

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

**UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA**

CHEMICAL PRODUCERS AND )  
DISTRIBUTORS ASSOCIATION, )

Plaintiff,

v.

PAUL E. HELLIKER, DIRECTOR )  
OF THE CALIFORNIA )  
DEPARTMENT OF PESTICIDE )  
REGULATION, )

Defendant.

\_\_\_\_\_)  
SYNGENTA CROP PROTECTION, )  
INC.; DOW AGROSCIENCES )  
LLC; BASF CORPORATION; )  
BAYER CROPSCIENCE LP; E.I. )  
DU PONT DE NEMOURS AND )  
COMPANY; AND MONSANTO )  
COMPANY, )

Defendants-in- )  
Intervention )

\_\_\_\_\_ )

CASE NO. CV 02-9781 AHM  
(PLAx)

ORDER DENYING PLAINTIFF'S  
SUMMARY JUDGMENT  
MOTION AND DISMISSING THIS  
ACTION

1 **INTRODUCTION**

2 Chemical Producers and Distributors Association (“Plaintiff”) is a voluntary,  
3 non-profit trade association consisting of approximately 90 companies involved in  
4 the production of generic pesticides.

5 Paul E. Helliker (“Defendant”) is the Director of California’s Department of  
6 Pesticide Regulation (“DPR”), the state agency charged with enforcing California’s  
7 pesticide regulation scheme.

8 Syngenta Crop Protection, Inc., Dow Agrosiences LLC, BASF Corp., Bayer  
9 Cropsience LP, E.I. du Pont de Nemours and Co., and Monsanto Co. (collectively,  
10 “Intervenors”) are pesticide manufacturers who have obtained California  
11 registrations for their products in the past. (In their respective briefs, the parties  
12 sometimes refer to the Intervenors as “the Basics,” in contrast to “the Generics.” For  
13 purpose of clarity, I will refer to the Intervenors as “the original applicants.”)

14 This matter is before the Court on Plaintiff’s Motion for Summary Judgment.  
15 Plaintiff contends that the Federal Insecticide, Fungicide, and Rodenticide Act  
16 (“FIFRA”) pre-empts Cal. Food & Agric. Code § 12811.5 (“Section 12811.5”)  
17 because the latter’s requirements for registering generic pesticides interfere with  
18 Congress’s goals in enacting FIFRA. Plaintiff seeks a declaration that FIFRA pre-  
19 empts Section 12811.5 and an injunction prohibiting its enforcement. Defendant  
20 does not oppose Plaintiff’s motion, but the Intervenors do, and in fact they also  
21 request that the Court enter summary judgment in their favor, *sua sponte*.

22 Pre-emption cases are plentiful and the decisions of the various courts that are  
23 asked to apply the doctrine are sometimes hard to reconcile. In cases such as this,  
24 where the issue comes down to whether Section 12811.5 frustrates the purposes  
25 and/or the implementation of FIFRA, the facts peculiar to the dispute are the decisive  
26 consideration. Here, Plaintiff has failed to meet its burden of proving, through facts  
27 and evidence, that Section 12811.5 does thwart FIFRA. Accordingly, the Court  
28 DENIES Plaintiff’s motion. The law does not entitle Plaintiff to a declaratory

1 judgment or an injunction. The Intervenor is entitled to summary judgment.

2 **DISCUSSION**

3  
4 **A. The Federal Insecticide, Fungicide, and Rodenticide Act**

5 FIFRA, 7 U.S.C. § 136 *et seq.*, which was enacted in 1947, requires that all  
6 pesticides be registered with the Administrator of the Environment Protection  
7 Agency (“EPA”), prior to being sold in interstate or foreign commerce.<sup>1</sup> In order to  
8 obtain a registration, an applicant is required to submit extensive scientific test data  
9 to the EPA, including data establishing that the pesticide is safe for human use and  
10 does not harm the environment. 7 U.S.C. § 136a(c)(1)(F); 7 U.S.C. § 136a(c)(2)(A).  
11 The EPA keeps this information on file even after it has issued a registration. *Id.*

12 In 1972, in response to public concern about the adverse effects of pesticides  
13 on human health and the environment, Congress amended FIFRA to provide a more  
14 comprehensive regulatory scheme, including regulating pesticides sold in both  
15 interstate and intrastate commerce. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986,  
16 991-92 (1984). The Supreme Court has described the 1972 amendments as “a  
17 comprehensive revision . . . [that] transformed FIFRA from a labeling law into a  
18 comprehensive regulatory statute.” *Id.* at 991. Among the changes was that for the  
19 first time, an applicant seeking to register a generic version of an already-registered  
20 pesticide could submit, and the EPA could consider, the test data submitted by the  
21 original applicant, provided the subsequent applicant offered to compensate the  
22 original applicant. *Id.* at 992.

23 In 1978 Congress amended FIFRA again. Under the 1978 amendments, an  
24 applicant who obtained a federal pesticide registration after September 30, 1978 is  
25 entitled to the exclusive use of the test data it submitted to the EPA, for a period of  
26 10 years. That is, the EPA may not consider such data in connection with a

27 \_\_\_\_\_  
28 <sup>1</sup> In 1970, the Environmental Protection Agency took over the Secretary of  
Agriculture’s responsibilities with regard to FIFRA.

