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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

AMGEN INC. and AMGEN MANUFACTURING LIMITED,

Plaintiffs,

v.

SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH, and LEK PHARMACEUTICALS D.D.,

Defendants.

Case No. 3:16-cv-02581-RS

DEFENDANTS' MOTION TO SEPARATE EQUITABLE RELIEF

Date: September 14, 2017
Time: 1:30 pm
Ctrm: Courtroom #3

The Honorable Richard Seeborg

NOTICE OF MOTION AND RELIEF REQUESTED

TO AMGEN INC. AND AMGEN MANUFACTURING, LIMITED ("AMGEN") AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE THAT on September 14, 2017, in the Courtroom of the Honorable Richard Seeborg, located at 450 Golden Gate Avenue, San Francisco, California at 1:30 pm., Defendants SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH, and LEK PHARMACEUTICALS D.D. ("Sandoz"), by and through its counsel, will move and hereby does move, pursuant to Rule 42(b) of the Federal Rules of Civil Procedure and Civil Local Rule 7-2, to separate the issue of Amgen's entitlement to future injunctive relief, specifically for the accused product (peg-filgrastim) that will not have been approved for sale by the time of trial, until after trial on the validity of Amgen's patent and infringement of the patent. Under Sandoz's proposal, the jury trial would consider the factual issues of infringement regarding the two accused Sandoz products – filgrastim (an FDA-approved product on sale in the United States), and peg-filgrastim (a yet-to-be approved product) which has never been sold or otherwise marketed and of the validity of the asserted patent. If the jury finds that the Sandoz products infringe and that the Amgen patents are not invalid, it will also determine an amount of damages for infringement stemming from sales of the filgrastim product. Pursuant to the Biologics Price Competition and Innovation Act and 35 U.S.C. § 271(e)(1), there can be no damages from the proposed sale of peg-filgrastim, as there have been no sales, and the statute limits Amgen's right to relief to declaratory judgment and injunctive relief. After trial, the Court, not the jury, will determine whether Amgen also is entitled to injunctive relief. Separation of equitable issues concerning an injunction will not prejudice Amgen.

This motion is based on this Notice of Motion and Motion, the accompanying Memorandum of Points and Authorities, the Declaration of Brian Kramer in Support of Sandoz's Defendants' Motion to Separate Equitable Relief, and on all of the documents and records on file in this action and all matters judicially noticeable.

Dated: July 28, 2017

MORRISON & FOERSTER LLP

By: */s/ Brian M. Kramer*
Brian M. Kramer

Attorneys for Defendants
Sandoz Inc., Sandoz International GmbH, Sandoz GmbH, and LEK Pharmaceuticals D.D.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

This motion seeks to confirm that the Court will consider Amgen's entitlement to injunctive relief separate from the trial on the merits in this action. This step merely confirms this Court's typical practice. Juries in patent cases decide facts, namely whether a product infringes, whether a patent is invalid, and what, if any, damages to award for infringing sales. After a trial in which a jury makes its findings, the Court, not the jury, thereafter decides whether injunctive relief is appropriate. This is all Sandoz requests.

While the Court's practice is consistent with this motion, the issue has become the subject of a debate during discovery. In connection with competing motions for a protective order and to compel discovery that Amgen concedes is only relevant to injunctive relief, Magistrate Judge James considered the Court's existing scheduling order to incorporate the issue of whether injunctive relief is appropriate in a jury trial set for March 2018. (Dkt. 262 at 8.) Thus, Sandoz seeks to confirm that proceedings on the question whether an injunction is appropriate will follow the trial and thereby avoid what is both unnecessary and otherwise intrusive discovery into Sandoz's preliminary plans for the launch of a product that will not be approved by the FDA until 2019. This approach leaves at least nine months (and likely much more time) to resolve questions of injunctive relief with regards to the peg-filgrastim product. Discovery on Sandoz's current plans regarding peg-filgrastim will be stale by the time of trial, but such discovery of current, competitively sensitive information risks substantial harm to Sandoz in the interim. Sandoz has agreed to provide the discovery, if needed, after trial.

If Amgen wins, it will have more than nine months to pursue the discovery and seek injunctive relief. As a result, Amgen will suffer no prejudice from the consideration of injunctive relief after (not during) the trial. Amgen's right to seek injunctive relief will be unaffected, and Amgen will have more than sufficient time to seek relief well in advance of Sandoz's product reaching the market. Moreover, discovery instituted after trial in Spring 2018 will result in more current, more relevant information about expected market dynamics that will better inform the questions that the Court will need to address.

What Sandoz seeks is both modest and consistent with the normal practices of this Court. The jury cannot consider questions of injunctive relief regarding peg-filgrastim, and, for the reasons described in this motion, the Court should not do so until after Amgen establishes liability in a trial.

II. FACTUAL BACKGROUND

The parties' patent disputes involve two cases and two products. They reflect the first cases brought under the Biologics Price Competition and Innovation Act ("BPCIA"). One case (3:14-cv-04741-RS) involves filgrastim, a currently approved and marketed pharmaceutical product. This motion will have no effect on that case. The second case (3:16-cv-02581-RS) involves peg-filgrastim, a product that is still under review by the FDA. It is undisputed that peg-filgrastim will not be approved by the FDA until 2019. Until it is approved, Amgen's sole basis for relief is a claim for declaratory relief under the BPCIA. The present motion deals solely with when the Court will address a claim by Amgen for injunctive relief regarding this second product.

The two cases are not formally consolidated, but they are on the same discovery and trial schedule. In Case 3:14-cv-04741-RS, Amgen accuses Sandoz's filgrastim product of infringing two patents. Filgrastim is a product marketed by Amgen as Neupogen®, and by Sandoz as Zarxio®. Sandoz's Zarxio product has been on the market for more than one year. Trial on the two patents is scheduled for March 2018.

In Case 3:16-cv-02581-RS, Amgen accused Sandoz's proposed *peg*-filgrastim product (a pegylated form of filgrastim marketed by Amgen as Neulasta®) of infringing one of the two asserted patents, referred to by the parties as the '878 Patent. Based on the '878 Patent, Amgen seeks a declaration that one among more than 30 purifications steps that occur in connection with the creation of peg-filgrastim infringe its patent. This second case was instituted solely pursuant to the BPCIA. Pursuant to this statute and 35 U.S.C. § 271(e)(1), Amgen cannot seek damages. It can only seek only declaratory relief, and, assuming it is victorious in this claim, injunctive relief regarding when the product can be launched.

Sandoz filed for FDA approval of its peg-filgrastim product in July 2016. The FDA has delayed approval, and it is undisputed that Sandoz will not obtain approval to market the product

until 2019 or after. Sandoz has publicly told investors and the market that it does not intend even to renew its application until after 2018. (Brian M. Kramer Decl. In Supp. of Mot. to Separate Equitable Relief ("Kramer Decl."), Ex. 1 at 11.) To confirm that the status quo will remain unchanged until well after trial, Sandoz has also agreed not to launch its product until months after the March 2018 trial, eliminating any possibility that launch will occur before post-trial motions can be resolved. (Dkt. 263-6 at 3.) In light of this, the scope of the trial with respect to the peg-filgrastim product will be limited to a declaration of the validity of the '878 Patent and whether the accused purification procedures infringe. Because there are issues of liability that overlap with the filgrastim case, the Court has set the trial of these issues for March 2018, at the same time as the trial of the filgrastim case discussed above.

In the spring of 2017, Amgen sought discovery on the timing for a launch of Sandoz's peg-filgrastim product and Sandoz's internal projections regarding future financial results, future pricing and future unit sales for the peg-filgrastim product. (*See* Dkt. 263-6 at 1.) Sandoz opposed the discovery. (*See* Dkt. 263-6 at 1-2.) Sandoz argued that the information sought was very competitively sensitive and had limited distribution even within Sandoz and that the information was not relevant to any issue that would be addressed at trial. (*See* Dkt. 263-6 at 2-3.) In response, Amgen claimed that the information is relevant to Amgen's plans to seek injunctive relief regarding the peg-filgrastim product, assuming it is successful in proving that the '878 Patent is infringed at trial. (*See* Dkt. 263-6 at 5.) The parties addressed the issue to Judge James in competing motions. (*See* Dkt. 263-6.)

Judge James agreed that the discovery being sought by Amgen was relevant only to injunctive relief. (*See* Dkt. 262 at 7-8.) Nonetheless, absent confirmation from the Court that the question of Amgen's entitlement to any injunction will be handled in post-trial proceedings, Judge James concluded that Amgen was entitled to discovery about "Sandoz's expected peg-filgrastim approval, marketing and sales." (Dkt. 262 at 8.) Judge James found the existing scheduling order to incorporate Amgen's claims for injunctive relief in the jury trial set for March 2018. (*See id.*) Judge James's Order suggested that the Court's ruling would differ if Sandoz confirmed that the Court would separate the proceedings. (*See id.*) Rather than appeal Judge

James's ruling, Sandoz seeks confirmation on this issue through the present motion. If this motion is granted, Sandoz will renew its motion for a protective order and propose a plan to produce the requested discovery following any finding of infringement. (*See id.*)

III. ARGUMENT

A. Separation of the Issues That The Jury Can Address from Issues Regarding an Injunction Will Promote Efficiency and Judicial Economy.

