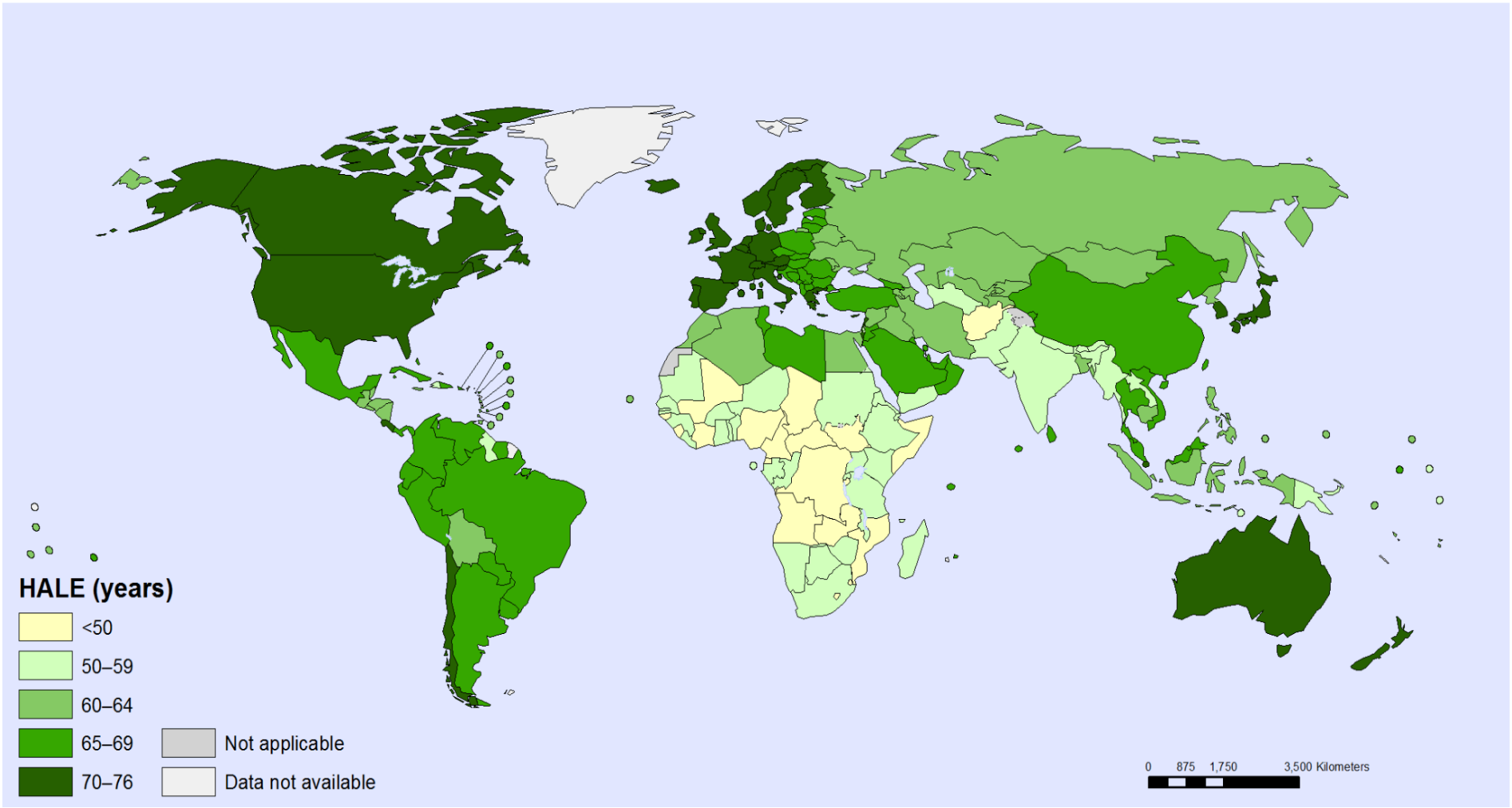
Options for IP Protection for CNS Drugs

William Fisher
January 20, 2015

January 26, 2015

Healthy Life Expectancy at Birth (2012)



Source: World Health Organization, http://gamapserver.who.int/mapLibrary/Files/Maps/Global_HALE_BothSexes_2012.png.

