

# ➤ New Generic Drugs Off-Patent

R & D  
Strategy

Drug Development  
Pipeline  
with niche products

by Year

Dori Belle BA D/Pharm - General Secretary IAGIM

Changes taking place in the pharmaceutical industry threaten to reduce the return on R&D investment, even though the per capita consumption of prescription drugs (US) has doubled over the past five years.

Foremost is the Waxman Hatch legislation. It has the effect of providing up to 30 months of additional monopoly protection by allowing innovator companies to delay generic entrants simply by filing a law suit within 45 days after being notified that an ANDA has been filed (The paragraph clause). If litigation continues for 30 months (few are settled sooner) the generic drug is then entitled to final marketing approval by the FDA.

These changes -a decline in the generic dollar share from 11.4 in 1994 to 8.7 in 1998, an increase in the number of generics per blockbuster or major product being approved in the first year and pressures from healthcare payers - make it increasingly important to analyse your R&D organisation's effectiveness. R&D is in fact a business and requires an organisational environment that carefully:

- ◆ establishes a well balanced product development pipeline
- ◆ Looks at least 5 -6 years ahead
- ◆ allows for rapid in-house development of the approved product pipeline
- ◆ Dovetails the registration process side-by-side with product development.

## R&D Strategy.

Ideally the product should be ready for submission shortly after the pivotal batch stability has been successfully completed.

This requires an effective management planning that treats development through scale-up, to pivotal, process validation, and registration as one integrated process. Products should be planned in concert rather than individually.

## Pipeline Strategy

A new product development portfolio should be balanced and contain not only blockbusters but a prudent product spread in most of the six underlying development categories:-

- ◆ Blockbusters (over US\$ 500 - 2500 m)
- ◆ Major Products (over US\$250 - 500 m)
- ◆ Minor Products (over US\$100 - 250 m)
- ◆ Drugs with No Approved ANDAs
- ◆ Lessor Products (between \$50-100 m)
- ◆ Niche Products (under US \$50 m)

## Risk Strategy.

A major product (with US \$250m sales) launched the day after the patent/exclusivity expiration date will have its sales reduced to less than \$30-40 million per player once four or five generic firms come into the market - (i.e. reduced to the niche level.)

# Drugs Off-Patent Reports



ISSN 0793694X

Electronic **DOP** Reports-on-Disk  
Reports-on- -the-Web  
**e-** Reports



## Drugs Under \$100 million US Dollars Year of Expiration - 1998

<b>Drug ON-OFF Patent</b>	<b>Generic Name</b>	<b>Patent Holder Marketer</b>	<b>Patent Expiry</b>	<b>Exclusivity Expiry</b>	<b>Patent &amp; Exclusivity</b>	<b>Earliest Generic</b>	<b>1998 1999<sup>1</sup></b>
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$ (Mil)
Femstat	Butoconazole Nitrate.	Roche/ Syntex	3/7/95 7/28/95	3/7/95 3/7/97		<b>Expired</b>	Class 1 Class 2
Zonalon	Doxepin HCl	Genderm	7/26/00 12/9/01	4/1/97	NDF	<b>Expired</b>	Class 1 Class 3
Cesamet	Nabilone	Lilly	5/2/95 2/17/96	5/2/97 5/2/97	-	<b>Expired</b>	Class 1 Class 3
Proculil	-	Merck Co.	5/17/94 8/13/94	5/17/97 5/17/97	-	<b>Expired</b>	Class 1 Class 3
Opcon-A	Naphoxoline HCl	Bausch & Lomb	6/8/97 NA	- 6/8/97	NC	<b>Expired</b>	Class 1 Class 4
Minizide	Polythiazide	Pfizer	12/19/95 7/8/97	- 7/8/97		<b>Expired</b>	Class 1 Class 4
Adagen	PegademaseB ovine	Enzon	12/18/96 7/28/97	- 7/28/97	ODE	<b>Expired</b>	Class 1 Class 3
Hexalen	Altretamine	US Bioscienc e	12/26/97 NA	NA 12/26/97	NCE ODE	<b>Expired</b>	Class 2 Class 2
Capozide	Captopril Hydrochloro- thiazide	Bristol Myers Squibb	8/12/97 12/27/97	- 12/27/97	-	<b>Expired</b>	Class 4 Class 6

### KEY

NA = Not Applicable

NC = Not confirmed in 1998

ODE = Orphan Drug Exclusivity

NCE = New Chemical Entity

NP = New Product

NS = New Substance

NDF = New Dosage Form

NC = New Combination

NE = New Salt or Ester

### USD \$

Class 1 -&lt;10m Class 2 -&lt;25m Class 3 -&lt;50m Class 4 -&lt;75m Class 5 -&lt;100m Class 6 -&gt;100m

Note: Some Brand leader drugs products have been omitted due to non-availability of sales data which will appear in the 2000/2001 DOP Report.

## Drugs Off-Patent Reports

### Year of Expiration - 1998 (<\$100M)

Drug ON-OFF Patent	Generic Name	Patent Holder Marketer	Patent Expiry	Exclusivity Expiry	Patent & Exclusivity	Earliest Generic	1998 1999 <sup>1</sup>
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$ (Mil)
Tonolate	Dihydroxy-alpha-amino methylbenzyl	Sterling	2/6/96 4/1/89	2/6/98 <b>2/6/98</b>		<b>Expired</b>	Class 1 Class 2
Leustatin	Cladribane	JNJ/ Ortho	2/26/98 NA	- 2/26/98	NCE	<b>Expired</b>	Class 2 Class 4
Equestrolin	NA	Merck	3/21/95 5/9/95	3/21/98 3/21/98		<b>Expired</b>	Class 1 Class 4
Synanthic	Anti-parasitic Benzene	Roche/ Syntex	3/21/95 12/29/92	3/21/98 3/21/98	-	<b>Expired</b>	Class 1 Class 3
Chibroxin	Norfloxacin	Merck & Co.	3/27/98 2/16/98	- 3/27/98	-	<b>Expired</b>	Class 1 Class 3
Ceredase	Alglucerase Injection	Genzyme	4/5/98 NA	- 4/5/98	NCE ODE	<b>Expired</b>	Class 2 Class 4
Cerebyx	Fosphenytoin Sodium	WLA / P Davis	4/7/98 NA	- 4/7/98	NCE	<b>Expired</b>	Class 1 Class 3
Cefpiramide Sodium	Cephalosporin Heterocycle	Sumitomo Chemical	5/29/96 9/8/95	5/29/98 5/28/98	-	<b>Expired</b>	Class 1 Class 2
Pilopine HS	NA	Alcon	6/2/98 1/25/98	- 6/2/98	-	<b>Expired</b>	Class 2 Class 2
Cibacalcin	Calcitonin	Ciba-Geigy	6/30/98 6/9/89	- 6/30/98	-	<b>Expired</b>	Class 1 Class 3
Orlaam	Levomethadyl Actate HCl	Roxane	7/9/98 NA	- 7/9/98	NCE	<b>Expired</b>	Class 1 Class 4
Inocor	Amrinone Lactate	Sanofi Winthrop	7/31/98 4-072-746		U7	<b>Expired</b>	Class 2 11
Normodyne Trandate	Labetalol	Schering A7H	8/2/98 4-012-444	-	-	<b>Expired</b>	Class 4 <b>60 + 41</b>
Tonocard	Tocainide HCl	Astra - Merck	12/2/97 7/28/91	9/9/98 9/9/98	-	<b>Expired</b>	Class 1 Class 3
Flumadine	Rimantadine	Forest Labs	9/17/98 NA	- 9/17/98	NCE	<b>Expired</b>	Class 2 Class 4
Nipent	Pentostatin	Parke- Davis	10/11/98 NA	10/11/98	ODE	<b>Expired</b>	Class 1 Class 3
Rocaltrol	Calcitriol	Roche/ Syntex	9/30/97 10/13/98	- 10/13/98		<b>Expired</b>	Class 3 Class 5
DIDRONEL	Etidronate Disodium	P&G	3/3/98 4-254-114	-	-	<b>Expired</b>	Class 2 17
CERVIDIL	Dinoprostone	Forest Labs	12/14/10 5-269-321	3/30/98-	- NDF	<b>Expired</b>	Class 2 29
Transderm SCOP	Scopolamine	Novartis	4/14/98 4-436-741	-	-	<b>Expired</b>	Class 2 21
Tagamet HB	Cimetidine	SKB	- -	6/19/98	- NS	<b>Expired</b>	Class 3 44
Caverject	Alprostadil	Pharmacia	3/16/97 4-127-188	7/6/98	- NP	<b>Expired</b>	Class 3 34