Separation of issues pursuant to Rule 42 is appropriate when a separate trial will promote efficiency or avoid prejudice. Federal Rule of Civil Procedure 42(b) provides:

> For convenience, to avoid prejudice, or to expedite and economize, the court may order a separate trial of one or more separate issues, claims, crossclaims, counterclaims, or third-party claims. When ordering a separate trial, the court must preserve any federal right to a jury trial.

Fed. R. Civ. P. 42(b). District courts have broad discretion in deciding whether to separate the consideration of issues, "thereby deferring costly and possibly unnecessary proceedings." *Zivkovic v. S. Cal. Edison Co.*, 302 F.3d 1080, 1088 (9th Cir. 2002) (citations omitted).

Here, separation of the issue of injunctive relief from the issue of the validity and infringement of the '878 Patent as applied to Sandoz's peg-filgrastim product has precisely this benefit. If needed, the jury in March 2018 will decide the facts regarding validity of the '878 patent and whether Sandoz infringes the '878 patent by means of the accused AEX step. These issues must be decided before Amgen can seek injunctive relief for Sandoz's peg-filgrastim product. *See* 35 U.S.C. § 271(e)(4)(B) ("[I]njunctive relief may be granted against *an infringer* to prevent the commercial manufacture, use, offer to sell, or sale . . . of an approved drug") (emphasis added). If the asserted patents are invalid or not infringed, then there is no need to address injunctive relief. *See id.* Moreover, a jury cannot resolve questions regarding whether an injunction should issue and should not consider those issues in any event. *See, e.g., eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006) ("The decision to grant or deny permanent injunctive relief is an act of equitable discretion by the district court.") The jury's role is limited to determining the overlapping issues of validity and infringement that arise under the '878 Patent.

Further, even if validity and infringement were found, the issue of injunctive relief will not arise until well after trial. Sandoz cannot sell its peg-filgrastim product until the FDA approves it. In other words, it is already "enjoined" by the FDA from selling its product. That "injunction" will not be lifted until 2019, months after trial. These assurances are on top of the BPCIA's notice of commercial marketing provision which provides for 180 days' notice of an intent to launch, which Sandoz has not yet provided. *See* 42 U.S.C. § 262(l)(8)(A).

B. Separation of the Issue of Injunctive Relief Would not Cause Amgen to Suffer Prejudice.

Amgen will not suffer prejudice if the issue of injunctive relief were separated for trial or if Sandoz provided its limited discovery on commercial product plans after trial. The law is clear that Amgen has no entitlement to a jury trial for the issue of injunctive relief, as it is equitable in nature. *See, e.g., Tegal Corp. v. Tokyo Electron Am., Inc.*, 257 F.3d 1331, 1341 (Fed. Cir. 2001) (finding neither party entitled to a jury trial in a patent infringement suit where the only remedy sought by the plaintiff-patentee was an injunction and the defendant asserted only affirmative defenses and no counterclaims); *In re Apotex, Inc.*, 49 Fed. Appx. 902, 902-903 (Fed. Cir. 2002) (nonprecedential) (upholding order striking jury demand because patent owner had no right to money damages in case seeking only "declaratory judgment of future infringement"); and *Biovail Labs., Inc. v. Torpharm, Inc.*, No. 01 C 9008, 2002 WL 1732372, at *2 (N.D. Ill. July 25, 2002) (granting motion to strike jury demand where generic manufacturer had not begun any commercial marketing of its accused product). The issue of injunctive relief can only be resolved by the Court as necessary following the jury trial.

There is little to no overlap of evidence between the issue of injunctive relief and the other issues to be tried in March 2018. Any discovery sought regarding peg-filgrastim approval, marketing, and sales is irrelevant to the other issues set to be decided by the jury at trial, including filgrastim damages. By the time Sandoz renews its request for approval for peg-filgrastim, the entire filgrastim district court litigation will be complete. Further, if the jury finds that Sandoz's production of peg-filgrastim infringes the Amgen patent, Sandoz would agree not to launch its product pending proceedings on an injunction and to provide immediate discovery into the

financial projections and approval projections. (Dkt. 263-6 at 3.)

C. Separation is Necessary to Avoid Prejudice to Sandoz.

Failure to separate equitable relief would be highly prejudicial to Sandoz. As discussed above, the discovery sought by Amgen about (1) how much product will Sandoz sell, (2) what price will Sandoz set, (3) what markets will Sandoz target, (4) what market share does Sandoz expect to capture from Amgen, and (5) what costs will Sandoz incur, are among the most competitively sensitive information available to each party at this stage. Amgen cannot articulate any legitimate need for that information now beyond its desire to gather more competitive intelligence for settlement negotiations and other business planning. Sandoz concedes that the information Amgen seeks now is valuable to Amgen, but not for reasons that would help Amgen prove any of its claims or defenses at the March 2018 trial. Unnecessarily revealing this information to Amgen and, in turn, Amgen in-house counsel, will put Sandoz at a competitive disadvantage. *See Covance, Inc. v. Inclin, Inc.*, No. 16-CV-00429-YGR (MEJ), 2016 WL 5870011, at *2 (N.D. Cal. Oct. 7, 2016) (denying motion to compel sensitive business information because "the potential burden to Plaintiff in exposing its [trade secrets] to Defendants may be significant"); and *Gilead Scis., Inc.* v. *Merck & Co, 5:13-cv-04057-BLF*, 2016 WL 146574, at *1 (N.D. Cal. Jan. 13, 2016) ("[A] party seeking discovery of relevant, non-privileged information must show, before anything else, that the discovery sought is proportional to the needs of the case"). Moreover, providing the information now will require more depositions, more written discovery, and more general burden when the parties are busy preparing expert reports and otherwise preparing for trial.

IV. CONCLUSION

For the foregoing reasons, Sandoz respectfully requests that the issue of injunctive relief with regards to Sandoz's peg-filgrastim product be separated pursuant to Rule 42 from the remaining issues set for trial on March 26, 2018.

Dated: July 28, 2017

MORRISON & FOERSTER LLP

By: */s/ Brian M. Kramer*
Brian M. Kramer

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

AMGEN INC. and AMGEN MANUFACTURING LIMITED, Plaintiffs, v. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH, and LEK PHARMACEUTICALS D.D., Defendants.	Case No. 3:16-cv-02581 **DECLARATION OF BRIAN M. KRAMER IN SUPPORT OF DEFENDANTS' MOTION TO SEPARATE EQUITABLE RELIEF** Date: September 14, 2017 Time: 1:30 pm. Ctrm: Courtroom #3 The Honorable Richard Seeborg

I, Brian M. Kramer, hereby declare as follows:

1. I am a member of the bar of the State of California and am a partner with Morrison & Foerster LLP, counsel of record for Defendants Sandoz Inc., Sandoz International GmbH, Sandoz GmbH, and Lek Pharmaceuticals D.D. ("Sandoz") in the above-captioned action. I am admitted to practice before this Court. I have personal knowledge of the facts stated herein and, if called as a witness, I could and would testify competently to these facts.

2. Attached as **Exhibit 1** is a copy of a transcript of the Novartis AG July 18, 2017, Q2 2017 Earnings Conference Call. Novartis AG is the ultimate parent company of Sandoz Inc. During the conference call, Dr. Vasant Narasimhan, Novartis's Global Head of Drug Development and Chief Medical Officer, updated the public regarding Sandoz's planned pegfilgrastim regulatory filing. He said that Sandoz "shifted the date of [its] pegfilgrastim filing in the U.S. by a quarter to early 2019." After the regulatory filing, the FDA will take some time to consider whether to approve it.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed on July 28, 2017, in San Diego, California.

/s/ Brian M. Kramer
Brian M. Kramer

EXHIBIT 1

Seeking Alpha

Novartis' (NVS) CEO Joe Jimenez on Q2 2017 Results - Earnings Call Transcript

Jul. 18, 2017 1:49 PM ET
by: SA Transcripts

Q2: 07-16-17 Earnings Summary

Slides *Analysis* *News* *Press Release*

EPS of $1.22 beats by $0.04 | Revenue of $12.24B (- 1.8% Y/Y) misses by $-30M

Novartis AG (NYSE:NVS)

Q2 2017 Earnings Conference Call

July 18, 2017 08:00 ET

Executives

Joe Jimenez - Chief Executive Officer

Harry Kirsch - Chief Financial Officer

Vas Narasimhan - Head, Global Drug Development

Paul Hudson - Head, Pharma

Bruno Strigini - Head, Oncology

Richard Francis - Head, Sandoz

Mike Ball - Head, Alcon

Samir Shah - Head, Investor Relations

Analysts

Tim Anderson - Bernstein

Graham Parry - Bank of America

Jeff Holford - Jefferies

Richard Vosser - JPMorgan

Seamus Fernandez - Leerink Partners

Matthew Weston - Credit Suisse

Florent Cespedes - Société Générale

Ian Lee - Citi

Vincent Meunier - Morgan Stanley

Michael Leuchten - UBS

Stefan Schneider - Vontobel

Steve Scala - Cowen

Naresh Chouhan - New Street Research

David Evans - Kepler Cheuvreux

Keyur Parekh - Goldman Sachs

Kerry Holford - BNP Paribas

Operator

Good morning and good afternoon and welcome to the Novartis Q2 2017 Results Release Conference Call and Live Audio Webcast. Please note that during the presentation, all participants will be in listen-only mode and the conference is being recorded. [Operator Instructions] A recording of the conference call including the Q&A session will be available on our website shortly after the call ends. [Operator Instructions]

With that, I would like to hand over to Mr. Joe Jimenez, CEO of Novartis. Please go ahead, sir.

