Osteoporosis

Osteoporosis is a systematic skeletal disease characterized by low bone mass, increase of bone fragility and susceptibility to fracture.

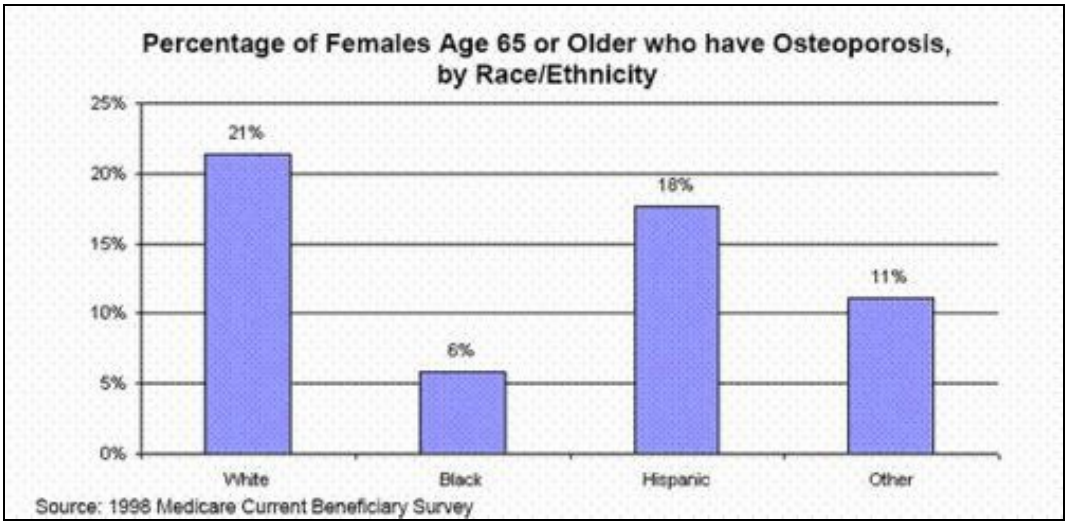
Types of Osteoporosis and its causes

1. **Primary osteoporosis(Type I (postmenopausal) or Type II (senile))**:
    1. *Type I (postmenopausal)*: Generally develops in women after menopause when the amount of estrogen in the body greatly decreases. This process leads to an increase in the resorption of bone (the bones loses substance).
    2. *Type II (senile)*: This involves a thinning of both the trabecular bone (the spongy bone inside of the hard cortical bone) and the hard cortical bone. This process often leads to hip and vertebral body (in the spine) fractures.
2. **Secondary osteoporosis**: Secondary osteoporosis has the same symptoms as primary osteoporosis. However, it occurs as a result of having certain medical conditions, such as hyperthyroidism or leukemia. It may also occur as a result of taking medications known to cause bone breakdown, such as oral or high-dose inhaled corticosteroids (if used for more than 6 months), too high a dose of thyroid replacement, or aromatase inhibitors (used to treat breast cancer).
3. **Osteogenesis imperfecta**: Osteogenesis imperfecta is a rare form of osteoporosis that is present at birth. Osteogenesis imperfecta causes bones to break for no apparent reason.
4. **Idiopathic juvenile osteoporosis**:Idiopathic juvenile osteoporosis is rare. It occurs in children between the ages of 8 and 14 or during times of rapid growth. There is no known cause for this type of osteoporosis, in which there is too little bone formation or excessive bone loss.

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Incidence and prevalence



Incidence

- 1 in 3 women over 50 will suffer a fracture due to osteoporosis; this increases to 1 in 2 over 60.
- 1 in 5 men over 50 will suffer a fracture due to osteoporosis; this increases to 1 in 3 over 60.
- Approximately 1.6 million hip fractures occur each year worldwide, the incidence is set to increase to 6.3 million by 2050.
- The highest risk of hip fractures are seen in Norway, Sweden, Iceland, Denmark and the USA.
- Currently, there is an increasing incidence of hip fractures in the developed cities in Asia. 1 out of 4 hip fractures occur in Asia and Latin America. This number of hip fractures will increase to 1 in 2 by 2050.
- In the Middle East, the burden of osteoporosis in the general population is expected to increase and is becoming a heavy financial burden.7
- The annual incidence rate of osteoporotic fractures in women is greater than the combined incidence rates of heart attack, stroke and breast cancer. (International osteoporosis foundation)