**INDUSTRY DRIVER:** A WAVE OF PATENT EXPIRATIONS Close to \$35 billion in brand sales is coming off patent between 1999 - 2005. The dollar value of drugs coming off-patent over the next five years is unprecedented and the generic prescription market should continue to grow driven by this new wave of patent expirations.

## Drugs Off-Patent Reports Year of Expiration – 1998 - (<\$100M)

Drug ON-OFF Patent	Generic Name	Patent Holder Marketer	Patent Expiry	Exclusivity Expiry	Patent & Exclusivity	Earliest Generic	1998 1999 <sup>1</sup>
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$ (Mil)
Flumadine	Rimantadine	Forrest	-	9/17/98	- NCE	Expired	Class 4 60
Metro Cream	Metronidazole		// 4--		- NCE	Expired	Class 2 15
ORUDIS KT	Ketoprofen	AHP	- 20-429	1-/06/98	- NS	Expired	Class 1 9.5
FEMSTAT 3	Butoconazole nitrate	P&G	3/7/97 4-078-071	12/21/98	- NP	Expired	Class 2 12
Dermadex	Torseamide	B Mann	8/11/06 RE-34-672	8/23/98	- NCE	Expired	Class 4 57

### USD \$

Class 1 -<10m    Class 2 -<25m    Class 3 -<50m    Class 4 -<75m    Class 5 -<100m    Class 6 ->100m  
 NA = Not Applicable                      NC = Not confirmed in 1998                      ODE = Orphan Drug Exclusivity  
 NCE = New Chemical Entity                      NP = New Product                      NS = New Substance  
 NDF = New Dosage Form                      NC = New Combination                      NE = New Salt or Ester

Note: Some Brand leader drugs products have been omitted due to non-availability of sales data which will appear in the 2000/2001 DOP Report.

US 2000 Pharmaceutical Industry value is just over US\$100 billion The average annual consumption of 270 million Americans is just exceeding \$400 per person (In 1994 the amount was \$200)

## CBI Conference ANNOUNCEMENT

24-25<sup>th</sup> January 2000  
The Westin Grand Washington DC

# International Generic Drugs FOR PRICING COMPETITION & REGULATIONS

Keynote Address  
THE HONORABLE  
HENRY A. WAXMAN  
 US Congressman Ca.

PLUS Pre-conference Workshop  
Sourcing API to meet Consumer Demand



## Drugs Off-Patent Reports

### Year of Expiration - 1999 (<\$100M)

Drug ON- or OFF Patent	Generic Name	Patent Holder Marketer	Patent Expiry	Exclusivity Expiry	Patent & Exclusivity	Earliest Generic	1998 1999 <sup>1</sup> (Millions)
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$
Didronel	Etidronate Disodium	Procter & Gamble	3/3/98 1/2/98	- 1/2/99	-		Class 3 Class 4
Maxair	Pirbuterol Acetate	3M Phar- maceuticals	11/20/96 1/3/99	- 1/3/99	-		Class 3 Class 4
Tussionex Pennatus Corsy	Chlorphe- niramine Polistirex	Rhone - Poulenc Rorer	9/9/97 1/8/99	- 1/8/99	-		Class 3 Class 5
Kerlone	Betaxolol	Searle	1/19/99 10/20/96	- 1/19/99	-		Class 2 Class 4
Rhinocort	Budesonide	Astra Zen	2/14/ 99 -	<b>2/14/99</b>	NCE	<b>2/14/99</b>	Class 5 80
Alfenta Inj.	Alfentanil	JNJ/ Jansen	<b>5/5/99</b> <b>4-167-574</b>				Class 1 5
Nizoral	Ketoconazole	JNJ / Jansen	6/15/99 1/31/97	- 6/15/99	I-30		Class 5 Class 6
Acesulfame Potassium	Acetosul- pham, etc.,	Hoechst- Roussel	6/12/96 6/22/97	6/12/98 6/22/99	-		Class 1 Class 3
Tornalate	Bitolterol mesylate	Dura Pharm.	6/22/99 4/1/89	- 6/22/99	-		Class 1 Class 3
Virazole	Ribavirin	ICN Pharm.	7/8/97 6/1/91	7/8/99 7/8/99	-		Class 3 Class 5
Betoptic S	Betaxolal HCl	Alcon	7/24/99 4-252-984	-	-	<b>4/24/99</b>	Class 3 55
Betoptic	Betaxolal HCl	Alcon	7/24/99 4-252-984	-	-	<b>4/24/99</b>	Class 2 22
Tegison	Etretinate	Roche Syntex	7/29/97 3/22/94	7/29/99 7/29/99	-		Class 2 Class 5
Alkeran	Melphalan	Burroughs Wellcome	3/5/08 11/18/08	- 11/18/99	ODE		Class 1 Class 3
Normo- dyne	Labetalol	Schering - Key	5/4/99 11/28/99	- 11/28/99	-		Class 4 Class 6
Luvox	Fluvoxamine Maleate	U.S. Phillips	4/18/95 3/19/96	- 12/5/99	NCE		Class 1 Class 4
Carnitor	Levocarnitine	Sigma Tau	- 19-948	12/16/99	I-86 ODE	<b>12/16/99</b>	Class 2 33
Osmovist	Iotrolan	Schering AG	12/16/97 6/14/97	12/16/99 12/16/99	-		Class 1 Class 3
Marinol	Dronabinol	Roxane BI	12/22/99 NA	- 12/22/99	I-85 ODE		Class 2 Class 0
Ceradon	Cephalosporin Dihydrochloride	Takeda	12/23/97 8/29/97	12/23/99 12/23/99	-		Class 1 Class 3
Navelbine	Vinorelbine Tartrate	Burroughs Wellcome	12/23/99 NA	- 12/23/99	NCE		Class 1 Class 4
Omnipaque	Iohexal	Sanofi Winthrop	2/10/98 6/10/97	12/26/99 12/26/99	I-97		Class 1 Class 3
Mefoxin	Cefoxitin Sodium Inj.	Merck & Co.	8/1/99 NA	--	-	<b>8/1/99</b>	Class 2 27

Note: Some Brand leader drugs products have been omitted due to non-availability of sales data which will appear in the 2000/2001 IAGIM DOP Report.

