New patent strategies for biofuel and biochemical companies in an era of patent reform

Protecting your ideas

Patents are an integral piece of the overall business plan for companies, universities and other institutions in developing biotechnologies, as they validate the technology, strengthen the patentee's position to investors and provide leverage during business transactions such as licensing, mergers, and acquisitions.

In September 2011 the Leahy-Smith America Invents Act (AIA) was signed into law by President Obama, bringing the most significant changes to US patent law since 1952. These changes better harmonise US patent law with the rest of the world and greatly affect patent protection strategies, particularly in emerging technologies such as the biofuel and biochemical industries.

The AIA, among other things, provided for prioritised examination of applications and introduced new ways to challenge competitors' patents and applications.

Expedited patent creation

In view of the importance of patent protection in emerging technologies, it is often desirable to obtain patent protection as quickly as possible. However, due to backlogs at the US Patent and Trademark Office (USPTO), many biotechnology-related patent applications do not receive any substantive action for at least two years.

The AIA, recognising the administrative delay, created a new process to expedite examination.

Request for prioritised examination

The USPTO began a new prioritised examination programme on 26 September 2011, also known as Track I. Under this programme, an application will be advanced out of turn for examination upon payment of a $4,000 (€2,950) petition fee and compliance with other formalities.

This fee is reduced by 50% for qualifying small entity applicants (typically an applicant who is an individual inventor, a business having less than 500 employees or a non-profit organisation or university). The application must be complete upon filing and contain no more than four independent claims and 30 total claims.

The USPTO's goal is to provide a final disposition of a Track I application within 12 months of prioritised status being granted. Final dispositions include an allowance, a final rejection, the filing of a notice of appeal and abandonment.

Current USPTO data indicate the average time from grant of the request for Track I examination to a first Office Action is about two months, and the time from grant to final disposition is only about six months.

Although the upfront costs are greater, small businesses, universities and other institutions in the emerging biofuel and biochemical industries should consider prioritised examination as a means to reduce delays in examination of core technologies in the US.

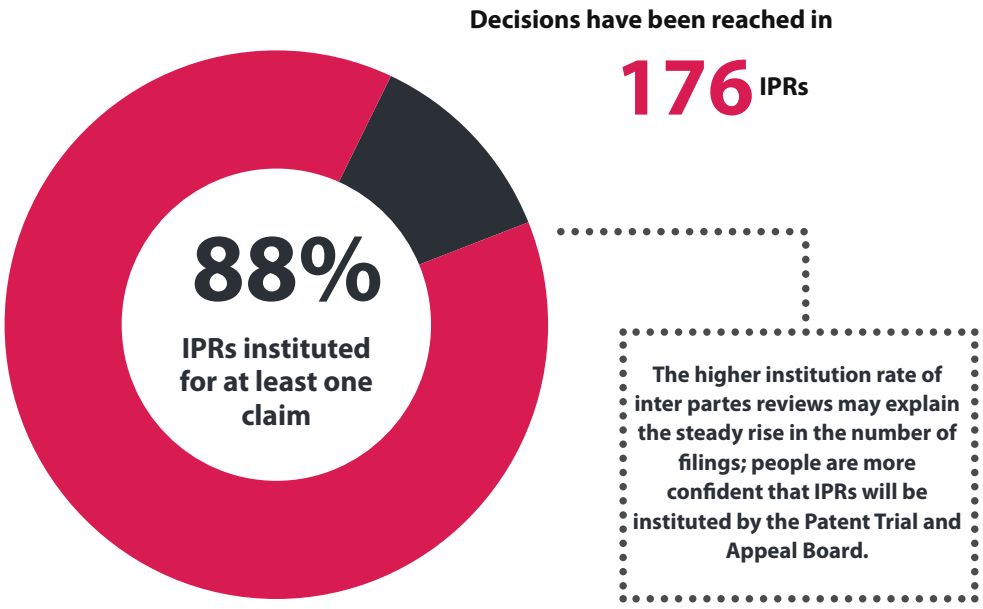
Patent prosecution highway

Another option for bio-companies looking to expedite their global patent portfolio creation is the Patent Prosecution Highway (PPH), which speeds up the examination process for corresponding applications filed in participating countries by allowing examiners to re-use search and examination results.

Under the PPH programme, an applicant receiving a ruling from the patent Office of First Filing (OFF) that at least one claim is patentable can request that the Office of Second Filing (OSF) fast track the examination of corresponding claims.

The PPH leverages fast-track examination procedures already available in the OSF to allow applicants to obtain patents faster and more efficiently. Examination typically begins within two to three months from the grant of the PPH request, and nearly 90% of PPH cases are allowed.

The allowance rate for non-PPH cases is less than 50%. Managers responsible for



Source: *One Year Later*, Sterne, Kessler, Goldstein & Fox

their organisation's IP strategy should consider the PPH as a means to deliver significant benefits to their businesses.