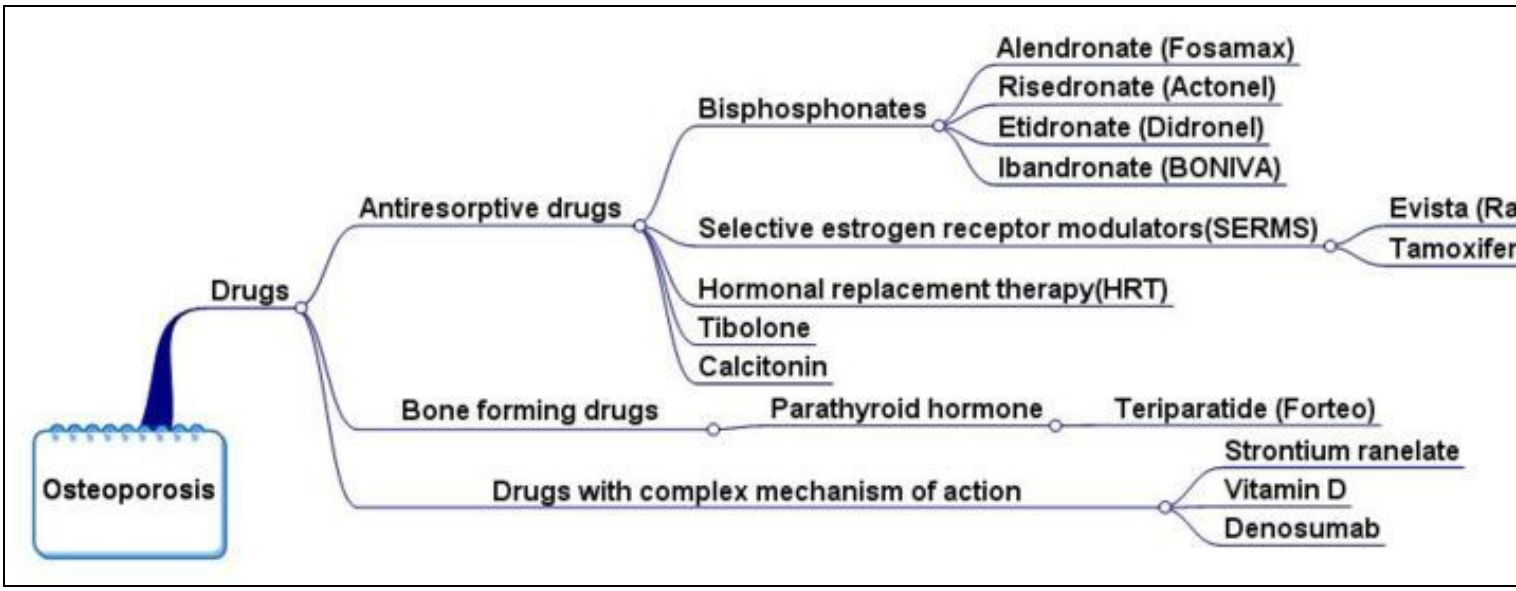
Prevalence

- 28 million Americans (10 million with osteoporosis; 18 million with low bone mass); eight million American women and 2 million men (NWHIC)(approx 1 in 9 or 10.29% or 28 million people in USA).
- Total prevalence rate of osteoporosis in the middle- aged and elderly in China was 16. 1% in 2002. The prevalence rate among males was 11. 5% and among females was 19. 9%.
- Prevalence increase to 2.2 million in 2006 and 3 million in 2021 in Australia.

- The prevalence of Khon Kaen (Thai rural area) women has osteporosis in femoral neck and lumbar spine is 19.3% and 24.7% respectively. (International osteoporosis foundation)

S.NO	Country/Region	Extrapolated Prevalence
1	USA	10 million cases (80% cases are women and 20% cases are men)
2	Australia	2.2 million
3	Middle east	18,603,593
4	Africa	47,233,590
5	Asia	359,862,754
6	Europe	80,590,570

Product Information



Overall categorization of osteoporosis treatments

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Products in market

Generic	Brand	Current Status	Type	Company
Antiresorptives				
Bisphosphonates				
Alendronate	FOSAMAX®	Approved by US	Postmenopausal	Merck
Risedronate	Actonel®	Approved by US/ES	Postmenopausal	Sanofi-Aventis/Procter & Gamble
Ibandronate	Boniva?	Approved by US	Postmenopausal	Roche
Etidronate	Didronel	Off Label		Proctor And Gamble
Zoledronic Acid	Aclasta	Approved	Postmenopausal	Novartis

