UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JANSSEN BIOTECH, INC. and
NEW YORK UNIVERSITY

Plaintiffs,

v.

CELLTRION HEALTHCARE CO., LTD.,
CELLTRION, INC., and
HOSPIRA, INC.

Defendants.

Civil Action No. 1:15-cv-10698
Civil Action No. 1:16-cv-11117

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR ENTRY OF FINAL JUDGMENT PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 54(b) REGARDING U.S. PATENT NO. 6,284,471

Judgment under Rule 54(b) is appropriate here because both of the Rule's requirements are satisfied. The first requirement is that there be a "final judgment as to one or more, but fewer than all, claims or parties." Fed. R. Civ. P. 54(b). The Court's holding that the '471 patent is invalid is a final and dispositive judgment on Janssen's claim that Defendants infringe the '471 patent, leaving nothing for the Court to do but enter judgment.

The second requirement—that "there is no just reason for delay"—is also met. Defendants have invested well over $100 million developing their biosimilar infliximab product, getting it approved by the FDA, and making preparations to bring it to market. Delaying an appeal would permit Janssen to maintain a cloud of uncertainty over Defendants' product at the expense of patients and to the benefit of Janssen's $4 billion-per-year monopoly on infliximab. Equally important, Janssen's '471 patent infringement claim is separable from the claims remaining in the case. The '083 patent infringement claims arise under a different patent listing

different inventors, relating to different technology, and claiming a purported invention created over a decade after the one described in the '471 patent. Janssen's claim about an alleged failure by Defendants to comply with the "patent dance" requirement of the BPCIA—which raises statutory construction issues—also shares no common questions of fact or law with the '471 patent infringement claim. Appeal at this juncture thus presents no risk of the appellate court duplicating work. The obviousness-type double patenting issues on which the Court entered judgment are unique to the '471 patent and will play no role in the adjudication of Janssen's remaining claims. Judgment under Rule 54(b) should be entered.

I. PROCEDURAL HISTORY

Janssen filed Civil Action No. 15-cv-10698 (the "2015 Action") against Defendants almost a year and a half ago, under the Biologics Price Competition and Innovation Act ("BPCIA"), in an effort to stop Defendants from selling their biosimilar version of Janssen's infliximab drug REMICADE®. *See* No. 15-10698 Dkt. 1. Janssen's complaint in the 2015 Action included eight counts:

- Count 1 claiming Defendants failed to comply with certain statutory requirements of BPCIA related to pre-litigation exchange of information, often referred to as the "patent dance";
- Count 2 claiming Defendants failed to comply with BPCIA requirements relating to Defendants' notice to Janssen of its intent to market a biosimilar version of Janssen's product REMICADE®; and
- Counts 3 through 8 claiming Defendants' submission to the FDA of its abbreviated Biologics License Application ("aBLA") for its biosimilar infliximab product was a technical act of infringement of six of Janssen's patents.

See No. 15-10698 Dkt. 1 at 29–35. BPCIA-related Count 2 has been dismissed as moot. No. 15-10698 Dkt. 228. Patent infringement counts 4, 5, 7 and 8 were dismissed pursuant to stipulations. No. 15-10698 Dkt. 83, 89, 138. The two patent infringement counts remaining in

the 2015 Action—Counts 3 and 6—allege infringement of U.S. Patent No. 6,284,471 (the "'471 patent") and U.S. Patent No. 7,598,083 (the "'083 patent"), respectively.

On August 19, 2016, the 2015 Action was consolidated with a second litigation Janssen filed against Defendants in June 2016, Civil Action No. 16-cv-11117 (the "2016 Action"). No. 15-10698 Dkt. 226; No. 16-11117 Dkt. 7. The complaint in the 2016 Action alleges that Defendants infringe the '083 patent under 35 U.S.C. § 271(a) and/or (b) (*i.e.*, "actual acts of infringement" rather than "technical acts"). No. 16-11117 Dkt. 1. The 2016 Action includes no allegations related to any other patents, and no allegations under BPCIA. *Id.* Defendants have asserted no counterclaims in either the 2015 Action or the 2016 Action. Accordingly, the claims remaining in the consolidated actions, taking into account stipulated dismissals, are as follows:

- 2015 Action Count 1 claiming Defendants "failed to comply with the mandatory requirements of the BPCIA" provision 42 U.S.C. § 262(l);
- 2015 Action Count 3 claiming Defendants infringe the '471 patent under BPCIA;
- 2015 Action Count 6 claiming Defendants infringe the '083 patent under BPCIA; and
- 2016 Action Counts 1–3 claiming Defendants infringe the '083 patent under 35 U.S.C. § 271(a) and/or (b).

Throughout this litigation, Janssen has made multiple efforts to avoid resolution of its own claim for infringement of the '471 patent, including by way of a motion to stay litigation of the '471 patent altogether. No. 15-10698 Dkt. 8, *et seq.* Defendants, however, have sought prompt resolution of the '471 patent, filing two motions seeking summary judgment that the '471 patent is invalid under the judicially created doctrine of obviousness-type double patenting ("OTDP"). No. 15-10698 Dkt. 127, *et seq.*; No. 15-10698 Dkt. 176, *et seq.* The Court denied Janssen's motion to stay and granted Defendants' summary judgment motions, finding the '471 patent invalid on both OTDP grounds presented by Defendants. No. 15-10698 Dkt. 226; No. 16-11117 Dkt. 7. Janssen's appeal of the Court's decision—which Janssen has publicly stated it

intends to pursue—should proceed now, rather than after resolution of the remaining, unrelated claims in the litigation.

II. LEGAL STANDARDS

Federal Rule of Civil Procedure 54(b) was enacted "to relax[] the restrictions upon what should be treated as a judicial unit for the purposes of appellate jurisdiction." *W.L. Gore & Assoc., Inc. v. Int'l Med. Prosthetics Research Assoc., Inc.*, 975 F.2d 858, 861 (Fed. Cir. 1992) (quoting *Sears, Roebuck & Co. v. Mackey*, 351 U.S. 427, 432 (1956)). The Rule states, in pertinent part:

> When an action presents more than one claim for relief--whether as a claim, counterclaim, crossclaim, or third-party claim--or when multiple parties are involved, the court may direct entry of a final judgment as to one or more, but fewer than all, claims or parties only if the court expressly determines that there is no just reason for delay.