Joe Jimenez

Thank you. I would like to welcome everybody to our second quarter earnings call. Joining me on the Novartis side are Harry Kirsch, our CFO; Vas Narasimhan, our Head of Global Drug Development; and the four business leaders, Paul Hudson, Head of Pharma; Bruno Strigini, Head of Oncology; Richard Francis, Head of the Sandoz business, and Mike Ball, Head of Alcon.

Before we start, I would like Samir to read the Safe Harbor statement. Samir?

Samir Shah

Thank you, Joe. The information presented today contains forward-looking statements that involve known and unknown risks, uncertainties and other factors. These may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. Please refer to the company's Form 20-F on file with the U.S. Securities and Exchange Commission for a description of some of these factors.

Joe Jimenez

Thanks, Samir. Okay. Starting on Slide #4, Q2 was a strong quarter from an innovation standpoint as well as operationally. When you take into account the Gleevec patent loss, our sales were in line with prior year in constant currencies and this was due to the strong performance of our growth drivers, including Entresto and Cosentyx which offset the patent loss on Gleevec. Core operating income was also in line with prior year in constant currency and this was driven by gross margin expansion as well as our productivity efforts, which allowed us to offset both the generic erosion and the investments that we are making in some of our key launches. Now, that said, the best thing about the quarter really was the positive innovation news. So in this 3-month period, we saw 14 approvals and positive recommendations, we saw 5 filings and we saw 9 major trial readouts. I think this is a testament to the strength of the pipeline and it reinforces our growth prospects going forward.

You can see a snapshot of that innovation news on Slide 5. Vas is going to go through it in more detail, but I just want to pick out a couple of highlights starting with RTH and ACZ on the next slide. We have two head-to-head studies on RTH and neovascular AMD readout positively. RTH dosed on a quarterly basis delivered non-inferiority to Eylea dosed every 2 months. Full data will be presented at the American Academy of Ophthalmology Meeting on November 10. And then secondly, the CANTOS Phase 3 study also readout positively as you know making ACZ the first and only drug to show that targeting inflammation reduces cardiovascular risk in people, who have survived a myocardial infarction and full data is going to be shown on August 27 at ESC.

We also advance our cell therapy platform as you can see on Slide #7. And as you heard last week, the FDA Advisory Committee unanimously recommended approval for our CTL019 in pediatric ALL. We also though plan to submit in Europe before the end of the

year. And if it's approved, this will be a transformational platform for cancer care. At the same time, we are continuing to advance other indications, including DLBCL, which Vas will talk more about later in the presentation.

On Slide 8, you can see that Sandoz also had a strong quarter for innovation. Our biosimilars of etanercept and rituximab were approved and launched in Europe. We also submitted biosimilar applications for adalimumab and infliximab also in Europe. So, we are building some good momentum on this pipeline.

Now, switching gears to review the commercial performance on Slide 9, you can see that our key growth drivers were on track in the second quarter. In addition to Entresto and Cosentyx, we also saw good growth in oncology. So, if you take Gleevec out, the oncology business grew 9% in constant currencies in the second quarter with some very strong performance by Promacta, Jakavi and Tafinlar Mekinist combination.

On the next slide, you can see that Entresto continued to show steady growth with sales of $110 million in the quarter. This reflects positive dynamics in the U.S. who have made good progress on access. As of now more than half of the Medicare patients no longer need a prior authorization and more than half have co-pay under $10. Outside the U.S., we are continuing to make progress on reimbursement. So, that's helping sales as well. Overall, we believe we are on track to reach about $500 million in sales this year. Cosentyx had a strong quarter as well delivering almost $500 million in sales. This represents double-digit growth quarter-over-quarter. And importantly, the growth was driven by all three indications in both the U.S. and ex-U.S. I think we are benefiting from the best-in-class profile of this drug, which was further reinforced this quarter with data showing sustained efficacy out to 5 years in psoriasis and 3 years in the spot indications. With the momentum that we are building behind this brand, we see $2 billion of full year sales within reach.

Moving on to Alcon on the next slide, we continued to make good progress on the turnaround. The division delivered 3% sales growth in the quarter on a constant currency basis driven not just by Vision Care, but also by surgical. And within surgical, we saw growth in key segments, including IOLs, which grew for the first time since 2014. We are starting to see the uptick in new innovative products that we have launched including UltraSert, which is our preloaded IOL as well as PanOptix, which is our trifocal IOL, both of those in Europe and then ReSTOR +2.5 Toric in the U.S. Additionally, Mike and his team are continuing to improve the commercial execution and the customer focus.

And lastly, I would like to point out that we are really starting to see the benefit of the new organizational structure that we put in place a year ago shown on Slide 13. By integrating drug development, for example, we have improved the transition from early research to clinical development. And as a result, we have seen the number of projects moving from research to development double in the past year. Our progress in cell therapy is another example since we integrated the standalone unit back into oncology. There has been a step change in the speed of development and in our interactions with regulators. This is due to having the full weight of Novartis global functions behind this program. We are also seeing benefits and operations through NBS. We have been able to reduce our costs by streamlining processes and in manufacturing we are improving resource allocation and reducing our external spend, which is contributing to an overall improvement in gross margin.

So, with that, I am going to turn it over to Harry to take us through the financials in more detail.

Harry Kirsch

Thank you, Joe. Good morning, good afternoon, everyone. As usual, my comments refer to growth rates in constant currencies unless otherwise noted. Slide 15 shows the summary of our performance. We delivered solid performance in the second quarter with net sales of $12.2 billion in line with prior years as growth drivers, including Cosentyx and Entresto and the new oncology assets offset the decline of Gleevec. Core EPS was $1.22 growing 2%, including a benefit from the share buyback program announced in January. Net income was $2 billion growing 14% with prior year benefiting from the higher divestment gains and lower amortization. Finally, it was another strong quarter for free cash flow at $3.2 billion, growing 28%, more on free cash flow later on my presentation.

On Slide 16, I want to highlight the underlying sales volume of plus 6% and underlying core operating income growth of plus 21%. This enabled us to offset the generics and pricing impacts both on top and bottom line in constant currencies. Please note that the minus 3% pricing impact is driven by Gleevec generic price erosion and U.S. pricing pressure on our Sandoz generics division.

Now, let’s turn to margins on Slide 17, overall the group core operating margin was 26.4%, in line with the prior year. Innovative medicines, sales grew 1% and corporate income also grew 1% as gross margin expansion and productivity offset growth investments and generic erosion resulting in a core margin of 31.1%. Sandoz sales declined minus 4% mainly due to higher pricing pressure in U.S. retail generics and prior year launch timing.

As you are aware this is not specific to Sandoz, it is genetic industry wide affect in U.S. Sandoz core margin declined slightly despite gross margin improvements, mainly due to M&S investments including biosimilar launches. Alcon sales grew 3% in the quarter driven by Surgical, with growth in key segments including intraocular lenses. As expected Alcon core operating income declined due to the higher investments in M&S behind the growth plan. This resulted in the core margin of 13.9%.

Slide 18 shows strong free cash flow of $4.9 billion in the first half, up 26% versus prior year. This was driven by favorable working capital including lower payments from provisions compared with the prior year period and higher dividend from the OTC joint venture, partly offset by lower operating income. On Slide 19 you can see that net debt stood at $22 billion at the end of the first half. The increase was mainly driven by the $6.5 billion annual dividend payment and net share repurchases, partly offset by our half one free cash flow of $4.9 billion.

On Slide 20 you would see that our currency outlook is in line with the guidance provided on our website monthly. As mid-July rates prevail, the full-year currency impact is expected to be minus 1% on net sales and minus 2% on core operating income. On slide 21, I would like to turn to our full-year outlook. We are reconfirming our full year group guidance. Group net sales are expected to be broadly in line with the prior year and group core operating income is expected to be brought in line to low single-digit decline versus prior year. By division we are confirming the guidance for innovative medicines and Sandoz. For Alcon in light of the first half sales performance, we are revising the full year sales guidance upward to low single-digit growth versus prior year.

And with that I hand over to Vas.

Vas Narasimhan

Thank you, Harry. As Joe mentioned, we had a strong quarter for innovation at Novartis we had nine major approvals in the U.S. and Europe, five positive CHMP positive opinions, as well as the positive ODAC recommendation for CTL019, two FDA breakthrough therapy designations, five major submissions in the U.S. and Europe and nine major trial positive readouts, so an excellent quarter.

Moving to Slide 24, when you look at that quarter and the context of our progressing on a late stage development of potential blockbusters, in the quarter we were able to advance 5 separate assets with positive submissions, approvals or readouts. And I will be reviewing some of those updates over the course of this presentation. Moving to Slide 25, let's start with our immuno-oncology strategy. Now, as we have outlined to you in the past

there are three pillars to our approach to immuno-oncology leading in CAR-T, building on our own PDR001 or PD-1 backbone and continuing to advance our portfolio of the second generation IO assets. Our goal today will be to go through our CAR-T portfolio, but I would also like to provide an update on PD-1 where we have now advanced five separate indications including orphan drug designations in neuroendocrine tumors which the FDA gave us in quarter two. And the complete enrollment of our Phase 2 neuroendocrine tumor program trial.