1 subsequent application without the written permission of the original applicant who  
2 submitted the data. 7 U.S.C. § 136a(c)(1)(F)(I). After this “exclusive use” period  
3 ends, the original applicant’s data becomes subject to a mandatory five-year  
4 licensing scheme, which allows a later applicant, such as one seeking registration of  
5 a generic version of an already-registered pesticide, to rely on the previously-  
6 submitted test data - - but only if the generic applicant (1) cites the original data in  
7 its application and (2) offers to compensate the original applicant. 7 U.S.C. §  
8 136a(c)(1)(F)(iii). During the 5 year mandatory licensing period, if the original  
9 applicant and the generic applicant cannot agree on the terms and amount of  
10 compensation due, FIFRA provides that their dispute will be resolved in binding  
11 arbitration. 7 U.S.C. § 136a(c)(1)(F)(iii). However, even while arbitration is  
12 pending, the generic applicant is entitled to rely on the original applicant’s data to  
13 obtain registration for his generic pesticide. *Id.* Together, then, the 10 year  
14 “exclusive use” and 5 year mandatory licensing periods require a generic applicant  
15 to compensate the original applicant for up to 15 years, if the generic applicant seeks  
16 to rely on that data the original applicant previously submitted to the EPA.  
17 Eventually, after expiration of both the 10-year exclusive use and 5-year mandatory  
18 licensing periods, the original applicant’s data becomes freely available to generic  
19 applicants, who may cite and rely on it to support their federal registration  
20 applications without compensating the original applicant. 7 U.S.C. §  
21 136a(c)(1)(F)(iv).

22 In the 1978 amendments, Congress also added a savings clause to FIFRA,  
23 entitled “Authority of States,” which explicitly confers limited authority on the states  
24 to regulate the registration, sale, use, labeling and packaging of pesticides sold  
25 within their borders. 7 U.S.C. § 136v. The savings clause provides, in relevant part:

26  
27 (a) In general: A State may regulate the sale or use of any federal  
28 registered pesticide or device in the State, but only if and to the extent  
the regulation does not permit any sale or use prohibited by this

1 subchapter.

2 (b) Uniformity: Such State shall not impose or continue in effect any  
3 requirements for labeling or packaging in addition to or different from  
4 those required under this subchapter.

5 (c)(1) A State may provide registration for additional uses of federally  
6 registered pesticides formulated for distribution and use within that  
7 State to meet special local needs in accord with the purposes of this  
8 subchapter and if registration for such use has not previously been  
9 denied, disapproved, or canceled by the Administrator. Such  
10 registration shall be deemed registration under section 136a of this title  
11 for all purposes of this subchapter, but shall authorize distribution and  
12 use only within such State...

13 **B. Cal. Food & Agric. Code § 12811.5**

14 Although under FIFRA sellers and distributors of pesticides are required to  
15 obtain federal registration before they can sell or distribute their pesticide *anywhere*  
16 in the country, there is no provision in federal law that entitles them to sell or  
17 distribute their products in any given state; once they obtain federal registration, they  
18 must also register the pesticide in each state in which they intend to sell or distribute  
19 it. *See, e.g., Cal. Food & Agric. Code § 12811.* Plaintiff contends that most state  
20 registration procedures (for both original and generic applicants) are simple; they  
21 merely require the submission of routine paperwork, the EPA-approved label for the  
22 pesticide and payment of a modest fee.<sup>2</sup> *See Statement of Genuine Issues (“SGI”)*  
23 *No. 6; Frazee Decl. ¶ 11; Collier Decl. ¶ 13; Vance Decl. ¶ 9; Kay Decl. ¶ 15.*

24 However, California law is different. Cal. Food & Agric. Code § 12811.5  
25 requires generic applicants to submit to the DPR the same data they submitted to the  
26 EPA in support of their application for federal generic registration, including the  
27 health and safety test data, in addition to any other information DPR determines to  
28 be relevant. *See Frazee Decl. ¶ 12-14; Cal. Code. Regs. tit. 3, § 6170(a).* Like  
FIFRA, California law requires a generic applicant either to duplicate the test data

---

<sup>2</sup> The Intervenors challenge this contention as lacking evidentiary support, but do not cite any authority or facts suggesting that Plaintiff’s characterization of other states’ registration procedures is incorrect.

1 previously submitted by an original applicant (sometimes at great expense) or to  
2 obtain written permission from the original applicant to cite and rely on the test data  
3 the original applicant previously submitted. Section 12811.5 provides,  
4 “[D]ata...previously submitted to the [DPR or EPA] to support an application for the  
5 original registration of a pesticide or to support an application for an amendment  
6 adding any new use to that registration and that pertains solely to that new use shall  
7 not, without the written permission of the original data submitter...be considered by  
8 the [DPR] to support an application by another person.”<sup>3</sup> *See also* Cal. Code Regs.  
9 tit. 3, § 6170(c) (“Data previously submitted to the director may be used by any  
10 applicant when an authorization is submitted in writing to the Department, by the  
11 owner of that data.”) However, unlike FIFRA, Section 12811.5 does not limit the  
12 duration of the original applicant’s exclusive use period, does not contain a  
13 mandatory licensing scheme, does not require that disputes be resolved in binding  
14 arbitration and does not allow the registration process to proceed while the original  
15 applicants and generic applicants resolve their disputes. The California scheme, in  
16 short, makes it costlier for generic applicants to qualify for registration. Hence,  
17 Plaintiff seeks to invalidate it. The “hook” it uses is the doctrine of pre-emption.