## Drugs Off-Patent Reports Year of Expiration – 1999 (<\$100M)

<b>Drug ON-OFF Patent</b>	<b>Generic Name</b>	<b>Patent Holder Marketer</b>	<b>Patent Expiry</b>	<b>Exclusivity Expiry</b>	<b>Patent &amp; Exclusivity</b>	<b>Earliest Generic</b>	<b>1998 1999<sup>1</sup> Millions</b>
<b>Trade</b>	<b>Generic</b>	<b>NAME</b>	<b>Patent #</b>	<b>DATE</b>	<b>CODES</b>	<b>DATE</b>	<b>USD\$</b>
NAPRILAN	Naproxin Na	AHP	16/10/14 5-637-320	1/5/99	- NDF		Class 5 80
Procanbid	Procain- amide HCl	WL	- -	1/31/99	- NP	<b>1/31/99</b>	Class 2 13
CO-VERA HS	Verapamil HCl	Monsanto Searle	6/27/11 5-252-338	2/26/99	- NP	<b>2/26/99</b>	Class 5 78
ACTIGALL	Ersodiol	Bil Therap	- 19-594	3/29/99	- I-147	<b>3/29/99</b>	Class 4 62
Nasacort AQ	Triamcinolon e Acetonide	RPR	- -	5/20/99	- NDF	<b>5/20/99</b>	Class 4 52
Fortaz	Glaxo - Wellcome	Ceftazidime	6/24/99 4-258-041			<b>6/24/99</b>	Class 5 78
Nicoderm CQ	Nicotine	SKB	- -	8/2/99	- NP	<b>8/02/99</b>	Class 4 74
Norcuron	Vecuronium Bromide	Akzo Org	8/20/99 4-297-351	-	-	<b>8/20/99</b>	Class 2 17
Lac-Hydrin	Ammonium Lactate	Westwood		8/29/99	- NDF	<b>8/29/99</b>	Class 4 65
NIX	Permethrin	WL	--	11/1/99	- 170	<b>11/1/99</b>	Class 2 24
Vanceril DS	Beclomethason e Dipropionate	S Plough	12/21/99 4-364-923	- -		<b>12/21/99</b>	Class 4 66
Vancenase	Beclomethason e Dipropionate	S Plough	12/21/99 4-364-923	- -		<b>12/21/99</b>	Class 3 52
Beclovent	Beclomethason e Dipropionate	Glaxo - Wel	12/21/99 4-364-924	- -		<b>12/21/99</b>	Class 2 42
Marinol	Dronabinol	Roxane	- -	12/22/99 -	- ODE	<b>12/22/99</b>	Class 2 23
Acular	Ketorolac Tromethamine	Allergan	5/5/09 5-110-493	12/31/99 -	U-55 I-176	<b>12/31/99</b>	Class 2 44

### KEY

### USD \$

Class 1 -<10m    Class 2 -<25m    Class 3 -<50m    Class 4 -<75m    Class 5 -<100m    Class 6 ->100m

NA = Not Applicable

NC = Not confirmed in 1998

ODE = Orphan Drug Exclusivity

NCE = New Chemical Entity

NP = New Product

NS = New Substance

NDF = New Dosage Form

NC = New Combination

NE = New Salt or Ester

### Note:

Some Brand leader drugs products have been omitted due to non-availability of sales data which will appear in the 2000/2001 IAGIM DOP Report.

Drugs Off-Patent Reports  
Year of Expiration - 2000 (<\$100M)

<b>Drug ON-OFF Patent</b>	<b>Generic Name</b>	<b>Patent Holder Marketer</b>	<b>PATENT Expiry</b>	<b>Exclusivity Expiry</b>	<b>Patent &amp; Exclusivity</b>	<b>Earliest Generic</b>	<b>1998 1999<sup>1</sup></b>
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$ (Mil)
Sular	Nisoldipine	Astra Zeneca	06/08/08 4-892-741	02/02/00 -	- NCE	02/02/00	Class 3 44
Ocupress	Carteolol	Otsuka	01/02/00 4-309-432	- -	- -	01/02/00	Class 2 18
Retin-A-Micro	Tretinoin	Johnson & Johnson	10/04/05 4-690-825	02/07/00 -	- NP	02/07/00	Class 3 37
Leustatin	Cladribane	Johnson & Johnson	- P	02/26/00	- NCE,ODE	02/26/00	Class 2 13
Condylox	Podofilox	Watson	06/14/04 4-680-399	03/13/00	- NDF	03/13/00	Class 2 15
Zebeta	Bisoprolol fumarate	AHP/Ledeele	03/24/00 4-258-062	07/31/97	U-63 NCE	03/24/00	Class 1 9
Hismanal	Astemizole	Johnson & Johnson	04/03/00 4-219-559	-	- -	04/03/00	Class 3 31
Novantrone	Mitoxantrone	AHP/ACY	07/14/00 4-278-689	- -	- -	07/14/00	Class 3 50
Loprox	Ciclopirox	Hoechst-Marion Roussel	- P	07/21/00	- NDF	07/21/00	Class 2 12
Niaspan	Niacin	Cos Pharmaceuticals	- P	07/28/00	- NDF	07/28/00	Class 2 17
Cytotec	Misoprostol	Monsanto/Searle	07/29/00 4-301-146	-	- -	07/29/00	Class 4 72
Oxistat	Oxiconazole Nitrate	Glaxo-Wellcome	- P	08/18/00 -	- I-200	08/18/00	Class 2 15
Pepcid AC	Famotidine	Merck & Co.	10/15/00 4-283-408	04/28/98	- NS	10/15/00	Class 5 105
Flagyl ER	Metronidazole	Monsanto/Searle	- P	11/26/00	- NDF	11/26/00	Class 2 18
Noroxin	Norfloxacin	Merck & Co.	02/16/00 4-146-719	10/24/97	- I-113	02/16/00	Class 3 34
Azelex	Azelaic Acid	Allergan	05/31/00 4-386-104	09/13/00 -	U-124 NCE	09/13/00	Class 1 17
Univasc	Moexipril HCL	Schwarz	10/03/00 4-344-949	04/19/00	- NCE	10/03/00	Class 2 25
Trasylol	Aprotinin Bovine	Bayer	- P	08/28/01	- NCE,ODE, I-233	12/29/00	Class 3 47

USD \$

Class 1 -<10m ; Class 2 -<25m ; Class 3 -<50m ; Class 4 -<75m ; Class 5 -<100m USD \$

