

landscape, particularly the achievement of freedom-to-operate licenses for use in developing countries.

Miralpeix, B. et al. (2014). "Strategic patent analysis in plant biotechnology: Terpenoid indole alkaloid metabolic engineering as a case study." *Plant Biotechnol J* 12(2):117–134.

The do-it-yourself patent search is a useful alternative to professional patent analysis particularly in the context of publicly funded projects where funds for IP activities may be limited. As a case study, we analyzed patents related to the engineering of terpenoid indole alkaloid (TIA) metabolism in plants. We developed a focused search strategy to remove redundancy and reduce the workload without missing important and relevant patents. This resulted in the identification of approximately 50 key patents associated with TIA metabolic engineering in plants, which could form the basis of a more detailed freedom-to-operate analysis. The structural elements of this search strategy could easily be transferred to other contexts, making it a useful generic model for publicly funded research projects.

Rommens, C. M. (2010). "Barriers and paths to market for genetically engineered crops." *Plant Biotechnol J* 8(2):101–111.

Each year, billions of dollars are invested in efforts to improve crops through genetic engineering (GE). These activities have resulted in a surge of publications and patents on technologies and genes: a momentum in basic research that, unfortunately, is not sustained throughout the subsequent phases of product development. After more than two decades of intensive research, the market for transgenic crops is still dominated by applications of just a handful of methods and genes. This discrepancy between research and development reflects difficulties in understanding and overcoming seven main barriers-to-entry: (1) trait efficacy in the field, (2) critical product concepts, (3) freedom-to-operate, (4) industry support, (5) identity preservation and stewardship, (6) regulatory approval and (7) retail and consumer acceptance. In this review, I describe the various roadblocks to market for transgenic crops and also discuss methods and approaches on how to overcome these, especially in the United States.

Schwartz, J. and C. Macomber (2017). "So, you think you have an idea: A practical risk reduction-conceptual model for academic translational research." *Bioengineering* (Basel) 4(2):29.

Translational research for new drugs, medical devices, and diagnostics encompasses aspects of both basic science and clinical research, requiring multidisciplinary skills and resources that are not all readily available in either a basic laboratory or clinical setting alone. We propose that, to be successful, "translational" research ought to be understood as a defined process from basic science through manufacturing, regulatory, clinical testing all the way to market. The authors outline a process which has worked well for them to identify and commercialize academic innovation. The academic environment places a high value on novelty and less value on whether, among other things, data are reproducible, scalable, reimbursable, or have commercial freedom to operate. In other words, when investors, strategic companies, or other later stage stakeholders evaluate academic efforts at translational research the relative lack of attention to clinical, regulatory, reimbursement, and manufacturing and intellectual property freedom to operate almost universally results in more questions and