

Lessons From IPRs Involving Agriculture-Related Patents

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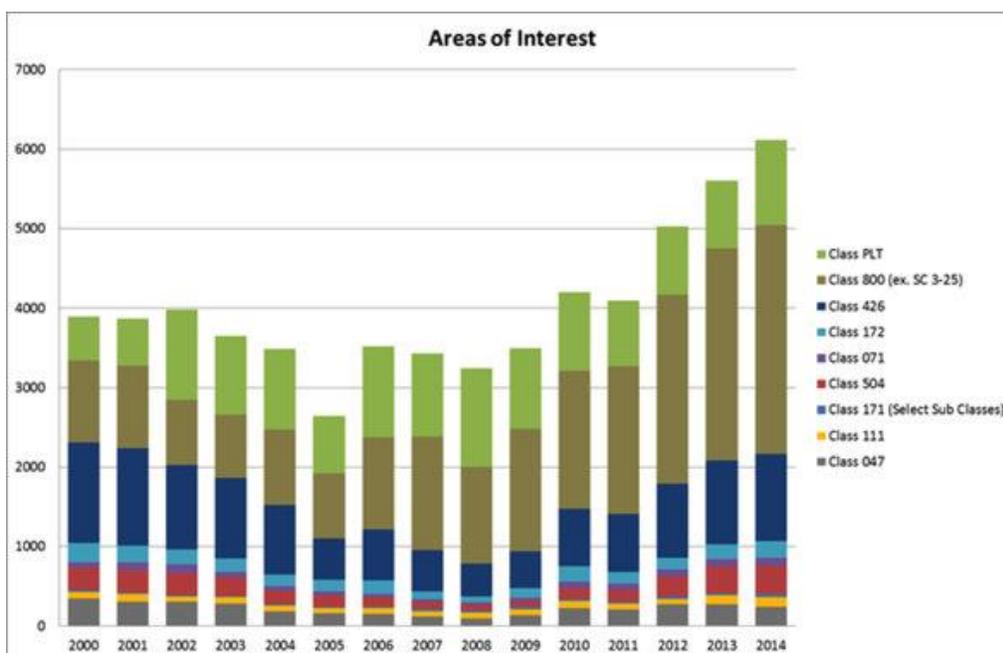
Modern agriculture is being transformed by a confluence of advancing technologies. Agricultural biology, cell biology, genome and proteome research, gene sequencing, and gene editing technology like CRISPR are reshaping agriculture to face the challenges of an expanding global population, climate change, and a finite natural resource base.[1]

Patents provide the infrastructure to protect innovation and enable technology progress in the area of agriculture, particularly plants.[2] Plant breeders can pursue their intellectual property rights through three regimes: utility patents, plant patents, and plant variety protection certificates.[3] According to data obtained from the U.S. Patent and Trademark Office, patenting in agricultural technologies has increased steadily over the past few decades. Figure 1 shows the total number of issued patents from different sectors in the agricultural industry over the past 15 years. The total number of patents has increased more than 50 percent during this time period. Interestingly, issued patents in class 800 (related to agricultural biology) almost tripled from 2000 to 2014.



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Figure 1: Issued Patents by Classification in the Ag Industry



For many years, the only way to challenge the validity of a patent was through protracted and expensive district court litigation. Inter partes review was introduced by the America Invents Act on Sept. 16, 2012,[4] and designed as an efficient alternative to district court litigation to challenge patent validity. An IPR can be filed by any person except the patent owner.[5] Since its debut, IPRs have enjoyed widespread adoption across many industries. As of September 2016, more than 5,000 petitions have been filed.

However, this new tool favors the petitioner in many aspects. First, it significantly lowers the burden of proof from the district court’s “clear and convincing evidence” standard to “preponderance of the evidence.”[6] As long as there is a reasonable likelihood of success of invalidating at least one claim, the Patent Trial and Appeal Board may institute an IPR proceeding. Second, unlike the district court’s “ordinary and customary meaning” standard to construe a disputed term,[7] the PTAB applies the “broadest reasonable interpretation” standard in claim construction, which can result in a broad interpretation that facilitates a validity challenge.

Third, a petitioner is given somewhat of an early advantage in an IPR proceeding. The ability to include declaratory evidence with the patent owner’s preliminary response (POPR) is a relatively new occurrence. However, from recent IPR data, filing a declaration makes little or no statistical difference on institution rate. Proceedings having a declaration with a POPR and those that don’t have roughly the same institution rate — roughly 70 percent (though the number of cases in which a POPR declaration was filed and the board has issued its institution decision is very small). In fact, in its rulemaking, the PTAB stated that regardless of the patent owner submitting declarations prior to institution, the PTAB will still weigh any disputes of fact in favor of the petitioner because there is no avenue by which to cross-examine experts prior to institution. Considering that more than 80 percent of instituted claims are canceled in IPR final written decisions, the patent owner may face enormous pressure when trial is instituted and is typically placed in a disadvantageous position in negotiating a settlement agreement.