## Drugs Off-Patent Reports Year of Expiration – 2001 (<\$100M)

<b>Drug ON-OFF Patent</b>	<b>Generic Name</b>	<b>Patent Holder Marketer</b>	<b>Patent Expiry</b>	<b>Exclusivity Expiry</b>	<b>Patent &amp; Exclusivity</b>	<b>Earliest Generic</b>	<b>1998 1999<sup>1</sup></b>
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$ (Mil)
Primacor	Milrinone	Sanofi Winthrop	<b>02/02/01</b> <b>4-313-951</b>	-	- -	<b>02/02/01</b>	Class 5 100+
Mesnex	Mesna	Asta - Werke	<b>03/06/01</b> <b>4-220-660</b>	-	U-21 -	<b>03/06/01</b>	Class 3 35
Estratab	Estrogens, esterified	Solvay	- <b>P</b>	<b>03/10/01</b>	- I-214	<b>03/10/01</b>	Class 3 24
Differin	Adapalene	Galderma	<b>04/10/01</b> <b>4-717-720</b>	<b>05/31/01</b>	U-134 NCE	<b>05/31/01</b>	Class 4 75
Stadol	Butorphanol tartrate	Bristol-Myers Squibb	<b>08/07/01</b> <b>/A4-464-378</b>	-	U-60 -	<b>08/07/01</b>	Class 2 18
Alphagan	Brimonidine tartrate	Allergan	- <b>P</b>	<b>09/06/01</b>	- NCE	<b>09/06/01</b>	Class 5 92
Proamatin e	Midazolam	Roberts Pharmaceutical	- <b>P</b>	<b>09/06/01</b>	- NCE	<b>09/06/01</b>	Class 2 12
Eulexin	Flutamide	Schering	<b>09/18/01</b> <b>4-472-382</b>	<b>06/21/99</b>	U-24 I-168	<b>09/18/01</b>	Class 4 73
Nilandron	Nilutamide	Hoeschst-Marion Roussel	- <b>P</b>	<b>09/19/01</b>	- NCE	<b>09/19/01</b>	Class 2 12
Roxicodone	Oxycodone hydrochloride	Roxane Laboratories	- <b>P</b>	<b>10/26/01</b>	- NS	<b>10/26/01</b>	Class 2 12
Terazol	Terconazole	Johnson & Johnson	<b>11/09/01</b> <b>4-358-449</b>	-	- -	<b>11/09/01</b>	Class 5 100+
Rocaltrol	Calcitriol	Roche	- <b>P</b>	<b>11/20/01</b>	- NDF	<b>11/20/01</b>	Class 3 39
Zanaflex	Tizanidine HCl	Elan	- <b>P</b>	<b>11/27/01</b>	- NCE	<b>11/27/01</b>	Class 3 28
Chymodiactin	Chymopapain	Knoll	<b>05/13/01</b> <b>4-439-423</b>	-	- -	<b>05/13/01</b>	Class 1 2
Tri-Norinyl	Ethinyl Estradiol	Roche Syntex	<b>08/10/01</b> <b>4-390-531</b>	-	- -	<b>08/10/01</b>	Class 3 36
Elocon	Mometasone Furoate	Schering	<b>09/18/01</b> <b>4-472-393</b>	- P	- -	<b>09/18/01</b>	Class 4 85
Vaseretic	Enalapril Maleate	Merck & Co.	<b>09/18/01</b> <b>4-472-380</b>	<b>07/12/98</b>	- NS	<b>09/18/01</b>	Class 4 73
Oxsoralen-Ultra	Methoxsalen	ICN Pharm.	<b>12/20/01</b> <b>4-454-152</b>	-	- -	<b>12/21/01</b>	Class 1 11

### USD \$

Class 1-<10m ; Class 2-<25m ; Class 3-<50m ; Class 4-<75m ; Class 5-<100m Class 6->100m USD \$

## Drugs Off-Patent Reports

### Year of Expiration - 2002 (<\$100M)

Drug ON-OFF Patent	Generic Name	Patent Holder Marketer	Patent Expiry	Exclusivity Expiry	Patent & Exclusivity	Earliest Generic	1998 1999 <sup>1</sup>
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$ (Mil)
Gastrocrom	Cromolyn Sodium	Rhone Poulenc Rorer	05/07/02 4-515-805	-	- -	05/07/02	Class 1 3
Photoplex	Avobenzone	Allergan	06/07/02 4-387-089	-	- -	06/07/02	NA
Cardiogen-82	Rubidium Chloride	Bristol - Myers Squibb	08/23/02 4-400-358	-	- -	08/23/02	NA
Nimotop	Nimodipine	Bayer AG	09/27/02 4-406-906	-	U-22 -	09/27/02	Class 2 23
Proleukin	Aldesleukin	Chiron	10/18/02 4-518-584	-	- -	10/18/02	Class 3 50
Sandostatin	Octreotide Acetate	Novartis	10/21/02 4-395-403	05/03/97	- I-106	10/21/02	Class 5 85
Cefotan	Cefotetan disodium	Stuart	11/21/99 4-263-432	-	- -	01/12/02	Class 4 53
Coreg	Carvedilol	Smith Kline Beecham	03/05/02 4-503-067	09/14/00	U-3 NCE	03/05/02	Class 5 100+
Agrylin	Anagrelide HCl	Roberts	- -	03/14/02	- NCE,ODE	03/14/02	Class 2 17
Tazorac	Tazarotene	Allergan	02/18/09 5-089-509	06/13/02	U-193 NCE	06/13/02	Class 2 17
Dostinex	Cabergoline	Pharmacia & Upjohn	07/02/02 4-526-892	12/23/01	- NCE	07/02/02	Class 2 22
Navelbine	Vinorelbine tartrate	Glaxo-Wellcome	07/08/02 4-307-100	12/23/99	- NCE	07/08/02	Class 4 63
Duract	Bromfenac sodium	AHP/Wyeth Ayerst	- -	07/15/02	- NCE	07/15/02	Class 3 35
Nolvadex	Tamoxifen citrate	Astra Zeneca	08/20/02 4-536-516	-	- -	08/20/02	Class 5 85
Anzemet	Dolasetron nesylate monohydrate	Hoechst Marrion Roussel	- -	09/11/02	- NCE	09/11/02	Class 3 42
Axiz AR	Nizatidine	Eli Lilly	10/02/02 4-375-547	05/09/99	- NS	10/02/02	Class 2 22
Cytosan	Cyclophosphamide	Bristol-M Squibb	11/12/02 4-537-883	-	- -	11/12/02	Class 3 37

**Delaying Tactics:** FDA interpretation of the paediatric six month exclusivity provisions of the FDA Modernization Act has additionally extended the patent protection for **ALL DOSAGE FORMS** of the drug - not just the drug product used in the paediatric clinical trials. Under the FDA Modernization Act provisions - a pharmaceutical product can attain and extra SIX month (additional) marketing exclusivity, if clinical studies are conducted on a Paediatric Population.