## 18 LEGAL ANALYSIS

### 19 A. General Pre-emption Principles

20  
21 Under the Supremacy Clause, state laws that “‘interfere with, or are contrary  
22 to the laws of Congress, made in pursuance of the constitution’ are invalid.” *See*  
23 *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 604 (1991) (citations  
24 omitted). The party contending that a state law is pre-empted has the burden of  
25

---

26  
27 <sup>3</sup> The parties refer to this documentation, which of course would only result if  
28 there were a negotiated agreement between the original applicant and the generic  
applicant, as a Letter of Authorization (“LOA”).

1 establishing pre-emption. *See Jimeno v. Mobil Oil Corp.*, 66 F.3d 1514, 1526 n.6 (9<sup>th</sup>  
2 Cir. 1995). The Supreme Court has explained that there are three ways in which  
3 federal law will pre-empt state law:

4  
5 First, Congress can define explicitly the extent to which its enactments  
6 pre-empt state law...Second, in the absence of explicit statutory  
7 language, state law is pre-empted where it regulates conduct in a field  
8 that Congress intended the Federal Government to occupy exclusively.  
9 Such an intent may be inferred from a “scheme of federal regulation...so  
10 pervasive as to make reasonable the inference that Congress left no  
11 room for the States to supplement it,” or where an Act of Congress  
12 “touch[es] a field in which the federal interest is so dominant that the  
13 federal system will be assumed to preclude enforcement of state laws  
14 on the same subject...”

15 Finally, state law is pre-empted to the extent that it actually  
16 conflicts with federal law. Thus, the Court has found pre-emption  
17 where it is impossible for a private party to comply with both state and  
18 federal requirements, or where state law “stands as an obstacle to the  
19 accomplishment and execution of the full purposes and objectives of  
20 Congress.”

21 *English v. General Elec. Co.*, 496 U.S. 72, 78-79 (1990) (citations omitted).

22 “Congressional purpose is the ‘ultimate touchstone’ of pre-emption analysis.”

23 *Oxygenated Fuels Assoc. v. Davis*, 331 F.3d 665, 668 (9<sup>th</sup> Cir. 2003). As the  
24 Supreme Court reiterated two weeks ago,

25 . . . ‘[i]n all pre-emption cases, and particularly in those [where]  
26 Congress has legislated . . . in a field which the States have traditionally  
27 occupied, we start with the assumption that the historic police powers  
28 of the States were not to be superseded by the Federal Act unless that  
29 was the clear and manifest purpose of Congress. *Medtronic, Inc. v.*  
30 *Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1966)  
31 (citation and internal quotation marks omitted); see also *Wisconsin*  
32 *Public Intervenor v. Mortier*, 501 U.S. 597, 605, 111 S.Ct. 2476, 115  
33 L.Ed.2d 532 (1991) (applying presumption against preemption to a local  
34 regulation).

35 *Engine Mfrs. Ass’n v. South Coast Air Quality Mgmt. Dist.*, \_\_\_\_ U.S. \_\_\_\_, 2004  
36 WL 893964 at \*8 (Supreme Court April 28, 2004).

37 The Ninth Circuit has noted that this presumption against pre-emption has two  
38 justifications. First, Congress has the power to be clear about when it intends a  
39 federal statute to have pre-emptive force. *See Chemical Specialties Manufacturers*

1 v. *Allenby*, 958 F.2d 941, 943 (9<sup>th</sup> Cir. 1992). Second, if a court erroneously finds pre-  
2 emption, the State is powerless to do anything about it. *Id.* In contrast, if a court  
3 erroneously finds no pre-emption, Congress can subsequently make its contrary intent  
4 clear. *Id.*

5  
6 **B. Here, Although There Is No Presumption Against Pre-emption, Several**  
7 **Courts Have Nevertheless Held That FIFRA Does Not Pre-empt Various**  
8 **State Laws**

9 Pesticide regulation reflects and derives from environmental concerns similar  
10 in nature to health and safety concerns, which are fields traditionally regulated by the  
11 states. “Environmental regulation [also] is an area of traditional state control.”  
12 *Oxygenated Fuels Assoc.*, 331 F.3d at 673 (holding that although not expressly  
13 exempted from pre-emption by the federal Clean Air Act, California’s ban on use of  
14 MTBE in gasoline nonetheless was not pre-empted because it does not conflict with  
15 the goals and purposes of that Act.)