Moving to Slide 26, as many of you saw and as Joe mentioned, we received a unanimous FDA advisory committee support for the profile of CTL019 for licensure in pediatric and young adult ALL. It's hard to underestimate I think the transformative impact this could have on the field where we are opening up a new era of oncology therapeutics that could have an impact on a broad range of cancers. It opens up an area of medicine and therapeutics that will allow us to advance cell therapies as an industry and as a company. Now, in terms of the specific takeaways from the advisory committee, there were three I wanted to highlight.

First the excellent efficacy the CTL019 demonstrated with 83% of patients achieving a CR or CRI within three months and 75% of patients were relapsed three at six months as you can see in the graph on the left. In addition, the near-term safety profile was viewed as well characterized and manageable, particularly given the algorithm that we have assembled with tocilizumab as well as a long-term risk management plan, which the committee endorsed for its ability to assess the longer term risks of this therapy. And finally, that our Novartis manufacturing process is robust with its ability to use cryopreservation and with our goal to get from clinic to clinic time of 22 days. One of the interesting things that happened in the panel was a patient story was brought up in which it was clear that cryopreservation is what allows the patient to be treated given the need for chemotherapy to assess whether or not transplant would be possible. I think it nicely highlighted why cryopreservation gives physicians flexibility, give patients flexibility and give our manufacturing footprint flexibility in order to have the global scale needed to provide this therapy to thousands of patient.

Now moving to Slide 27, CTL019 also had an important readout in June where we had the primary analysis of our DLBCL JULIET study. The 3-month and 6-month data from this primary analysis confirms the interim analysis with consistent results to what we saw at the interim analysis. There were no new safety signals detected in the study and we plan

to present the full results of this three-month and six-month update at a major medical congress in the fall. With this the primary analysis we are on track now to file in DLBCL in the U.S. in Q4 2017 and in DLBCL and pediatric ALL in the EU in Q4 2017.

Now moving to Slide 28, we are also advancing a broad portfolio of additional indications for CTL19 as well as our humanized CAR-T CTL119. We presented data at ASCO which showed that eight of the nine evaluable patients had no signs of CLL in their bone marrow at three months and for – in a refractory CLL population. These patients have been taking ibrutinib for at least the six months and were not in complete remission. So we look forward to continuing to advance this study and also to evaluate would there be the ability to discontinue ibrutinib after having CTL119 therapy. We are are also moving our CAR-T portfolio forward in earlier lines of therapy across B-cell tumors, expanding the range of B-cell cancers we will address with the therapy as well as advancing our solid tumor portfolio. So taken together, we believe now we have established ourselves as in the lead in CAR-T therapies when we look forward to advancing our portfolio well into the future.

Now moving to Slide 29, we also had other excellent pipeline achievements in oncology during quarter two. This included the positive CHMP opinion for Kisqali, the U.S. approval of Mekinist and Tafinlar for BRAF positive metastatic non-small cell lung cancer. We also received approvals for Zykadia in non-small cell lung cancer in the U.S. and EU in the first line for ALK positive patient. So overall, our oncology portfolio really shined in quarter two and we look forward now to advancing these therapies forward through the second half of the year.

Moving to Slide 30 as many of you saw on our CANTOS study read out positive for its primary endpoint and the full results as Joe noted will be presented at ESC on August 27. I wanted to take a moment to ensure that we will – had outlined again the design of the study and the secondary and exploratory endpoints in addition to the primary endpoint that we will be evaluating. Now patients enrolled in the study have a spontaneous MI at least 30 days prior to randomization and having elevated CRP. Patients were randomized to one of three different dose groups and with all of dose groups there was quarterly dosing and there was a placebo group as well. The primary endpoint was the classic MACE endpoint, but we also had important secondary endpoint looking at unplanned revascularization with or without hospitalization; mortality, though the study was not powered to look at mortality; as well as other pre-specified and exploratory endpoints, as you can see outlined in the slide.

We also had some important subgroups that are outlined on the Slide 31, and these are just the sample of some of the suburbs we will be evaluating in collaboration with the investigators. This includes looking at biomarker profiles and inflammatory cytokine profile. 10% of patients in the study had peripheral artery disease. 70% of patients were current or former smokers. 8% of patients had a previous stroke, or TIA. And I also wanted to note that in general, across the study, the patients were well-treated with standard secondary preventive therapies for this population. So we will look forward to providing all the full details on August 27 at ESC.

So moving to Slide 30. AMG 334 was submitted in the EU, and we believe, with this first-in-class therapy for migraine patients, we really have an excellent potential to address what is the significant unmet need. There are few elements of AMG 334, erenumab, I think that that are worth noting. First is the design of the antibody. This is a fully human potent antibody with low anti-drug antibodies, and it's a selective CGRP antagonist targeting the receptor. We believe that over time this could prove important in the persistence of response in these patients. The drug also had excellent efficacy with high response rates for the number of patients at a 50% reduction in monthly migraine days or a 100% reduction in monthly migraine day at month 15. In addition, it has a placebo-like safety profile that we plan to continue to establish over longer-term studies, and we hope to be first to market both in the U.S. and the EU.

So moving to Slide 30. There is, also, an important element I think of erenumab that will be important for payers both in the U.S. and in Europe. In patients who have previously had a prophylactic failure with a prior line of therapy, erenumab was able to show a 4.28-day reduction at the high dose, as you can see – in monthly migraine days, as you can see on the graph on the left. In addition, with patients who had overuse of prior lines of therapy, there was also an ability to reduce monthly migraine days, as you can see on the right. So we continue to advance this program. We also continue to launch additional studies to support the profile of erenumab, and we will look forward to advancing this filing towards an approval next year.

Moving to Slide 34. As Joe mentioned, the Cosentyx profile continues to be built out with strong long-term data. We released three-year data in ankylosing spondylitis, which showed an excellent sustained improvement in ankylosing spondylitis over the timeframe. Additional data we released as well in the quarter showed rapid and sustained pain relief in psoriatic arthritis. And in addition, we released five-year data, which showed that in psoriasis patients, we continue to maintain an excellent response with an excellent safety profile. We updated the label in the EU with head-to-head superiority data versus Stelara,

and we continue to advance our ongoing trials in non-radiographic axial SpA as well as head-to-head superiority data versus adalimumab. So again, Cosentyx continues to demonstrate that it can have a consistent response over time with excellent safety that provides patients and providers what they are looking for in such a medicine.

Moving to Slide 35. We also announced in the quarter that RTH258 hit its primary endpoint in both the HAWK and the HARRIER studies. I wanted to take a moment to go through with you the design of these studies, because I think that's been a question on many of your minds. There were two studies with identical endpoints with the only different that in HAWK we included a 3 mg dose arm. As you can see in this diagram, each colored box represents a dose of either RTH or aflibercept at specific time points. You can see that all patients in the study received loading doses at 10.0 week 4 and week 8. After week 8 and week 16, RTH patients were assessed for whether or not it would be appropriate to move to quarterly dosing based on an overall disease activity assessment, and this was also adjudicated by a central reading group. After that point in time, patients were followed over the course of the study with the primary endpoint at week 48, and an extension study will continue and with continued blinding out to week 96.

So when you look at the specific endpoints in this study, you can see on Slide 36, the primary efficacy endpoint was changed in best-corrected visual acuity from baseline to week 48, and there we demonstrated non-inferiority to aflibercept with highly significant p value. In addition, secondary endpoints included change in visual acuity over the last 12 weeks of the study, where we also showed a non-inferiority with highly significant p values, as well as the proportion of patients over the entire study from the start to week 48 that were on quarterly dosing with RTH, with 52% and 57% of patients on quarterly dosing. We also had additional efficacy endpoints that were in both studies and pre-specified, which include the anatomical parameters of disease activity, global disease activity assessments as well as patient-reported outcomes, and we'll look forward to presenting that data at AAO in the fall. And finally, the safety and tolerability of RTH versus aflibercept was similar both for ocular and systemic severe and non-severe adverse events. So given all this, we have made the decision now to move forward on the DME and RVO studies, and we will look forward to starting those studies later this year. And in addition, given the ongoing efforts, we have to finalize the manufacturing platform for the asset we plan to file in the second half of 2018.

Moving to Slide 37. As Joe mentioned on biosimilars, we have two marketing authorizations and two submissions in Europe in Q2, and we continue to advance the portfolio of biosimilars assets, as you can see on Slide 38. We are on track to file

adalimumab in the U.S. in 2017, in the second half. We are on track to – in addition to file pegfilgrastim in the EU and the second half of 2017, we have shifted the date of our pegfilgrastim filing in the U.S. by a quarter to early 2019 in order to accommodate a change in the study design.

Overall, on Slide 39, you can see we are making strong progress across our entire portfolio, as with the data we have in hand, we are confident we can deliver the second-half milestones in development for Novartis.

So, thank you very much. And with that, I'll hand it back to Joe.

Joe Jimenez

So to summarize, we had a strong quarter in Q2, and we are on track to deliver our objectives for the year. And now I would like to open the call to questions.