Drugs Off-Patent Reports  
Year of Expiration – 2002 (<\$100M)

Drug ON-OFF Patent	Generic Name	Patent Holder Marketer	Patent Expiry	Exclusivity Expiry	Patent & Exclusivity	Earliest Generic	1998 1999 <sup>1</sup>
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$ (Mil)
Prandin	Repaglinide	Novo Nordisk	10/06/06 5-216-167	12/22/02	- NCE	12/22/02	Class 3 31
Rilutek	Riluzole	Rhone-Poulenc Rorer	- P	12/23/02	- NCE,ODE	12/23/02	Class 3 24
Optiray 350	Ioversol	Mallinkrodt	12/30/02 4-396-598	-	- -	12/30/02	Class 4 59

**Whether your firm is an  
INNOVATIVE or a Generic Company  
This key conference is for you!**

WHEN 1 - 2<sup>nd</sup> March 2000  
WHERE - Thistle Westminster Hotel London

**Profiting & Competing  
IN THE EUROPEAN GENERIC INDUSTRY**

Plus Post Conference Workshop  
3<sup>RD</sup> MARCH 2000

**Basic Principles of Designing  
a Successful Bioequivalence Study**

BOOK NOW - Contact:  
Institute for International Research

+ 44-(0)-20-7915-5055 Quote CQ1492/ CQ1492W Fax: + 44-(0)-20-7915-5056

E-✉ : register@iir-conferences.com  
VIEW FULL PROGRAM & SPEAKERS

<http://www.iir-conferences.com>  
and  
<http://www.locumUSA.com/conference/>




## Drugs Off-Patent Reports Year of Expiration - 2003 (<\$100M)

Drug ON-OFF Patent	Generic Name	Patent Holder Marketer	Patent Expiry	Exclusivity Expiry	Patent & Exclusivity	Earliest Generic	1998 1999 <sup>1</sup>
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$ (Mil)
Fludara	Fludarabine Phosphate	Berlex	02/24/03 4-357-324	04/18/98	- ODE	02/24/03	Class 3 46
Brevibloc	Esmolol HCl	BOC Gr Ohmeda	06/03/03 4-593-119	-	- -	06/03/03	Class 2 25
Decabid	Indecainide	Lilly	06/05/03 4-452-745	-	- -	06/05/03	-
Dynacirc	Isradipine	Novartis	08/21/03 4-466-972	-	U-3 -	08/21/03	Class 3 44
Dynacirc CR	Isradipine	Novartis	08/21/03 4-466-972	-	- -	08/21/03	Class 2 13
Renormax	Spirapril HCl	Schering	09/11/03 4-470-972	12/29/99	U-3 NCE	09/11/03	-
Sildimac	Silver Sulfadiazinc	NA	01/07/03 4-563-184	-	- -	01/07/03	-
Serax	Oxazepam	AHP Wyeth - Ayerst	11/04/03 4-620-974	-	- -	11/04/03	Class 1 7
Blenaxane	Bleomysin sulfate	Bristol-M Squibb	- P	02/20/03	- OdE	02/20/03	Class 2 24
Xeloda	Capecitabine	Roche	- P	04/30/03	- NCE	04/30/03	Class 2 24
Advil Cold and Sinus	Ibuprofen	AHP/Wyeth -Ayerst	05/12/ 03 4-552-899	*PED -	- -	- 05/12/03	Class 3 26
Diprolene	Betamethasone Dipropionate	Schering-Plough	05/13/03 4-489-070	-	- -	05/13/03	Class 3 34
Diprolene AF	Betamethasone Dipropionate	Schering-Plough	12/09/03 4-489-071	-	- -	12/09/03	Class 3 45
Ocuflox	Ofloxacin	Allergan	05/10/00 4-382-892	05/22/03	- ODE	05/22/03	Class 3 34
Celexa	Citalopram Hydrobromide	Forest Lab.	- P	07/17/03	- NCE	07/17/03	Class 3 45
Renova	Tretinoin	Johnson & Johnson	07/29/03 4-603-146	12/28/98	U-131 NDE	07/29/03	Class 3 26
Lotensin HCT	Benazepril	Novartis	08/12/03 4-410-521	-	- -	08/12/03	Class 3 54
Serostim	Somatropin biosynthetic	Ares Serono	- P	08/23/03	- ODE	08/23/03	Class 3 37

**Tentative Approvals** A notable trend over the past year has been the dramatic increase of in FDA tentative versus full marketing approvals. Tentative approvals are granted by the FDA when all the technical CMC requirements for the ANDA have been met and the drug is deemed bioequivalent (AB Rated). However the product may not be marketed because of a patent or exclusivity period may still be in force or a pending or successful challenge by the brand leader to delay the generic competition.

## Drugs Off-Patent Reports

Year of Expiration – 2003 (&lt;\$100M)

Drug ON-OFF Patent	Generic Name	Patent Holder Marketer	Patent Expiry	Exclusivity Expiry	Patent & Exclusivity	Earliest Generic	1998 1999 <sup>1</sup>
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$ (Mil)
Topamax	Topiramate	R.W. Johnson	09/26/03 4-513-006	12/24/01	- NCE	09/26/03	Class 4 64
Abelcet	Amphotericin B	Liposome	- P	10/18/03	- ODE	10/18/03	Class 3 47
Cutivate	Fluticasone propionate	Glaxo-Wellcome	11/14/03 4-335-121	-	- -	11/14/03	Class 2 16
Copaxone	Glatiramer acetate	Teva Marion	- P	12/20/03	- NCE,ODE	12/20/03	Class 3 53

## Year of Expiration - 2004 (&lt;\$100M)

Protropin	Somatrem	Genentech	04/14/04 4-658-021	-	- -	04/14/04	Class 1 4
Ciloxan	Ciprofloxacin HCl	Alcon	06/02/04 4-670-444	03/30/01	U-223 NDF	06/02/04	Class 3 36
Adenocard	Adenosine	Fujisawa	06/16/04 4-673-563	-	U-38 -	06/16/04	Class 2 22
Ergamisol	Levamisole	Johnson & Johnson	06/19/04 4-584-305	-	U-42 -	06/19/04	Class 1 6
Dipentum	Olsalazine Sodium	Pharmacia Adria	08/04/04 4-559-330	-	U-58 -	08/04/04	Class 2 14
Tambocor	Flecainide acetate	3M Pharm	02/10/04 4-642-384	-	- -	02/10/04	Class 3 45
Maxair	Pirbuterol acetate	3M Pharm	05/12/04 4-664-107	-	- -	05/12/04	Class 2 21
Ambisome	Amphotericin B	Fujisawa	- P	08/11/04	- ODE	08/11/04	Class 2 20
Aldara	Imiquimod	3M Pharma Ceuticals	08/25/04 4-689-338	02/27/02	U-172 NCE	08/25/04	Class 3 29
Lariam	Mefloquine HCl	Roche	10/01/04 4-579-855	-	- -	10/01/04	Class 3 28
Romazicon	Flumazenil	Roche	10/10/04 4-316-839	-	- -	10/10/04	Class 3 35
Genotropin	Somatropin biosynthetic	Pharmacia Upjohn	- P	10/31/04	- ODE	10/31/04	Class 4 27
Livostin	Levocabastine HCl	Novartis	12/02/04 4-369-184	11/10/98	- NCE	12/02/04	Class 2 25
Ultravate	Halobetasol Propionate	Bristol-M Squibb	12/17/04 4-619-921	-	- -	12/17/04	Class 3 41
Vicoprofen	Hydrocodone Bitrtrate	Knoll	12/18/04 4-587-252	09/23/00	U-55 NC	12/18/04	Class 3 46
TOBI	Tobramycin	Pathogenesis	- *	12/22/04	- ODE	12/22/04	Class 3 45