16 However, the narrower “field” of pesticide use is not a field traditionally  
17 regulated primarily by the states. FIFRA’s “comprehensive” regulatory scheme itself  
18 so demonstrates. As stated somewhat confusingly in *United States v. Locke*, 529  
19 U.S. 89, 108 (2000), “...an ‘assumption’ of nonpre-emption is not triggered when the  
20 State regulates in an area where there has been a history of significant federal  
21 presence.” Put another way, the presumption against pre-emption does not  
22 necessarily apply in cases such as this, where there is a history of extensive federal  
23 regulatory involvement. Moreover, several courts have rejected Supremacy Clause-  
24 based efforts to use FIFRA to invalidate various state statutes and local ordinances.

25 In 1991, the Supreme Court held that FIFRA does not pre-empt a local  
26 ordinance requiring a permit for the application of any pesticide to public lands,  
27 private lands subject to public use and aerial application. *Mortier*, 501 U.S. at 616.  
28 First, the Court found no express pre-emption, noting that “the language [of FIFRA]



1 and the legislative materials relied on . . . are insufficient to demonstrate the necessary  
2 congressional intent to pre-empt.” *Id.* at 607. Next, the Court found that there was  
3 no “field” pre-emption. It stated,

4  
5 In the first place, § 136v itself undercuts such an inference. The  
6 provision immediately following the statute’s grant of regulatory  
7 authority to the States declares that “[s]uch State shall not impose or  
8 continue in effect any requirements for labeling and packaging in  
addition to or different from those required under” FIFRA, § 136v(b).  
This language would be pure surplusage if Congress had intended to  
occupy the entire field of pesticide regulation.

9 *Id.* at 612-13. After additional analysis, the Supreme Court declared,

10  
11 Whatever else FIFRA may supplant, it does not occupy the field of  
pesticide regulation in general or the area of local use permitting in  
particular.

12 *Id.* at 614. Finally, as to the basis for pre-emption urged here - - conflict pre-emption  
13 - - the Supreme Court could “discern no actual conflict either between FIFRA and the  
14 [local] ordinance . . . or between FIFRA and local regulation generally.” *Id.* It went  
15 on to observe that,

16  
17 There is no indication that any coordination which the statute seeks to  
18 promote extends beyond the matters with which it deals, or does so  
19 strongly enough to compel the conclusion that an independently enacted  
ordinance that falls outside the statute’s reach frustrates its purpose.

20 *Id.* at 615.

21 The Ninth Circuit, too, has held that FIFRA does not pre-empt a California  
22 state statute (“Proposition 65”) that imposes consumer product warning requirements  
23 on various products, including products regulated under FIFRA. *See Allenby*, 958  
24 F.2d at 950. In reaching that conclusion, the Court began with the observation that,

25  
26 To find that Proposition 65 is preempted under FIFRA . . . , this court  
27 must determine that all possible consumer product warnings that would  
28 satisfy Proposition 65 conflict with provisions of the federal statutes.  
This case turns on this standard.

*Id.* at 943. It then noted that under FIFRA § 136v (“Authority of States”),

1  
2 So long as additional labeling is not required, FIFRA expressly authorizes state  
3 pesticide regulation. Other than regulating labels, states are left free to impose  
4 whatever restrictions they may wish. Consequently, a state could prohibit the  
5 sale of a pesticide within its borders even though it could not require the  
6 manufacturer of the pesticide to change the label . . . Congress included the  
7 preemption provision in FIFRA to promote uniformity and ease distribution  
8 practices for chemical product manufacturers.

9 *Id.* at 944. The Ninth Circuit then found that point-of-sale signs were not “labels”  
10 within the meaning of FIFRA and thus were not subject to pre-emption. *Id.* at 947.  
11 The Court did not consider, however, whether Proposition 65 frustrates any  
12 Congressional purpose, because the Plaintiff conceded the possibility of complying  
13 both with Proposition 65 and FIFRA. *Id.* at 949.

14 Finally, a well-respected District Judge long ago ruled that FIFRA does not  
15 pre-empt the Director of the California Department of Food and Agriculture (the  
16 then-applicable state agency) from adopting and enforcing various requirements for  
17 the submission of data to register “restricted use” pesticides, even though the  
18 California requirements went beyond those imposed by FIFRA. *See, Nat’l Agric.*  
19 *Chems. Ass’n v. Rominger*, 500 F.Supp. 465, 468 (E.D. C.A. 1980) (Karlton, J.). He  
20 stated,

21 To put it bluntly, except as to labeling and packaging, a congressional  
22 intent to prohibit any registration which differs from the federal  
23 requirements is simply not to be found on the face of the statute.

24 *Id.* at 469.