Although the total number and frequency of IPR petitions filed related to the Ag industry are relatively low compared to other industries, the data are interesting. To date, about 20 IPRs have been filed with the PTAB attacking plant utility patents. Table 1 shows that the majority of plant IPR cases fall within class 47, which is related to plant husbandry. In contrast, class 800, which has the most issued patents and expands at the fastest rate, has the smallest number of patents challenged.

Table 1: IPR Statistical Data by Classification

Class 800* - Multicellular Organisms	Class 111 - Planting	Class 047 - Plant Husbandry	Class 426 - Food or Edible Material	Class 504 - Plant Protecting and Regulating Compositions
1 IPRs	3 IPRs	9 IPRs	3 IPRs	3 IPR
1 denied	3 instituted	6 denied; 1 settled prior to institution; 1 settled post-institution; 1 final written decision	2 denied; 1 request for adverse judgment	2 denied, 1 granted

Given the IPR filing rate in the biotech industry, it is reasonable to believe that more patents in this class will be challenged in the future. Patent owners who believe that their patents may be challenged in an IPR proceeding should consider adjusting their patent prosecution strategies accordingly.

This article provides an analysis of recent IPR filings related to the plant industry and discusses four action steps based on lessons learned from these proceedings to further strengthen patents/patent portfolios in view of IPRs.

1. Analyze the Patent Portfolio

To fend off an IPR, patent owners should identify the core IP assets and be proactive in strengthening the record during prosecution. Although traditional patent prosecution practice would suggest submitting no more evidence during prosecution than necessary to obtain a patent, the procedural realities associated with IPRs warrant reconsideration of this practice. Expert opinions/declarations can play an essential role in the PTAB's decision to grant institution of an IPR.

In *Scott v. Encap*, for example, the PTAB denied Scotts' first petition to review Encap's U.S. Patent No. 8,474,183 because Scotts did not provide an expert opinion regarding how a person of ordinary skill in the art would interpret a key prior art reference.[8] Subsequently, with the support of an expert's opinion, Scotts successfully persuaded the PTAB to grant the petition.[9] By submitting expert opinions or declarations during prosecution, patent owners are better able to refute petitioners' arguments in the preliminary response stage and increase their chances of having trial not instituted by the PTAB. Moreover, it is worth noting that submitting evidence supporting patentability during ex parte prosecution is easier than during an IPR which requires evidence to be corroborated.

In addition to submitting an expert opinion/declaration, patent owners should also consider submitting experimental data, such as unexpected results acquired during the process of innovation and describe such results in the specification or in declarations during ex parte prosecution. The PTAB is more likely to invalidate claims for novelty and obviousness than the district court because of the lower standard. With strong experimental data and unexpected results, the patent owner can better withstand an invalidity attack. In *Monsanto v. Pioneer*, one issue was whether enhanced seed vigor is obtained by following prior art defoliation techniques.[10] Although the petitioner provided an expert opinion to support their belief that enhanced seed vigor was a necessary result obtained by following the prior art, the PTAB was not persuaded because the specification of the patent at issue contained detailed experimental data and results to demonstrate that enhanced seed vigor was not a necessary result.[11] Because this element — enhanced seed vigor — could not be taught or suggested by the prior art, the patent owner withstood the invalidity attack.

2. Build Robust Claim Sets

Patent owners are finding it difficult to amend the claims during an inter partes review. Building a more robust claim set during prosecution may better help defend against prior art attacks.

It is interesting that most of the plant utility patents attacked in an IPR have 20 or fewer claims. Although the number of claims is not dispositive of the final decision of an IPR, robust claim sets can provide at least three benefits to patent owners in protecting their IP. First, a robust set of claims describes the invention at several levels of abstraction, each providing a different breadth of coverage. Even if a broad claim is invalidated by the PTAB, the patent owner may have narrow ones to fall back on. Second, robust claim sets provide the patent owner more options in the face of an IPR challenge. The

patent owner may cancel challenged claims, keep the remaining claims intact, terminate the IPR and save litigation costs. This is exactly what Pellet Technology did in defending its U.S. Patent No. 8,551,549.[12] Lastly, a collateral benefit of obtaining patents with robust claim sets is the increased burden and expense placed on the petitioner. IPR petitions are limited to 14,000 words.[13] When facing numerous claims, petitioners may need to file multiple IPRs to ensure that their arguments are fully developed, thereby increasing cost.

