I f e e f Sec d Med ca U e C a

d c f e e f a e c a bef e: Pe e e ed

! "#$%&'()"*+*,"*,)-%&./

! "#$%&'%()$*+&,"-(%./%$#*$-(%(&%()$%*0($/($,%./,.-0(.&/

! *"+*&#$'"12%*+$*0+./%'&+%()$%*0($/($,%"#$
4$535%'&+6"0(.&/7%,&#0$7%*0-803./37%109$11./37%*0-803$%1$0'1$(%0/,:&+%;6<=%&'%()$%
6$,.-06$/%>).-)%#*$-.'.-0112%,.+$-(%(&>0+,#%()$%*0($/($,%"#$?

! &''$+./37%*"((./3%&/%()$%60+8$(7%.6*&+(./30/,%*&##$##./3%&'%*+&,"-(#%()0(%)0,%
9$$/%*"+*&#$'"112%*+$*0+$,

01&)2"#$%&'()"*+#"*,"*,)-%&./

Inf ingemen of Second Medical U e Claim

indi ec inf ingemen of a i e claim befo e: Peme e ed

!""#$%&'(!$()*++,-%&'(within Germany
a drug suitable for the patented indication

"!$(+*$+!)#"*,,-(+$#+.$%&'(/%01%&(2#$3.&-("!$(01#(+.0#&0#4(%&4%5.0%!&
by e.g. label instructions, confectioning, ready-to-use preparation or dosage

&!06("!$(*)%&'(01#(&!0(+*$+!)#"*,,-(+$#+.$#4(4$*'(/%01%&(2#$3.&-("!$(01#(+.0#&0#4(
%&4%5.0%!&(7 8

%" the person offering or supplying the drug 9&!/) or it is obvious from the circumstances

- that the drug is suitable for getting purposefully prepared for the patented indication and

- 01.0(01#(5*)0!3#$(%&0#&4)(0!(+*$+!)#"*,,-(+$#+.$#(01#(4$*'("!$(01#(+.0#&0#4(%&4%5.0%!&

:&!06(01.0(01#(5*)0!3#$(%&0#&4)(0!(*)#(01#(&!0(+*$+!)#"*,,-(+$#+.$#4(4$*'("!$(01#(
+.0#&0#4(%&4%5.0%!&(7 8

I S c d M d ca U C a

2 2015

32 143/15, 2015, 0 6 1

I M C

!"#$%&'()*%+,-).' /0+,#)12)34,$()2567)18,"#'0'($&

92:);)6<9=67>)?"@A!B)2567>)5CDE6)

!"#$%& ' ()+,-*+#,*#.+/,*-+%+.#0%*#+%1.## '#,*+-,+*

2.#1%0%&/,+-.+)(33&4+2.#1%0%&/,+/,+5-(.)#+-6+)(57+%+.#0%#+*

%1.## '#,+/6+*7#+()#+-6+2.#1%0%&/,+6-.+*.#%*/,1+3%/,+/)+,-*+*

*#$5&(8#8+/,+*7%*+.#0%*#+%1.## '#,*+9/*7-(*+#$3&/5/*&4+*

! "#"$%&' ( ) *$+') ,' - * . +/0"'1 23' - * 4"'5627'1 8" 9 "+$" : "#

; '<='5>?2@A'B=C='5627A'>52'

Infringement of Second Medical Use Claims

direct infringement of a swiss type claim after: Pemetrexed

- ! "#$%&'%()$%*+&,"-(%./%+$#*$-(%(&%()$%*0($/($,%./ ,.-0(.&/%
- ! *"+*&#$'"112%*+$*0+./3%'&+%()$%*0($/($,%"#$ 4$535%'&+6"10(.&/7%,&#03$7%*0-803./37%109$11./37%*0-803$%1$0'1$(% 0/ ,:&+%;6<=%&'%()$%6$,.-06$/(%>).-)%#*$-.'.-0112%,.+$-(% (&>0+,#%()$%*0($/($,%"#$?
- ! &''$+./37%*"((./3%&/%()$%60+8$(7%.6*&+(./30/ ,%*&##$##./3%&'% *+&,"-(#%()0()0,%9$$/%*"+*&#$'"112%*+$*0+$,
- @% /&%*"+*&#$'"1%*+$*0+0(.&/%9"(%*+&($-($,%"#$%.#%$/#"+$,%A./% #&6$%&()$+%>02B

Higher Regional Court Duesseldorf - 5 May 2017 and 1 March 2018 - Estrogen Blocker and Dexmedetomidin

I-2 W 6/7 and I-2 U 30/17, GRUR 2017, 1107 and GRUR-RS 2018, 2410

! " # $ % " & ' (% ") " * + , $ - . % $ + / " $ 0 (% " 1 + $ (* - % (* 2 ") " * + $. - $ 3 $, " 1 . * 0 4
) " 0 (1 3 5 4 ' , " $ 1 5 3 ( ) 6

! " # $ % & # ' # $ ( ) * +) $, -) . - / # 0 % . - 1 $) + * 2) $, -) 3 % $ - 1 $ - /) 3 " 2 3 * 4 -
5 % 6 # 1 7) % / 8 % 1 $ % 7 - 4) * +) 0 # 2 0 " . 4 $ % 1 0 - 4) & ( ) $, -) 4 " 3 3 ' # - 2) * +) $, -)
. - / # 0 % . - 1 $ 9) : , # 0 ,) ; 4 # . # ' % 2) $ *) % 1) < % 0 $ # 8 - <) 3 " 2 3 * 4 - + " ')
3 2 - 3 % 2 % $ # * 1) & ( ) $, -) # 1 + 2 # 1 7 - 2) , # . 4 - ' +) ; - 1 4 " 2 -) $, % $) $, -)
. - / # 0 % . - 1 $) * + + - 2 - /) % 1 /) / # 4 $ 2 # & " $ - /) # 4) " 4 - /) + * 2) $, -)
3 % $ - 1 $ - /) $, - 2 % 3 - " $ # 0) 3 " 2 3 * 4 - =