Question-and-Answer Session

Operator

[Operator Instruction] The first question comes from the line of Tim Anderson from Bernstein. Please go ahead.

Tim Anderson

Thank you. A couple of questions on the CANTOS data. The size of the target market where that product will be launching is enormous, but investors perceived Novartis is being is cautious about the commercial opportunity, and I can envision several reasons why that might be the case. But can you provide us with more detail on how you are currently thinking about the commercial opportunity? And second question is onimmunooncology, are you happy with where you are with your IO efforts when you consider both the drug and cell-based platforms you have? As you likely know there has been speculation for quite some time that you have to essentially buy one of the bigger players to really be relevant, that you cannot catch up to competitors otherwise, how strongly would you repeat that claimed or do you think there is some truth to that?

Joe Jimenez

Okay. We will start with Paul on CANTOS.

Paul Hudson

So thanks, Tim, for the question. We get the data in just a few short weeks. And as you can imagine, there is a great deal of data. And as Vas said in his presentation, there are some pre-specified endpoints in secondaries. So we are going to take a good look at that. And as we shed that and additional subgroup data at ESC, we will be better able to calibrate the value proposition for payers and patients alike. Then we will probably be able to recognize what we think the opportunity could be.

Joe Jimenez

And Vas, on IO.

Vas Narasimhan

So in IO, as you heard, I mean, we're continuing to advance our portfolio. We believe we have an outstanding portfolio in CAR-T, our IO. Our PDR001, our anti-PD-1 antibody, is in a good place, and we are moving quickly now towards the files. And I think our second-generation IO assets – the portfolio we have built is second to none. So we feel very good in the place we are currently at with our immunooncology portfolio.

Joe Jimenez

Next question, please.

Operator

The next question comes from the line of Graham Parry from Bank of America. Please go ahead.

Graham Parry

Thanks for taking the question. So firstly on RTH258, what sort of label you would be expecting regarding dosing and would you expect something that reflects the Phase 3 trial? Are you effectively start with the 12 week of after the initial run-in and then intensify dose progression. And if that was the case as every physicians would be vary of starting therapy as they usually prefer to start with higher intensity and then extend treatment duration over time, but not see any deterioration in the patients? And then secondly on canakinumab and patent expires, I believe in late 2024. So, do you think you can get any extra IP on that? And if not what sort of profit you are making in the current indications and do you think if you went after a broader CV population that lowered the price that you could actually get this to profitability before patent expiry. And is that essentially why you are looking at subgroups that perhaps you could charge the existing higher price, but in

the smaller patient population? And then third and finally just on Sandoz U.S. generics or U.S. down 15% year-on-year, is there any respite on this or do you think that's an ongoing trend with the pricing in generics in the U.S. market now? Thank you.

Joe Jimenez

Vas on RTH?

Vas Narasimhan

Yes. On RTH, Graham, our plan would be to pursue labeling similar to what you have seen with other approved agents, where I think the various different regimens would be included in the indications they have been and it will be the physician's judgment to determine how best to treat the patients. And I think that's how we have designed the study as well to give the option to intensify therapy as that's desired. I think on the canakinumab IP right now, you are correct that the LOE at the end of 24 in the U.S. and 25 in the EU, however, of course that doesn't take into account many of the secondary IP that we have as well as the fact we will continue to look to file additional IP as we have more and more data come through from the CANTOS study. In addition to our knowledge, there is no biosimilar in the clinic for canakinumab. And I think on the broader CV indication, I will move it up to Paul.

Paul Hudson

Nothing I want to add, I think in terms of the broader CV indication, I think maybe just a quick comment on the RTH piece and the loading, I think we expect to be uniquely positioned post loading with our data. And don't expect anybody to be able to get there within the first year on load.

Joe Jimenez

And Richard, on U.S. pricing?

Richard Francis

Yes, I think Graham, as Harry mentioned, the whole sector in generics is feeling pricing pressure in the U.S. and this has been clearly shown in IMS data, which shows high single-digit decline. We don't – we felt that a bit more severely with our dermatology business, which was what we saw number of entrants come in. And to answer your

question, we see pricing pressure as a way of life, particularly in the generics business particularly in the U.S. And so we continue to execute our strategy of driving a differentiated portfolio based on biosimilars of 505(b)(2)s to offset that pressure.

Joe Jimenez

Next question please.

Operator

The next question comes from the line of Jeff Holford from Jefferies. Please go ahead.

Jeff Holford

Hi, thanks for taking my questions. So, I think most of the investors took home from the Meet Management Day that whilst you are committed to the process of strategic review and separation of Alcon, you don't want us to necessarily think for now that this could come as early as 2018 when your data is towards the end of the year? Maybe you can add some more color on that in light of the second quarter results, which must have been fairly pleasing to you? And then just secondly for Harry, you do seem to keep delivering incremental beats on core operating margin as the last few quarters have been progressing? Is this just some positive phasing in the last few quarter or do you think the underlying level of the efficiency programs are beginning to deliver above your expectations and can we expect more of this heading into 2018? Thank you.

Joe Jimenez

Thanks, Jeff. Okay. Starting with the Alcon review, as you know at the beginning of the year, I announced that we are taking a strategic look at Alcon. We are going to review all options, including keeping the business up to and including a capital markets exit. Now, the good news is – and Mike has said this in the past as you can't really call the quarter when the thing is going to start to turn, but we are starting to see some good momentum quarter-on-quarter sequentially that makes it feel like this is the beginning of the turn which is quite positive. And the thing that I would say is that this does increase optionality right, were we to move towards the capital markets exit, where we spun the business, let's say, we have to show a few quarters of solid sales growth as well as we would have to get that margin deterrent. So I don't want to speculate on timing other than the fact that I have said we are going to give an update at the end of the year and we will update you on the review at that time. Harry, on core EPS?

Harry Kirsch

Yes, thank you Jeff. So certainly we have been pleased with the progress we have made on core operating income and quarter one being flat ahead of what we mentioned in April. When we look at the first 6 months, we are at minus 2% in constant currency and core operating income, so we are right in line with our full year guidance. And it's due to two things. Number one, very good momentum mainly on the innovative medicines, key growth drivers, Alcon returning a bit earlier and on the other side also the new company structure is delivering be it on the development productivity as well as on MBS and technical operation manufacturing. So, we are pleased with the progress, but we are only half year way – halfway through. And I think we are making good progress towards delivering this year.

Joe Jimenez

And I would only add that longer term we have told you that we are not happy where our margins are and that is why we made the changes that we did structurally to this company. And so you are starting to see it in global drug development with the reduction in total spend if you look at the P&L. You are going to see more in operations. You are going to see it manufacturing. And this is a multiyear effort to improve margins of the company. Next question please.

Operator

The next question comes from the line of Richard Vosser from JPMorgan. Please go ahead.

Richard Vosser

Hi, thanks for taking my question. Couple of questions on Alcon please. First of all, how sustainable do you see the IOL growth. I think the base comparison was a relatively weak one. So, perhaps you could talk about the main drivers of growth for the IOL, please? Secondly, just on the margins of Alcon, I think we were expecting spends to be higher than last year in the first half then plateaud. So, are we at this trough margin level now and we can see some improvement in the second half? Then a couple of questions on Sandoz, just perhaps if you could give some color on the interactions with the governments and payers on Rituxan biosimilar in Europe and how we should think of the uptake in the second half of '17 and perhaps an update on the Glatopa 40 milligrams manufacturing remediation discussions with regulators in the U.S. as well? Thanks very much.

Joe Jimenez

Hey, Mike, on Alcon.

Mike Ball

Let's talk about the IOL to start off. So, let's talk about the IOLs to start off. So, the IOLs as Joe said this is the first quarter of growth since 2014. And what I said early on in taking over this position is that we had to come back to supply and service excellence as a condition to get this business turned around. And I also said it would take some time. And as I now look at supply and service, I am very pleased as to where we are. If you look at our intraocular lenses, service level right now we are up over 99%. If you look at custom packs and you recall that I talked about custom packs before as being a real issue with the sales force, we have the issues on those down by 90%. Now in fact, the condition we are in, in the second quarter is the best we have ever been since we started tracking them. And overall, back orders are down 50%. This has allowed our sales representatives then to get back into the office and start selling again and also to start going after new accounts, recall that in the past has been a defensive posture, it's not allowed them to either sell to current accounts really or certainly go after new accounts. So, having the base fundamentals then fix to a large degree has allowed them to get back out there. And as they have got back out there, they also have some new technology to talk about. Joe alluded to it in the United States we have got the ReSTOR Toric 2.5 and 3.0 out there. And those lenses seem to be getting some traction. Recall that one of our major competitors, Symphony has a Toric multi-focal lens as well and the fact that they have had a whole line and we really did not make for better fight. So, we have now leveled the playing field and the representatives I believe are taking full advantage of that. So, they are moving forward in the U.S. And what you find is once you start having success in these lenses, there is a halo effect around all of the products. So, I feel like in the U.S. we are starting to make a move. Now, I am not declaring victory on IOLs right now, what I would say is that we have stabilized the situation, I am looking forward to continuing quarters and we will see what happens, but I feel stabilization has come about. Outside the United States, we have got UltraSert, which seems to be going very well, as well as PanOptix and a PanOptix Toric that we are launching. So, as I step back and look at the IOL situation, I feel like again we are turning the corner there. We have got some stabilization likely to be bumpy over the next few quarters, but so far so good on that side.

