

Favourable developments in Eloxatin case

- **Sun pharma wins appeals decision in Eloxatin case:** On 22-Dec-10, the appeals court vacated the consent judgment and order given by the district court. Also the injunction under the consent agreement entered by the district court no longer holds. The case now goes back to the district court to provide an opportunity to conduct discovery and allow Sun/Sanofi's to present evidence as to the proper resolution of the ambiguous language in the license agreement that is incorporated in the parties' original proposed consent judgment.
- **Presents an interesting opportunity for Sun:** The appeals decision means that Sun can now launch the product at-risk which will mean other generic players also enter the market. Considering a best case scenario with potential for up to sales of \$50m/year (Pre-generic entry brand size: \$1.3bn; 40% share; 90% erosion), will be a +1-2% upside for Sun. Even if Sun does not launch the product immediately it will provide the company substantial advantage in the settlement discussions with Sanofi. Given the market dynamics, we believe Sun is likely to settle the case to maximise value. We believe such settlement could lead to 2-3% upside to Sun's market cap. Also appeals win in a US litigation (Sun has done this twice in a row now after Gemcitabine) will be a positive for sentiment.
- **Sun's stand vindicated:** Sun had earlier launched generic Eloxatin at-risk in Jan-10, following launch by other players from Aug'09. In Apr-10, Sanofi settled the litigation with other generic players such as Teva, Sandoz, Hospira, APP, Par and Actavis. As per that settlement, these generic companies were required to stop selling their products from 30th June, 2010 and were allowed to re-enter on 9th Aug, 2012. This settlement raised a question of whether even Sun would be required to stop selling its generic. According to Sanofi, their Consent Agreement required even Sun to stop selling. This was based on the interpretation of the term "decision (s) enjoining" to include settlements entered into with other parties that were entered by the court. However, Sun disputed this meaning. According to Sun, this term required a court-mandated injunction. The district court had previously adopted Sanofi's version of the agreement and Sun had appealed that decision. The appeals decision has vacated that district court decision recognizing that the term is ambiguous and asking the district court to conduct discovery on the issue and allowing both parties to present evidence. We believe this opens up an opportunity for Sun to launch its generic version, which may lead to even other companies launching their generic versions. On the other hand, a preferred outcome for both Sun and Sanofi would be to settle the dispute. We think this represents significant upside for Sun.
- **We reiterate our BUY on Sun pharma with a Dec-11 target price of ₹532**

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Please see important disclosure at the end of the report

Exhibit I. Eloxatin (Innovator - Sanofi Aventis)

