Institut Pasteur v. Focarino: A Breadth of Fresh Air in the Wake of the Galderma v. Tolmar Decision

The Galderma case,\(^1\) decided on December 11, 2013, created a dangerous new precedent for selection inventions. The Galderma court found an invention *prima facie* obvious simply because it was generically encompassed by a broad prior art disclosure, and then shifted to the patentee the burden at trial to prove non-obviousness. This has never been the law, and it represents a new analytical approach to obviousness that effectively eviscerates the presumption of validity for patented selection inventions.

While certainly not overruling the Galderma case, the decision of Institut Pasteur\(^2\) reinforces the viability of several well-established tenants of obviousness inquiries for all inventions, including selection inventions.

\(^1\) Galderma Laboratories, LP v. Tolmar, Inc., Court of Appeals, Federal Circuit 2013, Appeal No. 2013-1034

For starters, the *Institut Pasteur* decision reiterates that a proponent of obviousness must establish that the prior art provides motivation and a reasonable expectation of success in making the patented invention. The *Institut Pasteur* court then emphasizes that the evidence of reasonable expectation of success must match the motivation relied on from the prior art to make the invention. Where the *Galderma* court was prepared to “give away” inventions, particularly selection inventions, the *Institut Pasteur* court says “not so fast” and reinforces the patent challenger’s burden of proving obviousness by showing motivation as well as an expectation of success that matches the goal of the motivation chosen from the art.

Furthermore, the *Institut Pasteur* decision reiterates the importance of “secondary considerations” (or the so-called “objective indicia of non-obviousness”) to the overall assessment of obviousness. The Court specifically considered licensing, industry praise, and copying of the invention by others as significant components of the total evidentiary package in evaluating the invention’s obviousness.

For those litigating biotechnology patents, particularly on the patentee side, the *Institut Pasteur* decision constitutes a breath of fresh air in the wake of a malodorous holding in *Galderma* that arguably lowers the burden for the patent challenger and improperly shifts the burden to the patentee to prove non-obviousness.

**Discussion**

In the *Galderma* case, the patented invention was a composition containing 0.3% by weight adapalene and methods of treating acne with such a composition. The prior art generically disclosed compositions for treating acne containing adapalene preferably in a concentration range between 0.01% and 1% weight. The Court held that the patent challenger, Tolmar, met its initial burden of providing clear and convincing evidence of obviousness simply by demonstrating that the claim composition fell within the broad range disclosed in the prior art. According to the Court, where the dispute is only about the motivation to select the claimed concentration from within a range disclosed in the prior art, the patentee has the burden to provide evidence of non-obviousness, such as prior art “teaching away” from the claimed invention, new and unexpected results relative to the prior art, or other pertinent secondary considerations of non-obviousness. *Galderma* slip op. at p. 9. This holding creates an improper presumption of obviousness for selection inventions and incorrectly shifts the burden of persuasion to the patentee to show, presumably through secondary considerations, that the selection was non-obvious.
The Institut Pasteur decision does not overrule the Galderma decision. But it does give patentees, particularly biotech patentees, whose field of research is well-recognized as unpredictable, arguments to make in the fight against the erosion of their rights.³

The Institut Pasteur case resulted from appeals from the PTAB in reexamination proceedings holding the claims of three Institut Pasteur patents obvious. The claims on which the Court reached a decision on the merits⁴ are directed to a method for site-specific insertion of DNA sequences into the chromosomes of yeast or mammalian cells by homologous recombination using exogenous expression of a Group I intron encoded endonuclease (GIIE) and a specific GIIE DNA recognition site inserted into a chromosome.⁵ The issue was whether a skilled artisan would have had motivation and a reasonable expectation of success in transferring a targeted gene alteration method disclosed in the prior art from non-chromosomal DNA in prokaryotic cells to chromosomal DNA in eukaryotic cells, such as yeast or mammalian cells.

Reversing the PTAB’s findings of obviousness, the Court answered the issue in the negative. The Federal Circuit found the PTAB made erroneous factual determinations, the prior art significantly undercut motivation and expectation of success, and there were compelling objective indicia of non-obviousness, including licensing and industry acclaim for the patented invention. The latter two findings by the Court are the most significant to biotech litigators.