25 In addition, there are two Supreme Court cases dealing with FIFRA that  
26 provide some support for the Intervenors’ view that FIFRA does not pre-empt section  
27 12811.5, although they contain no holdings about pre-emption. In *Ruckelshaus v.*  
28 *Monsanto Co.*, 467 U.S. 986, 1013-14, 1016 (1984), the Court held that as to data  
submitted to the EPA within certain time periods an applicant could assert a Fifth  
Amendment “takings” claim, and that for purposes of the Fifth Amendment and the  
availability of a Tucker Act remedy, such data was “property” under applicable state

1 law. The Court noted that the EPA “encourage[d] [the court] to view the situation not  
2 as a taking of Monsanto’s property . . . but as a ‘pre-emption’ of whatever property  
3 rights Monsanto may have had in . . . [its] trade secrets.” *Id.* at 1012. The EPA also  
4 argued that “the proper functioning of the comprehensive FIFRA registration scheme  
5 depends upon its uniform application . . . [and should] not vary depending on the  
6 property law of the State in which the submitter is located.” *Id.* In rejecting the  
7 EPA’s contentions, the Supreme Court stated, “This argument proves too much. If  
8 Congress can ‘pre-empt’ state property law in the manner advocated by EPA, then the  
9 Taking Clause has lost all vitality.” *Id.*

10 In *Thomas v. Union Carbide Agric. Products*, 473 U.S. 568, 589 (1985), the  
11 Court held that FIFRA’s binding arbitration mechanism does not violate Article III  
12 of the Constitution. In *dicta*, the Court stated “Any right to compensation from  
13 follow-on registrants under § 3(c)(1)(D)(ii) for EPA’s use of data results from FIFRA  
14 and does not depend on or replace a right to such compensation under state law.” *Id.*  
15 at 584 (emphasis added.)

## 17 **C. The Parties’ Arguments Regarding Conflict Pre-emption**

### 18 **1. Plaintiff’s Pre-emption Argument**

19 Plaintiff does not contend that FIFRA pre-empts Section 12811.5 either  
20 expressly or through occupation of the field of pesticide regulation. Instead, Plaintiff  
21 argues that Section 12811.5 is pre-empted because it frustrates Congress’s purposes  
22 in enacting FIFRA. Plaintiff argues that the data sharing provisions of FIFRA  
23 implicate primarily intellectual property interests, which are peculiarly federal  
24 interests. Plaintiff contends that in enacting FIFRA, Congress intended to “balance[ ]  
25 two competing goals: (I) encouraging innovation in the development of new  
26 pesticides, and (ii) promoting the entry of generic products once any applicable  
27 patents on the new pesticide have expired.” Plaintiff argues that both in theory and  
28 in practice Section 12811.5 frustrates these goals and the methods by which Congress

1 sought to achieve them, by granting original applicants “exclusive use” rights of  
2 indefinite duration. According to Plaintiff, Section 12811.5 permits original  
3 applicants to demand excessive amounts of money from generic applicants who want  
4 to rely on their test data, to delay the registration of generic pesticides and/or to force  
5 generic applicants to duplicate their test data at great expense. As a result, Plaintiff  
6 argues, Section 12811.5 erects an entry barrier that Congress intended to tear down,  
7 and it ultimately discourages competition.

8 Plaintiff has been strangely oblique about the relief it seeks. Initially, Plaintiff  
9 sought an injunction that was close to incomprehensible. It would have enjoined the  
10 DPR from,

11  
12 Requiring any applicant for a generic pesticide registration in California  
13 to obtain a letter of authorization from any data submitter in order to  
14 reference, in support of its application for registration (including  
15 reregistration and amended registration), any data submitted to DPR that  
16 were also previously submitted to the United States Environmental  
17 Protection Agency (“EPA”) and are subject to the Federal Insecticide,  
18 Fungicide, and Rodenticide Act’s (“FIFRA”) mandatory data-licensing  
19 scheme.

20 DPR is also required, to the extent DPR concludes that any item of data  
21 is required to support any application for pesticide registration  
22 (including reregistration and amended registration) and (i) the data item  
23 was previously submitted to EPA and is subject to FIFRA’s mandatory  
24 data-licensing scheme, and (ii) the applicant chooses to reference that  
25 data item in support of an application, to consider such data without a  
26 letter or authorization, so long as the applicant provides proof that either  
27 (a) it has issued an offer to pay compensation under FIFRA to the data  
28 submitter for any such data item that was originally submitted to EPA  
within the previous 15 years, or (b) it is exempt from citing and offering  
to pay compensation under FIFRA for such data items pursuant to the  
“formulator’s exemption” of FIFRA § 3(c)(2)(D) and the supplier of the  
pesticide with which the applicant formulates its product has issued an  
offer to pay compensation under FIFRA with respect to any such data  
item that was originally submitted to EPA within the previous 15 years.

Following a hearing conducted on December 15, 2003, the Court issued an order  
requiring the parties to answer various questions. In response to the question “What  
is the precise relief Plaintiff is seeking?” Plaintiff stated at one point that it,

1 seeks relief that would conform DPR’s data reliance rules with those of  
2 FIFRA *with respect to all data submitted to both EPA and DPR*  
(emphasis in original). Thus, CDPA seeks a declaration striking down  
3 the letter of authorization (“LOA”) requirement as applied to data also  
4 submitted to EPA and for which any exclusive use period has expired.  
5 Thus . . . any applicant in California . . . [may] rely on an item of data  
6 previously submitted to DPR to support its application . . . without the  
7 permission of the data submitter provided only that the applicant  
8 demonstrates that (1) the data item was previously submitted to EPA and  
9 (2) the data item is not currently subject to exclusive use under FIFRA  
10 . . . .”

