IN THE UNITED STATES DISTRICT COURT
FOR EASTERN DISTRICT OF TENNESSEE
GREENVILLE DIVISION

KING PHARMACEUTICALS, INC.; MONARCH PHARMACEUTICALS, INC.; KING PHARMACEUTICALS RESEARCH AND DEVELOPMENT, INC. INC.; and GENTRAC, INCORPORATED	
Plaintiffs,	**Civil Action No.** 2:09-cv-244
v.	**JURY TRIAL DEMANDED**
ZYMOGENETICS, INC. and JOHN AND JANE DOES 1-50,	
Defendants.	

TEMPORARY RESTRAINING ORDER REGARDING DEFENDANT'S COMPARATIVE SAFETY CLAIMS

The Court, having considered fully Plaintiffs King Pharmaceuticals, Inc.; Monarch Pharmaceuticals, Inc.; King Pharmaceuticals Research and Development, Inc.; and GenTrac, Inc.'s (collectively, "Plaintiffs") Motion for Temporary Restraining Order regarding Defendant ZymoGenetics, Inc.'s ("Defendant") Failure to Cease Making False or Misleading Comparative Statements and all supporting papers, finds the Motion is well-taken and should be granted.

Accordingly, IT IS HEREBY ORDERED and DECREED as follows:

1. The Court hereby orders a temporary restraining order that restrains and enjoins Defendant, its officers, agents, servants, employees, attorneys, and any other persons who are in active concert or participation with any of the foregoing, from disseminating, distributing, and/or displaying any statement that affirmatively states or implies that Defendant's RECOTHROM®

product (or recombinant human thrombin generally) is generally superior to and/or safer than King's Thrombin-JMI® product (or bovine thrombin products generally).

2. The Court hereby orders a temporary restraining order that restrains and enjoins Defendant, its officers, agents, servants, employees, attorneys, and any other persons who are in active concert or participation with any of the foregoing, from disseminating, distributing, and/or displaying any statement that affirmatively states or implies that Defendant's RECOTHROM® product (or recombinant human thrombin generally) is superior to and/or safer than King's Thrombin-JMI® product (or bovine thrombin products generally) due to a lower incidence of antibody formation or superior immunogenicity.

3. The Court hereby orders a temporary restraining order that restrains and enjoins Defendant, its officers, agents, servants, employees, attorneys, and any other persons who are in active concert or participation with any of the foregoing, from violating the terms of the FDA approval letter dated January 17, 2008 that requires the following:

> All promotional claims must be consistent with and not contrary to approved labeling. **You should not make a comparative promotional claim or claim of superiority over other products** unless you have submitted data to support such claims to us [FDA] and received CBER approval for such claims.
>
> In particular, RECOTHROM[™] was non-inferior to a licensed bovine thrombin product. [Thrombin-JMI® product] (emphasis supplied)

Thus Defendant, its officers, agents, servants, employees, attorneys, and any other persons who are in active concert or participation with any of the foregoing, shall cease and stop the dissemination and promotion of all materials that claim its RECOTHROM® product is safer than King's Thrombin-JMI® product or any other comparative promotional claim of superiority over King's Thrombin-JMI® product.

4. The Court hereby orders a temporary restraining order that restrains and enjoins Defendant, its officers, agents, servants, employees, attorneys, and any other persons who are in active concert or participation with any of the foregoing, from violating the terms of the FDA Violation Letter dated April 25, 2008 that provides in part the following:

> The Advertising and Promotional Labeling Branch (APLB) in the Food and Drug Administration (FDA's) Center for Biologics Evaluation and Research (CBER) has reviewed information on your website www.zymogenetics.com, including a press release for Recothrom (Thrombin, Topical (Recombinant)). **This promotional material is false or misleading because it omits material facts about Recothrom.** Thus, the promotional material misbrands your Recothrom product in violation of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. §§ 352(a) and 321(n).
>
> In the "Newsroom" portion of your website, www.zymogenetics.com, the press release entitled "FDA Approves ZymoGenetics RECOTHROM[™] Thrombin, topical (Recombinant)", dated January 17, 2008, contains the following statement:
>
> - "A Phase 3 pivotal clinical trial showed that RECOTHROM[™]. had comparable efficacy and a significantly lower incidence of antibody formation compared to the commercially available bovine thrombin product."
>
> **This statement is false and misleading because it suggests that Recothrom is safer than the bovine thrombin product due to a lower incidence of antibody formation in the patients who took the Recothrom. However, this statement excludes important contextual information necessary to understand the limitation of this finding.**
>
> **Indeed, according to the "Immunogenicity" section of the Recothrom PI, the development of antibodies in either group did not lead to any adverse events such as excessive bleeding.** In addition, according to the "Adverse Reactions" section of the PI, the incidences of pre-specified adverse events were similar between Recothrom and bovine thrombin.

> **For reasons discussed above, your promotional material misbrands Recothrom within the meaning of 21 U.S.C. §§ 352(a) and 321(n) of the Act.**
>
> **We request that ZymoGenetics immediately cease the dissemination of the violative promotional material for Recothrom, as described above.**
>
> The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that the promotional material for your products comply with each applicable requirement of the Act and implementing. (emphasis supplied)

Thus, Defendant, its officers, agents, servants, employees, attorneys, and any other persons who are in active concert or participation with any of the foregoing shall immediately cease the dissemination of the promotional materials for its RECOTHROM® product that state or imply that Defendant's RECOTHROM® product is superior to and/or safer than King's Thrombin-JMI® product due to a lower incidence of antibody formation in the patients who were exposed to the RECOTHROM® product as compared to patients who were exposed to the Thrombin-JMI® product.

5. Defendant shall file with this Court and serve on King within ten (10) days after the service of this Order, a report in writing under oath, setting forth in detail the manner and form in which Defendant has complied with this Order.

6. King shall be entitled to enforce this Order until the Court determines whether the entry of a preliminary injunction is appropriate, without the requirement of a bond, or if bond is required, it is set at __- 0 -__.

7. A preliminary injunction hearing shall be set for NW. 16, 2009 at 1 p.m.

DATED this 3rd day of ~~October~~ NW., 2009.

U.S. District Judge

APPROVED FOR ENTRY BY:

Sam Berry Blair (TN BPR No. 10375)
(motion for pro hac vice filed herewith)
Michael Richards (TN BPR No. 7973)
(motion for pro hac vice filed herewith)
Clinton J. Simpson (TN BPR No. 20284)
(motion for pro hac vice filed herewith)
Samuel F. Miller (TN BPR No. 22936)
(admitted to E.D. Tenn.)
Sarah Elizabeth Moccaldi (TN BPR No. 24608)
(motion for pro hac vice filed herewith)
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