## Drugs Off-Patent Reports Year of Expiration - 2005 (<\$100M)

<b>Drug ON-OFF Patent</b>	<b>Generic Name</b>	<b>Patent Holder Marketer</b>	<b>Patent Expiry</b>	<b>Exclusivity Expiry</b>	<b>Patent &amp; Exclusivity</b>	<b>Earliest Generic</b>	<b>1998 1999<sup>1</sup></b>
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$ (Mil)
Testoderm	Testosterone	Alza Corp.	<b>02/16/05</b> <b>4-867-982</b>	-	- -	<b>02/16/05</b>	Class 1 3
Nuromax	Doxacurium Chloride	Glaxo Wellcome	<b>03/06/05</b> <b>4-701-460</b>	<b>12/08/97</b>	- I-121	<b>03/06/05</b>	Class 1 1
Ganite	Gallium Nitrate	Sloan Keterring	<b>01/17/05</b> <b>4-529-593</b>	<b>01/17/98</b>	U-49 ODE	<b>01/17/05</b>	Class 1 1
Survanta	Beractant	Abbott	<b>07/01/05</b> <b>4-397-839</b>	<b>07/01/98</b>	- ODE	<b>07/01/05</b>	Class 4 67
Fragmin	Dalteparin Sodium	Pharmacia Upjohn	<b>01/04/05</b> <b>4-303-651</b>	<b>12/22/99</b>	- NCE	<b>01/04/05</b>	Class 2 14
Salagen	Pilocarpine HCl	MGI Pharma	- -	<b>02/11/05</b>	- ODE	<b>02/11/05</b>	Class 2 13
Ultravist	Iopromide	Berlex	<b>03/06/05</b> <b>4-364-921</b>	<b>05/10/00</b>	U-13 NCE	<b>03/06/05</b>	Class 2 17
Amaryl	Glimepiride	Hoechst-Marion Roussel	<b>04/06/05</b> <b>4-379-785</b>	<b>11/30/00</b>	U-118 NCE	<b>04/06/05</b>	Class 4 64
Fentanyl	Fentanyl Citrate	AHP Wyeth Ayerst	<b>05/01/05</b> <b>4-671-953</b>	-	U-87 -	<b>05/01/05</b>	Class 1 20
Cytovene	Ganciclovir Sodium	Roche	<b>06/24/05</b> <b>4-642-346</b>	<b>10/27/98</b>	- I-140	<b>06/24/05</b>	Class 4 80
Lupron Depot Ped	Leuprolide acetate	TAP Pharm.	<b>07/03/05</b> <b>4-677-191</b>	<b>04/16/00</b>	- ODE	<b>07/03/05</b>	Class 3 28
Lexxel	Enalapril maleate	Merck & Co	<b>10/07/05</b> <b>4-703-038</b>	<b>12/27/99</b>	- NC	<b>10/07/05</b>	Class 1 11
Cholybar	Cholestyramine	Warner - Wellcome	<b>10/18/05</b> <b>4-778-676</b>	-	- -	<b>10/18/05</b>	NA



# Profiting & Competing

## IN THE EUROPEAN GENERIC INDUSTRY

WHEN 1 - 2<sup>nd</sup> March 2000  
WHERE -Thistle Westminster Hotel London

Plus Post Conference Workshop

3<sup>RD</sup> MARCH 2000

### Basic Principles of Designing a Successful Bioequivalence Study

Drugs Off-Patent Reports  
Year of Expiration - 2006 (<\$100M)

Drug ON-OFF Patent	Generic Name	Patent Holder Marketer	Patent Expiry	Exclusivity Expiry	Patent & Exclusivity	Earliest Generic	1998 1999 <sup>1</sup>
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$ (Mil)
Mivacron	Mivacurium Chloride	Glaxo Wellcome	01/22/06 4-761-418	01/22/97	- NCE	01/22/06	Class 2 20
Omniflox	Ternafloxacin HCl	Abbott	01/30/06 4-730-000	01/30/97	U-36 NCE	01/30/06	NA
Aceon	Perindopril Erbumine	Adir	08/21/06 4-508-729	12/30/98	- NCE	08/21/06	NA
Timoptic-XE	Timolol Maleate	Merck & Co.	08/29/06 4-861-760	-	- -	08/29/06	Class 5 85
Videx	Didanosine	Bristol Myers-Squibb	08/29/06 4-861-759	-	- -	08/29/06	Class 4 63
Tilade	Nedocromil Sodium	Schering-Plough	10/02/06 4-474-787	10/01/00	- NDF	10/02/06	Class 2 20
Mivacron	Mivacurium Chloride	Glaxo Wellcome	//06 4--	//06	- -	//06	Class
Metrogel	Metronidazole	Galderma	06/06/06 4-837-378	-	- -	06/06/06	Class 3 47
Flomax	Tamulosin HCl	Boehringer Ingelheim	09/19/06 4-868-216	04/15/02	U-181 NCE	09/19/06	Class 4 64
Phoslo	Calcium Acetate	Braintree	09/26/06 4-870-105	12/10/97	- ODE	09/26/06	Class 2 17
Prohance	Gadoteridol	Bracco	12/05/06 4-885-363	11/16/06	- NCE	12/05/06	Class 3 27
Mirapex	Pramipexole dihydrochloride hydrate	Pharmacia Upjohn	12/12/06 4-866-812	07/01/02	- NCE	12/12/06	Class 3 47

USD \$

Class 1 -<10m Class 2 -<25m Class 3 -<50m Class 4 -<75m Class 5 -<100m Class 6 ->100m

NOT EVERY ONE CAN GO TO

**16 - 21**

PHARMACEUTICAL CONFERENCES  
YEAR IN - YEAR OUT




Subscribe to the  
**INTERNATIONAL JOURNALS**  
For a great overview!

See 'WHAT'S NEW' & Conference Page  
[www.locumusa.com/conferences](http://www.locumusa.com/conferences)

## Drugs Off-Patent Reports Year of Expiration - 2007 (<\$100M)

Drug ON-OFF Patent	Generic Name	Patent Holder Marketer	Patent Expiry	Exclusivity Expiry	Patent & Exclusivity	Earliest Generic	1998 1999 <sup>1</sup>
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$ (Mil)
Dovonex	Calcipotriene	Bristol - Myers Squibb	12/29/07 4-866-048	03/03/00	U-88 NCE,NDF	12/29/07	Class 5 91
Betaseron	Interferon beta 1	Berlex	07/13/07 4-588-585	-	-	07/13/07	Class 2 17
Nasocort	Triamcinolone acetoneide	Rhone Poulenc Rorer	01/23/07 4-767-612	05/20/99	U-85 I-162	01/23/07	Class 4 74
Suprane	Desflurane	BOC Group/ Ohmeda	02/02/07 4-762-856	09/18/97	U-67 NCE	02/02/07	Class 4 80
Precose	Acarbose	Bayer	02/27/07 4-904-769	09/06/00	-	02/27/07	Class 3 35
Maxipime	Cefepime	Bristol Meyers Squibb	03/04/07 4-406-899	-	-	03/04/07	Class 2 18
Pulmicort	Budesonide	Astra Zeneca	03/13/07 4-907-583	02/14/99	-	03/13/07	Class 3 45
Omniscan inj.	Gadodiamide	Sanofi Winthrop	05/04/07 4-687-659	01/08/98	U-76 NCE	05/04/07	Class 3 45
Naserel	Flunisolide	Roche	06/12/07 4-933-168	-	-	06/12/07	Class 2 16
Tarka	Trandolapri l	Knoll	06/12/07 4-933-361	04/26/01	-	06/12/07	Class 2 15
Nasalide	Flunisolide	Roche	06/12/07 4-933-168	-	-	06/12/07	Class 2 13
Cerebyx	Fosphenytoin Sodium	Warner Lambert	08/05/07 4-925-860	08/05/03	-	08/05/07	Class 3 34
Posicor	Miberfradil dihydrochlori de	Roche	11/10/07 4-808-605	06/20/02	-	11/10/07	Class 2 23
Pentasa	Mesalamine	Hoechst Marion Roussel	12/25/07 4-980-173	-	U-78 -	12/25/07	Class 3 38