First, the Court found the PTAB’s assessment of the expectation of success to be flawed, holding that the evidence to support the reasonable expectation of success did not match the motivation chosen from the prior art. For motivation to pursue the claimed method of targeted gene insertion in eukaryotic cells, the PTAB relied on a prior art reference that stated “[i]t would be a great advance if such alterations could be engineered into copies of a chosen gene in situ within the chromosomes of a living animal cell.” Institut Pasteur slip op. at p. 18. At the same time, the PTAB disregarded a teaching of toxicity in the prior art when assessing the reasonable expectation of success, noting that the claims at issue do not expressly require that the cells remain viable. The Court found the PTAB’s disregard of the toxicity teaching erroneous, for that

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³ Institut Pasteur was decided about three weeks after Galderma, before Circuit Judges Newman, Clevenger, and Taranto. Of note, Judge Newman dissented in the Galderma case, harshly criticizing the majority’s “inappropriate rulings” regarding its presumption of obviousness and shifting of the burden of persuasion to the patentee. Galderma slip op. at p. 19 of the dissent.

⁴ All three patents had expired when the Federal Circuit reached its decision. The appeal regarding one patent was dismissed as moot because the claims at issue were substantively amended during reexamination and amended claims cannot be entered into an expired patent. Regarding another patent, the Court vacated the PTAB’s decision and remanded for further consideration.

⁵ Claims 10 and 12 of US Patent No. 6,610,545
teaching would have strongly affected whether a skilled artisan would have had a reasonable expectation of achieving the claimed targeted gene insertion method in a living animal cell. The Court emphasized that the expectation of success analysis must match the highly desired goal that provided the motivation to pursue the invention, in this case to achieve targeted gene alteration in a living animal cell and not some less challenging goal within the scope of the claims:

Importantly, without a sound explanation for doing otherwise, which is not present here, the expectation-of-success analysis must match the highly desired goal, not switch to a different goal that may be a less challenging but also less worthwhile pursuit.

_Institut Pasteur_ slip op. at p. 18.

Second, the _Institut Pasteur_ decision confirms the importance of objective indicia of non-obviousness and clarifies that these indicia should remain part of an overall assessment of all developed evidence to determine obviousness. The Court emphasized that “[o]bjective indicia of non-obviousness ‘can be the most probative evidence of non-obviousness in the record, and enables the court to avert the trap of hindsight.’” _Institut Pasteur_ slip op. at p. 19. It considered licensing, industry acclaim, and copying of the patented inventions, ultimately finding the first two indicia compelling indicators of non-obviousness in this case.

_Institut Pasteur_ presented evidence that the exclusive licensee of the patented technology entered into more than a dozen sublicense agreements to allow third parties access to the claimed invention. Institut Pasteur further presented eight press releases detailing such sublicense agreements, which included major players in the industry, such as BASF Plant Science, Bayer CropScience, Biogen Idec, Monsanto, and Pioneer Hi-Bred International. The PTAB rejected the evidence because Institut Pasteur did not clearly establish that the licensing occurred to obtain access to the subject matter claimed in the patent at issue, rather than subject matter described in the patent, but not claimed, or claimed in related patents. _Institut Pasteur_ slip op. at p. 20. The Federal Circuit stated that the PTAB “too finely parsed” the proffered licensing activity and held that this theoretical possibility posited by the PTAB does not diminish the strong probative value of the licensing evidence for non-obviousness.

The Court also considered evidence of industry praise for the claimed invention in assessing obviousness. The Court criticized the PTAB’s erroneous dismissal of Institut Pasteur’s evidence of industry acclaim based on the PTAB’s mistaken understanding that the prior art disclosed the claimed homologous recombination step. _Institut Pasteur_ slip op. at p. 21. Having found that the prior art did not disclose this step, the Federal Circuit credited the evidence of industry praise as another compelling indicator of the invention’s non-obviousness.
Finally, the Federal Circuit considered, but did not ultimately rely on, evidence of copying put forth by Institut Pasteur. Institut Pasteur presented excerpts of more than 20 scientific articles, all published after Institut Pasteur had published the claimed method in a scientific journal, to demonstrate that other scientists adopted the same method for targeted gene insertion. The PTAB did not give much, if any, weight to this evidence because Institut Pasteur did not show that the cited articles trace back to Institut Pasteur’s previous publication of the invention. The Court criticized the PTAB for prematurely cutting short its analysis of this evidence and stated that persuasive evidence of copying of Institut Pasteur’s published method would provide probative evidence of non-obviousness. *Institut Pasteur* slip op. at p. 22.

**Conclusion**

If the *Galderma* decision stands, it will undermine the validity of claims directed to selection inventions, severely dampening the incentive to pursue valuable modifications and improvements to prior inventions, particularly if these modifications and improvements are encompassed by a generic prior art disclosure. Though not overruling the *Galderma* decision, the *Institut Pasteur* decision nonetheless provides useful and valuable positions to those enforcing biotech patents in *Galderma*’s wake, including (1) that the evidence supporting the reasonable expectation of success must match the goal that provided the motivation to pursue the invention, and (2) that objective indicia of non-obviousness can have great probative weight and should be considered as part of all the evidence proffered on the question of obviousness.

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