11 The modified injunction that Plaintiff proposed in support of this “clarified”  
12 request would enjoin the DPR from,  
13

14 Requiring any applicant for a pesticide registration (including  
15 reregistration and amended registration) in California to obtain a letter  
16 of authorization or similar written permission from any data submitter  
17 in order to reference data previously submitted to DPR that (1) were also  
18 previously submitted to the United States Environmental Protection  
19 Agency, and (2) are no longer subject to the data submitter’s exclusive  
20 use pursuant to Section 3(c)(1)(F)(I) or (ii) of the Federal Insecticide,  
21 Fungicide, and Rodenticide Act.

22 Plaintiff’s position remains unclear. In some respects it appears to contend that  
23 because of FIFRA pre-emption, *at no time* may California lawfully require a generic  
24 applicant to pay any additional fee to any original applicant who has previously  
25 obtained FIFRA registration. Elsewhere, Plaintiff actually appears to concede that  
26 during the FIFRA 10 year “exclusive use” period California may condition a generic  
27 applicant’s registration on such an additional payment to the original applicant. But  
28 regardless whether that is Plaintiff’s position, it is clear that Plaintiff stops there.  
Plaintiff boldly asserts that at no point after that ten year period may California  
condition a generic applicant’s registration upon the issuance of a LOA - - even  
during the five year (years 11-15) period of mandatory licensing that FIFRA requires.  
7 U.S.C. § 136a(c)(1)(F)(iii). Thus, whereas FIFRA entitles an original applicant to  
compensation for up to 15 years, Plaintiff would limit California’s authority to require  
additional compensation to ten years. Plaintiff purports to seek to conform California  
law to what it contends is the pre-emptive mandate of FIFRA, but Plaintiff does not

1 offer a principled reason for the inconsistency.  
2

### 3 2. The Intervenor's Position

4 Intervenor's argue that FIFRA's primary goal is to ensure that pesticides are  
5 safe to both human health and the environment. They agree that in enacting FIFRA,  
6 Congress intended to encourage innovation, remove entry barriers and streamline the  
7 registration process. However, Intervenor's contend that these objectives were limited  
8 to the granting of federal registrations, without any concern for registration  
9 requirements that states might enact pursuant to 7 U.S.C. § 136v. Intervenor's also  
10 argue that Section 12811.5 actually promotes Congress's objectives, rather than  
11 frustrating them, by protecting innovator's proprietary interest in their test data and  
12 by providing an avenue for generic registrants to avoid having to duplicate data.<sup>4</sup>

13 Intervenor's rely on such legislative history as House Report 95-663, which  
14 provides:  
15

16 [The 1978 Amendments to FIFRA which added the ten year  
17 exclusive use and five year mandatory licensing provisions] will  
18 assure availability of pesticides for agricultural and forestry  
19 production in the United States while at the same time providing  
20 needed safeguards against unreasonable adverse effects on human  
21 health and the environment...To this end the legislation would  
22 expedite the registration and reregistration of pesticides by the  
23 Environmental Protection Agency, encourage greater research for  
24 safe and effective pesticides by manufacturers and formulators of  
25 pesticides...It also strengthens the authority of states in  
26 administering pesticide programs... [The 1978 amendments]  
27 ha[ve] struck a careful balance between the interests of the small  
28 formulator and the need for encouraging competition in the  
pesticide business, on the one hand, and the need to assure the  
continued research and development of new pesticides by  
recognizing the limited proprietary interest of those who have  
incurred the expense of developing health and safety data.

---

<sup>4</sup> Although it is Congress's objective(s) that are relevant for purposes of pre-emption analysis, Intervenor's point out that the DPR characterized the bill that became Section 12811.5 as "a provision similar to the one in FIFRA" in that it would "prevent unauthorized use of another person's data, which was developed at the other person's expense." See DPR *Enrolled Bill Report* at 2 (Sept. 9, 1996).

1 *House Rpt. No. 95-663, reprinted at 1978 U.S.C.C.A.N. 1988 (p. 3-4).*

2 Intervenor also cite a Senate Report stating: “Generally, the intent of  
3 [subsection (a)] is to leave to the States and local governments the authority to impose  
4 stricter regulations on pesticides use than that required under the Act.” *Senate Rpt.*  
5 *No. 92-970, reprinted at 1972 U.S.C.C.A.N. 4092.*

6 This federal legislative history is not very illuminating. In enacting FIFRA  
7 Congress had several objectives. In providing economic incentives for the  
8 development of scientific data, Congress at the same time promoted health and safety;  
9 the process and requirements for registration are inextricably related to sale, use,  
10 labeling and packaging. (That connection also is present in California’s scheme.)  
11 Thus, by limiting subsection 136v(b)’s uniformity requirement to the labeling and  
12 packaging of pesticides, Congress may not have intended to permit states to enact  
13 registration requirements imposing costs on generic applicants in addition to those  
14 required by FIFRA. On the other hand, FIFRA’s legislative history does not reflect  
15 an intent by Congress to protect generic applicants for federal registration from  
16 having to pay again for the right to use original applicants’ data in obtaining state  
17 registration.<sup>5</sup>