	A	B	C	D	E	F
1		**Low Income Countries**	**Lower Middle Income Countries**	**Upper Middle Income Countries**	**High Income Countries**	**All countries**
2	Population (in thousands)	846,348 (12%)	2,506,068 (35.4%)	2,429,453 (34.3%)	1,293,593 (18.3%)	7,075,456
3	Infectious and Parasitic Diseases	153,294 (35.4%) .181	213,576 (49.4%) .085	53,902 (12.5%) 0.22	11,676 (2.7%) .009	432448 .061
4	Respiratory Infections	47,865 (31%) .057	77,189 (50%) .031	21,561 (14%) .009	7,554 (5%) .006	154,169 .022
5	Maternal Conditions	8352 (42%) .010	9708 (48%) .004	1799 (9%) .0007	233 (1%) .0002	20,092 .003
6	Neonatal Conditions	65465 (27%) .077	136527 (58%) .054	30443 (13%) .013	4502 (2%) .002	236,938 .033
7	Nutritional Deficiencies	26415 (32%) .031	41486 (51%) .017	11677 (14%) .005	2504 (3%) .002	82082 .012
8	Noncommunicable Conditions	155,429 (10.3%) .184	530,318 (35.1%) .212	504,353 (33.3%) .208	322,478 (21.3%) .249	1,512,578 .214
9	Injuries	50,808 (16.6%) .060	130,045 (42.6%) .052	84,977 (27.8%) .035	39,721 (13.0%) .031	305,552 .043
10	**All Causes**	**507,628 (18.5%) .600**	**1,138,851 (41.5%) .454**	**708,712 (25.8%) .292**	**388,668 (14.2%) .300**	**2,743,857 .388**

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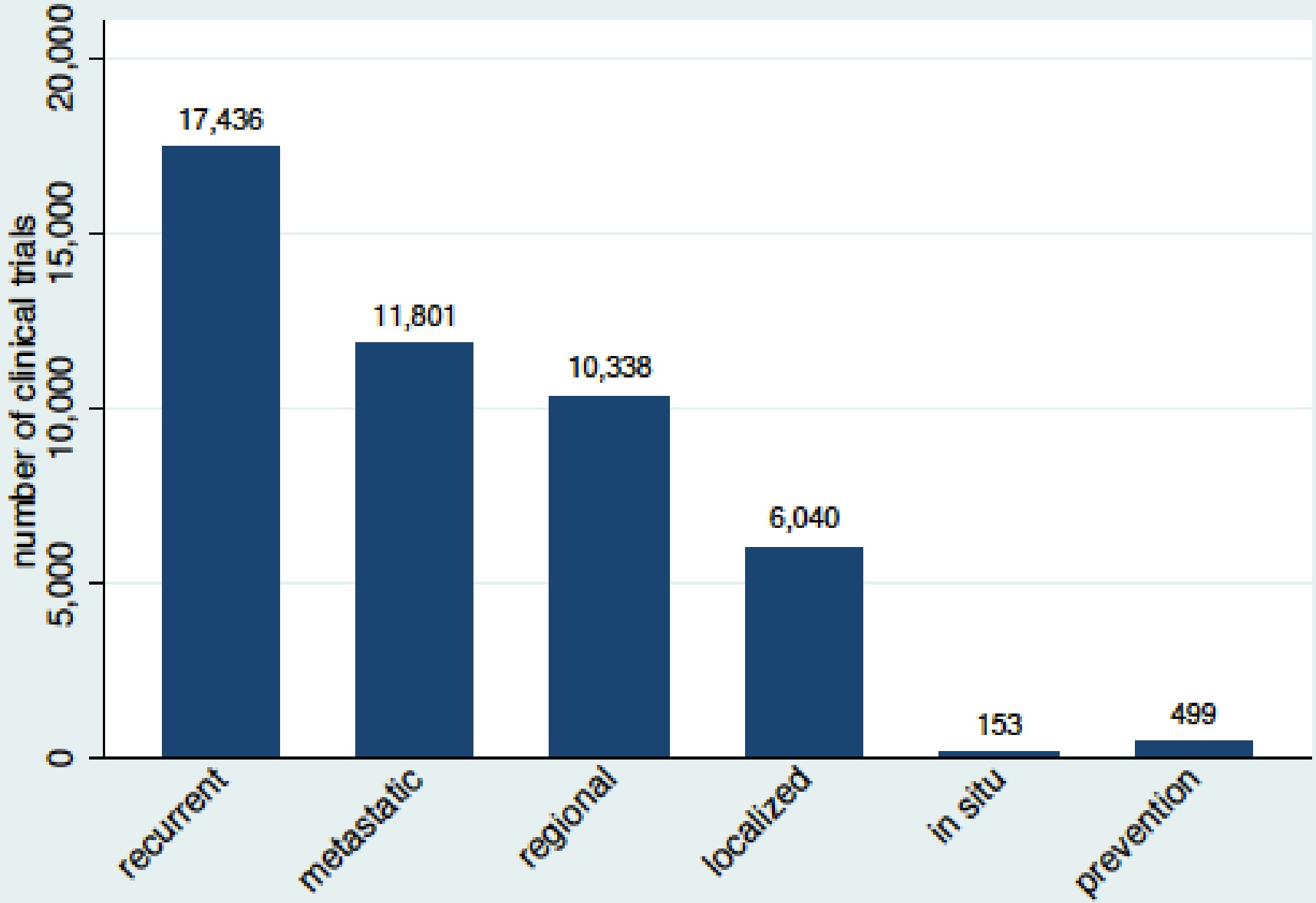
Explanation of the Table