Fed. R. Civ. P. 54(b). "Federal Circuit law applies to Rule 54(b) certification…issues." *State Contracting & Eng'g Corp. v. State of Florida*, 258 F.3d 1329, 1334 (Fed. Cir. 2001); *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 830 (Fed. Cir. 2003). In applying Rule 54(b), the Federal Circuit looks to Supreme Court precedent. *Gore*, 975 F.2d at 861.

There are two requirements for a judgment to be certified for appeal under Rule 54(b). *First*, the judgment must be "final with respect to one or more claims," meaning it must be "'an ultimate disposition of an individual claim entered in the course of a multiple claims action.'" *Gore*, 975 F.2d at 861–62 (quoting *Sears*, 351 U.S. at 436) (emphasis omitted); *see also Curtiss-Wright Corp. v. Gen. Elec. Co.*, 446 U.S. 1, 7 (1980). *Second*, the Court must make a finding that there is "no just reason to delay the appeal." *Gore*, 975 F.2d at 862. An inquiry into whether there is no just reason to delay involves looking at the "separateness" of the claim sought to be appealed from the remaining claim(s) in the case. *Id.* It also involves consideration

of whether the "appellate court would have to decide the same issues more than once even if there were subsequent appeals." *Id.* (quoting *Curtiss-Wright*, 446 U.S. 8).

III. THE COURT'S JUDGMENT THAT THE '471 PATENT IS INVALID SHOULD BE MADE APPEALABLE

A. The Judgment Is Final With Respect To Janssen's Claim For Infringement Of The '471 Patent

There can be no dispute that the first requirement for entry of judgment under Rule 54(b)—that the judgment is final with respect to one or more claims—is met. As noted above, Count 3 of Janssen's complaint in the 2015 Action sets forth Janssen's claim that Defendants infringe the '471 patent. No. 15-10698 Dkt. 1 at 31–32. The Court's judgment that the '471 patent is invalid due to OTDP is an "ultimate disposition" of that "individual claim." *Gore*, 975 F.2d at 861–62. It "ends the litigation on the merits and leaves nothing for the court to do but execute the judgment." *Id.* at 863 (quoting *Catlin v. United States*, 324 U.S. 229, 233 (1945)); *accord Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 407 F. App'x 481, 482 (Fed. Cir. 2011). Although Defendants pled other defenses in response to Janssen's allegation of infringement of the '471 patent, such defenses do not preclude the judgment of invalidity from being final. "The law is clear that a 'defendant need only sustain one decisive defense, not all of them.'" *Gore*, 975 F.2d at 863 (citation omitted).

B. There Is No Just Reason To Delay The Appeal

The second factor for application of Rule 54(b) is met as well. There is no just reason to delay appeal of the Court's order finding the '471 patent invalid. To the contrary, there are compelling reasons to allow the appeal to proceed promptly.

1. Janssen's Claim for Infringement of the '471 Patent Is Separable from its Remaining Claims

As noted above, when assessing requests for judgment under Rule 54(b), the Federal Circuit has directed courts to look to the separability of the claim sought to be appealed from the remaining claims in the case. Here, the claims remaining in the consolidated actions fall into two categories: (1) Janssen's claim that Defendants violated the "patent dance" information-exchange procedures of BPCIA; and (2) Janssen's claims that Defendants infringe the '083 patent. These claims are separable from Janssen's claim that Defendants infringe the '471 patent.

Janssen's claim that Defendants failed to abide by the "patent dance" requirements of 42 U.S.C. § 262(l) is unrelated legally and factually to its claim for infringement of the '471 patent. Janssen asserts that "[u]nder 42 U.S.C. § 262(l)(2)(A), Defendants were required to provide Janssen, within twenty days of when Defendants' aBLA was accepted for review, with a copy of the aBLA 'and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application,'" that "Defendants failed to provide such information in violation of the BPCIA," and that "Defendants' violations of the BPCIA's mandatory procedures, individually and collectively, have caused and will cause Plaintiffs injury." No. 15-10698 Dkt. 1 at 30.

None of this has anything to do with Count 3 relating to the '471 patent. Janssen's baseless allegations about the "patent dance"—which do not even form a cognizable claim for relief—raise questions of statutory interpretation centered on the language of the BPCIA.[1]

[1] Defendants have informed Janssen that the "patent dance" allegations (2015 Action Count 1) are baseless—Janssen received all of the information to which it was entitled under the law. Moreover, there is no private right of action for the "violations" of BPCIA Janssen alleges. Defendants have pressed Janssen to identify the injury it allegedly suffered as pled in Count 1, and have asked Janssen to dismiss it. Janssen has not identified any alleged injuries, and has not agreed to dismissal. *See* Ex. 1 (Klein email to Royzman).

Janssen's claim that Defendants infringe the '471 patent, on the other hand, involves unrelated questions specific to patent law, for example, the proper construction of claims in the '471 patent, invalidity due to OTDP, and questions related to the sufficiency of the disclosures in the '471 patent specification. In short, there are no overlapping factual or legal inquiries between Janssen's "patent dance" claim and its claim that Defendants infringe the '471 patent. Courts have regularly recognized that it is appropriate to certify judgment on a patent-related claim under Rule 54(b) where a non-patent claim remains in the case. *See, e.g.*, *Schoenhaus v. Genesco, Inc.*, 440 F.3d 1354, 1356 (Fed. Cir. 2006) (noting district court's entry of final judgment on noninfringement under Rule 54(b) where state law claims remained); *Gore*, 975 F.2d at 864 (certification of patent infringement claim under 54(b) was proper despite remaining antitrust counterclaim); *see also* Ex. 2, *Amgen, Inc. v. Sandoz, Inc.*, No. 3:14-cv-04741-RS, Dkt. 111 at 2 (N.D. Cal. March 25, 2015) (entering 54(b) judgment on claims that "all relate to the correct interpretation of the BPCIA and do not address the sole subject of the remaining claims and counterclaims…which relate to enforceability, infringement, and validity of the '427 patent").