### USD \$

Class 1 -<10m    Class 2 -<25m    Class 3 -<50m    Class 4 -<75m    Class 5 -<100m    Class 6 ->100m

NA = Not Applicable

NC = Not confirmed in 1998

ODE = Orphan Drug Exclusivity

NCE = New Chemical Entity

NP = New Product

NS = New Substance

NDF = New Dosage Form

NC = New Combination

NE = New Salt or Ester

Note: Some Brand leader drugs products have been omitted due to non-availability of sales data which will appear in the 2000/2001 DOP Report.

Note: Since 1996, when the average operating margin of the five major generic companies (Alpharma, Barr, Mylan, Teva and Watson) fell to 15.5% from its historical average of around 16-17%, the average operating margin has risen dramatically - to almost 21% in 1997 and even higher to 22.8-23.0% in 1998. Operating margins for the above five in 1999 and 2000 are projected to be around 23% to 24%.

Drugs Off-Patent Reports  
Year of Expiration - 2008 (<\$100M)

<b>Drug ON-OFF Patent</b>	<b>Generic Name</b>	<b>Patent Holder Marketer</b>	<b>Patent Expiry</b>	<b>Exclusivity Expiry</b>	<b>Patent &amp; Exclusivity</b>	<b>Earliest Generic</b>	<b>1998 1999<sup>1</sup></b>
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$ (Mil)
Ifex	Ifosfomide	Bristol Myers - Squibb	03/03/08 4-882-452	-	- -	03/03/08	Class 4 80
Neurolite	Technetium	DuPont	11/23/08 5-279-811	11/23/99	U-101 NCE	11/23/08	NA
Semprex-D	Acrivastine	Glaxo-Wellcome	03/26/08 4-650-807	03/25/97	U-93 NC	03/26/08	Class 2 11
Actinex Cream	Masoprocol	Reed & Carnick	04/17/08 4-695-590	09/04/07	- NCE	04/17/08	
Hivid	Zalcitabine	Roche	07/02/08 5-028-595	06/19/97	U-65 NCE	07/02/08	Class 2 14
Trusopt	Dorzolamide HCl	Merck & Co	04/28/08 4-797-413	12/09/99	- NCE	04/28/08	Class 5 100+
Requip	Ropinirole HCl	Smith Kline Beecham	05/19/08 4-854-860	09/19/02	U-212 NCE	05/19/08	Class 2 21
Restoril	Temazepam Hydrochloride	Novartis	07/09/08 5-326-758	-	U-70 -	07/09/08	Class 2 18
Amerge	Naratriptan Hcl	Glaxo-Wellcome	08/12/08 4-997-841	02/10/03	U-232 NCE	08/12/08	Class 3 36
Alkeran	Melphalan	Glaxo-Wellcome	11/18/08 4-997-651	11/18/99	- ODE	11/18/08	Class 2 15

Upcoming  
Conferences

During The New Millennium



International Journal of  
**Drug Development**  
and the  
International Journal of  
**Generic Drugs**  
will be sponsoring  
the Years Key Generic Conferences



THE OFFICIAL REVIEWERS FOR  
PHARMACEUTICAL CONFERENCES PUBLISHED in the International Journals

## Drugs Off-Patent Reports

### Year of Expiration - 2009 - (<\$100M)

Drug ON-OFF Patent	Generic Name	Patent Holder Marketer	Patent Expiry	Exclusivity Expiry	Patent & Exclusivity	Earliest Generic	1998 1999 <sup>1</sup>
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$ (Mil)
Permax	Pergolide Mesylate	Athena Neuroscience	10/19/09 5-114-948	-	-	10/19/09	Class 3 40
Ultiva	Remifentanyl HCl	Glaxo - Wellcome	02/15/09 5-019-583	07/12/01	- NCE	02/15/09	Class 1 5
Baycol	Cerivastatin Sodium	Bayer	01/17/09 5-006-530	06/26/02	- NCE	01/17/09	Class 3 29
Tricor (micronised)	Fenofibrate	Fournier Research	01/19/09 4-895-726	-	-	01/19/09	Class 2 15
Mepron	Atovaquone	Glaxo - Wellcome	08/15/09 4-981-874	01/05/06	- ODE	08/15/09	Class 2 23
Astelina	Azelastine HCl	Carter Wallace	11/17/09 5-164-194	11/01/01	U-207 NCE	11/17/09	Class 3 38
Migranal	Dihydro ergotamine Mesylate	Novartis	12/08/09 5-169-849	12/08/00	- NDF	12/08/09	Class 2 18
Arimidex	Anastrozole	Astra Zeneca	12/27/09 4-935-437	12/27/00	- NCE	12/27/09	Class 3 45
Andro-derm	Testosterone	Smith Kline Beecham	10/06/09 5-152-997	-	-	10/06/09	Class 2 21

### Year of Expiration - 2010 - (<\$100M)

Drug ON-OFF Patent	Generic Name	Patent Holder Marketer	Patent Expiry	Exclusivity Expiry	Patent & Exclusivity	Earliest Generic	1998 1999 <sup>1</sup>
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$ (Mil)
Kadian	Morphine Sulphate	Faulding	04/13/10 5-202-128	07/03/99	- NDF	04/13/10	Class 1 4
Feridex	Ferumoxides	Advanced Magnetics	09/28/10 5-248-492	08/30/01	- NCE	09/28/10	Class 1 1
Iodipine	Apraclonidine Hydrochloride	Alcon	05/18/10 4-517-199	-	U-120,U-15 -	05/18/10	Class 2 19
Hycamtin	Topotecan HCl	Smith Kline Beecham	05/28/10 5-004-758	05/28/01	- NCE	05/28/10	Class 4 78
Climara	Estradiol	Berlex	06/29/10 5-223-261	03/05/02	- I-254	06/29/10	Class 4 72
Invirase	Saquinavir Mesylate	Roche	11/19/10 5-196-438	12/06/00	- NCE	11/19/10	Class 4 67
Patanol	Olopatadine HCl	Alcon	12/18/10 5-116-863	12/18/01	- NCE	12/18/10	Class 4 73

Drugs Off-Patent Reports  
Year of Expiration - 2011 (<\$100M)