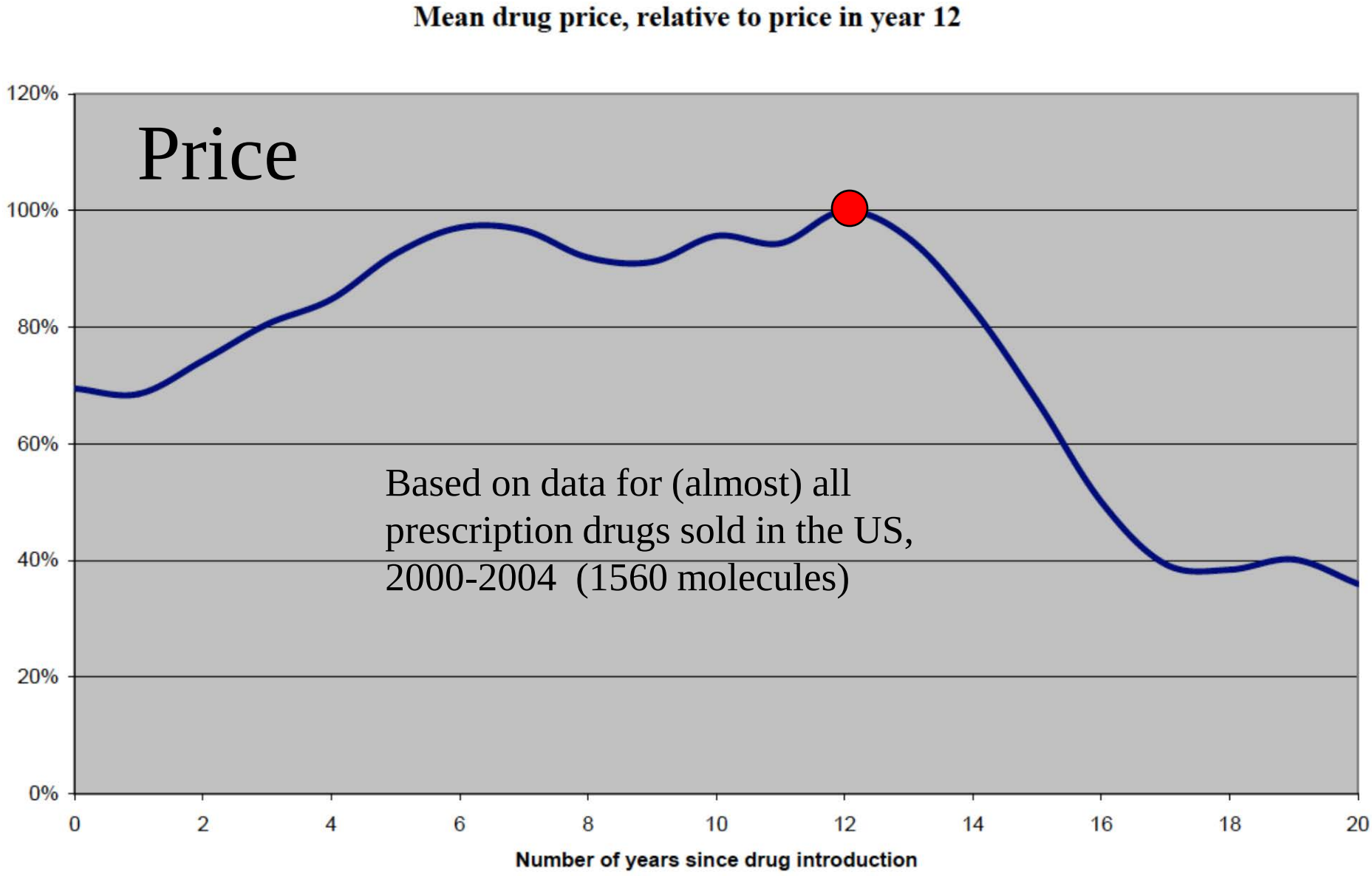
- The numbers in the cells in Row 2 indicate the number of persons and the percentage of the global population that lives in each region.
- In all of the other cells in the table:
  - the first number indicates (in thousands) the total number of DALYs caused in that region by diseases or conditions of the type at issue,
  - the second number shows the percentage borne by countries in that region of the number of DALYs caused by that disease or condition globally, and
  - the third number indicates the number of DALYs per person suffered in that region as a result of the disease or condition.
- All data are derived from WHO, "World Health 2014". The four income groups used in this chart were derived (by the WHO) from the World Bank's classification of countries for the fiscal year 2014. See http://data.worldbank.org/about/country-and-lending-groups.