Joe Jimenez

And top margin?

Mike Ball

And then on the margins I have consistently said that 2017 will be a year with trough margins. We are looking to invest to continue to drive this turnaround. I would describe our situation has not turned around, but turning around and we need to keep the pedal to the metal in terms of driving that top line. As we move forward, I think you will find we will get a more efficient spend from two ways, one is by moving expenses from internally focused to externally focused, but also, I would say that we will gain, I think some momentum from the top line, which will contribute then to the margin expansion and ultimately where we want to go to is a place where most of the industry is right now, which is over 20% margin over the longer term.

Joe Jimenez

Okay. Richard on Rituximab?

Richard Francis

Yes, hi, Richard. So, first of all, I'll just start by saying that with the launch of etanercept and rituximab in the EU. We are now the only company with 5 biosimilars out there in the market. And so your question was how is rituximab being received? Well, it's only 2 weeks in. So, let me just preface it with that. But the reception receiving from physicians and payers and key stakeholders is very positive. And I think a lot of that is because of the work we have done with our heritage of making sure people understand the value proposition of biosimilars, which is becoming something which people are really understanding. So I feel very positive about that, but very early days.

Joe Jimenez

Now, on to your question on Glatopa 40 milligrams, obviously this is something we are very keen to bring to the market in the U.S. for both patients and payers and we are working very hard with the FDA as well as Pfizer to our third-party manufacturing to make that happen. We continue to do that. But as of now where there is no further news and update on that for the full year. Thank you. Next question please.

Operator

The next question comes from the line of Seamus Fernandez from Leerink Partners. Please go ahead.

Seamus Fernandez

Thanks very much. So, maybe the first question for Joe. Joe, I think you gave us a good assessment of the timing of updates for proposals with regard to pharmaceutical pricing. Just wondering if what your sense is in terms of the proposal and again how you see things moving forward with the U.S. ACA from here? And then the second question is gross margins were, I think unusually strong this quarter or looked unusually strong this quarter relative to our expectations. I am just hoping you could give us a sense of the impact of mix versus currency on that, Harry? Thanks so much.

Joe Jimenez

Okay. Thanks, Seamus. Look, in terms of the proposals coming out of the administration, we still haven't seen anything and it would be premature to speculate on what it's going to look like. We have made our points very strongly and I think successfully around the fact that we have to shift to value-based pricing in the U.S. and there are number of regulatory hurdles that prevent us from doing that such as Medicaid best price, anti-kickback in terms of how you contract, if you are not contracting for something that's in the label, that gets in the way of an outcomes based contract. And the administration has been quite receptive to listening to that. We have also made pretty pointed effort around the supply chain and how pharmaceutical companies capture about 62% of the total price of the drugs and that we would – it will be good if more of the rebates were reflected down to the patient level. So, I don't know what's going to come out. All I know is that we have made our case sense. We probably will see relatively shortly. In terms of the overall ACA repeal and replace, your guess is as good as mine in terms of what's happening now because we are saying the early news today. So, I just cannot speculate. The thing that the industry is doing in and we are doing at Novartis is we are all about access, patient access to innovative medicine. So, whenever we are on the hill or we are talking with policymakers, we talk about the fact that we need to ensure that Americans have access to innovative drugs and that's kind of our compass and that's what we are going to continue to advocate. Harry, on gross margins?

Harry Kirsch

Yes. On the gross margins overall, when you look at the total group came down a bit, very little in terms of currency, but most of it was mix, but also some contribution already from our centralized manufacturing.

Joe Jimenez

Next question, please.

Operator

The next question comes from the line of Matthew Weston from Credit Suisse. Please go ahead.

Matthew Weston

Thank you very much. A number of questions if I can. The first around Cosentyx, clearly, a very strong performance and good momentum. At the end of the quarter, we also saw with J&J's guselkumab approved. And Paul, I'd just be interested in your thoughts and albeit early as to how you see the 2018 competitive environment changing? I am aware that clearly you are negotiating for formulary access right now and whether you expect that to impact or whether or not you think 2018 is unlikely to see incremental competition? And Mike, I would be very interested to understand around whether or not you have seen any change in the competitive environment, which has allowed Alcon to grow. I am aware that the AMO acquisition by J&J took place at the end of Q1 and I just wonder whether or not you have seen a disruption in one of your key competitors, which is allowing you to take a foothold? And then finally just a quick question Vas alluded to the delay in Neulasta to 2019. Can you just give us a little bit more detail about what the change in the clinical trial is that's led to the delay? Many thanks.

Joe Jimenez

Okay. Paul?

Paul Hudson

Matthew, thank you for the compliments on Q2 Cosentyx performance that we are pleased actually with the progress we are making just some headlines actually to put some context around it. We have a good, stable position in psoriasis and we are growing as – I think Joe mentioned we are growing across all three indications in all geographies. There is of course new competition. I think we have tried to remind everybody continually about the opportunity outside psoriasis as well, which is psoriatic arthritis and ankylosing spondylitis. We have a reasonably unique position. You mentioned guselkumab specifically don't think it raises the bar in efficacy at least that's what I heard at the ADV last year. No surprises in the label and probably no entry into ASO PSA before 2021. So, we have a very good run and exclusivity just versus Lilly over that period. In terms of the 5-year data that we brought out at the end of last week, I think it's also worth reminding ourselves that we have a very well differentiated product profile. So as we get into access the 2018 we are

feeling comfortable with the conversations we have had at this point. We are the incumbent of the next generation of medicines and we do have some scale. So we are optimistic about what that means for our performance through 2018.

Joe Jimenez

And Mike on competition?

Mike Ball

Yes. From a competitive environment standpoint, we do see formidable [indiscernible] of our competitors. So, if you look at our growth, I don't think it will do.

Joe Jimenez

Go ahead.

Mike Ball

So I was saying on the competitive environment then, so I think it's a minimal disruption that we have seen in the marketplace. And that as you look at our growth, I don't think it was really due to disruption of the competitive environment.

Joe Jimenez

Okay. And Vas on Neulasta?

Vas Narasimhan

Yes. Neulasta is a pegylated product Matthew as you know and this is a very complex biologic, which I think number of companies have struggled with and it's really manufacturing and we have solved those problems, but along the way, we needed to do additional PK studies. We have completed the PK study for Europe and that looks very good. That's why I am confident and are being able to file in the second half of this year in Europe. We had to run a separate PK study for the U.S. And given the result from Europe, we have just resized the U.S. study to give ourselves a plenty of margin to be successful, which is why the readout got pushed back a quarter and the filing got pushed back a quarter.

Joe Jimenez

Next question.

Operator

The next question comes from the line of Florent Cespedes from Société Générale. Please go ahead.

Florent Cespedes

Good afternoon, gentlemen. Thank you much for taking my questions. Three quick ones. First for Mike, I think we said that Alcon is returning to growth earlier than expected, so please Mike, could you confirm that you are ahead of schedule? And is it fair to say that the second half of this year, you will have a more favorable comparison base which will be very easier to grow. Second question for Richard, despite the U.S. – the pressure in the U.S. markets the margin remains above the 20% mark. Is it sustainable or is the margin of the second quarter is helped by some one-off? And my last question is for Bruno. Bruno, could you give us an update on the key Kisqali launch and also some color, the feedback from some doctors about the money going of the side effect, and also if the callback is a good element of differentiation versus your main competitor? Thank you.

Mike Ball

So from an Alcon standpoint, I feel that we are I feel that we are moving forward much as we have planned. You know I have said at the outset was that we need to get the vision care business turned first and that it would respond the soonest to direct to consumer investments, et cetera. That would take a while for the surgical business to follow along as we fix the supply and service issues and got the sales force back to selling. So from that regard, I feel very good about where we are. As I look forward to the rest of the year, Harry said, we are taking guidance up to low single digit. So beyond that, I'm not going to comment on the rest of the business in terms of what we are actually going to sell from that standpoint. But as I look at market shares, so you talked about year-to-year comparisons, the market shares are really what I'm looking at and I'm seeing some nice stabilization. Certainly, in the contact lens area, you recall that I have said previously that contact lenses in the United States have gone down in terms of share for 14 consecutive months between mid-'15 and mid-'16, and now we are on a stabilization and actually a bit of a winning trend in terms of market share in the United States on contact lenses. As I look at intraocular lenses, we still don't have second quarter data, but first quarter data indicated some sort of stabilization. So we are looking forward to the second quarter data, and what I'm looking to see is, have the ATI well-started to move forward and are we seeing either more stabilization or maybe, perhaps, share growth as we move forward.

Joe Jimenez

Richard, on margin?

Richard Francis

Thanks for the question. So around margin, yes, it is a ambition to, obviously, grow margin long term. That said, as Harry mentioned, we are in the process of launching biosimilars and we got more biosimilars to come in reference to the findings that the Vas talked about, and that requires investment. So we need to balance making sure we maximize these assets with the investments we need. And we also are investing in our branded generics business and the rest of world, which is why we are seeing some solid growth there. So I would say the margin is something which long term we want to grow, but we got to be mindful of the assets we have to launch. And I probably end with the fact that if you look at our gross margin, we are seeing some positive movement on that, and that reflects the strategy we have been executing around making sure we are focused on the right products, the right portfolio as well as the right markets in right geographies, which allows us to have that improvement in sales mix that helps our margins. So I think that hopefully answers your question.