Selective Estrogen Receptor Modulators				
Raloxifene	Evista®	Approved by US	Osteoporosis	Eli lilly
Hormone Replacement Therapy				
Conjugated estrogen	Premarin®	Approved by US	Postmenopausal	Wyeth
Conjugated estrogen	Cenestin?	Approved by US	Postmenopausal	Duramed
Esterified estrogens	Estratab®	Approved by US	Postmenopausal	Solvay
Esterified estrogens	Menesta	Approved by US	Postmenopausal	Monarch
Estradiol Transdermal System	Menostar	Approved by US	Postmenopausal	Bayer
Estradiol Transdermal System	Vivelle Dot	Approved by US	Postmenopausal	Noven
Estradiol	Estrace®	Approved by US	Postmenopausal	Bristol-Myers Squibb
Estradiol	Gynodiol	Approved by US	Postmenopausal	Novavax
Tibolone	Livifem		Postmenopausal	
Calcitonin				
Calcitonin Salmon Injection	Miacalcin®	Approved by US	Postmenopausal	Novartis
Calcitonin Salmon Nasal Spray	Miacalcin®	Approved by US	Postmenopausal	Novartis
Calcitonin Salmon Nasal Spray	Fortical®	Approved by US	Postmenopausal	
Bone Forming Drugs				
Teripratide	Forteo®	Approved by US	Osteoporosis	Pfizer
Drugs with Complex Mechanisms of Action				
Strontium Ranelate	Protelos	Not approved in USA	Postmenopausal osteoporosis	Servier
Vitamin D				
Calcium		FDA is considering amending rules so that companies can now claim that calcium and Vitamin D in their food supplements can prevent osteoprorosis in all ages and both sexes		FDA

Product pipeline

Product Pipeline

DRUG	COMPANY	DESCRIPTION	STAGE
RANKL Inhibitors			
Denosumab	Atlantos, Amgen	A monoclonal antibody	3
Bisphosphonates			
Minodronate (YM529)	Astellas	Nitrogen containing bisphosphonate	
Calcium Antagonist			
423557	Glaxosmithkline		1
423562	Glaxosmithkline		1
Calcilytics (751689)	NPS and Glaxosmithkline	Calcilytics antagonize calcium receptors on parathyroid glands resulting in a transient release of the body?s own stores of parathyroid hormone (PTH).	1

Parathyroid Hormone			
768974	Glaxosmithkline	Parathyroid Hormone Agonist	1
Preos (rDNA origin)	NPS	Recombinant Parathyroid Hormone	Registration Filed
PTH1-34	Nastech	Intranasal Parathyroid hormone	2
PTH1-34	Novartis, Emisphere	Oral Parathyroid hormone	1
PTH Analogs	Unigene		2
Cathepsin k Inhibitor			
Relacatib (SB-462795)	GlaxoSmithkline		1
AAE581	Novartis		
MK-0822	Canadian Institutes of Health Research, Merck		2
Selective Estrogen Receptor Modulators			
Bazedoxifene	Wyeth, Ligand	A Third-Generation Selective Estrogen Receptor Modulator for Treatment of Postmenopausal Osteoporosis	
Lasofoxifene (Oporia)	Pfizer,Ligand	A Third-Generation Selective Estrogen Receptor Modulator for Treatment of Postmenopausal Osteoporosis	NDA
Arzoxifene	Eli lilly		
Taromifene (Fareston)	Orion		
Calcitonin			
	Nastech		NDA
Salmon calcitonin	Unigene	Nasal	3
Salmon calcitonin	Unigene	Oral	2
Salmon calcitonin (SMC 021)	Novartis, Emisphere, Nordic	Oral	3
Salmon calcitonin	Nobex (Biocon)	Oral	3
Vitamin D			
ED 71	Bone/ Chugai	Activted Vitamin D derivative	3
Doxercalciferol (Hectorol)	Bone Care Int.	Synthetic Vitamin D	
Nitrates: Research is going on to determine if nitrates can prevent osteoporosis in women.			
Isosorbide mononitrate	St. Michael?s Hospital, Toronto		3
Nitroglycerine	Canadian Institutes of Health Research (CIHR)		3
HCT 1026 (NO releasing Derivative of NSAIDs)	NicOx SA		2
Selective Androgen Receptor Modulator (SARM)			
LGD-2941	Ligand, TAP		3
LGD-3303	Ligand, TAP		3
Ostarine	GTx		2
Intermittent Versus Continuous Androgen Suppression	Ontario Cancer Research Network		