	Global Deaths (thousands)	Global DALYs (thousands)
HIV/AIDS	1,534	91,907
Tuberculosis*	935	43,650
Malaria*	618	55,111
Diarrhoeal Diseases	1,498	99,728
Meningitis	395	30,182
Encephalitis	78	5,418
Hepatitis		
B	149	6,416
C	39	1,270
Dengue	29	1,445
Tropical Diseases		
Trypanosomiasis*	18	1,264
Chagas*	8	528
Schistosomiasis	22	4,026
Leishmaniasis*	48	3,374
Lymphatic filariasis (elephantiasis)	0	2,839
Onchocerciasis (river blindness)	0	598
STDs (excluding HIV/AIDS)		
Syphilis	79	7,039
Chlamydia	1	1,430
Gonorrhoea	1	545
Childhood Diseases		
Pertussis ("whooping cough")	67	6,142
Diphtheria	3	223
Measles	130	11,531
Tetanus	66	5,656
Leprosy	8	257
Trachoma (infectious blindness)	0	299
Rabies	35	2,265
Intestinal nematode infections		
Ascariasis	3	1,355
Trichuriasis	0	666
Hookworm	0	3,246
Totals	**5,764**	**388,410**



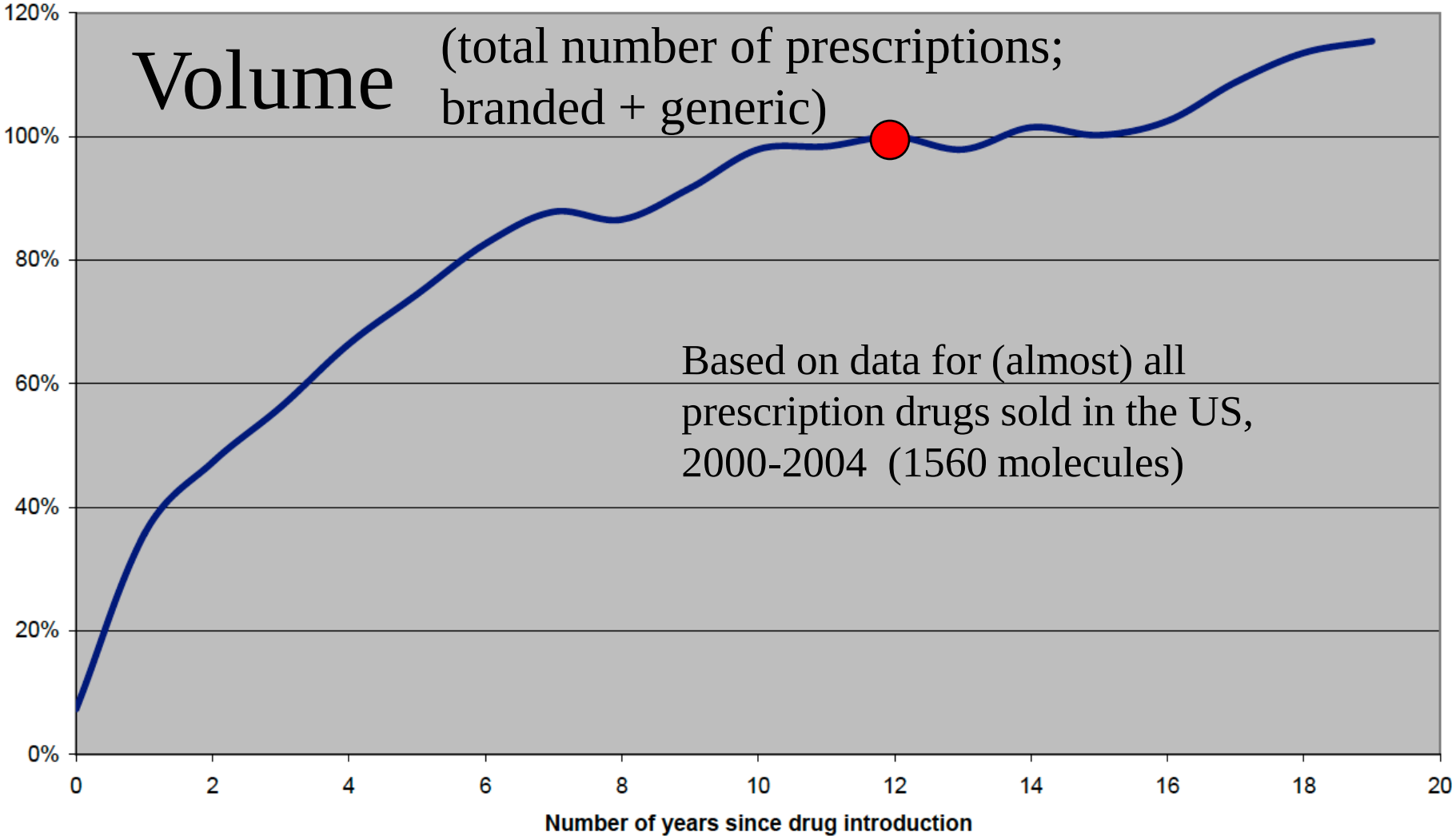
Source: Roin et al.

