

## GOODRICH, RIQUELME Y ASOCIADOS



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### **Important notice for patent owners for pharmaceuticals in Mexico**

Last September 19, 2003, President Fox administration amended the Rules of the Industrial Property Law and of the Rules of Health Supplies (*Reglamento de Insumos para la Salud*).

#### **New list of patented active ingredients**

As you may know, one of the most usual problems in Mexico in connection to patents on medicines has been the lack of communication between the Mexican Patent and Trademark Office (MPTO) and the Ministry of Health (MH).

The MH has authority to approve the manufacture, commercialization and importation of medicines in Mexico. No pharmaceutical product can be sold in Mexico without the approval of the MH. In many cases, the MH has authorized products that infringe Mexican patents.

For years the MH argued that patent matters were completely out of its jurisdiction, and if there were patent infringement problems, they should be addressed to the MPTO or the courts.

This circumstance created a contradictory situation, where a federal government agency such as the MPTO was issuing patents on medicines, granting to the patentee the exclusive right to the use of the invention in Mexico, while the MH was authorizing the commercialization of products that may infringe a patent on a medicine.

On September 19, 2003, the federal government amended the Rules of the Industrial Property Law and of the Rules of Health Supplies. The amended

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provisions stipulated, on one hand, that the MPTO has to issue a list of patented active ingredients of allopathic medicines stating the expiration term of the patent and the name of the owner (*47 Bis List*); on the other hand, the MH may request the applicant of an authorization to prove that it is the owner or *recorded licensee of the Mexican patent*, or state under oath that there is no patent in Mexico for the active ingredient contained in the pharmaceutical product; in this last case, the MH has to contact the MPTO to verify such statement.

If the MPTO fails to answer within ten days after receiving the verification request from the MH, the MH will consider there is no patent and may issue the authorization for the commercialization of the product.

The amended provisions expressly excluded from the 47 Bis List those patents that protect production processes and/or formulation of medicines. Of course, it does not mean that third parties are free to infringe these sort of patents, although the existence of the patent will be not as evident for the MH as in the case of the listed products, and stopping the commercialization of the infringing medicines later will be as difficult as it is now.

On November 17, 2003, the MPTO published the 47 Bis List. In theory the list is intended to block third parties from trying to obtain the MH's authorization for a generic product due to the existence of a patent on the relevant active ingredient; however, there is no way to assure that the 47 Bis List will be that effective.

You and your clients may want to verify that the information contained in the published 47 Bis List is accurate. The following is the list of the patents involved in the publication:

<b>Patent No.</b>	<b>Active ingredient (in Spanish)</b>
<b>183639</b>	<b>ABACAVIR</b>
<b>208686</b>	<b>ADALIMUMAB</b>
<b>182808</b>	<b>ANASTRAZOL</b>
<b>197681</b>	<b>APREPITANT</b>
<b>186552</b>	<b>ARIPIRAZOLE</b>
<b>207246</b>	<b>ATAZANAVIR</b>
<b>178535</b>	<b>ATORVASTATINA</b>
<b>214428</b>	<b>ATORVASTATINA CRISTALINA</b>
<b>210935</b>	<b>ATRASENTAN</b>
<b>190105</b>	<b>CANDESARTAN</b>
<b>190978</b>	<b>CANGRELOR</b>
<b>185169</b>	<b>CAPECITABINA</b>

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186806	CASPOFUNGINA
188780	CEFEPIME
200516	CELECOXIB
184814	CISATRACURIO BESILATO
178820	CLOPIDOGREL
189647	DELAVIRDINE
181403	DOCETAXEL
177265	DOFETILIDE
182605	DOLASETRON MESILATO
181349	DONEPECILO CLORHIDRATO
181723	DORZOLAMIDA
192812	EFAVIRENZ
183407	ELETRIPTAN
188551	ERTAPENEM
208595	ETORICOXIB
181201	EXEMESTANO
196935	EZETIMIBA
177770	FINASTERIDA
179953	FLUVASTATINA
181348	GRANISETRON
181402	IBANDRÓNICO ÁCIDO
190786	IMATINIB MESILATO
178720	INSULINA LISPRO
176397	IRBESARTAN
176805	LAMIVUDINA
193791	LAMIVUDINA
182131	LANSOPRAZOL
205143	LASOFOXIFENE
200835	LASOFOXIFENE
174756	LETROZOL
183197	LEVOFLOXACINO
197282	LINEZOLID
205936	LOPINAVIR
178771	LOSARTAN
173359	MEROPENEM
175371	MIZOLASTINE
177872	MOFETILO MICOFENOLATO
190796	MOLGRAMOSTIM
177307	MOMETASONA
179763	MONTELUKAST
189629	MOXIFLOXACINO
186561	NADROPARINE CALCIUM
191584	NELFINAVIR MESILATO

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176695	NEVIRAPINA
173791	OLANZAPINA
184567	OPRELVEKINA
185996	PAMIDRONATO DISÓDICO
177372	PANTOPRAZOLE
181354	PIOGLITAZONA
181303	PRAMIPEXOL
181203	QUINUPRISTINA
179117	RABEPRAZOLE
194909	RALOXIFENO
179683	RALTITREXED
183546	REMACEMIDE
176311	RISPERIDONA
191767	RITONAVIR
189544	RIZATRIPTAN
189259	ROBALZOTAN
194277	ROFECOXIB
178451	ROIIVACAINA CLORHIDRATO
194435	ROSIGLITAZONA MALEATO
182960	SALMETEROL
173630	SAQUINAVIR
177057	SIBUTRAMINA
181244	SILDENAFIL
179644	SUMATRIPTAN
185242	TACROLIMUS
196955	TADALAFIL
189745	TEGASEROD
191778	TELITROMICINA
190103	TELMISARTAN
185142	TIOTROPIO BROMURO
188859	TIROFIBAN
183747	TOLCAPONA
211935	VALDECOXIB
195601	VALGANCICLOVIR
177165	VALSARTAN
207031	VARDENAFIL
178370	VENLAFAXINA
180362	VERTEPORFIRINA
178140	VORICONAZOLE
173362	ZIPRASIDONA
203066	ZIPRASIDONA
184189	ZIPRASIDONA
174759	ZOLENDRÓNICO ÁCIDO

**185978**

**ZOLMITRIPTANO**

If you need additional information, we will be glad to provide it:

It is unclear what would be the legal consequences of the MPTO's failure to include in the 47 Bis List a patented active ingredient that should have been published. In theory the 47 Bis List is not intended to limit in any way the patent rights, and the failure of the MPTO to include certain patented active ingredients should not limit the ability of a patent owner to file infringement actions. However, this is a questionable, and therefore dangerous issue.

We do not know either if the MPTO will publish additional 47 Bis Lists in the future, and when it may happen.

It is also unclear what would be the legal remedies available to force the MPTO to include a patented active ingredient in the 47 Bis List. It would be necessary to analyze each case to determine what would need to be done to avoid potential adverse effects associated to the MPTO's failure to include certain active ingredients in the 47 Bis List.

It was obvious that the intention of the government was to enhance the protection of patents on pharmaceuticals, and improve the communication between the MPTO and the HM. However, the amendments were very poorly drafted and they raise too many questions about its potential effectiveness or even if the amendment will actually result in a limitation of the patent rights in Mexico.

Sincerely,

Arturo D. Reyes