3. Control Claim Construction/Define Terms

The PTAB's validity analysis generally starts with claim construction. When construing the claims, the PTAB comprehensively considers all evidence in the specification and prosecution history to determine the meaning of disputed terms. Patent owners could control claim construction to a certain extent by defining terms in a clear manner and avoiding inconsistency during prosecution.

In *Geosys-Intl. v. Farmer's Edge Precision*, the claim term "maximum possible crop yield" needed construction.[14] Although the specification described "the maximum possible crop yield" as "yield goal," the PTAB did not agree that the term "maximum possible crop yield" should be construed in a manner different than its ordinary meaning.[15] According to the PTAB, "where an inventor chooses to be his own lexicographer and give terms uncommon meanings, he must set out his uncommon definition in some manner within the patent disclosure so as to give one of ordinary skill in the art notice of the change." [16] Therefore, a well-thought-out glossary may be an effective tool to define terms.

In addition to including well-defined terms when drafting a patent application, patent applicants should be mindful to keep the scope of a claim term consistent during prosecution. In *Aceto Agricultural Chemicals v. Gowan*, the meaning of the term "synergistically effective amounts of" two herbicides in U.S. Patent No. 8,791,049 was debated.[17] The patent owner contended that "synergistically" meant "greater control than expected." Although this interpretation was supported by the ordinary meaning and the specification of the patent, the PTAB found that during prosecution the patent owner had argued that "synergistically" meant "any combination." Because of this prosecution record, the PTAB broadly construed the term to mean "any combination" thereby rendering the patent invalid in view of prior art combinations.

4. Consider a Patentability Search

In an IPR, the petitioner can raise invalidity arguments in view of Sections 102 or 103 on the basis of patents or printed publications. A thorough patentability search upfront can help patent owners distinguish their invention from the prior art during preparation and prosecution of the patent application, leading to a more robust claim set, and to minimize the patent being attacked in an IPR.

Interestingly, six out of seven challenged patents did not withstand a §102 challenge. Failure to conduct a robust patentability search at the outset can be fatal because §102 prior art identified by your competitors will anticipate the claims and render them invalid but yet can be easily identified through a patentability search.

In addition, a robust patentability search can better define claim scope and guide patent applicants not to argue an over-broad meaning of a claim term during prosecution. In IPR2016-00076, the patent applicants may not submit that "synergistically" meant "any combination" in prosecution if they had a robust patentability search report.

In conclusion, patent owners often do and should monitor their competitors closely. Knowing a competitor's patent portfolio is critical for developing a patent strategy. Early identification of a potential patent dispute can help patent owners prepare a strategic defense at an early stage.

Lastly, if a patent owner receives notice that her patent has been challenged in an IPR proceeding, the USPTO's Track One program should be considered to obtain rapidly (typically nine to 12 months) child patents with narrower claim scope prior to receiving a final written decision. This approach can effectively avoid patent owner estoppel^[18] and may also provide a fallback position to protect the IP.

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[1] Michael A. Kock, Adapting IP to an Evolving Agricultural Innovation Landscape, WIPO (April 2013), available at http://www.wipo.int/wipo_magazine/en/2013/02/article_0007.html.

[2] John R. Thomas, Plants, Patents, and Seed Innovation in the Agricultural Industry, Report for Congress (Sept. 2002), available at <http://congressionalresearch.com/RL31568/document.php?study=Plants+Patents+and+Seed+Innovation+in+the+Agricultural+Industry>.

[3] *Id.*

[4] 35 U.S.C. §§311-319 (2012).

[5] 35 U.S.C. §311(a) (2012).

[6] 35 U.S.C. §§316(e), 326(e) (2012).

[7] In litigation, claims are generally given their "ordinary and customary meaning" as understood by a person of ordinary skill in the art in question at the time of the invention. See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc).

[8] IPR 2013-00491, paper 9 at 7.

[9] IPR2014-01110, paper 11 at 11.

[10] IPR2013-00023, paper 32 at 8.

[11] *Id.*, at 9.

[12] IPR2015-01621, paper 12 at 2 (Patent Owner filed a motion for entry of adverse judgment

requesting cancellation of claims 23–28 and 30 of the '549 patent.)

[13] 37 C.F.R. § 42.24(a)(1)(i)

[14] IPR2015-00711, paper 9 at 8.

[15] Id.

[16] Id.

[17] IPR2016-00076, paper 9 at 7.

[18] 37 C.F.R. §42.73(d)(3) (prohibits obtaining claims patentably indistinct from claims lost in an IPR.)