



**BERGESON & CAMPBELL, P.C.**

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## ***BERGESON & CAMPBELL, P.C.***

### ***FIFRA Practice***

This document is intended to introduce you to Bergeson & Campbell, P.C.'s (B&C) diverse and highly specialized pesticide registration, reregistration, and data compensation arbitration practice areas. Each of B&C's legal and business professionals is highly skilled in various aspects of pesticide product registration and defense, and in marshalling compelling arguments to preserve market segments that are threatened by evolving Food Quality Protection Act (FQPA) science policies and the United States Environmental Protection Agency's (EPA) application of them. Additionally, B&C professionals have significant experience in data compensation arbitrations -- in both bringing them on behalf of data owners and in defending follow-on registrants against data owners. Finally, B&C business and legal professionals are expert in issues involving antimicrobials, including fashioning claims that fall inside the treated article exemption, the growing jurisdictional quagmire between EPA and the Food and Drug Administration (FDA), antimicrobial resistance issues, and related law and business matters.

Registering a molecule under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is the beginning, not the end, of a long and challenging process. That process can either represent significant financial opportunity or business ruin, depending upon how well the registrant plays the FIFRA game. B&C is well suited to assist registrants in the difficult legal and commercial challenges that inevitably arise once a registration is issued. These include:

- ***Protecting the registration*** -- Follow-on registrants sometimes obtain registrations fraudulently. Illegally obtained registrations can ruin a legitimate registrant's market sector and deny a data owner its lawful right to data compensation. B&C obtained the landmark pesticide registration revocation issued in *In Re Termilind*, and was successful in forcing EPA to exercise its seldom used authority under FIFRA to revoke as void *ab initio* a registration issued fraudulently to a B&C client's competitor.
  
- ***Protecting a registrant's right to data compensation*** -- Once a registration is issued, it is difficult and costly to persuade EPA that certain data were administratively relied upon such that those data are now compensable. It is thus important to protect a registrant's right to data compensation before a follow-on registration is issued to a competitor. Care must be taken to steward the data, as well as the rights that attach to those data, at all times during the 15-year compensation period.



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- ***Ensuring that costly non-DCI data are determined to be compensable*** -- Not all data are subject to a Data Call-In (DCI), but are nonetheless important for the continued registration of the molecule. Data that may be essential for product stewardship and other product defense purposes, and likely to cost hundreds of thousands of dollars, should also be considered necessary for the continued registration of the molecule and compensable for follow-on registrants. A contrary view could result in an unintended windfall for a company's competitor.
- ***Ensuring business records are maintained in a way to maximize return on the financial and intellectual property investment*** -- Maintenance means more than ensuring records are organized and relatively protected. It involves maintaining the business records with a view to defending one's entire business investment in them in the context of a data compensation arbitration, a civil action in which allegations of business theft or other intellectual property tort of one form or another are in dispute, and other business disputes, the resolution of which could make or break a business or product line
- ***Ensuring that a new or recently acquired molecule is managed thoughtfully*** -- Generating data in a way that will enhance, not diminish, the value of the molecule, is a challenge that requires skill and experience. Given the global scientific and public relations challenges that businesses confront, data generation must be undertaken prudently and strategically. Minor protocol differences can mean that a costly chronic study is determined to be useful in maintaining a registration in only a single country as opposed to multiple jurisdictions. Positive findings in studies that should have been designed differently can mean the demise of a molecule or, if you are lucky, only a product line.
- ***Positioning the registrant in the strongest possible position in data compensation arbitration proceedings*** -- Care must be taken in advocating positions on the actual data costs, the costs to manage the production of the data, and what factors determine interest costs. Issues beyond the straight data cost type issues that can significantly increase or decrease an award include how shares are determined -- per capita or market share -- and whether additional costs can be recovered to compensate the registrant for the risks it undertook in developing the data before the new registrant obtained its registration.



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As skilled and experienced professionals, B&C attorneys and non-attorneys offer assistance in these and many other areas. We offer our skills as both attorneys and business counselors because to offer less will not provide value to our clients.

Value is also offered in a more quantitative form -- as a small and highly specialized business, B&C is able to offer its professionals' legal skills, business judgment, and years of experience at rates below those of our competitors. Because we do not need to carry hundreds of attorneys throughout the world, we offer fixed, flat-fee, or other competitive business arrangements, including contingency-based and fixed flat-fee arrangements for arbitrations. Moreover, the professionals with whom you begin a project are the same ones with whom you close it. Efficiencies are maintained and maximized by having a core group of professionals devoted to projects from start to finish. You will not be paying to train inexperienced or new attorneys. Indeed, none of our professionals has less than six years of experience in these areas. Senior professionals have over two decades of experience in these areas.

We append for your information and consideration briefing papers on various pesticide registration, data compensation, and cost sharing topics. We hope you find these papers useful. They are indicative of the quality of our work product, the depth of our experience, and the focused nature of our practice.

What we cannot as easily share in this communication is the value we offer to your business and the enthusiasm and creativity with which we approach all representations. We invite you to experience both. Additionally, we invite you to speak with us about our diverse billing arrangements. All are intended to enhance the value of our representation and your business.

For further information, please call Lynn Bergeson at (202) 557-3801 or Lisa Campbell at (202) 557-3802.

Attachment

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