18 ///

19 ///

20 ///

21  
22 **D. Here, Section 12811.5 Does Not Conflict With FIFRA In A Manner**

23  
24 <sup>5</sup> Arbitrators who have resolved disputes under FIFRA’s mandatory licensing  
25 scheme have sometimes ruled that the scheme entitles a generic registrant to use an  
26 original applicant’s data to obtain only a federal registration, not a California  
27 registration. *See Opp. at 13 n. 6; Microgen, Inc. v. Lonza, Inc.*, No. 23-171-00003-96  
28 (Am. Arb. Ass’n, May 5, 2000) at 8 (attached to Schuda Decl., Exh. J). One panel  
noted, “While it may be that the purposes for which FIFRA was enacted would be  
better served if [the generic] had an absolute right to sell its products throughout the  
United States, including in California, that proposition should be addressed to  
Congress or the California legislature, not to this panel.” *Id.*

1           **Requiring Pre-Emption**

2           Conflict pre-emption may occur not only when the state law interferes with the  
3 purposes of the federal law - - which (as shown above) is not clearly the case here - -  
4 but also when the state law interferes with the methods by which the federal statute  
5 was designed to reach its goals. *See Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 494  
6 (1987). In order to determine whether a conflict exists, courts must consider the  
7 relationship between the state and federal laws as they are “interpreted and applied,  
8 not merely as they are written.” *Jones v. Rath Packing Co.*, 430 U.S. 519, 526  
9 (1977). “What is a sufficient obstacle is a matter of judgment, to be informed by  
10 examining the federal statute as a whole and identifying its purpose and intended  
11 effects.” *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000).

12           FIFRA applies only to federal registration. It does not authorize a pesticide  
13 manufacturer to register or sell its products in any given state. If Section 12811.5  
14 truly imposes prohibitive costs on generic applicants, which deter or prevent them  
15 from obtaining California registration, and if identical legislation were enacted in all  
16 other states, then on a nationwide basis original applicants would enjoy indefinite  
17 exclusive use over their data - - beyond FIFRA’s 15 years. National safety standards  
18 for pesticides would be in place, but the registration process would not be streamlined  
19 and there would be high entry barriers and reduced, or even minimal, competition.  
20 Plaintiff argues that it is this scenario that presents a conflict requiring pre-emption.  
21 It claims legal support for this argument in *Bonito Boats, Inc. v. Thunder Craft Boats,*  
22 *Inc.*, 489 U.S. 141 (1989). There, the Supreme Court ruled that federal patent laws  
23 pre-empted a Florida law that made it unlawful to duplicate a vessel hull without  
24 obtaining written permission from the original creator. The Florida law granted an  
25 original creator indefinite exclusive use of its design, even after any federal patent  
26 protection on the design had expired. The Supreme Court held that the Florida law  
27 was pre-empted because it created an obstacle to the patent laws’ goals of creating  
28 national uniformity in intellectual property rights and encouraging innovation while  
preserving competition. *Id.* at 146-162. As the Court reasoned, “. . . States may not



1 render the [patent laws] fruitless by offering patent-like protection to the subject  
2 matter of . . . [an] expired patent.” *Id.* at 152. *Bonito Boats* is of little import here,  
3 however, because under the Constitution patent regulation is an exclusively federal  
4 function; that is not the case with pesticide regulation. More importantly, Plaintiff’s  
5 “actual conflict” arguments are either factually unsupported or exaggerated, as the  
6 ensuing analysis demonstrates.

7       There is, in fact, nothing even approaching a nationwide conflict between  
8 FIFRA and the states. Moreover, even in California the purported conflict, or at least  
9 the adverse consequences of that purported conflict, fall far short of thwarting FIFRA.  
10 Plaintiff vigorously complains that the LOA requirement of Section 12811.5 imposes  
11 impermissible costs and delays on generic applicants. To support this contention  
12 Plaintiff has provided evidence that at least several of its members (including  
13 Albaugh, Inc., Griffin LLC, Farmsaver and Agtrol Chemical Products) have tried to  
14 register generic pesticides in California, but were unable to do so (or suffered  
15 substantial delay before obtaining registration) because the original applicants refused  
16 to permit them to use their test data. *See Frazee Decl.* ¶ 11-60; *Collier Decl.* ¶ 19-76;  
17 *Kay Decl.* ¶ 22-35. The Intervenor do not dispute that delay and/or non-consent  
18 actually occurred, at least in these few instances. *See, e.g. Stubbs Decl.* ¶ 4-10;  
19 *Fowler Decl.* ¶ 4-9; *Burkey Decl.* ¶ 4-5; *Goette Decl.* ¶ 6-81 *Cain Decl.* ¶ 4-7; *Priscila*  
20 *Decl.* ¶ 4-5. However, these examples of excessive cost and delay are isolated, and  
21 the Intervenor dispute the reason for the delay or non-consent, placing the fault on  
22 the generic applicant.

23       The limited facts Plaintiff has adduced do not establish that Section 12811.5  
24 has stifled innovation or decreased competition on a large scale. Indeed, Intervenor  
25 provide evidence that in California between 1993 and 2003, original applicants  
26 provided permission to generic applicants to rely on their test data 13,290 times. *See*  
27 *Melnicoe Decl.*, ¶ 3-17 and Ex. A.