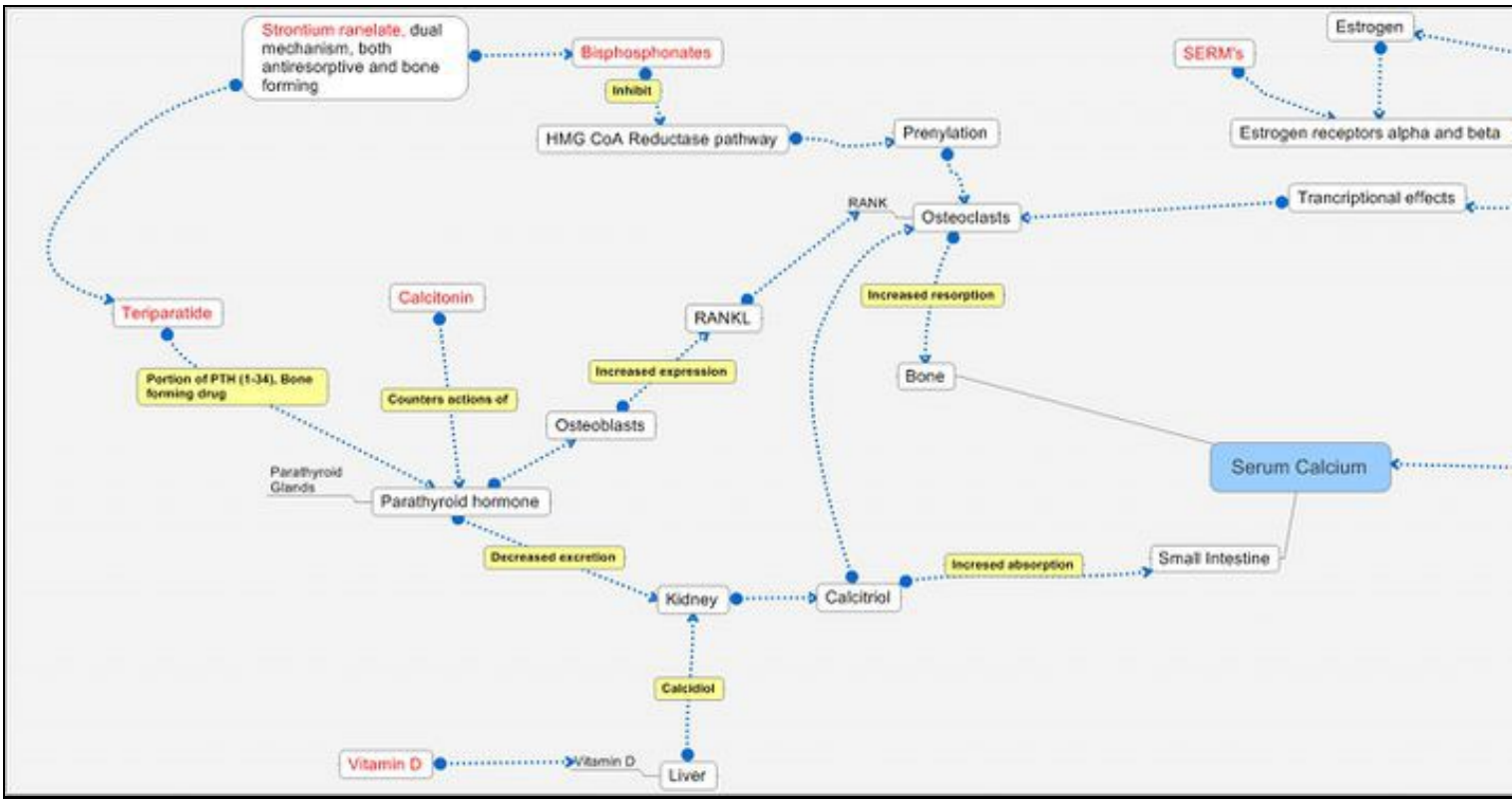
Mk 0733	Merck		1
TH0229	Theratechnologies		
c-8500	Merck		2
c-3578	Merck		2

apomorphine	Ilex Oncology		2	
Genistein	Primus Pharmaceuticals, Inc.	isoflavones have been shown to interact with animal and human estrogen receptors, causing effects in the body similar to those caused by the hormone estrogen.	Available	
Soy estrogens	(NIAMS)		3	
Hesperidin	Nestle clinical nutrition		3	
Davallia Divaricata	National Taiwan University Hospital		1	
Atorvaststin	[1]			
Potassium citrate	Weill Medical College of Cornell University		4	
Phosphorus	National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)		3	

