

# Update

## Biotechnology & Pharmaceutical Group Newsletter

### Canada Proposes Increased Data Exclusivity For Innovators, But Less Patent Roadblocks To Generic Market Entry

Pharmaceutical companies bringing new brand name drugs to market in Canada will receive 8 years of data exclusivity, up from the current 5 years. However, companies will also have less clout in using patents to block generic drugs before Canadian market entry. This is likely to create increased reliance on patent infringement lawsuits after generic entry.

These are among the proposed changes in regulations announced on December 11, 2004 that would revise the Canadian Patented Medicine (Notice of Compliance) Regulations (the Canadian version of the US Orange Book) and the Food and Drugs Act Regulations. There is a 75 day period for the public to submit comments.

See [www.bereskinparr.com](http://www.bereskinparr.com) for full details.

### Poster Presentation Kills US Patent Application

The US Federal Circuit recently affirmed a USPTO decision to reject a patent application for methods of preparing soy fiber foods. The application was rejected because the methods had already been described in a printed publication more than one year before the application filing date. The "publication" consisted of a poster displayed at a meeting of chemists (2 days) and at a university (1 day). The poster provided an enabling disclosure of every claimed limitation of the invention. No copies of slides pasted on the poster were distributed. There was no prohibition on note-taking or copying. The presentation was not indexed for a library or database. The Court held that the poster constituted a printed publication citable against patentability because it had been made publicly accessible.

*In Re Klopfenstein*, 380 F.3d 1345.

### US Willful Infringement Softens

In the US, patent infringement defendants who engage in reprehensible conduct may receive a court order to pay punitive damages. The US Federal Circuit has recently issued a decision helpful to defendants accused of willful infringement. The Court decided that an adverse inference of willful infringement cannot be drawn when a defendant does not obtain legal advice or refuses to produce an infringement opinion received from its lawyers. Furthermore, when an infringer merely fails to exercise a duty of care to determine whether or not it is infringing, this is not sufficiently reprehensible by itself to warrant punitive damages. The totality of the circumstances should be considered.

*Knorr-Bremse v. Dana Corp.*, Fed. Cir., No. 01-1357.

**Continued on reverse...**

**Biotechnology & Pharmaceutical Group Members:**

**Micheline Gravelle**  
B.Sc., M.Sc. (Immunology)  
mgravelle@bereskinparr.com

**Andrew McIntosh**  
B.Sc. (Chem.), J.D., LL.B.  
amcintosh@bereskinparr.com

**Anita Nador**  
B.A. (Molec. Biophys/Biochem), LL.B.  
anador@bereskinparr.com

**Christine M. Pallotta**  
B.Sc.H. (Biology), J.D.  
cpallotta@bereskinparr.com

**Noel Courage**  
B.Sc. (Biochem.), LL.B.  
ncourage@bereskinparr.com

**Patricia Power**  
B.Sc., Ph.D. (Chem.)  
ppower@bereskinparr.com

**Christopher Tortorice**  
B.Sc., M.Sc. (Biology), LL.B.  
ctortorice@bereskinparr.com

**Jennifer Jones**  
B.Sc., M.Sc. (Mol. Bio. & Gen.), LL.B., LL.M.  
jjones@bereskinparr.com

**Tina Loucaides**  
B.Sc., M.Sc. (Immunology), LL.B.  
sjacka@bereskinparr.com

**Melanie Szweras**  
B.Sc., Ph.D. (Genetics), LL.B.  
mszweras@bereskinparr.com

**Carol Yip**  
B.Sc., M.Sc. (Chem.)  
cyip@bereskinparr.com

## USPTO Plays Grinch: Fee Hikes

Those planning to file a patent application this holiday season will have to dig a little deeper. Fees have increased as follows, effective Dec. 8, 2004:

Item (utility patent application)	Fee (US\$); reduce by half for small entity
Provisional application filing fee	\$200
Regular application fees due on filing	\$1000 (includes \$300 filing fee, \$200 examination fee and \$500 search fee; may be partly refundable if application abandoned/withdrawn by applicant)
Excess claims fee	\$50 per claim over 20
Independent claim fee	\$200 per claim over 3
Multiple dependent claim fee	\$360
Extensions of time (response within 1st/2nd/3rd month)	\$120/\$450/\$1020
Excess pages fee (new fee category)	\$250 per each 50 sheets in excess of 100 (not including sequence listings)
Issue fee	\$1400
Maintenance fees (1st-3rd)	\$900/\$2300/\$3800

Fees for design patent applications and plant patent applications have also increased.

A schedule of the new fees can be found on the USPTO website at <http://www.uspto.gov/web/offices/ac/qs/ope/fee2004dec08.htm>

Please contact Bereskin & Parr for additional information on fees.

Edited by **Noel Courage**. Please send feedback and suggestions to Noel at [ncourage@bereskinparr.com](mailto:ncourage@bereskinparr.com).

The contents of this update are informational only, and do not constitute legal or professional advice.

2000 Argentia Road, Suite 430, Plaza 4, Mississauga, Ontario  
Canada L5N 1W1 Tel: 905 812 3600 Fax: 905 814 0031

Scotia Plaza, 40 King Street West, 40th Floor, Toronto, Ontario  
Canada M5H 3Y2 Tel: 416 364 7311 Fax: 416 361 1398

Waterloo Technology Campus, 408 Albert St., Ste 2, Waterloo, Ontario  
Canada N2L 3V3 Tel: 519 783 3210 Fax: 519 783 3211

[www.bereskinparr.com](http://www.bereskinparr.com)

Visit [www.bereskinparr.com](http://www.bereskinparr.com) for the latest developments in IP law.