(b) R&D investments by stage



Source: Frank R. Lichtenberg and Gautier Duflos, "The Effect of Patent Expiration on U.S. Drug Prices, Marketing, and Utilization by the Public," *Manhattan Institute for Policy Research* (2009), http://www.manhattan-institute.org/html/mpr_11.htm

Figure 5
Mean number of prescriptions, relative to number of prescriptions in year 12



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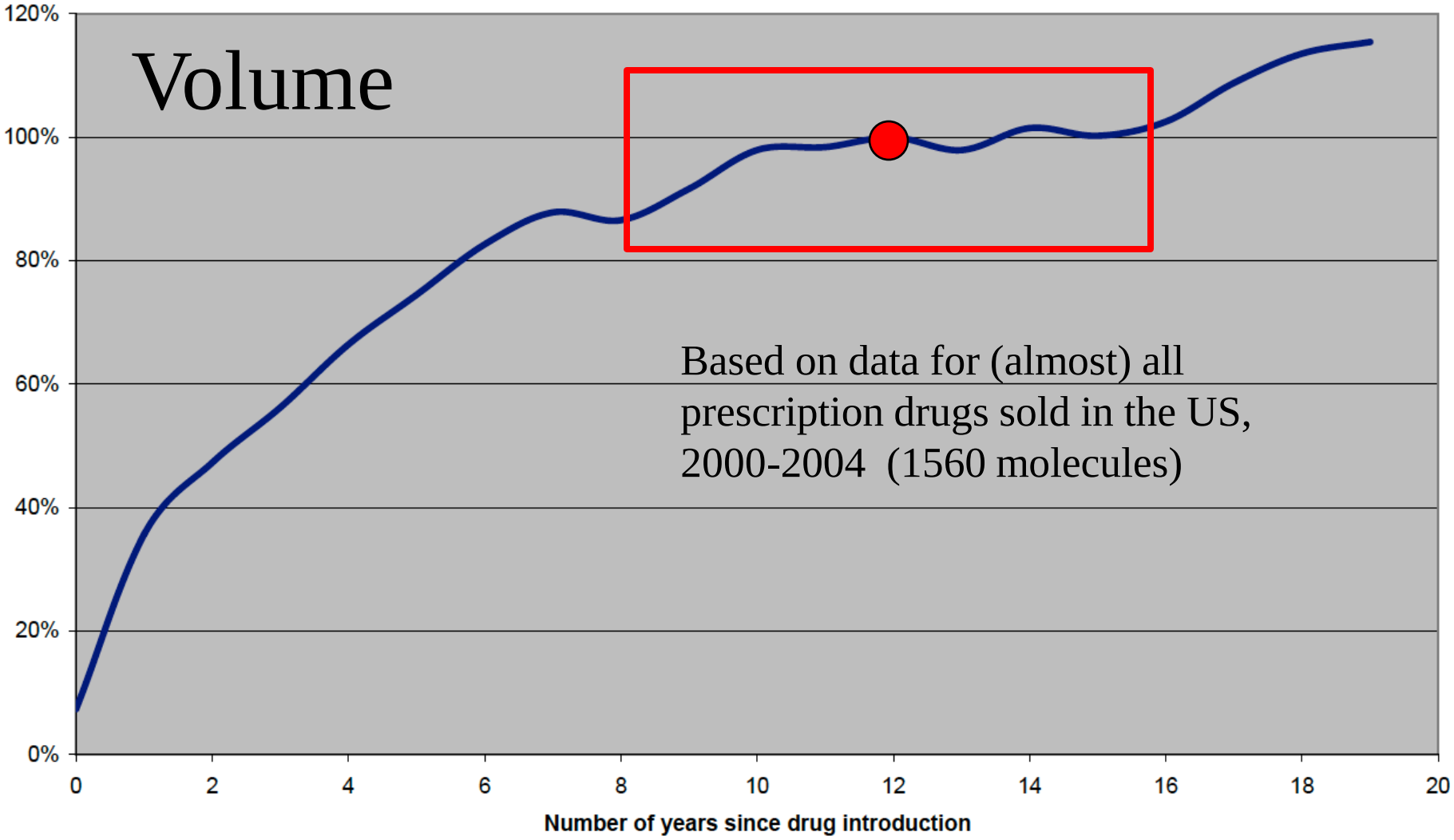