Similarly, Janssen's claims that Defendants infringe the '083 patent are factually and legally different than, and therefore separable from, its claim for infringement of the '471 patent. These patents relate to completely different technologies. The '471 patent, colloquially referred to throughout this litigation as the "antibody patent," claims chimeric antibodies that bind the immune system molecule TNF-α, including the infliximab (cA2) antibody in REMICADE®. No. 15-10698 Dkt. 1 at 8-9; No. 15-10698 Dkt. 1-1 ('471 patent). The '083 patent, referred to in this litigation at times as the "soup patent," claims soluble compositions suitable for producing cell culture media—liquid (*i.e.*, "soup") in which cells that produce desirable antibodies or

proteins can be grown. No. 15-10698 Dkt. 1 at 10-11; No. 15-10698 Dtk. 1-4 (’083 patent). The ’083 patent states that it “relates to chemically defined media compositions for the culture of eukaryotic cells,” generally. *Id.* at 1:13-14. It makes no mention of infliximab (cA2). No. 15-10698 Dtk. 1-4.

The ’471 and ’083 patents are not part of the same patent family (*i.e.*, do not share common lineage); they have no common named inventors; and the work allegedly supporting the inventions disclosed in the patents took place at different times—the March 1991 priority date of the ’471 patent is more than thirteen years before the October 2004 priority date of the ’083 patent. No. 15-10698 Dkt. 1-1; No. 15-10698 Dtk. 1-4. There are no overlapping claim construction issues between the two patents, and no overlapping factual or legal issues related to infringement or invalidity. The only connection between the patents is that they are owned by Janssen and asserted against Defendants. Courts have routinely issued Rule 54(b) judgments on patent infringement or other patent-related claims where claims related to a different patent or patents remained in the case. *See, e.g., Medeva Pharma Suisse A.G. v. Par Pharm., Inc.*, 430 F. App’x 878, 880 (Fed. Cir. 2011) (denying motion to dismiss appeal where district court had entered final judgment under Rule 54(b) on one of two patents); *Emhart Indus., Inc. v. Universal Instruments Corp.*, 925 F.2d 1480, at *1 (Fed. Cir. 1991) (per curiam) (“While other counts under other patents remain in the case for decision, we have jurisdiction at this time because the district court certified its judgment with respect to the ’087 patent under Fed. R. Civ. P. 54(b)…”); *HTC Corp. v. IPCom GMBH & Co., KG*, 285 F.R.D. 130, 132 (D.D.C. 2012) (entering final judgment under Rule 54(b) as to one of two patents where they “deal with different technologies, the infringement evidence for each is unique, and HTC’s invalidity argument for each is distinct”); *Augme Techs., Inc. v. Yahoo! Inc.*, 305 F.R.D. 112, 114–15 (N.D.

Cal. 2012), *aff'd*, 755 F.3d 1326 (Fed. Cir. 2014) (certifying under Rule 54(b) summary judgment on patent infringement claim where counterclaims for infringement of other patents were "separable"); *Decade Indus. v. Wood Tech., Inc.*, 145 F. Supp. 2d 1075, 1079–80 (D. Minn. 2001) (certifying under Rule 54(b) summary judgment on infringement counterclaim where infringement counterclaim on different patent remained).

2. There Is No Risk that the Federal Circuit Will Have to Decide the Same Issues More than Once

There is no just reason to delay appeal for the additional reason that an immediate appeal presents no risk of duplicate efforts by the Federal Circuit. *See Gore*, 975 F.2d at 862. The issues presented on appeal will focus on whether the '471 patent is invalid due to OTDP over the '444, '195 and '272 reference patents. To the extent any separate, later appeals arise out of Janssen's "patent dance" or '083 patent infringement claims, they will present none of the same issues. Defendants' OTDP defense—which is premised on the specific relationships between the '471 patent term and the terms of each of the reference patents—is unique to the '471 patent. *See, e.g.*, Ex. 3, *Gilead Sci., Inc. v. Natco Pharma, Ltd.*, Nos. 11-01455 and 11-04969, Dkt. 85 at 2 (D.N.J. May 9, 2013) (certifying under Rule 54(b) summary judgment of no OTDP where "there is no possibility that any appellate court will be obliged to consider the issue as to whether the '375 patent qualifies as a prior art reference against the '483 patent for purposes of [OTDP] raised in Defendants' appeal a second time, inasmuch as it presents a unique and dispositive issue of law controlling the outcome of this case").

For the same reasons, further proceedings by this Court will not moot appeal of the Court's invalidity ruling. Moreover, if the Federal Circuit were to vacate this Court's judgment finding the '471 patent invalid, such an outcome would not complicate adjudication of the remaining claims. Trial on the '083 patent claims is scheduled to begin in February 2017,

meaning that the ’083 patent issues will be resolved by the Court in advance of a final decision on appeal of the OTDP issues that could require remand to the District Court. For the same reasons the ’471 patent issues and the remaining case issues can easily be appealed separately, they could easily be tried separately, if necessary.

3. Defendants Are Entitled to Certainty and Prompt Resolution

The relationship between Janssen and the Defendants here, and the policies underlying the BPCIA, provide additional reasons why appeal of the Court’s judgment should proceed immediately. The stated goal of BPCIA is to “establish[] a simple, streamlined patent resolution process” for sellers of biologic drugs and applicants for biosimilar approval that “will help ensure that litigation surrounding relevant patents will be resolved expeditiously and prior to the launch of the biosimilar product, providing certainty to the applicant, the reference product manufacturer, and the public at large.” No. 15-10698 Dkt. 40-1 (Hearing Before Subcomm. on Courts and Competition Policy of the H. Comm. on the Jud., 111th Cong. at 9 (2009) (Test. of Rep. A.G. Eshoo)) at 14. Delaying this appeal would frustrate the BPCIA goal of resolving patent issues “expeditiously” and providing certainty to all involved, and would vitiate the Court’s efforts to reach prompt decisions on Defendants’ summary judgment motions. Indeed, a delayed appeal could result in a Federal Circuit decision as late as early or mid-2018, mere months before the ’471 patent expires in September 2018.

Janssen has publicized its intent to appeal the Court’s invalidity ruling. *See* Ex. 4 (press release, Aug. 17, 2016). It has no legitimate reason to delay. Defendants, on the other hand, would be prejudiced by delay. Their biosimilar product INFLECTRA® has been approved by the FDA, and Janssen has agreed that under BPCIA, Defendants may launch as soon as October 3, 2016. No. 15-10698 Dkt. 207. Defendants have devoted over $100 million to the development of INFLECTRA®, and its entry to the market will provide the public with a more

affordable alternative to REMICADE®, which currently can cost as much as $20,000 per year. Ex. 5 (REMICADE® co-pay support web page). The court presiding over the first-ever litigation under BPCIA acknowledged similar concerns when it entered a Rule 54(b) judgment in 2015, noting that the adjudicated claims "raise[d] important legal issues that are time-sensitive not only to the emerging biosimilar industry but also to the parties here: the Food and Drug Administration has now approved Sandoz's application for its biosimilar product (the first biosimilar that the FDA has approved), implicating concerns about prejudice to the parties that could result from a delayed appeal on the BPCIA-related claims and counterclaims." Ex. 2, *Amgen*, No. 3:14-cv-04741-RS, Dkt. 111 at 2–3. As this Court has explained, "[f]or each side, the first choice is that you prevail, but the second choice is you know what the decision is, so then you can decide what to do about it." May 19, 2016 Hearing Tr. at 54:1-4. The shortest, clearest path to knowing the final decision is an immediate appeal.

