 788 F.3d 1371 (Fed Cir 2015); *Roche Molecular Systems v Cepheid*, 905 F.3d 1363 (Fed Cir 2018).
3. 887 F.3d 1117 (Fed Cir 2018).
4. 139 S Ct 358 (2018).
5. See *Electromotive Div of General Motors Corp v Transportation Systems Division of General Electric Co,* 417 F.3d 1203 (Fed Cir 2005) identifying factors used to determine whether a sale is commercial.
6. JACC: Basic to Translational Science 2016, Vol 1(3), p. 170-179.
7. 909 F.3d 1367 (Fed. Cir. 2018).
8. PTE is awarded to compensate for marketing approval delay, eg, time lost to clinical testing and to the drug approval process.
9. 649 F.3d 1276 (Fed Cir 2011).
10. 888 F.3d 1231 (Fed Cir 2018).
11. 864 F.3d 1343 (Fed Cir 2017); rehearing *en banc* denied, 878 F.3d 1041 (Fed Cir 2017); writ of *certiorari* denied, 139 S Ct 122 (2018).
12. Rice, Janice V 'Preparing for IP diligence: ensuring proper inventorship and ownership of patents.' *Global IP & Technology Law Blog*, Squire Patton Boggs, published 15 Mar 2019, https://bit.ly/2HtDDRJ

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