Joe Jimenez

Yes. And the only thing I would add to that is you are right in your observation that even in the face of pretty significant price decline, we are able to maintain margin or grow gross margin on Sandoz because of those two reasons: mix, and Richard and his team are doing a good job to push that mix towards biosimilars and then secondly, cost. So it is very aggressive cost program, and we are going to continue to maintain that. Bruno on Kisqali?

Bruno Strigini

So, Florent, in terms of performance of Kisqali, it is still early days as we are in the PI launch phase. We are planning to launch of full commercial campaign once our FDA material has been approved, and that should happen later on this summer. We are also working on coverage. And today, we are at about 50% of coverage, and we anticipate that we will be at 80% in the fall, probably in September. And we are utilizing samples, vouchers and also Access programs to expand our patient base. Regarding feedback from the medical community, physicians like choice and they welcome the options of another the CDK4/6. They are responding very positively to our message around efficacy and convenient dosing. They appreciate, also, the Kisqali Femara Co-Pack, which allows the patient to not have second co-pay, and that spectrum of convenience is perceived as being very important. Finally, regarding the side effects and particularly ECG monitoring,

most oncologists find it manageable and are familiar with it. And as you know, there are approximately 20 products today, oncology products, that require ECG monitoring, and that includes a large product like Herceptin.

Joe Jimenez

Thanks. Next question, please?

Operator

And the next question comes from the line of Andrew Baum from Citi. Please go ahead.

Ian Lee

Thank you. This is Ian Lee speaking on behalf of Andrew Baum. Two questions, please. So first, now that you are very close to the approval of our CAR-T therapy CTL019, could you maybe outline the U.S. payment model for this new class of drug? How should we think about the reimbursement process? Do you believe pay-for-performance may be the best strategy here? Is there any other option if you could highlight? And the second question. Could you possibly provide an update on your plans for the Roche stake, if any? We are curious because you are now starting to launch biosimilars that could impact Roche's top line. Any thoughts around this would be very helpful. Thank you.

Joe Jimenez

Okay. Bruno on CAR-T pricing?

Bruno Strigini

So we are looking at a number of options, including health economic models and also outcomes models that consider the significant value CTL019 brings to patients, its scientific innovation and the high cost of manufacturing. We will disclose the price at the time of launch of the product. In terms of Access, our team has started to provide appropriate information to payer describing the patient population unmet needs, limited treatment options for eligible patients and manufacturing process. We believe that like for and Allogenic transplant, Access coverage will be determined on a patient-by-patient basis and payers are used to take rapid decisions for these types of patients.

Joe Jimenez

And Harry?

Harry Kirsch

Yes, on the Roche stake, no update. It continues to be financial investment with a strategic element to it. We look for ways to maximize shareholder value on it.

Joe Jimenez

Okay. Next question, please?

Operator

The next question comes from the line of Vincent Meunier from Morgan Stanley.

Vincent Meunier

Hello. Thank you for taking my questions. Actually, a few follow-up questions on Alcon, ACZ and RTH. On Alcon, thank you for your comments on the margins, but do you need to invest more? Or do you think that now it is enough that to drive the recovery of the top line and bottom line? The question on ACZ is, I mean, we understand that you are probably moving towards a high-price, low-volume positioning, given the selection of specific subgroups and the use of biomarkers. Even if the indication is different compared to THF, what have you learned from the commercial launch of ENTRESTO, which will be applicable for the launch of ACZ and the positioning of ACZ, including the price? And last question on RTH, is it possible to further extend the dosing for the DME and the RVU trial or would you prefer to secure the quarterly dosing and what about the commercial operations in the U.S.? Thank you.

Joe Jimenez

Okay. Mike, margin?

Mike Ball

Okay. So, again, with respect to margin, what we are looking at again is '17 being the trough for this – for the – for Alcon, so obviously we are looking to build it going out. I do believe that what we are doing is the right thing. It takes a lot of efforts to get a declining business turned around and headed in the right direction. So if this business was already heading in the right direction, then we could say we would need as much funding behind it as something that needs to be turned around. So that would be kind of my net-net on your question.

Joe Jimenez

And Paul on CANTOS?

Paul Hudson

So, I think, on lessons learned, I think we were – we are being appropriately reflective on the data, and we will get more of it, as I said, at ESC. The subgroups and the pre-specified secondary endpoints are coming into the dialogue as much driven by payers, frankly, and patient need as much by ourselves. And so I think we want to see the data. We want to see the value proposition, because when we look at recent cardiovascular launches right across the industry, that is where payers have taken that into more specific group. So we are open-minded clearly on the opportunity, but we do need to make sure that we have the right value for the right patient group, and more to follow after ESC.

Joe Jimenez

Vas on RTH?

Vas Narasimhan

So RTH. First, let me highlight again that we ran a prospective randomized study with RTH in order to update the dosing and why, I think there is a lot of discussion in the market about using alternative post-hoc analyses of extension study. Just want to highlight again that our study here was a prospective randomized pre-agreed with FDA with two separate trials that replicated the analysis as pre-specified. Then when you think about extending dosing we are certainly evaluating all options in DME and RVO. Right now our base plan is to go with quarterly dosing, but my teams are currently assessing what other options might exist.

Paul Hudson

And then – the final comment about commercializing RTH and that you know was the final question and just to be really explicit that Roche, there were no obligations to Roche on RTH. And so let's stop there. We fully intend to maximize both assets. And in the U.S. this will be the first time for us with RTH in the U.S. market a $4 billion, $5 billion wet AMD market in retina. And we are excited about what we can do. We look forward to the rest of the data and we will take it from.

Joe Jimenez

Okay, next question, please.

Operator

The next question comes from line of Michael Leuchten from UBS. Please go ahead.

Michael Leuchten

Thank you. A question for pharma, one for Alcon and one for Sandoz please. On pharmaceuticals they innovative medicine, could you tell us please what percentage of your interest of patients are currently Medicare. The Alcon question just going back to the margin profile, I am sorry, just the comment in your interim report obviously that R&D phasing I was wondering if you could elaborate on that given R&D was down I think 6% or 7% in Q2. And then on Sandoz, could you explain why you selected the UK and Germany as selected countries for your Rituxan biosimilar launch, why aren't we seeing a broader launch across Europe?

Joe Jimenez

Paul?

Paul Hudson

So about two-thirds of interested patients are to Medicare and also worth noting is that over 50% but closer to 60 of prior authorization in the Medicare patient population and over half have less than $10 co-pay. So we are well positioned in that group.

Joe Jimenez

And Mike on R&D phasing.

Mike Ball

So from an R&D standpoint, this is simply a timing issue. We are looking for R&D to be very much in line with what we spent last year, so just simply a timing issue.

Joe Jimenez

And Richard on UK, Germany.

Richard Francis

Yes. So I mean how we think about our launches is about a number of factors. One is, obviously two speed of access we can get to the market both in reimbursement and access to the patients that's one. But I think you will see actually make ready for a speedy rollout across some of the other countries. So I wouldn't read too much into it. Obviously the opportunities we had in Germany and the UK once we can take on pretty quickly that's why we have had it there. But we will begin to other geographies in the not too distant future.

Joe Jimenez

Okay, next question please.

Operator

The next question comes from line Stefan Schneider from Vontobel. Please go ahead.

Stefan Schneider

Yes. Hi and Thanks for taking my questions. Just back to RTH258, I just wanted to know with the current treat and extend protocols that are being applied you get about an average of five injection per year but sentimentally yes, so that's almost the three months, so do you think you can make a clinical impact with the label you are striving for. And secondly on manufacturing, can you give us that – this update on that and what is the form you are going to be coming out with this, that a pre-filled syringe or can you comment on there. And lastly European – in Europe can you comment on what – whether you will be launching there and whether you have any obligations related to the current contacts with Genentech?

Joe Jimenez

Vas?

Vas Narasimhan

So for RTH258 I mean FDA currently requires fixed dosing protocols to the best of our knowledge in order to update labeling. So that's why in all of our studies we always have fixed dosing, which is what FDA's expectation is in terms of labeling how products are going to be ultimately used. And we do believe the labeling will matter in terms of guiding how physicians ultimately use the product. In addition, it's important to know we had a range of pre-planned, pre-specified secondary endpoints in both studies that look at a variety of efficacy parameters including anatomic into these activities for efficacy parameters. And we will be – look forward to sharing those at AAO and I think those will inform physician decisions. In terms of manufacturing, the important thing to note here is that there is only one change we have made to the manufacturing process. They keep the same cell line, we keep the same formulation, what we have changed is the scale of with which we produce the drug substance which is important for the scale up and the potential for this product to enable us to have adequate supply chain, as well as appropriate COGS. And so with that we expect to have to run an additional PK bridging study. But that would enable us to file in the second half of 2018. I will hand over to Paul on Europe.

Paul Hudson

Yes. So as I have mentioned a moments ago Roche have no right on RTH, so we will fully maximize RTH in Europe and the entire world in fact and of course we will be maximizing Lucentis and this provision for us to do that in the contract. And just a couple of additional points on the COGS I think the – whilst it's a little bit of time until we – until we file the benefit in COGS I think will allow us some additional commercial flexibility that we will be glad that we have taken the time to get as we get into competitive market.