IV. CONCLUSION

The Court's judgment that the '471 patent is invalid is final, and there is no just reason to delay appeal. The Court should certify the judgment for appeal under Rule 54(b).

Dated: August 22, 2016

Respectfully submitted,
Celltrion Healthcare Co., Ltd., Celltrion, Inc. and Hospira Inc.
By their attorneys,

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Attorneys for Defendants Celltrion Healthcare Co., Ltd., Celltrion, Inc., and Hospira, Inc.

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on August 22, 2016.

/s/Andrea L. Martin
Andrea Martin, Esquire

4843-1440-3895.1

Exhibit 1

From: Klein, Chuck
Sent: Sunday, August 14, 2016 11:29 AM
To: Royzman, Irena (x2081)
Subject: RE: Janssen v. Celltrion - protective order/ order of argument

Hi Irena,

Your email doesn't address the issue I'm raising. Of course we dispute Janssen's claim in count 3 for lost profits or injunctive relief for the '471 patent, but this is not relevant to count 1. Unless I'm missing something, this is the relief you seek as to count 1:

> (a) a declaration that Defendants have failed to comply with the requirements of the BPCIA patent dispute resolution process, including 42 U.S.C. § 262(l)(2)(A) and 42 U.S.C. § 262(l)(4);
>
> (b) an order compelling Defendants to comply with the BPCIA patent dispute resolution process set forth in 42 U.S.C. § 262(l);

Even if we were to assume, for purposes of argument, that Janssen has a private right of action to bring count 1, does Janssen really intend to go to trial to try to compel defendants to comply with the BPCIA patent dispute resolution procedures? What "harm" is Janssen seeking to redress in count 1, and what is the requested relief? To date, I have not received any answer to these questions.

As far as I see it, count 1 is pointless and, thus, we intend to move to dismiss unless Janssen is not willing to enter into a stipulation resolving this claim. Again, we are not seeking as part of such a stipulation a waiver by Janssen of any preserved patent infringement contentions or damages claims.

I'm happy to discuss at your convenience.

Regards,

Chuck

Chuck Klein
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winston.com

From: Royzman, Irena (x2081) [mailto:iroyzman@pbwt.com]
Sent: Sunday, August 14, 2016 10:51 AM
To: Klein, Chuck
Subject: RE: Janssen v. Celltrion - protective order/ order of argument

Chuck,

I don't have time on Monday but, in addition, based on our prior discussion I don't think there is any progress to be made unless defendants' positions have changed.

Do defendants agree that Janssen is entitled to lost profits and injunctive relief for the 471 patent and will not argue otherwise in the litigation? Do defendants agree that they failed to follow the procedures of the BPCIA, thereby causing plaintiffs harm?

If the answer to any of those questions is no (and my understanding from our prior discussion and arguments that defendants' are making in the case that the answer is no), then we have a live controversy. If defendants are willing to stipulate to not having followed the procedures of the BPCIA, harm to plaintiffs resulting from those actions and drop defendants' argument that plaintiffs are not entitled to lost profits and injunctive relief, then we can discuss dismissing count 1 as moot.

Irena

From: Klein, Chuck [mailto:CKlein@winston.com]
Sent: Sunday, August 14, 2016 9:26 AM
To: Royzman, Irena (x2081)
Subject: RE: Janssen v. Celltrion - protective order/ order of argument

Hi Irena,

Thanks for your email and the agreement as to count 2. I don't think it's too early to discuss count 1. No matter what happens at the hearing, we will need to file a motion to dismiss count 1 if Janssen declines to dismiss it voluntarily.

We intend to raise this issue on Tuesday. Please let me know if you have a few minutes Monday afternoon to discuss.

Regards,
Chuck

Chuck Klein
Winston & Strawn LLP

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From: Royzman, Irena (x2081) [mailto:iroyzman@pbwt.com]
Sent: Sunday, August 14, 2016 8:52 AM
To: Klein, Chuck
Subject: Re: Janssen v. Celltrion - protective order/ order of argument

Hi Chuck,

Sorry. I can't on Monday. Let's see what happens. It seems too early to discuss Count 1. We don't see the hearing going as you do. As to Count 2, we can agree to dismiss it as moot in view of Hospira/Cellrtion agreeing to follow the law.

Separately, for the SJ motions, we expect that you will go first since they are your motions. For claim construction of our patent, we will go first. And for our motion to expedite the 083 trial and set a schedule for the 471, we will go first as well.

See you Tuesday,

Irena

Sent from my iPad

On Aug 12, 2016, at 4:28 PM, "Klein, Chuck" <CKlein@winston.com> wrote:

> Hi Irena – I'm available to discuss today if you're still around, or Monday afternoon.
>
> Regards,
> Chuck
>
> **Chuck Klein**
> Winston & Strawn LLP
> D: +1 (202) 282-5977
> winston.com
> <image001.jpg>
>
> **From:** Klein, Chuck
> **Sent:** Sunday, August 07, 2016 6:40 PM
> **To:** Royzman, Irena (x2081)
> **Subject:** Re: Janssen v. Celltrion - protective order
>
> Hi Irena - Friday afternoon will be tough. But maybe we can resolve this by email.
>
> I propose that counts 1 and 2 be dismissed as moot -- but such dismissal will not be construed to limit any Janssen defenses that have otherwise been preserved. The goal would be simply to clean up the pleadings and avoid a motion to dismiss these counts.

I think we need to at least try to resolve this issue before the hearing. We would like to know before the hearing if a motion to dismiss will be necessary. And if Judge Wolf grants summary judgment as to the '471 and '083 counts, he will want to know if final judgment can be entered -- and, if not, what else is left to resolve before final judgment.