> 4 " + + # 0 # - 1 $) % 1 /) 1 * $) * 1 ' ( ) * 0 0 % 4 # * 1 % ') " 4 -) * +) $, -) . - / # 0 % . - 1 $)
% 0 0 * 2 / # 1 7) $ *) $, -) 3 % $ - 1 $)
>

I S M U C

Higher Regional Court Duesseldorf - 5 May 2017 and 1 March 2018 - Estrogen Blocker and Dexmedetomidin

I-2 W 6/7 and I-2 U 30/17, GRUR 2017, 1107 and GRUR-RS 2018, 2410

S ab b ab

!"##$%&'()*(+,&(- &.%/0 - &1+(%!($%02$&3(%*4

5 ,&(61)7!()'(!,)"$.(,08&(61)71(+,&(#'&!/'%#+%)1(01.(
!"2!+%+"+%)1(#'0/+%/&3(7 ,%/ ,(%!(*08)'02$&(*)'(,% -
5 +06&!(0.801+09&()*(+,%!(#'0/+%/&(1&8&'+,&$&!!(2:(!"##$:%19(
7 ,)$&!0$&'!(7%+,(!6%11:($02&$&.(.'"9

P aba a

!"#$%#&'( ) *++'#, -$'. /+"0$'1$0*2$3'*%4536. *%0'"'5/" . *%0'. /+$

-"47"0$'*%8/12"#*/%&'. /'%/#'"--5,'"'5/" . *%0'. /+$'8/1'2$. *4*%"5'
1$"+/%+

9/'-1//8'#:"#'7%/)5$. 0$'/1'1$"+/%'#/'7%/) '#:"#'6+$1+'*0%/1$'#:$'
-"47"0$'*%8/12"#*/%'

→ no direct infringement!

;4"+$'+#" ,$. '*%'1$+-$4#'#/'"6<*5*"1,'1$=6$+#';-"#$%#'"+'01"%#$. '>
) *#:/6#'5/" . *%0'. /+$'? @6#'*%A"5*. "#$. '@,'B$. $1"5'

Infringemen of Second Medical U e Claim

Concl ion

! "#"$%&$'( ) &$*#&+'*,"-(' . "(/$01$(
) "%2+&) "$'(2$(3",) &$4(&$%
5 6*,60-"#*774(6,"6&,"-(2'(#0,(' . "(6&'"$'"%(*-"(2$(
3",) &$4(
5 -/2$$4(7&8"7-(' . "(6,0%*+'(8*'(6,0'"+'"%(*-"(2$(
3",) &$4(2-("$-*,"%(92$(-0) "(0' . ",(1&4:(;"<=<(
,"8&'"(&=," ") "$'>

? (%2,"+'(2$#,2$=") "$'

Infringement of Second Medical Use Claims

Conclusions

*!"#$%&%'() *%+, -.$ +&/(0*1&%12&.$1/'(34¹$ &+5'(6ᵓ789(:%5(;83<*

E ample

Regi a C M ich l 12 J 2017 7 O 9110/17 E e a e l hibi
b i hed

! "#$%"&'$()*"#+*," -),.#/*0.#*1#/,.234*.#*5)(6"#7*%8(*'3)*
9"')#')+*$2)*-$'*):98('*'8*'3)*;<*"#+*= $#+.29$')+*> +"#/)(*8%*
%.(2'*.#%(.#/)6)#'*?.'3.#*5)(6"#7

6"#$%"&'$()*%8(*;<*):98('2*@*.#%(.#/)6)#'*.#*5)(6"#7A

Plausibility

!

La e Amendmen s

!"#$%&'%()*"+*%,#*-

!"#$%&'$(')'*+,$-+.'/.$012*.$3+4$*'5'6.$3'+/7$18$6&+,,'/9'$1*$)'8'/6':/.*1)26')$;4$
+$<+*.4$1*$+$6&+/9'$.1$.&'$+6.:1/$1*$+$)'8'/6';*129&.$81*=+*)$;4$.&'$)'8'/)+/.$;4$
3'+/7$18$+/$).'+/"/%0"1234+%45%*6"%7)*"+*%=&:6&$+*'$;*129&.$81*=+*)$1/,4$+8.'*$.&'$
'><:*4$18$+$.:3'$,:3:.$7'.$81*$.&:7$2/)'*$72;7'6.:1/$!?#$+/)$3+4$)'6:)'$=:.&12.$82*.&'*$
'>+3:/+.:1/$:8

@A$9:B:/9$61/7:)'*+.:1/$.1$.&'$/'=$72;3:77:1/$849:/%1";931"%*6"%742*74+".'+*%45%
*6"%2#6"/9:"/%41):%714#""/3+<2C$+/)

?A$.&'$<+*.4$+88'6.')$)1'7$/1.$7288:6:'/.,4$'>627'$.&'$)',+4C$+/)

DA$.&'$<+*.4$+88'6.')$&+7$;''/$:/7.*26.')$+;12.$.&'$61/7'E2'/6'7$18$8+:,:/9$.1$1;7'*B'$
+$.:3'$,:3:.A

%&'$9*12/)$18$'>627'$7&+,,$;'$72;7.+/.:+.')A$

!)*%=>?-%F'6A$@@G$-+.'/.$H6.I$F'6A$J?KLJD@C$?KM$01)'$18$O:B:,$-*16')2*'#

Late Amendments

Federal Court of Justice - 2 Dec. 2014 – X ZR 151/12 - Forced Action Mixer

IIC 2015, 974