28       In their initial sets of voluminous briefs and declarations, the parties failed to  
address certain key aspects of how the respective federal and state registration and

1 licensing systems really work. Following the December 15, 2003 hearing, the Court  
2 ordered the parties to file supplemental materials clarifying several issues. In general,  
3 the Court sought more information about the economic impact of Section 12811.5.  
4 According to the response of Plaintiff, in the five year period from 1999-2003,  
5 generic applicants for California registrations had to and did pay a second, or  
6 additional, fee to original applicants for the right to submit the original applicants'  
7 California test data to the DPR. But Plaintiff also acknowledged that,

8  
9       The two amounts are not typically broken out separately in data compensation  
10 settlement agreements between generic and . . . Basic registrants. Rather, such  
11 agreements typically state a single amount due for the generic's reliance on the  
12 Basic registrant's data. In the course of the negotiations the parties will either  
13 agree, or not agree, that the settlement will include a provision obligating the  
14 Basic to provide an LOA to the generic . . . If an LOA will be included as part  
15 of the settlement, the agreed-amount of compensation will be substantially  
16 greater than if no LOA will be provided.

17  
18 In their response to a different question, Intervenors confirmed what Plaintiff stated:  
19 “[I]t is not possible to calculate [the] ‘average fee’ that generics paid [for an LOA]  
20 . . . because compensation for use of data in support of federal . . . and California  
21 registrations . . . normally are [sic] negotiated concurrently and not broken out  
22 separately in data compensation agreements.”

23  
24       Thus, it appears that when a generic applicant seeks to register its generic  
25 version of a pesticide in California, its negotiations with the original applicant almost  
26 always encompass the generic's right to use the original applicant's data to obtain  
27 *both* a federal license under FIFRA and a California registration under Section  
28 12811.5. That the negotiations result in generic applicants having to pay additional  
amounts is not, from an economic perspective, either surprising or problematic. It  
is not clear just how much additional money is involved, but even if the amounts are  
sizeable that, too, would be unremarkable. The original applicants developed this  
scientific and technical data at great expense. California has not only the largest  
population in the Nation, but also the largest agricultural economy. For generic

1 companies seeking to sell their pesticides in California to have to pay an “extra” fee  
2 is not inherently anti-competitive; basic laws of the marketplace do tend to work their  
3 way even into regulated industries, after all.

4 And so do political considerations. I deem it telling that Plaintiff did not bring  
5 this, or any, FIFRA pre-emption challenge to Section 12811.5 for a period of 22  
6 years.<sup>6</sup> It is not disputed that during that lengthy period many thousands of LOAs  
7 were granted. In response to the Court’s question as to why it waited that long to  
8 sue, Plaintiff did not attribute the delay to any previous, but no longer-existing, legal  
9 barrier. Instead, with commendable candor Plaintiff admitted, “As generic activity  
10 has increased, the problems for generic competition posed by California’s Letter of  
11 Authorization requirement have been felt more broadly in the generic industry.”  
12 Plaintiff went on to add that because of the cost and uncertainty of litigation, it had  
13 pursued a legislative solution first, but that the bill it introduced “to conform  
14 California’s Pesticide Data Reliance Rules with those of FIFRA . . . was strongly  
15 opposed by Basic registrants and failed to garner the support needed for passage.”<sup>7</sup>

16 Evidently, the original pesticide manufacturers have considerable “clout” in  
17 Sacramento. If I were passing judgment about whether from a public interest  
18 standpoint the legislative and gubernatorial decision to enact Section 12811.5 was  
19 wise, I might well conclude that it was not. On this record, however, to strike down  
20

---

21 <sup>6</sup> Section 12811.5 was enacted in 1996, but before that time the DPR had  
22 imposed a LOA requirement pursuant to regulation (3 CRR § 6170(c). That  
23 regulation was adopted in 1982.

24 <sup>7</sup> Plaintiff also represented that in 2002 two of the Intervenor (Syngenta and  
25 Dow Agrosiences) filed lawsuits against DPR in California state court that sought  
26 “rulings that would substantially expand the scope of the LOA requirement and thus  
27 raise the barrier to generic entry even further. In the face of these lawsuits, CPDA  
28 concluded that bringing a pre-emption lawsuit against DPR was its only recourse.”  
On March 3, 2004 the Superior Court entered a Final Judgment that provides that  
“Pursuant to Section 12811.5 . . . the [DPR] may not actively or passively, use or [sic]  
an original registrant’s data in support of a subsequent application for registration of  
a pesticide without the original data owner’s consent.”

1 that provision as unconstitutional would be unjustified.

2 For the foregoing reasons, Plaintiff's motion for summary judgment<sup>8</sup> is  
3 DENIED. The Court GRANTS summary judgment to the Intervenor*s sua sponte*. This  
4 action is dismissed in its entirety with prejudice. Intervenor*s* shall lodge a proposed  
5 judgment by not later than May 18, 2004.

6

7 IT IS SO ORDERED.

8

9 DATE:

\_\_\_\_\_  
A. Howard Matz  
United States District Judge

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

---

<sup>8</sup> Docket number 64.