Thanks,
Chuck

Sent from my iPhone

On Aug 7, 2016, at 6:14 PM, Royzman, Irena (x2081) <iroyzman@pbwt.com> wrote:

> Chuck,
>
> I need to move our call to discuss counts 1 and 2 until later in the week. I have an argument in another case. Let me know if Friday afternoon works or we can talk when I see you in Boston next week.
>
> Hope all is well,
>
> Irena
>
> ---
>
> **From:** Klein, Chuck [mailto:CKlein@winston.com]
> **Sent:** Tuesday, July 26, 2016 7:50 PM
> **To:** Royzman, Irena (x2081)
> **Subject:** RE: Janssen v. Celltrion - protective order
>
> Sounds good.
>
> **Chuck Klein**
> Winston & Strawn LLP
> D: +1 (202) 282-5977
> winston.com
> <image001.jpg>
>
> ---
>
> **From:** Royzman, Irena (x2081) [mailto:iroyzman@pbwt.com]
> **Sent:** Tuesday, July 26, 2016 7:47 PM
> **To:** Klein, Chuck
> **Subject:** Re: Janssen v. Celltrion - protective order
>
> Let's do 3 PM. Talk to you then.
>
> Sent from my iPad
>
> On Jul 26, 2016, at 4:45 PM, "Klein, Chuck" <CKlein@winston.com> wrote:
>
> > Yes – I'm open. What works. Thanks
> >
> > **Chuck Klein**
> > Winston & Strawn LLP
> > D: +1 (202) 282-5977
> > winston.com

<image001.jpg>

From: Royzman, Irena (x2081) [mailto:iroyzman@pbwt.com]
Sent: Tuesday, July 26, 2016 7:45 PM
To: Klein, Chuck
Subject: Re: Janssen v. Celltrion - protective order

I can't on the 3rd. Monday the 8th good in the afternoon though. That work?

Sent from my iPad

On Jul 26, 2016, at 4:41 PM, "Klein, Chuck" <CKlein@winston.com> wrote:

> I can't do Aug 4 or 5. Aug 3 ok though.
>
> **Chuck Klein**
> Winston & Strawn LLP
> D: +1 (202) 282-5977
> winston.com
> <image001.jpg>
>
> **From:** Royzman, Irena (x2081) [mailto:iroyzman@pbwt.com]
> **Sent:** Tuesday, July 26, 2016 7:40 PM
> **To:** Klein, Chuck
> **Subject:** Re: Janssen v. Celltrion - protective order
>
> No problem. Can we make it Aug 5? 10 AM? Afternoon works too if better for you.
>
> Sent from my iPad
>
> On Jul 26, 2016, at 10:14 AM, "Klein, Chuck" <CKlein@winston.com> wrote:
>
> > Sorry Irena – I need to push our call again. Have a telephonic hearing at 3. How's 4pm? Thanks
> >
> > **Chuck Klein**
> > Winston & Strawn LLP
> > D: +1 (202) 282-5977
> > winston.com
> > <image001.jpg>
> >
> > **From:** Royzman, Irena (x2081) [mailto:iroyzman@pbwt.com]
> > **Sent:** Wednesday, July 20, 2016 8:30 AM
> > **To:** Klein, Chuck
> > **Subject:** Re: Janssen v. Celltrion - protective order

Yes

Sent from my iPad

On Jul 20, 2016, at 8:06 AM, "Klein, Chuck" <CKlein@winston.com> wrote:

> Can we move the call to 3? Thanks
>
> Sent from my iPhone
>
>> On Jul 19, 2016, at 8:29 AM, Royzman, Irena (x2081) <iroyzman@pbwt.com> wrote:
>>
>> Jammed and then out for vacation. Can you talk on Aug 2 in the afternoon? 2 PM?
>>
>> Sent from my iPad
>>
>> On Jul 19, 2016, at 8:26 AM, "Klein, Chuck" <CKlein@winston.com> wrote:
>>
>>> Are you available later today or tomorrow to discuss claims 1 and 2? Thanks
>>>
>>> Sent from my iPhone
>>>
>>>> On Jul 19, 2016, at 8:09 AM, Royzman, Irena (x2081) <iroyzman@pbwt.com> wrote:
>>>>
>>>> Thanks. I appreciate it.
>>>>
>>>> Sent from my iPad
>>>>
>>>> On Jul 19, 2016, at 8:07 AM, "Klein, Chuck" <CKlein@winston.com> wrote:
>>>>
>>>>> Irena - I think he was cleared previously.
>>>>>
>>>>> Sent from my iPhone
>>>>>
>>>>>> On Jul 17, 2016, at 10:21

PM, Royzman, Irena (x2081)
<iroyzman@pbwt.com> wrote:
>>>>>>
>>>>>> Hi Chuck,
>>>>>>
>>>>>> We'd like to add Rob Fletcher, General Counsel of the J&J Pharmaceutical Sector under the protective order. He has no involvement in prosecution. Please let me know if ok.
>>>>>>
>>>>>> Thank you,
>>>>>>
>>>>>> Irena
>>>>>>
>>>>>> Privileged/Confidential Information may be contained in this message. If you are not
>>>>>> the addressee indicated in this message (or responsible for delivery of the message to
>>>>>> such person), you may not copy or deliver this message to anyone. In such case, you
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>>>>>

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>>>>

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Exhibit 2

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

AMGEN INC. and AMGEN MANUFACTURING, LIMITED, Plaintiffs, v. SANDOZ INC., SANDOZ INTERNATIONAL GMBH, and SANDOZ GMBH, Defendants.	Case No. 3:14-cv-04741-RS **~~[PROPOSED]~~ FINAL JUDGMENT UNDER RULE 54(B) AND ORDER ESTABLISHING SCHEDULE FOR RULE 62(C) PROCEEDINGS AND STAYING ALL OTHER PROCEEDINGS** The Honorable Richard Seeborg

On March 19, 2015, the Court issued its Order on Cross Motions for Judgment on the Pleadings and Denying Motion for Preliminary Injunction. (ECF No. 105.) The Court's Order dismissed with prejudice the first and second causes of action brought by Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited (collectively, "Amgen") and entered judgment in favor of Defendant Sandoz Inc. ("Sandoz") on Sandoz's first, second, third, fourth, and fifth counterclaims insofar as those counterclaims are consistent with the Court's interpretation of the Biologics Price Competition and Innovation Act ("BPCIA"). The Order also denied Amgen's motion for a preliminary injunction, as well as Amgen's motion for judgment on the pleadings (or alternatively for partial summary judgment) on Sandoz's sixth and seventh counterclaims, allowing those counterclaims to proceed.