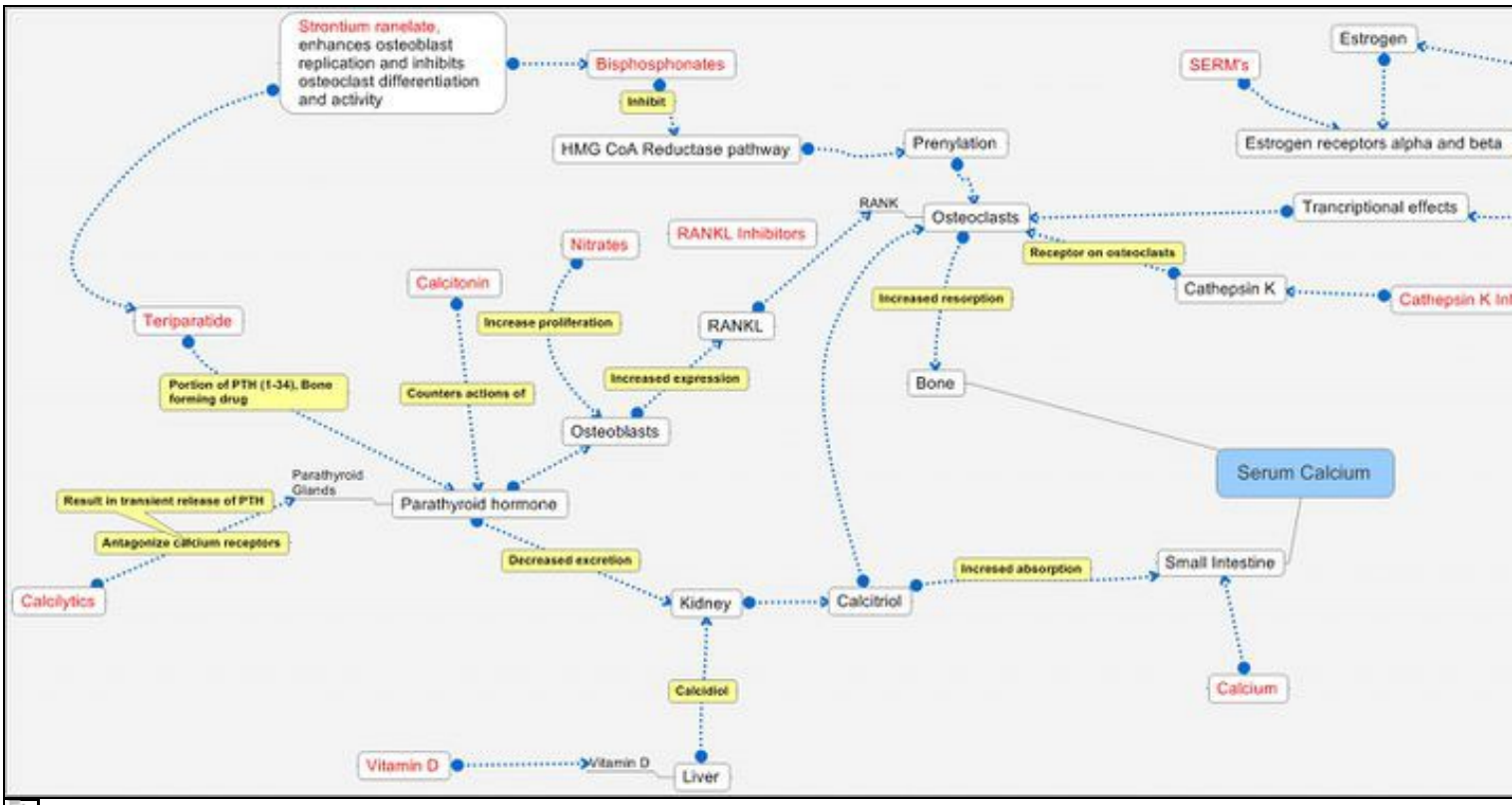
Devices

Hip Protector	Hip pads with special underwear with pockets		Children?s Mercy Hospital Kansas City	

Pathways



PRODUCT PATHWAY



PRODUCT PIPELINE

Market Information

Prescription Trends in USA									
Source: Arch Intern Med. 2004;164:1525-1530									
	1988	**1990**	**1992**	**1994**	**1996**	**1998**	**2000**	**2002**	**2003**
Patients (Millions)	NA	0.6	0.6	0.5	1.2	2	2.6	2.8	3.6
Drugs Prescribed %									
Bisphosphonates (total)	1	9	17	14	48	49	54	71	73
Alendronate	0	0	0	0	45	47	48	53	51
Risedronate	0	0	0	0	0	0	4	17	22
Etidronate	1	9	17	14	3	1	1	0	0
Calcium	39	33	33	43	31	26	29	26	24
Calcitonins	5	9	10	13	13	16	15	7	5
Estrogens	35	25	33	27	17	12	8	5	3
SERMs	0	0	0	0	0	9	14	12	12

Clinical Trials

Trial No.	Condition	Description	Intervention	Therapy	Route of admn	Sponsors & Collaborators	Phase	Date
1	Postmenopausal Osteoporosis	Investigate Patient Preference On Dosing In Ibandronate And Risedronate in korean women	Ibandronate	Drug	Oral	GlaxoSmithKline	Phase IV	May-07
2	Osteoporosis Osteopenia	Texture Analysis for Postmenopausal Osteoporosis	Alendronate	Drug	Oral	University of Chicago	-	Mar-07
3	Osteoporosis	A Phase II Study Evaluating	SB-751689	Drug	Oral	GlaxoSmithKline	Phase II	May-07