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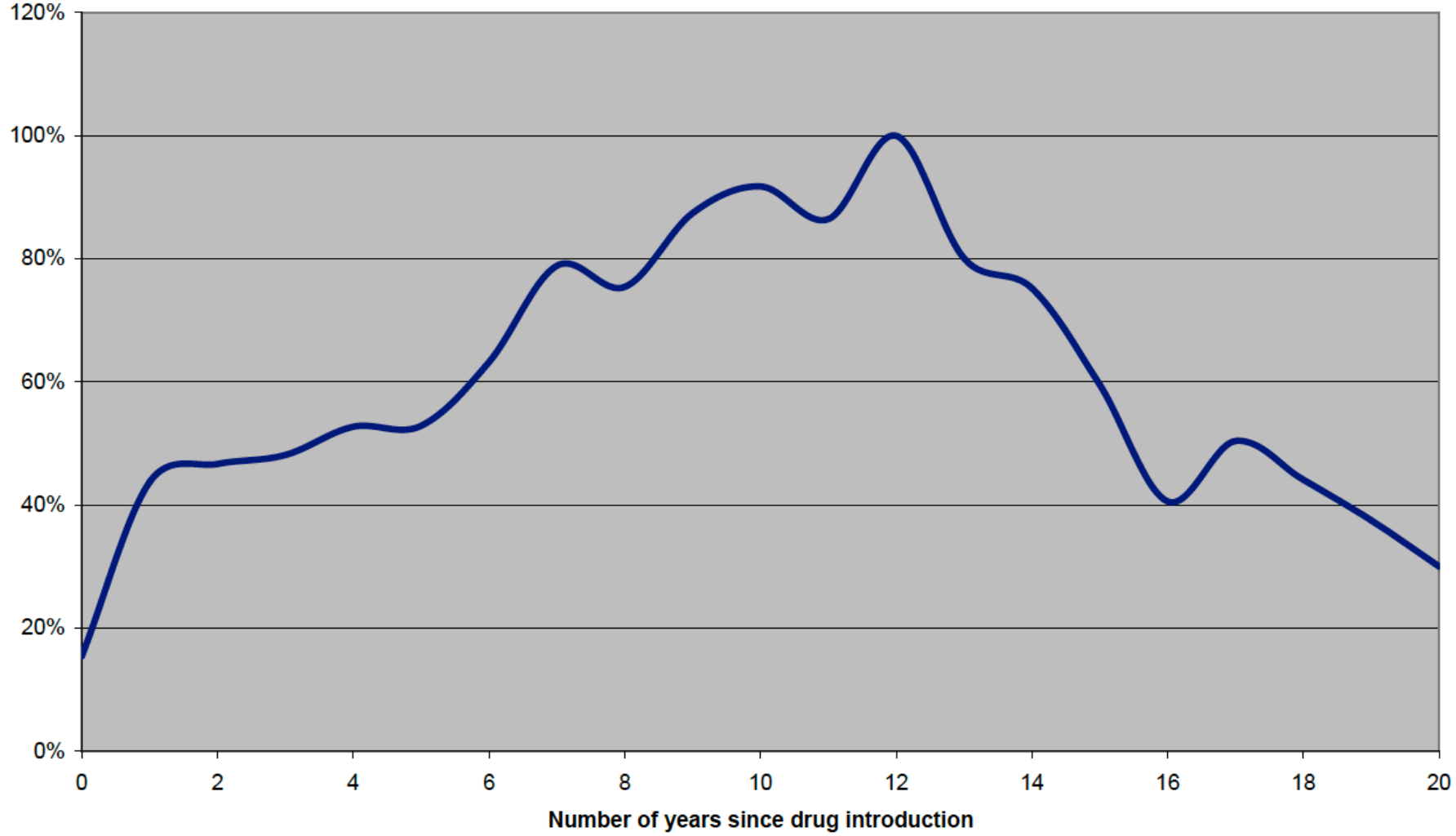
Figure 4
Mean professional promotion expenditure, relative to expenditure in year 12



