Microbix Biosystems Inc.

December 18, 2000

Re: Generic Drug Study – FTC File No. V000014

Dear Sir/Madam,

I write in response to your Public Comment Request for the upcoming FTC study entitled "Generic Drug Study – FTC File No. V000014" as reviewed in your release of October 11, 2000.

It is imperative that FTC investigate anti-competitive activities that misuse the provisions of the Hatch-Waxman Act. Abuse of such provisions prevents the healthcare consumer from enjoying the benefits of generic drugs. By preventing competition, unnecessarily inflated drug prices are maintained, thereby limiting the value of the healthcare dollar (the numbers of which are finite). In more extreme cases, continuance of monopolies can put patients at risk. The loss of a single source manufacturer due to GMP deficiencies could potentially remove a lifesaving drug from the marketplace. This, in fact, has already happened with the thrombolytic drug Abbokinase (Urokinase for Injection) from Abbott Laboratories. Abbott's Urokinase patents expired in 1993. As reviewed in Judge Garbis' Summary Judgment Opinion of March 2000 from the US District Court for the District of Maryland, Abbott interfered with the Urokinase development program of its competitor, Microbix Biosystems, by contracting to buy up the entire supply of the only source of key raw material used for Urokinase production. This was in violation of the Sherman Act. Subsequent to this activity, Abbokinase was removed from the marketplace by FDA after Abbott's manufacturing processes, used to produce Urokinase in its facility in Chicago, were found by FDA to contain significant deficiencies in GMP. As a result of these events, there is currently no Urokinase product in the marketplace. I am aware, from sworn testimony, that patients have died as a result of Urokinase being unavailable. Microbix' Urokinase product was projected to be in the marketplace in year 2000, before Abbott's interference with the raw material supply.

The original intentions of the Hatch-Waxman Act were appropriate and clear. By ensuring that patent rights were enforced, the incentive to develop and market innovative drugs was maintained. Generic drug development, after the appropriate period of patent exclusivity, was to be encouraged by the "180-day" period.

In the period when drugs were new, and patents were listed in the "Orange Book" in a contemporary fashion, the Hatch-Waxman provisions were effective. However, the same

companies that benefited from Hatch-Waxman are now abusing the Act to maintain market share. The Hytrin (Abbott again) and Buspirone (BMS) fiascoes are clear examples. The approach is clear:

1. As the original patent estate expires, patent some new aspect of the drug product
2. List the new patent in the Orange Book
3. Await ANDA filings
4. Ignore paragraph IV certifications of non-infringement
5. Sue generic drug manufacturer
6. Obtain 30-month stay and maintain monopoly

Unfortunately, there is no check as to the applicability of the new patents to the stated objectives of the "Orange Book" in requiring the listing of patents which refer to the "active ingredient" and "clinical use". FDA will not review the nature and defendability of such new patents and paragraph IV certification can be ignored. Hence, the generic drug company has no defense against this approach, even if the new patents are irrelevant and undefendable, as precipitation of the 30-month stay is the objective of the exercise. It is clear that such a delay in the marketing of generic drugs could have disastrous effects on the finances of subsequent entry manufacturers, particularly smaller entrepreneurial groups, and could potentially eliminate all future competition.

A possible solution to the issue would be that only patents that have issued at the time of regulatory approval can be added to the Orange Book. Although subsequent patent infringement suits may lead to the removal of product from the market, the onus should be on the group that brings the lawsuit to prove infringement. Though this may lead to FDA spending resources to approve a drug that cannot ultimately be marketed, the benefits of approving generic drugs to the healthcare consumer will outweigh this risk.

Additional beneficial changes to current policy would be to have FDA work more closely with the Patent Office in exercising some discretion as to which patents should be listed in the Orange Book. Clearly, someone should be checking that listed patents are not irrelevant to the ingredient and the use of the drug. By the same token, perhaps relationships between certain companies and the Patent Office should be investigated by FTC. This would scrutinize how certain patent applications ever come to issue and how claims that are not supported by enablement, and are subject to prior art, still seem to be granted (see Amgen patents on Erythropoietin as an example).

To conclude, the current abuse of the Hatch-Waxman Act is leading to restraint of trade, inflated healthcare prices and may lead to patient suffering. All of this is occurring to allow monopolists to extend their lucrative period of patent protection. I am convinced that this was not the intention of Senators Hatch and Waxman when this Act was passed.

Thank you for you kind attention. If you require further information, please contact me here at Microbix.

Sincerely,

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