		SB-751689 in Post-Menopausal Women With Osteoporosis.						
4	Osteoporosis	Fall prevention program	Procedure	-	-	Sint Maartenskliniek ZonMw: The Netherlands Organisation for Health Research and Development		Apr-07
5	Osteoporosis Osteopenia	High Dosage Vitamin D and Osteoporosis	Cholecalciferol	Drug	Oral	University Hospital of North Norway	Phase IV	Jun-07
6	Osteoporosis	Effect of PTH(1-84)or Strontium Ranelate on Bone Formation Measured by Bone Markers	Parathyronine hormone	Drug	Oral	Nycomed	Phase IV	May-07
7	Post-Menopausal Osteoporosis	A Study of Quarterly Intravenous Bonviva (Ibandronate) in Women With Post-Menopausal Osteoporosis.	ibandronate [Bonviva/Boniva]	Drug	Intravenous	Hoffmann-La Roche	Phase IV	Jul-07
8	Osteoporosis	A Study for Patients With Osteoporosis	1.Salmon Calcitonin 2.Teriparatide	Drug	Nose/intravenous	Eli Lilly and Company	Phase III	Jun-07
9	Osteoporosis	Safety/Efficacy of Zoledronic Acid and Alendronate on Bone Metabolism in Post Menopausal Women With Osteoporosis	Zoledronic acid and alendronate	Drug	Oral	Novartis	Phase III	May-07
10	Osteoporosis	Efficacy in Reducing Fractures and Safety of Zoledronic Acid in Men With Osteoporosis	zoledronic acid	Drug	Intravenous	Novartis	Phase III	Feb-07
11	Osteoporosis	Davallia Divaricata BL: The Use of Traditional Chinese Native Medicine for Osteoporosis	Gu-Sui-Bu (Davallia Divaricata)	Drug		National Taiwan University Hospital	Phase I	Jan-07
12	Osteoporosis	Dose Ranging Study - Macroflux PTH in Postmenopausal Women With Osteoporosis	Macroflux PTH	Drug	Subcutaneuos	The Macroflux Corporation	Phase II	Jun-07
13	Osteoporosis	Fosamax for Childhood Cancer Survivors	Alendronate	Drug	Oral	Chinese University of Hong Kong	Phase III	Oct-06
14	Osteoporosis	This study is currently recruiting patients.	Parathyroid Hormone (PTH)	Drug	Subcutaneuos	Nycomed	-	Feb-07
15	Osteoporosis	This study is currently recruiting patients.	Alendronate with cholecalciferol and Os-Cal with extra D	Drug	Oral	National Institute on Aging (NIA),Glaxosmithkline	Phase III	May-07
16	Primary Osteoporosis	Phase II/III Clinical Study of R484iv (Ibandronic Acid) for Primary Osteoporosis	Ibandronic acid	Drug	Oral	Chugai Pharmaceutical	Phase III	Mar-07
17	Postmenopausal Osteoporosis, Back pain and	Effect of Teriparatide Compared to	Teriparatide and risedronate	Drug	Oral/Subcutaneuos	Eli Lilly and Company	Phase III	Jul-07

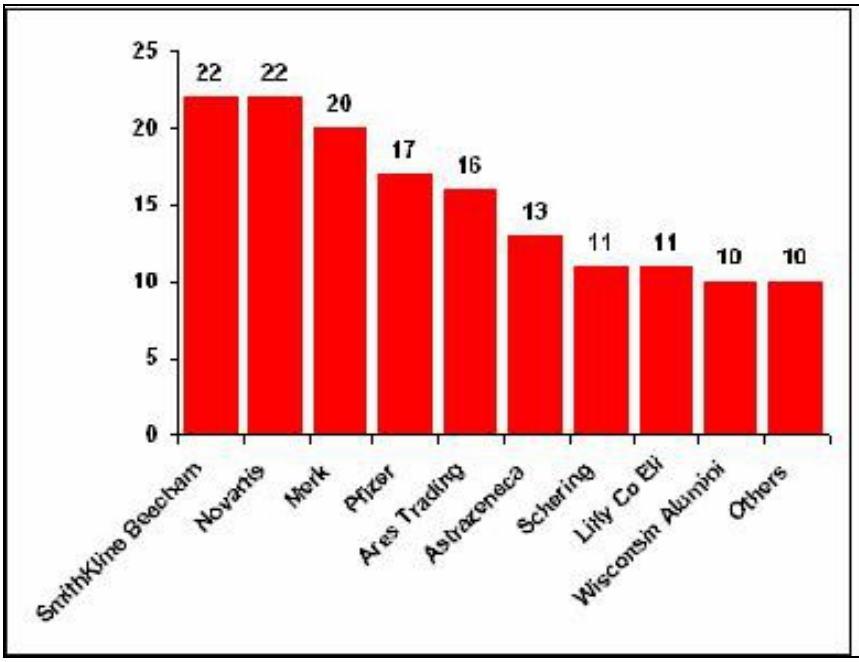
	Spinal Fracture	Risedronate on Back Pain in Women With a Spine Fracture Caused by Osteoporosis						
18	Osteoporosis	BONDIR Study: A Study of Intravenous Bonviva (Ibandronate) After Recent Vertebral Osteoporotic Fracture in Patients With Osteoporosis.	Ibandronate [Bonviva/Boniva]	Drug	Intravenous	Hoffmann-La Roche	Phase III	Jul-07