Product description							
Molecule	Form	Strength	Patents	Expiration	Coverage	Sales	NCE-expiration
oxaliplatin	Injectable	100mg/20mL,	5290961*PED	12-Jul-13	Process patent cis-oxalato patent cis-oxalato and process patent formulation patent process patent	1,300	Expired
		200mg/40mL,	5338874*PED	7-Oct-13			
		50mg/10mL	5420319*PED	9-Feb-17			
			5716988*PED	7-Feb-16			
5,959,133							
Generic filers							
Generic companies	ANDA filing	First to file	Sued on/notice date	Litigated patents	30-month expiry	Tentative/Final approval	Comments
Sun	50/100mg/vial	Shared FTF	Jun-07	874, '133	Feb-2010	7-Aug-09 (FA)	Settled
Sandoz	50/100mg/vial		Jul-07		Feb-2010	Aug-09	Settled
	200mg		May-08	874,'988	Nov-10		
Teva	NDA		May-07	874	Feb-2010	7-Aug-09 (FA)	Settled
Fresenius Kabi	50/100mg/vial	Shared FTF		874,961		7-Aug-09 (FA)	Settled
Onco							
Actavis						Jan-10	Settled
Mustafa/Par	50/100mg/vial			874,'988		7-Aug-09	Settled
	200mg		Nov-07	874,'988	May-10		
Teva/Pharmachemie	50/100/200mg/vial	Shared FTF	May-07	874,319	Feb-2010		
Abraxis							
Ebewe		Shared FTF	Nov-08	874	May-11	7-Aug-09 (FA)	Settled
Heraeus			May-08	874			Supplies API to Sandoz, Ebewe, Hospira, Mayne
Barr	50/100/200mg/vial		Nov-07	874	May-10	Jan-10	
Mayne	50/100mg/vial		Jun-07	874	Feb-2010	7-Aug-09 (FA)	Settled
Apotex	50/100mg/vial		Jul-08	874	Jan -11		
Hospira	50/100mg/vial	Shared FTF				7-Aug-09 (FA)	Settled
Litigation status							
Date	Update						
	Hospira, Teva, Sun, Dabur, Ebewe were FTF.						
Jun-09	District court ruled in favour of generics, as claim 1 of '874 is construed as product-by-process claim limited to optically pure oxaliplatin that has been resolved by HPLC described in patent. Finding non-infringement. Entered final judgment. Sanofi appealed the same day.						
10-Jul-09	Appeals stayed the judgment.						
Aug-10	Teva and Hospira launch their generic versions. Sun decides not to launch.						
Sep-09	Sanofi's motion granted and after expedited hearing, appeals court ruled in favour of Sanofi, reversing district court ruling.						
Jul-09	Ebewe settles with Sanofi and signs a consent order admitting '874, '988 are valid, enforceable and infringed						
Oct-09	Sandoz writes a letter for temporary suspension of its litigation, post its acquisition of Ebewe						
Oct-09	Court grants ruling in favour of Sun that its settlement agreement with Sanofi is binding						
3Q09	Hospira announces results with estimated \$90m quarterly sales from this product						
4Q09	Sandoz launches Ebewe product						
4Q09	Hospira announces 4Q09 results with another c.\$90m sales of generic oxaliplatin						
Jan-10	Fresenius launches its generic						
Feb-10	Fresenius renews litigation after settlement talks are unsuccessful						
1-Mar-10	Courts rules in favour of Sun that the agreement with Sanofi is enforceable						
Early-Mar-2010	Sun launches its product						
9-Mar-10	Trial to begin from 20th April						
12-Mar-10	Courts construes "optically pure" in favour of innovator and finds infg by Dabur/Fresenius						
18-Mar-10	Court denies SJ on 988/961 for both parties due to insufficiency						
22-Mar-10	Pretrial conference scheduled						
1-Apr-10	Sanofi partially settles with Teva, Fresenius and Sandoz - cease selling on 30-June-10, restart on 9-Aug-2012.						
6-Apr-10	Sanofi settles with Par, Hospira and Actavis for similar terms. Further, Sanofi believes that as per court-determined agreement with Sun, the latter would continue selling until the generic players cease selling.						
	Sandoz files consent judgment. Key terms:a) Para-IV on '874, '988 maintained, but case stayed, b) stay will be temporarily lifted if i) Sun is not prohibited from launching on 30-June-10 and ii) "injunction date" occurs. Sandoz will be enjoined till 12-July-10. c) After 12-July, Sandoz will not be enjoined if Sun is not prohibited, d) if Sun is enjoined by 31-Mar-11, then Sandoz is enjoined, e) if launch date occurs before injunction date and/or Mar-11 then case is dismissed w/prejudice, f) if on 31-Mar-11, injunction date has not occurred, the agreement will be terminated, g) no damages on sales before Feb-10 and until earlier of injunction date/launch date. Implication of this in our view - It is not clear if Sun will withdraw and we expect further litigation on this front. If Sun does not, all companies will likely get a chance to launch their own generics after 12-July. Those willing to take a risk may launch.						
14-Apr-10							
21-Apr-10	Courts accepts Sanofi's version of settlement, requiring Sun to stop selling like other companies						
30-Apr-10	Caraco files appeal with Federal Circuit						
20-May-10	Sun files motion to stay court's adoption of Sanofi's version of settlement, pending appeal						
	Court denies Sun's motion to suspend order and leave for expedited discovery, as Sun raised the same argument of "decision" not being consent judgment						
25-Jun-10	Stipulation of dismissal, against WCH						
26/31-Aug-10	Both parties have filed briefs with CAFC, Sun files reply brief also						
Sep-10	Court dismisses Teva case with prejudice						
10-Nov-10	Court dismisses Teva case with prejudice						
22-Dec-10	Appeals court rules in favour of Sun; vacates the consent judgment and injunction						

Source: FDA, Bloomberg, JM Financial (FA=final approval, TA=tentative approval)

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