Following the Court's March 19, 2015, Order, the only claims remaining before the Court relate to Amgen's '427 patent: Amgen's claim of infringement, and Sandoz's counterclaims of noninfringement and invalidity. These remaining patent claims are distinct and separable from the two claims and five counterclaims that were adjudicated in the March 19, 2015, Order.

Pursuant to the parties' agreement that, should either party appeal the decision of this Court, the parties would jointly seek expedited review in the Federal Circuit, the parties have jointly moved for entry of final judgment under Rule 54(b) of the Federal Rules of Civil Procedure so as to facilitate an immediate appeal of the BPCIA-related claims, all of which were resolved by the Court's March 19, 2015, Order.

Rule 54(b) certification is not available as of right. Rather, it requires that the judgment to be entered be final as to the claims it addresses, and that there be no just reason for delay. *See e.g., W.L. Gore & Associates, Inc. v. International Medical Prosthetics Research Associates, Inc.*, 975 F.2d 858, 862 (Fed. Cir. 1991). A judgment is final for Rule 54(b) purposes where it is "an ultimate disposition of an individual claim entered in the course of a multiple claims action." *Id.* at 861-62 (emphasis omitted) (citing *Sears, Roebuck & Co. v. Mackey*, 351 U.S. 427, 436 (1956)). In determining whether there is just reason for delay, the Court considers "such factors as whether the claims under review [are] separable from the others remaining to be adjudicated and whether the nature of the claims already determined [are] such that no appellate court would have to decide the same issue more than once even if there were subsequent appeals." *Id.* at 862 (quoting *Curtiss-Wright Corp. v. General Elec. Co.*, 446 U.S. 1, 8 (1980)).

Having considered the standard for entry of judgment under Rule 54(b), the Court finds that it is appropriate to enter judgment under Rule 54(b) as to Amgen's first and second causes of action and as to Sandoz's first through fifth counterclaims. There is no just reason to delay entry of final judgment on these adjudicated claims and counterclaims. They all relate to the correct interpretation of the BPCIA and do not address the sole subject of the remaining claims and counterclaims (Amgen's third cause of action and Sandoz's sixth and seventh counterclaims), which relate to enforceability, infringement, and validity of the '427 patent. Moreover, the claims and counterclaims decided by the Court's March 19, 2015, Order raise important legal issues that

are time-sensitive not only to the emerging biosimilar industry but also to the parties here: the Food and Drug Administration has now approved Sandoz's application for its biosimilar product (the first biosimilar that the FDA has approved), implicating concerns about prejudice to the parties that could result from a delayed appeal on the BPCIA-related claims and counterclaims. Finally, entry of a Rule 54(b) judgment is especially appropriate here, where Amgen intends to appeal now the denial of the preliminary injunction under 28 U.S.C. § 1292(a), because entry of such judgment will allow the entire March 19, 2015, Order to be appealed together.

The parties have also jointly requested entry of a scheduling order for Amgen's contemplated motion for an injunction under Rule 62(c). Additionally, the parties jointly have requested entry of an order staying all remaining proceedings in this Court (apart from those on the contemplated Rule 62(c) motion) until issuance of the Federal Circuit's mandate in the appeal from this Rule 54(b) judgment and this Court's March 19, 2015, Order.

Accordingly, it is ORDERED and ADJUDGED:

1. FINAL JUDGMENT is hereby entered under Rule 54(b) of the Federal Rules of Civil Procedure in favor of Sandoz and against Amgen on Amgen's first and second causes of action, as well as on Sandoz's first, second, third, fourth, and fifth counterclaims in accordance with the Court's March 19, 2015, Order.

2. Amgen will make any motion for an injunction under Rule 62(c) no later than Tuesday, March 24, 2015. Sandoz will file its response to any such motion by March 31, 2015. Amgen will file its optional reply by April 2, 2015.

3. All other proceedings in this Court related to this matter, except for the entry of the jointly requested Rule 54(b) judgment and Amgen's contemplated Rule 62(c) motion, are STAYED until issuance of the Federal Circuit's mandate in the appeal from this Rule 54(b) judgment and this Court's March 19, 2015, Order. During the period of the stay imposed by this paragraph, Amgen may continue efforts to effect service on Sandoz International GmbH and Sandoz GmbH, provided, however, that the time to move, answer, or otherwise respond to the complaint for either entity so served is tolled until twenty days after the expiration of the stay imposed by this paragraph.

Dated: 3/25, 2015

THE HONORABLE RICHARD SEEBORG
UNITED STATES DISTRICT JUDGE

Exhibit 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

GILEAD SCIENCES, INC., HOFFMANN-La ROCHE INC., F. HOFFMANN-La ROCHE LTD. and GENENTECH, INC., Plaintiffs, v. NATCO PHARMA LIMITED and NATCO PHARMA INC., Defendants.	**C.A. No. 1:11-cv-01455-SDW-MCA** **consolidated with** **C.A. No. 2:11-cv-04969-SDW-MCA**

[PROPOSED] ORDER

IT IS on this 6th day of May, 2013, hereby **ORDERED**:

1. The Stipulation and Order filed by the parties herewith (the "Stipulation") is, in all things, **ADOPTED**;

2. Pursuant to Rule 54(b) of the Federal Rules of Civil Procedure, the Court hereby enters final judgment as to the validity of claims 1-7 and as to infringement of claims 2 and 3 of U.S. Patent No. 5,763,483 (the "'483 patent"). The only unadjudicated claims relate to Plaintiffs' assertions of infringement over claims 1 and 4-7 of the '483 patent;

3. This Court finds the present case appropriate for certification under Rule 54(b). First, Defendants' claim for invalidity of the '483 patent is a cognizable claim for relief. Second, there is no just reason for delaying appeal because this Court has ruled that Defendants' only invalidity defense on the '483 patent, obviousness-type double patenting, is incorrect as a matter of law, thus resolving validity of the '483 patent for purposes of appeal. Specifically, this Court's December 21, 2012 Opinion (D.I. 67) and Order (D.I. 68) (the "Opinion and Order")

held that U.S. Patent No. 5,952,375 (the "'375 patent") does not qualify as a prior art reference against the '483 patent for purposes of obviousness-type double patenting. Third, the only unadjudicated claims – Plaintiffs claims of infringement over claims 1 and 4-7 of the '483 patent – are narrow in scope and moot if Defendants' appeal is unsuccessful. Fourth, there is no possibility that any appellate court will be obliged to consider the issue as to whether the '375 patent qualifies as a prior art reference against the '483 patent for purposes of obviousness-type double patenting raised in Defendants' appeal a second time, inasmuch as it presents a unique and dispositive issue of law controlling the outcome of this case;