Joe Jimenez

Next question please.

Operator

The next question comes from the line of Steve Scala from Cowen. Please go ahead.

Steve Scala

Thank you. I have two questions, first on RTH258, we show non-inferior to Eylea, but if it turns out to be numerically worse that could be a real issue for adoption, so first you agree with that statement and you view our RTH258 as fully competitive with Eylea. Second question is a few years ago after the paradigm AHF data was top line, but before the full data was released on a quarterly conference call David Epstein deliberately talk down expectations for the full data, you are not doing that with Cantos other than risk reduction being very robust, what other interpretation can we draw? Thank you.

Joe Jimenez

Harry Kirsch?

Harry Kirsch

So I think as you saw on my slide, we hit the primary endpoint with a highly significant P-value in terms of the comparability to Aflibercept we hit the end point for the 12 weeks at the end of the study. And we look forward to providing the secondary efficacy endpoints, which are adequately powered and pre-specified. And I think when you look at the safety profile as well as I said it is comparable both from an ocular and non-ocular severe and non-severe adverse event profile. So we view we have a highly competitive product that we look forward not advancing towards the submission.

Joe Jimenez

But also more data to come.

Harry Kirsch

And more data to come in AAO.

Joe Jimenez

Paul.

Paul Hudson

Yes. Just to support what Vas said, I mean ideally we would achieve the q12, which we want to do and once we get the data and all the secondary endpoints, we have to have a very competitive profile and we look forward to that. As for the previous comments on I think Entresto and heart failure, I wasn't here but I think we are just being appropriately conservatively with how we describe where we are with data. I am often asked what are the lessons learned for you personally Paul in joining the company, I would say to fully understand what we have in our hands before we start trying to communicate the ambition. And so we are so close to the data now, just a few weeks from ESC [ph]. I think we are better just waiting and going deeper there.

Joe Jimenez

Okay. Next question please.

Operator

Your next question comes from the line of Naresh Chouhan from New Street Research. Please go ahead.

Naresh Chouhan

Hi. Thanks for taking my questions. Joe when we met in Boston, you suggested that the pay for performance and possible rule changes may be announced kind of around now around mid-year are there timelines still your expectation particularly given yesterday's event or is there any kind of update you can give us with respect to that. And then secondly, on pharma R&D and we have obviously seen it come down in the first half and that before the RTH and [indiscernible] studies that have come out with the numbers, I suspect so should we expect ongoing margin delivery in pharma and R&D to be a material component of that? Thank you.

Joe Jimenez

Okay. Starting with the administration or the act – administrative action that we expect to come out, we really don't know the timing. We would have thought it would be this month, it hasn't. And I think just because of the speed of affairs in Washington around the ACA it would be not wise I think to speculate when it will come out. But I definitely thought it would be out by now and it will probably be out sometime this summer I would assume. Everything that we hear is that they had been working on it for quite a while, got an input from a lot of different stakeholders and they formulated. And now – so I can't speculate as to why they haven't released it, but I think it will be coming soon. And Vas on pharma R&D?

Vas Narasimhan

So I think as we have guided now for some time, our goal is a glide path to a 20% R&D spend in innovative medicines. And the way we are achieving that through is rigorous portfolio prioritization where we have a central portfolio evaluation of every project in the group, heavy investment to ensure that we have in it right capabilities and then to drive productivity out of that investment which is actually showing up in how fast we are enrolling trials to cost per patient in the way we are now able to apply digital technologies across development to drive down our speed and cost profile and we will continue to expect to be on that glide path towards 20%.

Joe Jimenez

Next question, please.

Operator

The next question comes from the line David Evans from Kepler Cheuvreux. Please go ahead.

David Evans

Hi there. Thanks for taking my questions. So just a couple on a project that doesn't really seem to be major focus currently, but on your BRAF-MEK combination in adjuvant melanoma that seems to move forward to 2017, filing from 2018 previously, I am just wondering what driven change in timeline and it seem like it commercially could be a pretty big market, if I would say, any particular reasons we should show some portion or do you feel that it represents big opportunities as well? Thanks.

Vas Narasimhan

On the adjuvant program in melanoma we have now – we are now in a position to readout the study in the second half of this year. So we still don't have the result in hand, but it was because of accelerated enrollment times driven by the productivity now we now have in the development organization. And so that's really the story and will look forward to give you additional insights once we have the data in hand.

Joe Jimenez

Next question please.

Operator

The next question comes from line of Keyur Parekh from Goldman Sachs. Please go ahead.

Keyur Parekh

Hi, good afternoon. Two questions please, one Joe there has been some comments on – you gave this morning attributing kind of – attributed to you on your views on M&A, it would be great if you can clarify kind of the latest thoughts on where you see the priorities for Novartis from an M&A perspective, but also obviously how you see asset valuation more generally across the Biopharma space. And then secondly on Kisqali, should we think of this kind of sampling/patient access program as the new way in which oncology drugs get launched or do you think there is something unique about the CDK46 market that meant that you have to do this? Thank you.

Joe Jimenez

Okay. Thanks for the question. In terms of M&A, we are still very focused on our strategy of bolt-on acquisitions anywhere from $2 billion to $5 billion would be our sweet spot. I have said previously that valuations are such that it's very difficult to find acquisitions that are in that range that would add value for Novartis shareholders. So what's happened is we have moved upstream in terms of earlier stage assets. So you saw us buy Ziarco is one example for atopic dermatitis and a few others over the last six months. So we are still focused on the bolt-on strategy that will strengthen either oncology or the pharmaceutical business or differentiated generics business. And that's where we are going to invest. But we are not going to invest in a place where we can't see a clear path to adding a tremendous amount of value from Novartis shareholders. And if you look at the existing what you would describe as bolt-ons or even bigger than a bolt on at the tender to $15 million range, we just don't see it yet from a valuation standpoint. And Bruno on Kisqali.

Bruno Strigini

So on the use of the samples, really as the environment becomes more competitive and while we wait for coverage and to gain coverage from the payers, we thought it would be important to recruit as many patients as possible and that's why we came up with that bridging model, whereby we provide up to six months of free samples to patients so that they can get on to treatment as soon as possible.

Joe Jimenez

Okay. I think we have time for one more question.

Operator

The next question comes from the line of Kerry Holford from BNP Paribas. Please go ahead.

Kerry Holford

Thank you. Just two last for me please. And I guess in the Q2 press release that DoJ and the SEC have started an investigation of Alcon business, the practices in Asia and Russia, can you give us any more information on this at this point, the reasons for that investigation timeline. And then a quick one for Harry on net financials going for the full year, you reached raising the guidance that you have given previously $850 million to $950 million for the year just because the first half run rate will suggest full year could be lower than that so if you could clarify please?

Joe Jimenez

Mike.

Mike Ball

So, on the DoJ question then, so we had an information request from the DoJ and SEC and as you said focuses on the age of business, obviously we are taking it seriously and co-operating fully on this. In terms of the period of time subpoenas really covered a period from both before Novartis acquired Alcon and after Novartis acquired Alcon.

Joe Jimenez

And Harry.

Harry Kirsch

Kerry on the net financial expenses, we expect to be at the lower end, so around $850 million mark and that is due to a more favorable interest rate environment and in the first half some more positive than expected currency results. We expect some higher interest expenses in the second half due to the bonds we have issued over the last two months, but overall, more favorable versus the initial guidance in January, so at lower end around $850 million.

Joe Jimenez

Okay. Thanks for tuning in and we look forward to giving you an update at Q3. This closes the call.

Operator

Thank you for joining today's conference call. You may now replace your handsets.

Comments (0)

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

AMGEN INC. and
AMGEN MANUFACTURING LIMITED,

Plaintiffs,

v.

SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH, and LEK PHARMACEUTICALS D.D.,

Defendants.

Case No. 3:16-cv-02581

[PROPOSED] ORDER GRANTING DEFENDANTS' MOTION TO SEPARATE EQUITABLE RELIEF

Date: September 14, 2017
Time: 1:30 pm.
Ctrm: Courtroom #3

The Honorable Richard Seeborg

[Proposed] ORDER

On July 28, 2017, Defendants SANDOZ INC., SANDOZ INTERNATIONAL GMBH, SANDOZ GMBH, and LEK PHARMACEUTICALS D.D. ("Sandoz"), by and through its counsel, moved pursuant to Rule 42(b) of the Federal Rules of Civil Procedure and Civil Local Rule 7-2, to separate the issue of Amgen Inc.'s and Amgen Manufacturing Limited's ("Amgen") entitlement to future injunctive relief for the accused product (peg-filgrastim) until after trial on the validity and infringement of Amgen's patent-in-suit. A hearing on this matter was held on September 14, 2017.

Having fully considered the moving and opposing papers, the arguments of counsel, and the files and records in this case, it is HEREBY ORDERED:

Sandoz's motion to separate the issue of Amgen's entitlement to future injunctive relief for the accused product (peg-filgrastim) from the other issues scheduled to be heard by a jury in a trial beginning on March 26, 2018 is GRANTED in its entirety. Discovery on the issues that relate to Amgen's entitlement to injunctive relief is hereby stayed pending resolution of the issues of liability.

IT IS SO ORDERED.

Dated: _____

_____
Honorable Richard Seeborg
United States District Court Judge