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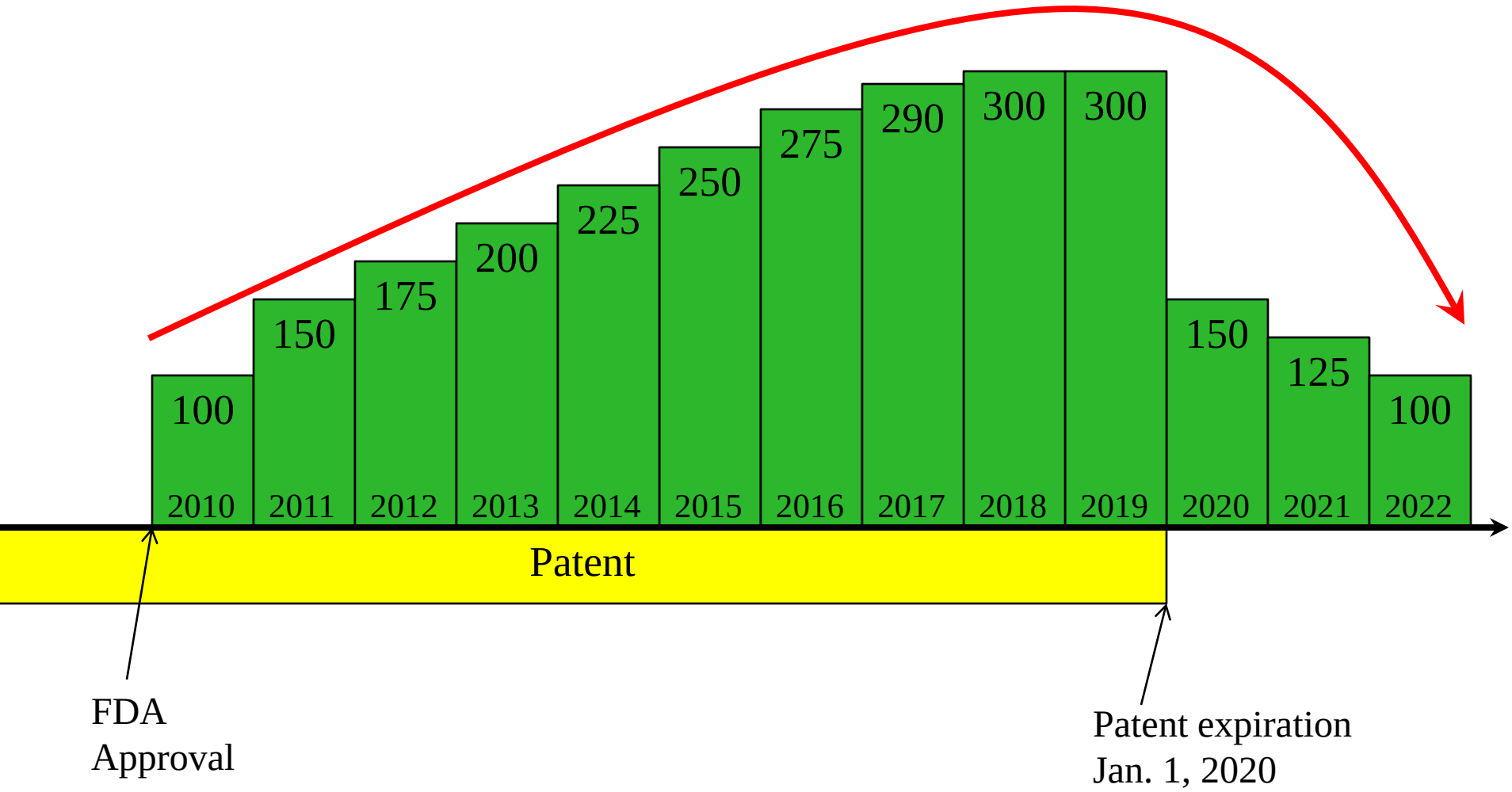
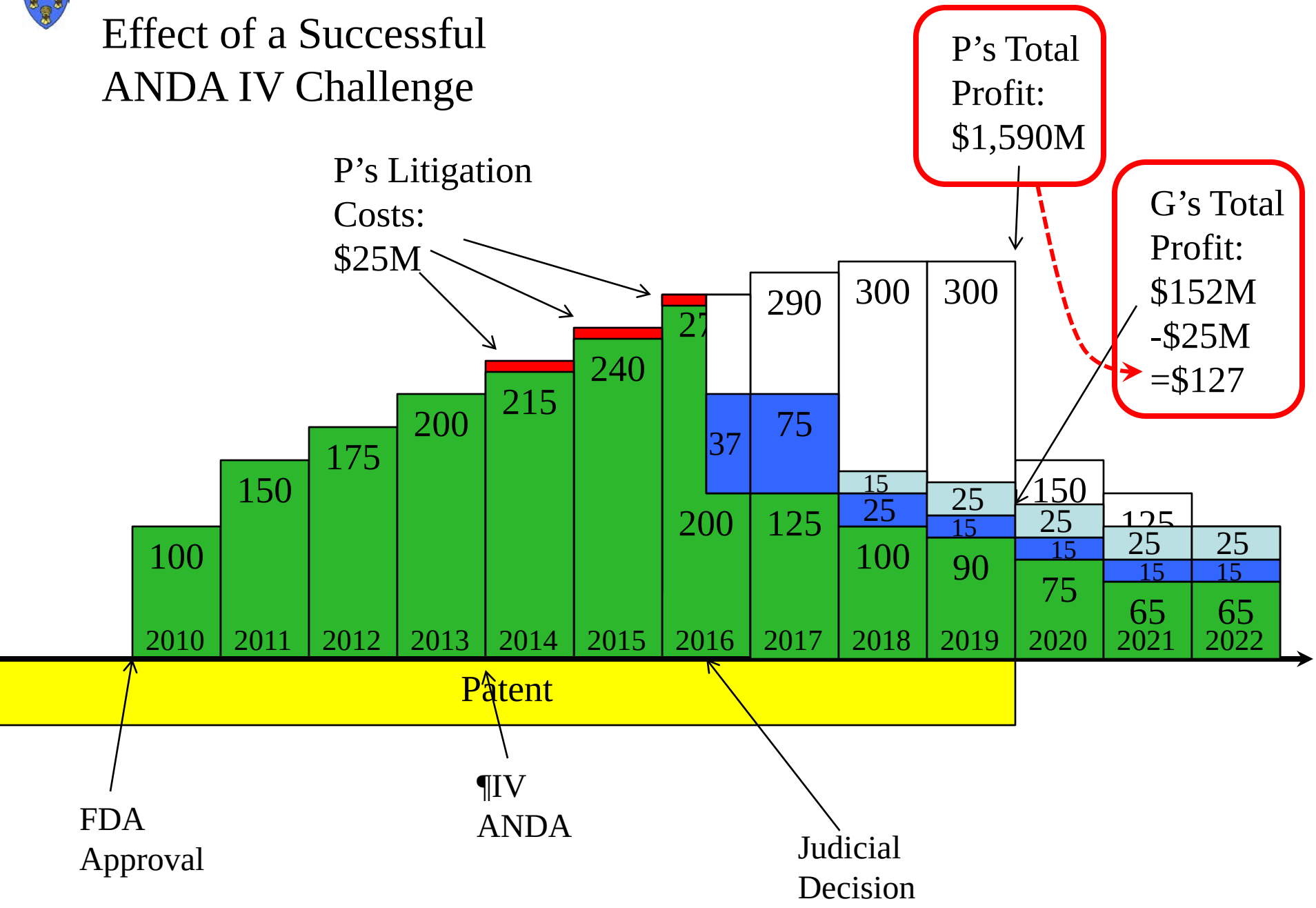
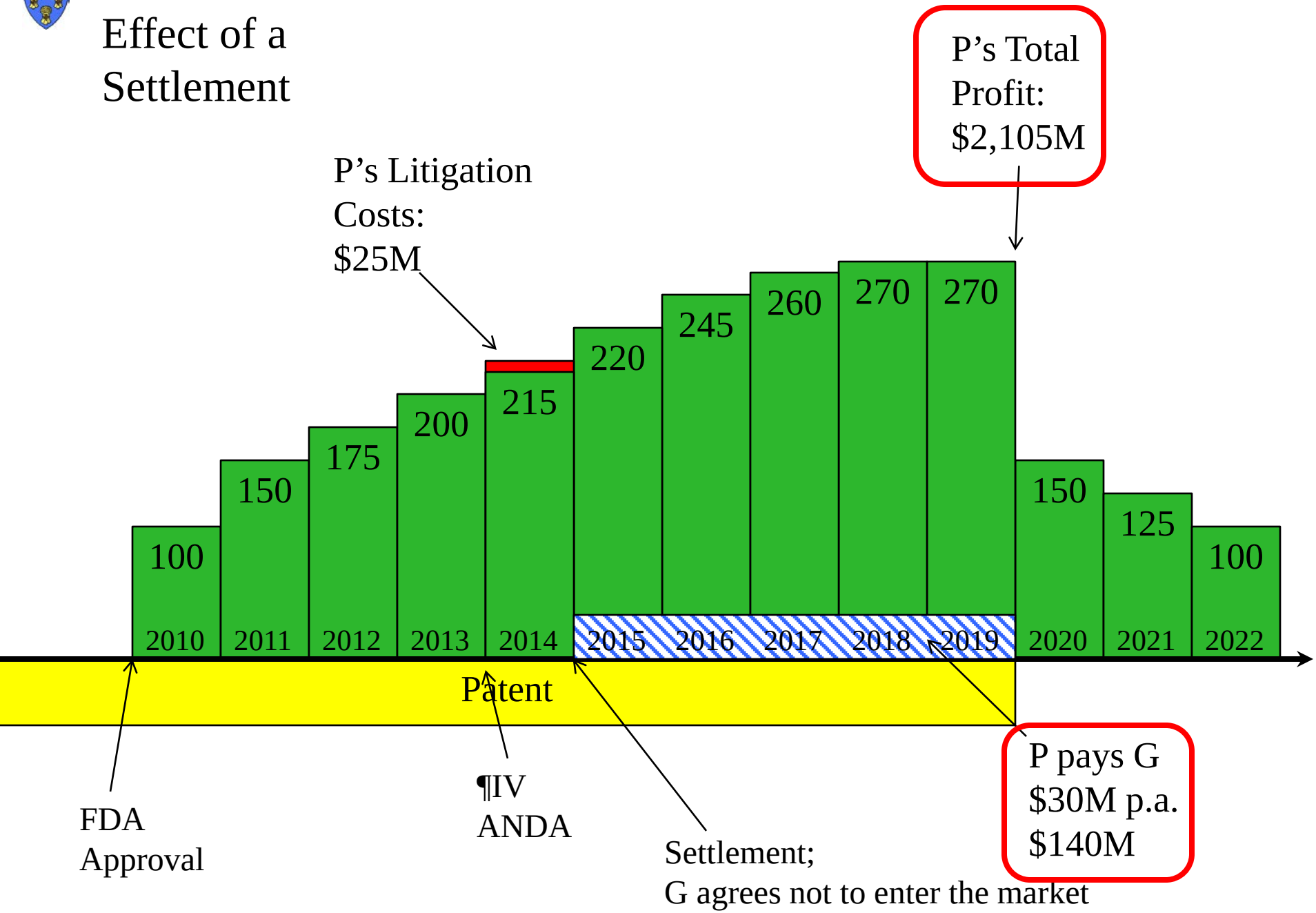
Typical Revenue Streams for Patented Drug



Effect of a Successful ANDA IV Challenge



Effect of a Settlement



Issues

- Data/Market Exclusivity or Patent-term adjustment?
- How long?
- Which drugs?