

August 30, 1999

Dr. R. Pritchard  
President  
University of Toronto  
Room 206, Simcoe Hall  
27 Kings College Circle  
Toronto, Ontario M5S 1A1

Dear Dr. Pritchard:

**MOST URGENT**

As you know, Apotex has committed to donate to the University of Toronto \$20 million for the new Medical Sciences Building, and is close to finalizing an agreement to increase the donation to \$55 million, which would also encompass a new building for the Faculty of Pharmacy and other projects.

I am writing to advise you that Apotex is now confronted with an impending force majeure, which, if not averted, will likely compel cancellation of our entire commitment to the University.

What is at issue is the publication by the Hon. John Manley, Minister of Industry, of his intention to precipitously and retroactively expand the scope, yet again, of the astoundingly unfair Patented Medicines (Notice of Compliance) Regulations ("the Regulations").

The Regulations had their origin in 1993, when the Mulroney government passed Bill C-91, not only to cancel pharmaceutical compulsory licenses (including some licences retroactively), but also to authorize certain regulations. In March 1993, in its last days, the Mulroney government then promulgated (without advance notice or any opportunity for comment) the Regulations, specific to pharmaceuticals, purporting them to be necessary to prevent infringement, and including provisions making them retroactive to all generic submissions already filed and awaiting approval.

The Regulations were and are astoundingly unfair.

They are irrelevant to preventing infringement, because a pharmaceutical patentee, like all others, is fully protected by the Patent Act. If a patentee believes a patent is being infringed, he can sue, and, if found correct, he obtains an injunction, an award of damages or the infringer's profits, as well as delivery up of all inventory, and costs.



The effect of the Regulations is thus not to prevent infringement, but to enable brandname companies to prevent generic approvals, almost without limit, simply by asserting that a patent will be infringed, even if such assertion is without merit. As was predictable, the Regulations have, since 1993, been systematically abused by "Patentees" to prevent or delay generic approvals, thus causing enormous damage to the generic industry and Canada's healthcare system, all with impunity.

In 1997, the effects of Bill C-91 were reviewed by a Parliamentary Committee, as had been mandated by Bill C-91. It is our understanding that, at the conclusion of the hearings, the Committee stood ready to strongly recommend helpful changes to the Regulations, but the Liberal members were then directed to change the report to simply recommend that the Regulations be reviewed by the Government, thus entirely subverting the Committee process.

Subsequently, in 1998, Mr. Manley moved, not to rescind the Regulations or to reduce the scope for abuse by patentees, but to make the Regulations even worse by an amendment that provided that a generic firm cannot even begin the process under the Regulations until after it has completed its development and filed its New Drug Submission, thus adding more years to the delay.

Then on July 31, 1999 Mr. Manley published a further proposed amendment, again not to address abuse by "patentees", but to expand the scope for abuse. The Regulations until now have applied only when a generic submission makes a comparison to a brand product for which there is a Patent List. The amendment would make the Regulations apply to all generic submissions, even if no such comparison is made. Even worse, the proposed change is to apply retroactively to some generic submissions already filed.

Apotex and others filed a submission in opposition to the proposed amendment, pointing out:

1. That the Regulations, even as unamended, were enormously damaging and persistently abused by "patentees".
2. That the proposed change would enormously widen the abuses and further damage the generic industry.
3. That it was particularly unfair that the change would apply retroactively to some generic submissions.



We were then subsequently informed by Mr. Manley's officials that they were directed by him to ignore all suggestions to reduce the scope for abuse by patentees, and to proceed only with the change to widen the scope.

On Friday, August 27 we were then provided with a revised draft, which astoundingly provides as follows:

1. In response to our protest that the changes apply retroactively to some generic submissions, the proposed amendment was modified to provide that the changes will apply retroactively to all submissions, even those filed long ago in accordance with the current Regulations, thus adding years of further delay.
2. Interested parties have only until Tuesday, August 31 to provide comments.

It is thus clear that the PMO and Mr. Manley are intent on rushing into force changes to further assist "patentees" in their campaign to strangle the generic industry, without regard to the astounding unfairness and the devastating adverse impact on the generic industry and Canada's healthcare system.

We enclose for your reference the following:

1. The proposed amendment published on July 31, 1999.
2. The Apotex responding brief dated
3. An appendix relevant to adverse impact.
4. The revised text given to us on August 27, 1999.
5. A responding letter from CDMA dated August 27, 1999.

We urgently need your help, as you also need our help. We appreciate that we may have called upon you in the past, but we are now facing a clear plan which is endangering our business.

We urge you to immediately contact the Prime Minister, Hon. Herb Gray, Hon. David Collinette, Hon. Allan Rock and others to state that you have just become aware of the proposed amendment and are concerned about likely adverse impact, and to ask that the Government not rush forward, but to provide at least another 30 days for comment, so that you may have an opportunity to fully consider the matter and provide comment before the changes become a fait accompli.



We ask that you then meet with Jack Kay and me on an urgent basis to fully discuss the matter and its implications.

Yours very truly,

APOTEX INC.

Bernard C. Sherman, Ph.D., P.Eng.  
Chairman and C.E.O.

BCS/jm



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CANADIAN  
SUCCESS



# University of Toronto

J. Robert S. Prichard,  
President

August 31, 1999

The Rt. Hon. Jean Chrétien  
Prime Minister  
Langevin Block  
80 Wellington Street  
Ottawa, ON K1A 0A3

Dear Prime Minister:

I write to bring an urgent matter to your attention pertaining to the review of the Patented Medicines Regulations.

The University of Toronto has not previously taken a position on these Regulations. However, a serious and urgent concern has been expressed to us about the Regulations and the impending deadline for comments of August 31, 1999, which of course is today. I strongly urge that you extend the deadline for at least another thirty days, i.e. September 30, 1999, to allow fuller debate and input on the issue.

Our reason for requesting this is the following: the University of Toronto is currently in late stage discussions with a major benefactor, Dr. Barry Sherman, Chairman and Chief Executive Officer of Apotex Inc, to secure a very substantial philanthropic commitment in support of our academic priorities. This commitment is the private sector component of the funding for the University's proposed Centre for Cellular and Molecular Biology Research, which has successfully attracted extraordinary support from the Canada Foundation for Innovation. The Apotex commitment to us would not only be an outstanding act of philanthropy, but it would invaluablely enhance our academic status in Canada and indeed globally. Apotex has advised us that the adverse effect of the new Regulations could make it impossible for Apotex to make its commitment to us. If Apotex's commitment were lost, the damage to our academic mission and capacity for research and innovation would be immense.

I would respectfully urge you to provide this extension in order to ensure time for full debate on the issue and to avoid the serious negative consequences to our very important medical sciences initiative. Thank you in advance for your consideration.

Warm regards,

  
J. Robert S. Prichard

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