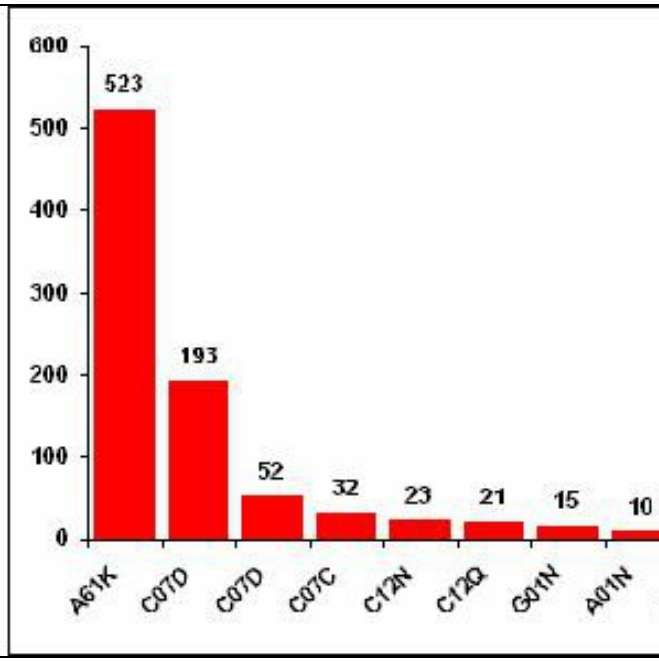
Intellectual Property

Search strategy

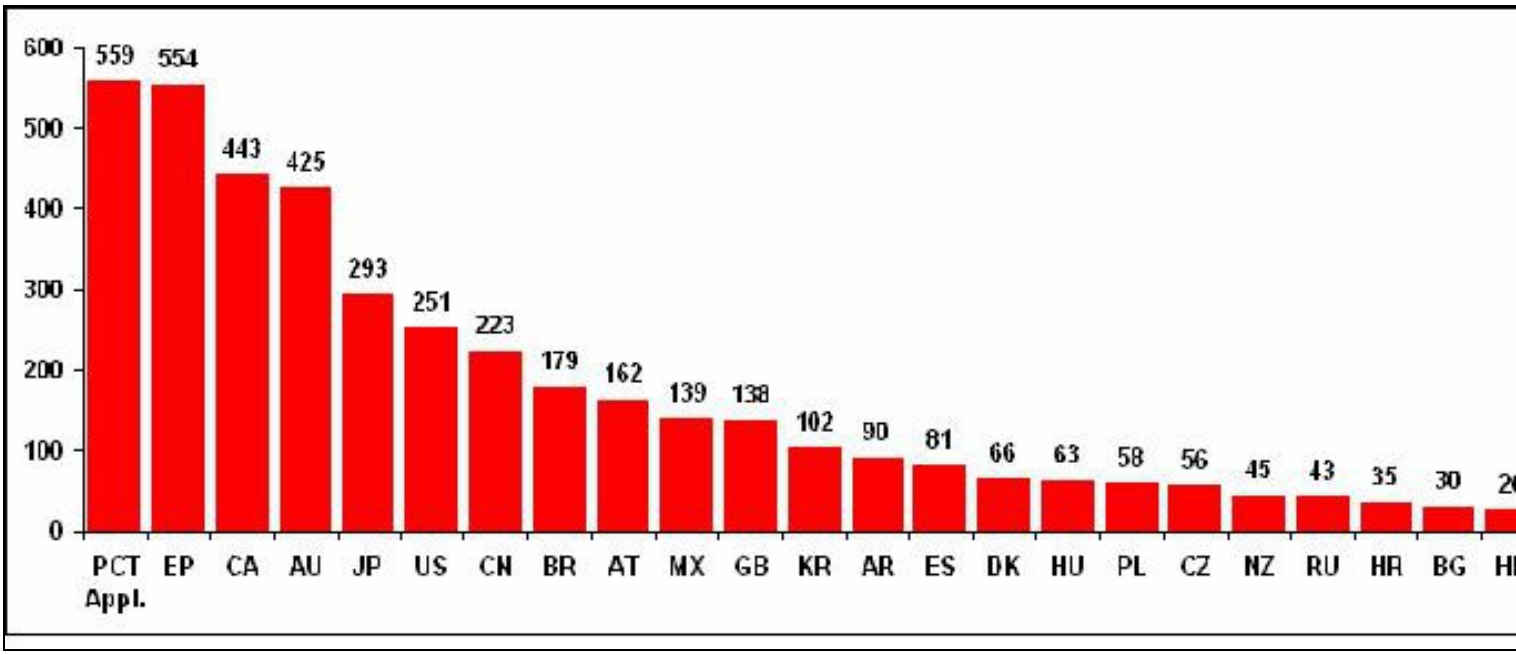
- **Database/Vendor**: Micropat
- **Search scope**: US Granted US Applications EP-A EP-B WO JP (bibliographic data only) DE-C,B DE-A DE-T DE-U GB-A FR-A; **Claims**
- **Years**: Issue/Publication Date: >20051231
- **Search String**: ((Osteoporosis OR (bone Near3 regeneration)) AND (treatment))
- **Hits**: 1261/982 patents (with/with out family members)
- **Date of search**: 14th September 2007