<b>Drug ON-OFF Patent</b>	<b>Generic Name</b>	<b>Patent Holder Marketer</b>	<b>Patent Expiry</b>	<b>Exclusivity Expiry</b>	<b>Patent &amp; Exclusivity</b>	<b>Earliest Generic</b>	<b>1998 &amp; 1999<sup>1</sup></b>
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$ (Mil)
Synarel	Naferlin Acetate	Roche	06/11/11 4-234-571	-	- -	06/11/11	Class 1 10
Visipaque 270	Iodixanol	Nycomed	09/20/11 5-349-085	03/22/01	- NCE	09/20/11	Class 3 39
Avapro	Ibesartan	Sanofi/BMY	03/20/11 5-270-317	09/30/02	- NCE	03/20/11	Class 4 72
Follistim	Follitropin Alfa/beta	Organon	03/20/11	09/29/00	- NP	03/20/11	Class 4 56
Astelin	Azelastine Hcl	Wallace	10/16/11 5-164-194	-	U-207 -	10/16/11	Class 3 37
Viramune	Nevirapine	Boehringer Ingleheim	11/22/11 5-366-972	06/21/01	U-167 NCE	11/22/11	Class 5

NA = Not Applicable

NCE = New Chemical Entity

NDF = New Dosage Form

NC = Not confirmed in 1998

NP = New Product

NC = New Combination

ODE = Orphan Drug Exclusivity

NS = New Substance

NE = New Salt or Ester

USD \$

Class 1 -<10m    Class 2 -<25m    Class 3 -<50m    Class 4 -<75m    Class 5 -<100m    Class 6 ->100m

# Upcoming Conferences

For the New Millennium

## International Journal of Drug Development

and the

## International Journal of Generic Drugs




### WORLD LEADERS in GENERIC DRUG CONFERENCES

THE OFFICIAL REVIEWERS FOR  
PHARMACEUTICAL CONFERENCES PUBLISHED in LIG's International Journals

## Drugs Off-Patent Reports Year of Expiration - 2012 (<\$100M)

Drug ON-OFF Patent	Generic Name	Patent Holder Marketer	Patent Expiry	Exclusivity Expiry	Patent & Exclusivity	Earliest Generic	1998 1999 <sup>1</sup>
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$ (Mil)
Photofrin	Porfimer Sodium	QLT Photo Therapeutics	08/01/12 5-438-071	12/27/00	U-128 NCE	08/01/12	Class 1 4
Imodium Advanced	Loperamide HCl	Johnson & Johnson	05/21/12 5-716-641	06/26/00	- NC	05/21/12	Class 2 15
Gabitril	Tiagabine HCl	Abbott	03/24/12 -	09/30/02	- NCE	03/24/12	Class 2 14
Motrin	Ibuprofen	Johnson & Johnson	06/20/12 5-374-659*PED	-	-	06/20/12	Class 2 22
Tasmar	Tolcapone	Roche	12/19/12 5-476-875	01/29/03	- NCE	12/19/12	Class 3 31
Fortovase	Saquinavir	Roche	11/19/12 5-196-438	12/06/00	- NCE	11/19/12	Class 4 78
Diovan HCT	Valsartan-hydrochlorothiazide	Novartis	03/21/12 5-399-578	12/23/01	U-3 NCE	03/21/12	Class 2 20
Nimbex	Cisatracurium Besylate	Glaxo Wellcome	09/26/12 5-453-510	12/15/98	U-127 NE	09/26/12	Class 3 36

## Year of Expiration - 2013 (<\$100M)

Drug ON-OFF Patent	Generic Name	Patent Holder Marketer	Patent Expiry	Exclusivity Expiry	Patent & Exclusivity	Earliest Generic	1998 1999 <sup>1</sup>
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$ (Mil)
Cerezyme	Imiglucerase	Genzyme	08/28/13 5-549-892	05/23/01	U-252 NCE,ODE	08/28/13	Class 2 16
Humalog	Insulin Lispro	Eli Lilly	05/07/13 5-514-646	06/14/01	U-111 NCE	05/07/13	Class 4 63
Raxar	Grepafloxacin HCl	Glaxo-Wellcome	10/08/13 5-563-183	11/06/02	- NCE	10/08/13	Class 2 15
Crinone	Progesterone	AHP/Wyeth-Ayerst	09/15/13 5-543-150	07/13/00	- NP	09/15/13	Class 2 19
Propecia	Finasteride	Merck & Co	10/15/13 5-547-957	12/19/00	U-236 NP	10/15/13	Class 3 36

USD \$

Class 1 -<10m    Class 2 -<25m    Class 3 -<50m    Class 4 -<75m    Class 5 -<100m    Class 6 ->100m

**Note:** The generic share of total prescription has leveled in recent years with the first decline showing in 1998 (41.5%) for the first time in many years (Highest was 42.2% in 1997) while the generic share of dollar sales is only 8.75% (Declined over the past 3 years from a high of 11.4% in 1995.)

## Drugs Off-Patent Reports

### Year of Expiration - 2013 (<\$100M)

Drug ON-OFF Patent	Generic Name	Patent Holder Marketer	Patent Expiry	Exclusivity Expiry	Patent & Exclusivity	Earliest Generic	1998 1999 <sup>1</sup>
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$ (Mil)
Cerezyme	Imiglucerase	Genzyme	08/28/13 5-549-892	05/23/01	U-252 NCE,ODE	08/28/13	Class 2 16
Humalog	Insulin Lispro	Eli Lilly	05/07/13 5-514-646	06/14/01	U-111 NCE	05/07/13	Class 4 63
Raxar	Grepafloxacin HCl	Glaxo-Wellcome	10/08/13 5-563-183	11/06/02	- NCE	10/08/13	Class 2 15
Crinone	Progesterone	AHP/Wyeth-Ayerst	09/15/13 5-543-150	07/13/00	- NP	09/15/13	Class 2 19
Propecia	Finasteride	Merck & Co	10/15/13 5-547-957	12/19/00	U-236 NP	10/15/13	Class 3 36

### Year of Expiration - 2014 (<\$100M)

Drug ON-OFF Patent	Generic Name	Patent Holder Marketer	Patent Expiry	Exclusivity Expiry	Patent & Exclusivity	Earliest Generic	1998 1999 <sup>1</sup>
Trade	Generic	NAME	Patent #	DATE	CODES	DATE	USD\$ (Mil)
Sustiva	Efavirenz	DuPont Pharm.	09/02/14 5-663-169	09/17/03	- NCE	09/02/14	Class 2 18
Mavik	Trandolapril	BASF	04/28/15 5-744-496	04/26/01	- NCE	04/28/15	Class 2 18
Gonal-F	Follitropin Alpha/beta	Serona Laboratories	06/16/15 5-767-251	06/16/15	- -	06/16/15	Class 4 85
Adenoscan	Adenosine	Jujisawa	03/24/15 5-731-296	05/18/98	U-221 I-126	03/24/15	Class 3 55
Proventil-HFA	Albuterol sulfate	Schering-Plough	06/16/15 5-766-573	09/23/01	- I-235	06/16/15	Class 4 69
Proventil-HFA	Albuterol sulfate	Schering-Plough	06/16/15 5-766-573	09/23/01	- I-235	06/16/15	Class 4 69
Aggrastat	Tibofiban HCl	Merck & Co.	10/23/16 5-733-919	05/14/03	- NCE	10/23/16	Class 2 18

#### Extended Patent Protection:

One of the provisions in GATT (July 8, 1995) provided extra patent protection by extending the patent life to **20** years from the date of filing with the FDA agency. Previously product patent protection had been **17** years from patent approval. Patents generally take no longer than 2 to 3 years to get through the US Patent Office (PTO) while the average new drug patent approval is about 18 months.