4. In accordance with the Stipulation, judgment of infringement of claims 2 and 3 of the '483 Patent by Defendants is **GRANTED**;

5. In accordance with the Stipulation, Plaintiffs' claims of infringement of claims 1 and 4-7 of the '483 patent are **STAYED** pending disposition of any appeal by Defendants of the Opinion and Order;

6. In accordance with the Stipulation, all of Defendants' pending counterclaims in this case are **STAYED** pending disposition of any appeal by Defendants of the Opinion and Order (with the exception of the portion of Defendants' counterclaim seeking a declaration of noninfringement of claims 2 and 3, which will be **DISMISSED** with prejudice); and

7. Based on the Court's express determination, pursuant to the provisions of Rule 54(b) of the Federal Rules of Civil Procedure, that there is no just reason for delaying an appeal of this Court's ruling on Summary Judgment, the Court directs the Clerk to issue a final judgment in favor of Plaintiffs on (i) Plaintiffs' claim for infringement of claims 2 and 3 of the '483 patent and (ii) Defendants' counterclaim for invalidity of the '483 patent. If the '375 patent is found to qualify as a prior art reference against the '483 patent for obviousness-type double patenting

purposes, Defendants' counterclaim for invalidity of the '483 patent shall be reinstated in its entirety.

Susan D. Wigenton, U.S.D.J.

Exhibit 4

News

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Johnson & Johnson Announces Ruling Related to REMICADE® in the District of Massachusetts Federal Court Hearing

New Brunswick, NJ (August 17, 2016) – Johnson & Johnson (NYSE: JNJ) today announced that the District of Massachusetts Federal Court has issued a ruling on a summary judgment motion filed by Celltrion Healthcare Co. Ltd. and Celltrion Inc. (together, Celltrion) and Hospira Healthcare Corporation (Hospira) in the infringement lawsuits related to REMICADE® (infliximab) filed by the company's subsidiary, Janssen Biotech, Inc. (Janssen).

The court issued a ruling in favor of Celltrion and Hospira, holding that U.S. Patent No. 6,284,471 for REMICADE® ('471 patent) is invalid. Janssen is disappointed with the court's ruling and plans to appeal the decision to the Court of Appeals for the Federal Circuit. Janssen is also continuing the appeal process in the proceedings related to the '471 patent before the U.S. Patent & Trademark Office, and is awaiting a date to be set for an oral hearing in the appeal.

Janssen will continue to defend its intellectual property rights relating to its innovative medicines. A commercial launch of an infliximab biosimilar prior to the outcome of the appeals would be considered an at-risk launch.

The company reaffirms its sales guidance for operational sales growth for the full-year 2016 of 3-4%, notwithstanding the possibility of a biosimilar launch on or after October 3, 2016.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Biotech, Inc. and Johnson & Johnson. Risks and uncertainties include, but are not limited to, the on-going USPTO appeal process related to the '471 patent and the current, or any other, litigation challenging the coverage and/or validity of the company's patents related to REMICADE®. A further list and description of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2016, including in Exhibit 99 thereto, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither Janssen Biotech, Inc. nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.)

###

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(917) 697-2318 (M)

Investor Contacts:
Lesley Fishman
(732) 524-3922

Joseph J. Wolk
(732) 524-1142

Last Updated: 08/22/2016

Exhibit 5

MODERATELY TO SEVERELY ACTIVE Crohn's Disease

Co-pay support with RemiStart®

RemiStart® could help with your medication out-of-pocket costs

If you need help paying for your treatment with REMICADE®, you're not alone. Many people need help paying for their medication.

If your doctor thinks REMICADE® is the right choice for you, and you need assistance with your medication out-of-pocket costs, you may be eligible for the **RemiStart® Patient Rebate Program.**

Before the calendar year ends, you will receive information and eligibility requirements for continued benefit in the program.

RemiStart® Patient Rebate Program

Based on your eligibility, RemiStart® may provide a rebate for your medication out-of-pocket costs, including deductible, co-pay, and co-insurance, with a $20,000 maximum program benefit per calendar year. RemiStart® rebates are determined by medication cost only. If eligible, you will pay just $5 per infusion. Rebate amounts are not determined by costs associated with administration of the IV infusion. Additional restrictions apply.

You can find out more about eligibility requirements, restrictions, and program enrollment by visiting RemiStart.com.

Eligible patients enrolled in the **RemiStart®** patient rebate program

PAY $5 PER INFUSION*†

ADDITIONAL RESTRICTIONS APPLY‡§

RemiStart® Patient Rebate Program for REMICADE®

*If eligible.

†This program is only available to individuals using private or commercial health insurance to cover a portion of medication costs. This program is not available to individuals who use any state or federal government subsidized healthcare program to cover a portion of medication costs, such as Medicare, Medicaid, TRICARE, Department of Defense, or Veterans Administration. Patients confirm that they will not seek reimbursement from any of these programs or from pharmaceutical patient assistance foundations and accounts such as a Flexible Spending Account (FSA), Healthcare Savings Account (HSA) or Health Reimbursement Account (HRA).

‡Eligible patients pay $5 per infusion, with up to $20,000 maximum benefit each calendar year. For Massachusetts residents only, this offer is subject to change per state legislation.

§RemiStart® rebates are determined by medication cost only. Rebate amounts are not determined by costs associated with administration of the IV infusion.

SELECTED IMPORTANT SAFETY INFORMATION

REMICADE® can lower your ability to fight infections. Serious and sometimes fatal events can occur. There have been reports of serious infections including tuberculosis (TB) and infections caused by bacteria, fungi, or viruses that have spread throughout the body. Lymphoma, including a fatal kind called hepatosplenic T-cell lymphoma, and other cancers have been reported in children and adults taking REMICADE®. Some people with heart failure should not take REMICADE®. Other serious side effects reported include skin cancer, hepatitis B, liver injury, blood problems, allergic reactions, nervous system problems, or lupus-like syndrome. To learn more about these and other risks, please read the Important Safety Information and the Medication Guide, and talk with your doctor.