Top players and IPC classes



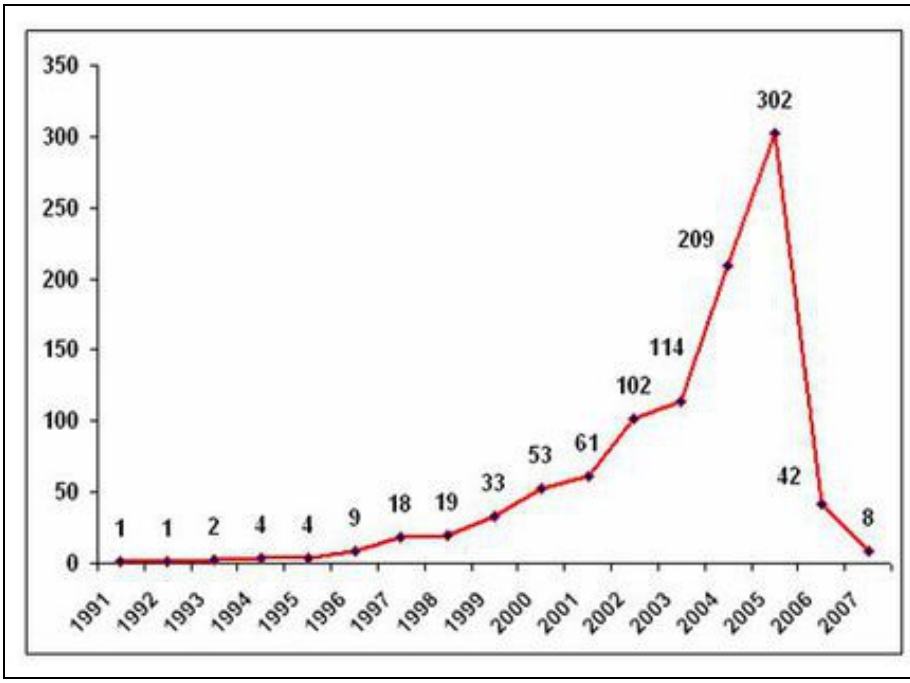


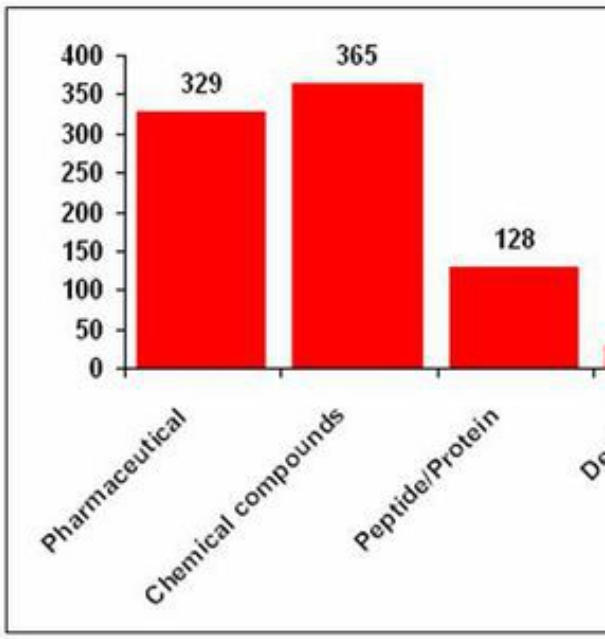
Geographical Distribution and Treatment Approaches



IP activity and Treatment Approaches

- Decline in the IP activity during 2006 and 2007 is due 18 months publication delay of patent document.





Conferences

- International Conference on Osteoporosis and Bone Research to be held on Oct 15-18, 2008 in Beijing, China.
- 2008 IOF World Congress on Osteoporosis to be held on December 2-7, 2008, Bangkok, Thailand
- 2007 World Congress on Osteoarthritis, December 6-9, 2007, Marriott Harbor Beach Resort & Spa in fabulous Ft. Lauderdale, Florida
- American Society of Bone and Mineral Research Annual Meeting, September 12-16, 2008, Montreal, Canada

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