Accelerated examination of cleantech applications

In an effort to promote the development and commercialisation of technologies that conserve natural resources or reduce negative environmental impact, patent offices around the world have adopted programmes to expedite the examination of patent applications pertaining to clean technologies, such as biofuels and biochemicals.

Australia, Canada, Israel, Japan, Korea and the UK have recently put in place measures to fast track 'green' patent applications. More recently, Brazil and China have launched similar programmes. In the US, the Green Technology Pilot Programme for expediting examination of clean technology applications closed last year in favour of Track I examination, with over 1,000 patents issued.

In view of the numerous international opportunities for accelerated examination and the growing importance of clean technologies, patent applicants should carefully consider these expedited options as part of a global IP strategy to patent their environmental innovations and bring them quickly to market.

New Freedom to Operate strategies

The AIA has also fundamentally changed how US patents and applications are challenged. For biofuel and biochemical companies facing Freedom to Operate obstacles, the AIA established the following new processes to challenge the validity of patents and applications directly at the USPTO as an attractive alternative to costly and lengthy district court litigation.

The two post-issuance options next described are conducted before the newly-formed Patent Trial and Appeal Board (PTAB), have limited discovery and typically will be resolved within about 18 months.

Post-grant review

Similar to European Oppositions, the AIA provides for a new post-grant review (PGR) proceeding whereby a third party can petition for cancellation of patent claims based on any ground of invalidity, such as obviousness, indefiniteness and lack of utility, novelty, enablement or written description.

The petitioner must demonstrate that it is more likely than not that at least one of the claims challenged in the petition is unpatentable to trigger a PGR.

PGRs are available only for patents issuing from applications filed on or after 16 March 2013, and the petition must be filed within nine months after issuance of the patent. As such, no petitions for PGR have been filed to date. However, PGR has the potential to become a very attractive mechanism for challenging patents.

Inter partes review

Inter Partes Reviews (IPRs) are available to patents issuing from applications subject to the new first-inventor-to-file provisions of the AIA as well as those patents issuing from applications subject to the old first-to-invent provisions.

For those patents subject to first-inventor-to-file provisions, a petition for IPR cannot be filed until after the later of:

(i) nine months after the grant of a patent or

(ii) the date of termination of any PGR of the patent.

Unlike PGRs, a petition for IPR can be based only on obviousness or lack of novelty grounds using prior art patents and printed publications. The standard for instituting an IPR is arguably higher than for PGR, in that the petition must demonstrate a reasonable likelihood that the petitioner would prevail with respect to at least one challenged claim. Before instituting an IPR, the USPTO will consider any preliminary response the patent owner has filed.

As of 21 November, 680 petitions for IPR have been filed. While the majority of IPR petitions have been filed in the electrical arts, over 100 have been filed in the biotech and chemical arts as well. Of those IPR petitions filed, about 80% have a co-pending litigation. In addition, 254 petitions have been decided and about 88% of those have been granted for at least one claim. Of the 217 that have been granted, 26 settlements have been reached and no IPR has been continued by the PTAB after settlement.

In addition to the short timeframe until resolution of the PGR and IPR proceedings at the USPTO, several other features make them an attractive alternative, or supplement, to challenging patents in district court.

First, whereas there is a presumption of validity of the patent in court, there is no such presumption at the USPTO. Second, the USPTO gives patent claim terms their 'broadest reasonable' construction, whereas in district court claim terns are construed more narrowly in view of the specification and the patent procurement history.

Finally, the USPTO uses the preponderance of evidence standard for invalidity, whereas district courts use the higher clear and convincing standard.

Third party submissions

The AIA also created an option to challenge competitors' applications before they issue into problematic patents.

A third party may file any patents, published patent applications or other printed publications of potential relevance to the examination of a patent application. The submission can be filed in any non-provisional utility, design or plant application, as well as in any continuing application, even if the application to which the submission is directed has been abandoned or has not been published.

Third-party submissions may not be filed in any issued patent, reissue application or reexamination proceeding. The submission must be made before the earlier of:

(a) a notice of allowance is mailed or

(b) the later of (i) six months after publication or (ii) the first rejection on the merits.

In addition, the submission must include a concise description of the asserted relevance of the submitted patents and publications, explaining how each reference is of potential relevance to the examination of the application in which the third party submission has been filed.

These new offensive processes now available under the AIA may be advantageous for small businesses, universities and other institutions in emerging biofuel and biochemical technologies from a freedom-to-operate perspective because they may be less expensive and result in quicker resolution of patent disputes than conventional patent litigation.

Also, in view of the limited 'windows' within which to initiate PGR proceedings and file third party submissions, there is an increased emphasis on the proactive monitoring of competitors' patents and applications. Understanding all of the options for expediting patent application examination and contesting patentability at the USPTO as a result of the recent patent reform is essential for bio-based companies to maximise their patent positions. ●

For more information:
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