Download the Medication Guide to learn more about REMICADE®. (Requires Adobe® Reader®. Click here to download.)

Next: About AccessOne®

Important Safety Information

Only your doctor can recommend a course of treatment after checking your health condition. REMICADE® (infliximab) can cause serious side effects such as lowering your ability to fight infections. **Some patients, especially those 65 years and older, have had serious infections caused by viruses, fungi or bacteria that have spread throughout the body, including tuberculosis (TB) and histoplasmosis. Some of these infections have been fatal. Your doctor should monitor you closely for signs and symptoms of TB during treatment with REMICADE®.**

Unusual cancers have been reported in children and teenage patients taking TNF-blocker medicines. Hepatosplenic T-cell lymphoma, a rare form of fatal lymphoma, has occurred mostly in teenage or young adult males with Crohn's disease or ulcerative colitis who were taking REMICADE® and

What conditions is REMICADE® used to treat?

REMICADE® is a prescription medication used to treat:

Crohn's Disease

- Can reduce signs and symptoms and induce and maintain remission in adult patients with moderately to severely active Crohn's disease who haven't responded well to other therapies

Pediatric Crohn's Disease

- Can reduce signs and symptoms and induce and maintain remission in children (ages 6-17) with moderately to severely active Crohn's

AccessOne®—Customized Care

A single care coordinator will provide you with customized one-to-one support.

accessone the janssen biotech support system

Learn more here ▶

Your insurance questions answered

A comprehensive list of the most common insurance and support questions answered here.

PATIENT SUCCESS STORIES

Hear from other REMICADE® patients or share your own experiences here.

CHOOSE ANOTHER CONDITION

Please read the Important Safety Information about REMICADE® below.

MANAGING TREATMENT

Find resources to help you get the most out of your treatment here.

azathioprine or 6-mercaptopurine. For children and adults taking TNF blockers, including REMICADE®, the chances of getting lymphoma or other cancers may increase.

You should discuss any concerns about your health and medical care with your doctor.

What should I tell my doctor before I take REMICADE®?

You should let your doctor know if you have or ever had any of the following:

- Tuberculosis (TB) or have been near someone who has TB. Your doctor will check you for TB with a skin test. If you have latent (inactive) TB, you will begin TB treatment before you start REMICADE®.
- Lived in a region where certain fungal infections like histoplasmosis or coccidioidomycosis are common.
- Infections that keep coming back, have diabetes or an immune system problem.
- Any type of cancer or a risk factor for developing cancer, for example, chronic obstructive pulmonary disease (COPD) or had phototherapy for psoriasis.
- Heart failure or any heart condition. Many people with heart failure should not take REMICADE®.
- Hepatitis B virus (HBV) infection or think you may be a carrier of HBV. Your doctor will test you for HBV.
- Nervous system disorders (like multiple sclerosis or Guillain-Barré syndrome).

Also tell your doctor if you:

- Use the medicines Kineret (anakinra), Orencia (abatacept) or Actemra (tocilizumab) or other medicines called biologics used to treat the same problems as REMICADE®.
- Are pregnant, plan to become pregnant, are breast-feeding, or have a baby and were using REMICADE® during your pregnancy. Tell your baby's doctor about your REMICADE® use. If your baby receives a live vaccine within 6 months after birth, your baby may develop infections with serious complications that can lead to death.
- Recently received or are scheduled to receive a vaccine. Adults and children taking REMICADE® should not receive live vaccines or treatment with a weakened bacteria (such as BCG for bladder cancer) while taking REMICADE®.

disease who haven't responded well to other therapies

Ulcerative Colitis

- Can reduce signs and symptoms, induce and maintain remission, promote intestinal healing, and reduce or stop the need for steroids in adult patients with moderately to severely active ulcerative colitis who haven't responded well to other therapies

Pediatric Ulcerative Colitis

- Can reduce signs and symptoms and induce and maintain remission in children (ages 6-17) with moderately to severely active ulcerative colitis who haven't responded well to other therapies

Rheumatoid Arthritis

- Can reduce signs and symptoms, help stop further joint damage, and improve physical function in patients with moderately to severely active rheumatoid arthritis, in combination with methotrexate

Psoriatic Arthritis

- Can reduce signs and symptoms of active arthritis, help stop further joint damage, and improve physical function in patients with psoriatic arthritis

Ankylosing Spondylitis

- Can reduce signs and symptoms in patients with active ankylosing spondylitis

Plaque Psoriasis

- Approved for the treatment of adult patients with chronic severe (extensive and/or disabling) plaque psoriasis under the care of a physician who will determine if REMICADE® is appropriate considering other available therapies

What should I watch for and talk to my doctor about before or while taking REMICADE®?

The following serious (sometimes fatal) side effects have been reported in people taking REMICADE®.

You should tell your doctor right away if you have any of the signs listed below:

- Infections (like TB, blood infections, pneumonia)—fever, tiredness, cough, flu, or warm, red or painful skin or any open sores. REMICADE® can make you more likely to get an infection or make any infection that you have worse.
- Lymphoma, or any other cancers in adults and children.
- Skin cancer—any changes in or growths on your skin.
- Heart failure—new or worsening symptoms, such as shortness of breath, swelling of your ankles or feet, or sudden weight gain.
- Reactivation of HBV—feeling unwell, poor appetite, tiredness, fever, skin rash and/or joint pain.
- Liver injury—jaundice (yellow skin and eyes), dark brown urine, right-sided abdominal pain, fever, or severe tiredness.
- Blood disorders—fever that doesn't go away, bruising, bleeding or severe paleness.
- Nervous system disorders—numbness, weakness, tingling, changes in your vision or seizures.
- Allergic reactions during or after the infusion—hives, difficulty breathing, chest pain, high or low blood pressure, swelling of face and hands, and fever or chills.
- Lupus-like syndrome—chest discomfort or pain that does not go away, shortness of breath, joint pain, rash on the cheeks or arms that gets worse in the sun.
- Psoriasis—new or worsening psoriasis such as red scaly patches or raised bumps on the skin that are filled with pus.

The more common side effects with REMICADE® are respiratory infections (that

may include sinus infections and sore throat), headache, rash, coughing and stomach pain.

Please read the Medication Guide for REMICADE® and discuss it with your doctor. (Requires Adobe® Acrobat® Reader®. **Click here** to download.)

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Back to top